Enhancing the transparency and communication of the results of randomised trials to patients and the public



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A thesis submitted for the degree of

Doctor of Philosophy

Trinity Term

2026

Abstract

Patients and trial participants are key stakeholders and intended users of research, yet there is no consensus-based reporting guideline to support the preparation of patient-facing trial result summaries. While reporting standards for trial protocols and results have improved transparency for scientific audiences, guidance on sharing trial results with patients and the public remains inconsistent and fragmented. The aim of this thesis was to develop a reporting guideline for sharing trial results with patients and the public that will provide a consistent framework for reporting trial results to these audiences and aid in enhancing the transparency of trial result communications for patients and the public.

I followed an established mixed-methods approach to develop a reporting guideline, with patient and public involvement (PPI) embedded throughout. I began with a scoping review to identify existing guidance and generate an initial list of reporting items (Chapter 2). I then carried out 29 qualitative interviews and 3 focus groups with patients, members of the public, and trial professionals to identify key information needs and generate additional candidate reporting items (Chapter 3). The resulting list of candidate items was refined through a three-round international Delphi survey involving multiple stakeholder groups (n=178, Round 3), with PPI representatives participating alongside professionals and responses analysed separately to ensure equal weight (Chapter 4). Delphi results were discussed at an expert consensus meeting (n=23), where professionals and PPI representatives worked together to finalise the reporting items (Chapter 5).

The draft guideline was then pilot-tested in real-world settings with trial teams, medical writers, and patient representatives to assess its usability, clarity, and feasibility in practice (Chapter 6). Pilot testing showed that the checklist was feasible to use within existing workflows and helped improve the clarity and completeness of trial result summaries. User feedback led to refinements in the wording and structure of several items and identified the need for practical guidance and worked examples, which were incorporated into the Explanation and Elaboration document (Chapter 7). The final reporting guideline comprises ten essential items and seven additional items covering key aspects of reporting trial results to patients and the public.

This thesis presents the first consensus-based reporting guideline developed specifically for sharing the results of randomised trials with patients and the public. By providing practical recommendations developed with patients, public contributors, and trial professionals, it aims to support more consistent, accessible, and meaningful communication of trial results.

Acknowledgements

A thesis is never really written by one person. It is fuelled by supervision, coffee, deadlines, occasional panic, and the quiet belief of people who continue to say "you're nearly there" even when that clearly isn't true. Although this thesis bears only my name, it is the product of the kindness, generosity and support of many people.

My deepest thanks go to my supervisors. **Sally**, thank you for your unwavering support, guidance and remarkable ability to bring me back whenever I disappeared into thesis-induced madness! **Jen**, thank you for your meticulous reviews and thoughtful feedback on countless drafts. **Gary**, thank you for your wisdom and humour, and **Charlotte**, thank you for your kindness and encouragement. I am also grateful to **Afsie**, for her kindness and support throughout my DPhil.

To **Sayeem**, thank you for being my constant partner, my biggest supporter and for being there throughout this journey. From dreaming about our future together to working towards making those dreams a reality, we have always been a team. My partner in crime, we have come so far together, and here's to many more dreams we will fulfil, side by side. To **Serhan**, thank you for bringing so much joy and meaning into my life. You have sacrificed so much time with Mumma during these years, and I am truly thankful to you for being so patient, so brave and so understanding. I hope that one day, when you're old enough to read these words, you will know how much you have meant to this journey and, above all, that you will be proud of your mum.

To **Abbu** and **Ammu**, thank you for everything you have done for me, not just throughout this PhD but throughout my life. Every opportunity I have had is because of your sacrifices and encouragement. To **Apu, Ariyan, Baba, Ma, Ehsan Vaiya** and **Tasria**, thank you for your love, prayers and support.

To **Eva**, thank you especially for keeping me sane and patiently listening to endless conversations about PhD stresses, reviewer comments and deadlines. I wouldn’t have survived this journey without you! **Jyoti**, thank you for sharing every high, low and PhD crisis alongside me and for making the days lighter.

Finally, I would like to thank all of the patient partners, public contributors, trial professionals and research participants who generously shared their time, experiences and perspectives throughout this research. This thesis is dedicated to you.

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List of Abbreviations

AI	Artificial intelligence
BISS	Botnar Institute Student Symposium
BRC	Biomedical Research Centre
ChiCTR	Chinese Clinical Trial Registry
CONSORT	CONsolidated Standards of Reporting Trials
CRN	Clinical Research Network
CTIS	Clinical Trials Information System
CTSU	Clinical Trial Service Unit
CTU	Clinical Trials Units
DTU	Diabetes Trials Unit
E&E	Explanation and Elaboration
EMA	European Medicines Agency
EMWA	European Medical Writers Association
EQUATOR	Enhancing the QUAlity and Transparency Of health Research
EU CTR	European Union Clinical Trials Regulation
FGD	Focus group discussion
HRA	Health Research Authority
ICTMC	International Clinical Trials Methodology Conference
IMD	Index of Multiple Deprivation
IRB	Institutional Review Board
JCE	Journal of Clinical Epidemiology
MRC	Medical Research Council
MRCT	Multi-Regional Clinical Trials Center of Brigham and Women's Hospital and Harvard
MS IDREC	Medical Sciences Interdivisional Research Ethics Committee
NDORMS	Nuffield Department of Orthopaedics, Rheumatology and Musculoskeletal Sciences
NDPCHS	Nuffield Department of Primary Care Health Sciences
NIHR	National Institute for Health and Care Research
NPEU	National Perinatal Epidemiology Unit
OCTRU	Oxford Clinical Trials Unit
ORA	Oxford University Research Archive
OSF	Open Science Framework
PCC	Participants, concept and context

PCER	Public and Community Engagement with Research
PCORI	Patient Centered Outcomes Research Institute
PI	Principal investigator
PIS	Participant information sheet
PLS	Plain language summary
PLSP	Plain language summaries of publications
PPB	Pharmacy and Poisons Board
PPI	Patient and public involvement
PPIE	Patient and public involvement and engagement
PRISMA-ScR	Preferred Reporting Items for Systematic reviews and Meta-Analyses extension for Scoping Reviews
SANCTR	South African National Clinical Trials Register
SITU	Surgical Intervention Trials Unit
SORT	Standards of Reporting Trials
SPCR	School for Primary Care Research
SRQR	Standards for Reporting Qualitative Research
TCPS	Tri-Council Policy Statement
TMRP	Trials Methodology Research Partnership
UK	United Kingdom
UKCRC	UK Clinical Research Collaboration
UKTMN	UK Trial Manager's Network
US	United States
US FDA	United States Food and Drug Administration
WHO	World Health Organisation
WHO ICTRP	World Health Organisation International Clinical Trials Registry Platform

Chapter 1: Background

1.1 Context, motivation, and scope of the thesis

The motivation for this thesis can be traced back to my time working in trial management at the Cambridge Clinical Trials Unit, where I was first introduced to the concept of 'Patient and public involvement' (PPI). I found the idea immediately compelling and closely aligned with my values. Growing up in a family of doctors, I was quite well-versed in medical terminologies and research from an early age, yet I also saw friends and relatives struggling to understand information about their health or the research that informed their care. PPI felt like a long-overdue response to this gap.

However, I soon encountered the reality that PPI was often treated as tokenistic - a 'tick-box' exercise rather than a meaningful influence on research. [1, 2] During the COVID-19 pandemic, I observed encouraging progress, with patients contributing not only as participants but also to study design and conduct. Yet I still felt that something important was missing.

Once a study was completed, the primary focus remained on dissemination through journal articles, seminars and conferences, entirely to the scientific community. While these are essential, they did little to support understanding among patients and members of the public. I often found myself questioning how many of my relatives or friends could realistically understand a journal article if that was the only source of information available to them. Research is ultimately conducted for the benefit of patients and the

public, but when the information it generates is not accessible, much of that potential value is lost.

Although PPI is increasingly embedded in trial design and governance, far less attention is given to how participants are informed about study findings once a trial has ended. In my experience, result sharing is often delayed, inconsistent, or reduced to minimal summaries that did not reflect the time, contribution, or expectations of participants. These experiences prompted me to question how trial results should be communicated to patients and the public, and why practical guidance in this area remains limited despite growing ethical and policy support.

When I came across this DPhil opportunity, these questions came sharply into focus. The aim of developing a reporting guideline for sharing results of randomised trials with patients and the public resonated with my personal belief in meaningful patient and public involvement and with my desire to develop a practical solution to the problem of sharing trial results in ways that people can genuinely understand.

In this chapter, I introduce the evidence gap I have addressed and the approach I have taken to address it. I begin by describing why sharing trial results with patients and the public matters, explore the legislations and policy that are in place to support this movement and introduce the concept of reporting guidelines and how I chose to develop mine. I then outline my thesis aims, objectives, and thesis structure.

In this thesis, I have used the terms patients and participants interchangeably. While the term 'participants' might be more accurate to describe individuals involved in a study or trial, I chose the term 'patients' due to its widespread usage in the 'patient and public' terminology. [3, 4] Although trial participants are the primary audience for many trial result summaries, trial results are often made available more broadly to patients, patient representatives, and members of the public. I therefore considered perspectives on communicating trial results beyond trial participants alone. Where discussing the ethical rationale for result sharing, I refer specifically to trial participants; where discussing dissemination materials and reporting guideline, I refer more broadly to patients and the public.

1.2 Why sharing trial results matters: expectations and reality

Sharing trial results with patients and the public promotes transparency, accountability and trust in clinical research. It also demonstrates respect for participants, fosters engagement and ownership, and is widely regarded as a basic right. [5-7]

Researchers and participants alike value the opportunity to share and receive trial results. [5, 8] A survey showed that 95% of clinicians (135 out of 141) and 99% patients (78 out of 79) believe that trial participants should be offered a lay summary of trial results. [8] However, evidence shows that trial results have rarely been shared in a consistent manner. A study that surveyed authors of 1,818 clinical trials indexed in PubMed in 2014–2015 reported that only 27% shared results with participants, 13% planned to offer to share, 10% were unsure, and 33% never planned to share. [9] One industry estimate

suggested that only approximately 2% of global industry-funded trials completed between 2015 and 2017 shared plain language summaries with the trial participants. [10] The United Kingdom (UK) Health Research Authority (HRA) 2021 transparency report showed that 90% of clinical trials in the UK did not share findings with their participants. [11] Things have improved more recently; the latest HRA transparency report found that 52% of UK trials completed in 2023 had shared, or were in the process of sharing, results with participants. [12] A 2025 systematic review highlighted that even among investigators who plan to share trial data, 81% rely entirely on passive dissemination methods that require participants to independently locate the information. [13] Across Europe, only 14% of trials between 1 January 2017 and 30 June 2020 successfully provided plain language summaries (PLSs) within the public domain, and these remained difficult to find via standard search engines. [14] Even when summaries are shared with participants, in a sample of National Institute for Health Research (NIHR)-funded trials published between 2016 and 2021, over 85% were flagged as difficult to read. [15]

Studies have identified several barriers to effective trial result reporting. Researchers are often uncertain about what to communicate, the most appropriate format, and the timing of dissemination. The result is considerable variation in practice. [16] These challenges are compounded by the absence of clear guidance or institutional processes to support reporting of trial results to patients and the public. [9, 16-18] A survey of principal investigators (PIs) published in 2003 found that only 5 out of 150 (~3%) institutions had established mechanisms to share study results with participants. [19] Most of the Institutional Review Boards (IRBs) in the United States lack clear guidance and policy in regard to sharing results with study participants. [20]

1.3 Legislative and policy context: a global overview

Most funding bodies and regulatory agencies now mandate the sharing of results with patients and the public following trial completion. The 2022 World Health Organisation (WHO) update on public disclosure of clinical trial results recommends that all clinical trials be prospectively registered in a publicly accessible registry before enrolment begins, with key trial results posted to the registry within 12 months of study completion and full findings published within 24 months. [21]

There are indications of movement in enhancing transparency efforts in public release of clinical trials information around the world as described below. However, few countries have legally required sharing trial results until recently. The global landscape of reporting trial results to participants can be roughly grouped into three models:

1. **Regulatory transparency: mandated result reporting to participants**

Under the new UK clinical trials regulations (The Medicines for Human Use (Clinical Trials) (Amendment) Regulations 2025), effective 28th April 2026, sponsors must offer participants a summary of trial results written in plain language within 12 months of trial completion. [22] The HRA has also made this a priority area as part of their research transparency agenda. [23]

2. **Result reporting to trial registry: transparency without participant focus**

The European Union Clinical Trials Regulation (EU CTR) No 536/2014, effective from 31 January 2022, requires technical summaries and user-friendly lay summaries for all Phase

I-IV trials to be submitted to the EU Clinical Trials Information System (CTIS), typically within 12 months of trial completion (6 months for paediatric trials). [24]

The United States (US) introduced the Plain Writing Act of 2010, requiring federal agencies to use clear and consistent language in all public communication. [25] The FDAAA 801 Final Rule (42 CFR Part 11), effective from 18 January 2017, also mandates registration of applicable clinical trials and submission of structured summary results to ClinicalTrials.gov, a public registry. [26] While this regulation has significantly improved transparency and public access to trial information, it provides technical, tabulated summaries and does not require the provision of plain language summaries for participants or the public. As a result, participants may technically have access to trial results without being able to meaningfully understand them.

In Canada, requirements for both trial registration and results reporting were incorporated into the Tri-Council Policy Statement (TCPS) in 2010 and retained in the 2022 update. [27] Although not legislation, the TCPS serves as the national framework for research ethics and is generally mandatory for institutions receiving Tri-Agency funding. [28] In 2019, Health Canada also introduced the 'Public Release of Clinical Information' initiative, requiring anonymised clinical study reports and summary documents from approved drug and device submissions to be made publicly available for 'non-commercial' purposes following regulatory review. [29] Despite these policies, compliance with trial registration and results reporting remains suboptimal in Canada. [30]

China requires registration and disclosure of drug clinical trial information through platforms such as the Chinese Clinical Trial Registry (ChiCTR) and ChinaDrugTrials.org.cn. [31-33] While the 2020 'Drug Clinical Trial Registration and Information Disclosure' regulations mandate results disclosure, information is generally visible only to regulators, and there is no requirement to provide plain language summaries directly to participants. [32]

In Kenya, clinical trials must be registered with both the Pharmacy and Poisons Board (PPB) Clinical Trials Registry and the Pan African Clinical Trials Registry. Sponsors are also required to submit final study reports, including a lay summary, to the regulator. [34] However, compliance data are currently unavailable.

3. **Ethics-driven expectation to share results**

In Australia, the National Statement on 'Ethical Conduct in Human Research' recognises that communicating research findings to participants may be appropriate depending on the nature of the research, and recommends that dissemination approaches reflect the ethical principles of justice, respect, and beneficence. [35]

In South Africa, all clinical trials conducted since December 2005 must be registered in the South African National Clinical Trials Register (SANCTR). [36] The South African Good Clinical Practice Guidelines (2020) state that sponsors and principal investigators are responsible for reporting and disseminating trial findings in a timely and accessible manner, including providing feedback to participant communities where appropriate. [37] However, there is no

legal requirement to provide plain language summaries or communicate results directly to individual participants.

In India, registration of clinical trials in the Clinical Trials Registry–India (CTRI) has been mandatory since 2009, with prospective registration becoming compulsory from 2018. [38] However, many registered trials in India remain unpublished or do not report results publicly [39] and there is currently no formal requirement to provide plain language summaries to participants. [40]

Similarly, Brazil requires registration of many clinical trials through ANVISA (Brazilian Health Regulatory Agency) and the national ethics review system, and has strengthened participant protections in recent years. However, there is currently no explicit requirement to provide plain language summaries directly to trial participants. [41]

These examples were selected to illustrate the diversity of regulatory approaches and practices for dissemination frameworks across different geographical regions. Collectively, these examples demonstrate that although many countries now require trial registration and some form of results reporting, clear requirements for patient-friendly or plain language summaries remain inconsistent and are often presented as ethical recommendations rather than enforceable legal obligations. Consequently, patients and members of the public may receive very different levels of information depending on where a trial is conducted, highlighting the need for practical guidance that can be applied across different healthcare systems and research settings.

1.4 Plain language summaries of results

The traditional communication of scientific findings is highly saturated with specialised language and professional jargon, which creates a scientific 'bubble' that is harder to understand for those outside the bubble (e.g., patients and the public). [42, 43] For example, "*The intervention demonstrated efficacy.*" can be simplified in plain language to say: *"The treatment was shown to work."*

PLSs offer a viable solution to meet the health information needs of those interested in learning about clinical study results. [44, 45] A plain language summary is a document that provides a simple overview of a study and its main implications and helps to attain a broader understanding of the clinical study results in simple language. [43, 44] The target audience may include study participants, healthcare professionals, policymakers, caregivers, and the general public, particularly people with limited health literacy or scientific expertise.

However, there is no established definition of what a PLS is or should entail, other than that it should be easily understandable. [46] Terminology, format requirements (e.g., word limits), content guidance, and sharing mechanisms (e.g., websites and social media) vary widely. PLSs are described using various terms, including lay summaries, lay abstracts, plain language summaries, patient summaries, author summaries, and plain English summaries, making them harder for the public to identify and find through online searches. [46]

An example of a visual plain language summary is shown in Figure 1.1. While formats vary considerably, this example illustrates how research findings can be presented using plain language, visual elements, and simplified layouts to improve accessibility for patients and the public.

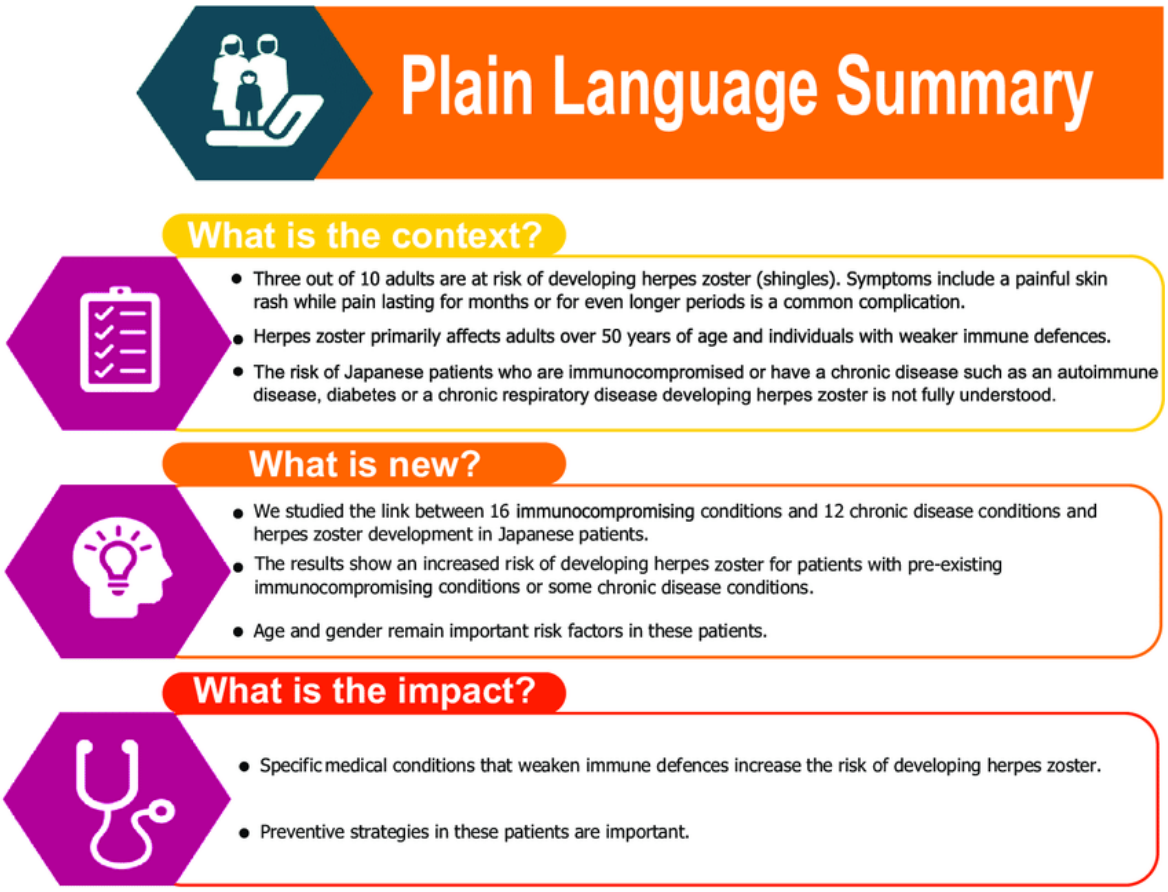


Figure 1.1: Example of a visual plain language summary accompanying a published clinical research article. *Reproduced from Imafuku et al.* [47] *© 2020 The Authors. The Journal of Dermatology published by John Wiley and Sons Australia, Ltd on behalf of the Japanese Dermatological Association. Reproduced under the terms of the Creative Commons Attribution 4.0 International (CC BY 4.0) licence.*

PLSs are increasingly popular, with many journals, institutes and commercial organisations actively endorsing and publishing them. [46] Several journals now publish PLSs alongside the main article, including the *Journal of Clinical Epidemiology*, *Research Involvement and Engagement*, *BMJ Open*, *PLoS One*, and a growing number of journals within the BMC, Elsevier, SAGE, Springer Nature, Taylor & Francis, and Wiley portfolios. Many journals also specify word limits for these summaries; for example, *Pain and Therapy* and *Research Involvement and Engagement* limit PLSs to 250 words. [48, 49] Regulatory agencies also require summary reports, which are made publicly available (for example, summaries included in final Research Ethics Committee reports published by the HRA). Some trial teams send results directly to their participants or publish them on their websites (e.g., Pfizer publishes PLSs in a dedicated public website. [50])

1.4.1 Do plain language summaries work?

The internet is now a major source of health information, although it also increases exposure to misinformation. In response, the research community has developed plain language resources, such as Cochrane Plain Language Summaries, to provide accessible evidence-based information for the public. [51, 52] PLSs can improve the accessibility of research for public audiences, [53] and, alongside video abstracts, have shown greater comprehension, perceived understanding, and enjoyment than graphical and published abstracts. [54]

The importance of developing a PLS can perhaps be emphasised with the fact that the average reading age of adults in the UK is estimated to be between 9 and 11 years old, while nearly one in six adults in England have very poor literacy skills. [55] Therefore, public

information, particularly health information, should be targeted at this 9-11 year age range to ensure that simple, comprehensive, and clear communication is accessible to all.

PLSs can streamline communication between healthcare providers and patients and support shared decision-making by improving health literacy, which is fundamental to patient engagement. [56] The recognition of the importance of PLSs is reflected in the increasing use of PLSs in funding applications, clinical trial registries and regulatory reports, and journal publications. [44]

Despite their increasing use, there is considerable variation in how PLSs are developed, structured, and presented. [43] While formal reports by journals or regulatory agencies are typically text-based, trial teams also use visual or interactive formats to communicate findings. There is no consistent standard for what information should be included, how it should be prioritised, or how it should be tailored to different audiences. [46] This lack of standardisation risks important information being omitted or presented in ways that are difficult to understand, potentially limiting the value of these summaries for patients and the public. Standardising the content of PLSs may help ensure that patients and the public receive clear, consistent, and sufficiently complete information to support understanding and informed decision-making.

1.5 Reporting guidelines: an overview

1.5.1 History of reporting guidelines

Transparent reporting is essential for reproducibility, correct interpretation and ensuring that research findings can inform healthcare decision-making. Concerns about poor reporting in medical research have existed for decades, particularly when important methodological details are missing or unclear. [57] As systematic reviews and evidence-based medicine became more common during the 1980s and 1990s, the need for clearer and more consistent reporting became increasingly recognised. In 1994, two independent groups developed guidance for reporting randomised controlled trials: the Standards of Reporting Trials (SORT) and the Asilomar recommendations. [58, 59] On the suggestion of *JAMA*'s deputy editor, representatives from both groups met in 1996 and combined their recommendations to create the CONsolidated Standards of Reporting Trials (CONSORT) statement. The CONSORT statement described the minimum information needed to report randomised controlled trials and included a checklist and a flow diagram. [60] Following an update in 2001, an accompanying Explanation and Elaboration (E&E) document was also published, which explained the rationale for each checklist item and provided examples of good reporting. [61] Both the checklist and E&E papers were updated again in 2010 and more recently in 2025. [62, 63]

CONSORT became highly influential and led to the development of many other reporting guidelines for different study designs and research fields. Over time, reporting guidelines expanded beyond clinical trials to include observational studies, systematic reviews, qualitative research, and many other forms of health research. To support this growing

field, Professor Douglas Altman and colleagues established the EQUATOR (Enhancing the QUAlity and Transparency Of health Research) Network, which provides a central resource for reporting guidelines and guidance on their development and use. [64] There are now about 700 reporting guidelines (as of 12th August 2026), many of which are widely endorsed by journals and research organisations internationally. [65]

1.5.2 What is a reporting guideline?

Reporting guidelines are sets of minimum recommendations to aid the transparency, accountability, and completeness of reporting study findings. [66] Reporting guidelines provide a minimum list of information to be reported and also describe the process of how the list was developed. [64]

The EQUATOR Network defines a reporting guideline as:
"A checklist, flow diagram, or structured text to guide authors in reporting a specific type of research, developed using explicit methodology." [64]

Usually, reporting guidelines are first published as a journal article that describes their development process and presents the reporting tool, which can be structured text, a checklist or a flow diagram. Most often they are presented as a checklist of key reporting items. [67] Alongside the checklist, many guidelines also provide an E&E document, which offers detailed guidance, examples, and rationale for each item. [66, 68] Together, the checklist and E&E help authors report their work more clearly and consistently, [69] and support readers in understanding and assessing the research.

1.5.3 The role of reporting guidelines in improving research reporting

Reporting guidelines are increasingly recognised not only as methodological tools but also as part of researchers' broader ethical responsibilities. The 2024 revision of the Declaration of Helsinki states that researchers have a duty to make research findings publicly available and that "all parties should adhere to accepted guidelines for ethical reporting." [70]

Studies have shown that reporting guidelines such as CONSORT and PRISMA are associated with improved reporting completeness and adherence to recommended reporting items, particularly when journals actively endorse and implement them. [71-74] For example, journals endorsing PRISMA published systematic reviews with better reporting and methodological quality than journals without endorsement. [72] A masked randomised trial found that guideline-based peer review improved manuscript quality, [75] and Hopewell et al. showed that active implementation of the CONSORT for Abstracts guideline improved the reporting of randomised trial abstracts. [76]

However, findings for some guidelines have been mixed. Reporting quality remained poor in some observational studies following endorsement of STROBE. [77, 78] Howell et al. similarly found no clear improvement in reporting of quality improvement studies after publication of SQUIRE. [79]

Large-scale analyses similarly suggest that reporting quality has improved over time, but that important gaps remain. Dechartres et al. examined approximately 20,000 randomised trials included in Cochrane reviews and found that although reporting had

improved, many were still reported too poorly for reviewers to assess risk of bias confidently. [57] Similarly, Kilicoglu et al. analysed approximately 170,000 randomised trial reports and found substantial improvements in reporting of CONSORT items following publication of the guideline, although adherence remained incomplete. [80] Together, these findings suggest that reporting guidelines are associated with improved reporting quality but are not sufficient on their own to ensure complete and transparent reporting.

Several factors have been associated with better reporting standards, including journal policies, funding source, study design, author factors, more recent publication years and study/author country. [81] Journal endorsement of reporting guidelines appears to improve reporting completeness. [76, 82] The International Committee for Medical Journal Editors encouraged journals "to ask authors to follow [reporting] guidelines". [83] However, implementation varies considerably, ranging from passive recommendation to mandatory compliance. Even for widely endorsed guidelines such as CONSORT and PRISMA, journal instructions are often ambiguous regarding whether adherence is mandatory or encouraged. [84]

Beyond journal endorsement, the design of a reporting guideline may also influence its use. Factors such as clarity, ease of use, accessibility, and the availability of supporting explanations and examples are likely to affect whether authors can apply a guideline consistently in practice. [69] The effectiveness of reporting guidelines therefore depends not only on their publication but also on thoughtful design, implementation, and uptake by intended users. Initiatives such as the EQUATOR Network provide central repositories of reporting guidelines, training resources, and educational materials for researchers,

reviewers, and editors. [85] Additional tools, including writing software, checklist applications, and reviewer resources, have also been developed to support guideline use during manuscript preparation and peer review. [86, 87]

1.6 Gaps and thesis objectives

While recent legislation and regulatory initiatives in several countries signal growing recognition of the importance of sharing trial results with patients and the public, legislation alone is unlikely to be sufficient. Regulatory requirements typically focus on *whether* results are shared, rather than *how* they are communicated or whether they are understandable to non-technical audiences. In practice, this can result in compliance-driven outputs that meet legal obligations but do not support meaningful understanding or engagement. Without clear, practical guidance on content, language, and presentation, trial teams may struggle to produce summaries that are both accurate and meaningful. Structured guidance is therefore needed to complement legislation and help translate transparency requirements into communication that is genuinely useful for patients and the public.

Existing reporting guidelines have been developed primarily to improve scientific reporting for academic audiences. Similar principles may also be important when communicating research findings to patients and the public. Although reporting guidelines such as the CONSORT Statement provide recommendations for reporting randomised trials in scientific publications,[62] to my knowledge, no reporting guideline

specifically addresses how results of randomised trials should be communicated to patients and the public. I explore this evidence gap further in Chapter 2.

I chose to focus specifically on randomised trials because they provide important evidence about the effects of healthcare interventions, but their design and interpretation can be complex. [88] Features such as randomisation, blinding, comparator groups, and statistical analyses may be difficult to communicate clearly to non-specialist audiences, yet are important for understanding what a trial found and how the findings should be interpreted. Randomised trials also carry important ethical responsibilities towards those who participate, strengthening the case for communicating their findings accurately and clearly.

While a reporting guideline alone would not address all organisational and resource-related barriers, it could provide a structured framework to support more consistent and transparent communication of trial results. Recognising this gap, and the increasing emphasis on transparency in clinical research, I aimed to develop a standardised reporting guideline to support clear, accessible, and meaningful communication of results of randomised trials to patients and the public.

1.7 Development of reporting guidelines

The methods used to develop reporting guidelines vary widely. Differences arise both in the composition of the development group (typically including methodologists, clinicians, content experts, and statisticians) and in the techniques used to reach agreement (such as

the Delphi consensus process). [64, 66] The scope of the guidelines also differ as they are developed by different groups of research expertise and address specific research areas.

Evidence suggests that development methods are not always consistently reported or applied. [89] A 2023 review of 262 reporting guidelines indexed in the EQUATOR Network database found considerable variability in development methods. [67] Around half used literature appraisals to inform their list of reporting items, less than 30% reported using a Delphi survey and around 59% reported finalising items through consensus meetings, usually involving researchers, clinicians and journal editors. Only 29.3% reported pilot testing the guideline. [67]

The EQUATOR Network provides a toolkit on how to develop a reporting guideline to support researchers. [85] The toolkit is based on the widely cited framework by Moher et al., "Guidance for developers of health research reporting guidelines". [66] This process is a staged mixed-methods approach involving: identifying the need for the guideline, conducting a literature review, performing a Delphi exercise, organising a face-to-face consensus meeting, formulating the guidance statement, and engaging in post-publication activities. [66] The framework has been highly influential and remains the most established approach available for reporting guideline development. However, this guidance was published over 15 years ago and was based primarily on the experience and expert opinion of a group of reporting guideline developers at that time, rather than on empirical evaluation of the effectiveness of the different development methods. [66, 67] The framework also provides limited discussion of alternative methodological approaches or how methods should be adapted for different contexts and audiences. In particular, there

is little consideration of user experience, accessibility, usability testing, or meaningful involvement of patients and the public throughout the development process. These steps are essential for ensuring that a guideline is well-informed, evidence-based, and aligned with the needs of the stakeholders in health research.

For my DPhil, I followed the EQUATOR framework as described by Moher et al., [66, 85] as the guiding structure for the development of a reporting guideline because it remains the most established and widely accepted approach and also because there is little alternative formal guidance available for reporting guideline development.[67] This decision was also supported by the expertise of my supervisory team. However, I adapted several stages of the process to better address the aims of this project, which focused on reporting trial results to patients and the public. For example, in addition to a literature review to establish the need for a reporting guideline, I chose to do a qualitative study including interviews and focus groups to further explore perspectives, opinions, and needs of relevant stakeholders. I also aimed to ensure that the development process included broader stakeholder involvement by including patient and public representatives, policymakers, journal editors, and medical writing professionals alongside trial professionals, clinicians, and methodologists. This broader involvement aimed to enrich the reporting guideline development process and help address known barriers for reporting guideline use, including issues relating to clarity, dissemination strategies, and usability. [67, 90] I also included pilot testing as a major part of the development process to evaluate the draft reporting guideline. The EQUATOR framework largely neglects this step and provides relatively little attention to how pilot testing should be conducted. [85]

As the first step in the framework, a literature review needs to be done to identify the need for developing the guidance and summarise the current available resources. This will lay the groundwork for the subsequent stages of guideline development. [66, 85] I first established the need for a reporting guideline through a scoping review to explore what guidance currently exists (Chapter 2). Scoping reviews are commonly used to map broad areas of evidence, identify gaps in the literature, and clarify key concepts where evidence is heterogeneous or underdeveloped. [91] Unlike systematic reviews, which are designed to determine "*what works*" by answering focused questions, scoping reviews are used to explore "*what is out there*" by mapping the available evidence, examining the range and nature of research activity, and identifying gaps in emerging or underdeveloped fields. [92] This approach was appropriate because guidance on sharing trial results with patients and the public remains limited and inconsistently reported. The scoping review allowed me to summarise existing guidance, explore communication approaches, and identify limitations of current guidance and areas of development.

However, literature reviews alone cannot determine what information end users consider meaningful, understandable, or useful. I therefore complemented the review with qualitative interviews and focus groups to explore the views and experiences of patients, members of the public, and trial professionals (Chapter 3). Qualitative methods are particularly valuable when developing patient-centred interventions or guidance because they allow exploration of perspectives, preferences, language, and informational needs that may not be captured in published literature alone. [93]

Using findings from both the scoping review (Chapter 2) and the qualitative study (Chapter 3), I generated an initial list of candidate reporting items, which I refined through a structured consensus process (Chapter 4 and 5) to develop evidence-based recommendations that formed the foundation of the reporting guideline.

A number of methods exist to solicit group opinions and achieve consensus, such as nominal group techniques, Delphi consensus, and consensus development conferences. [94] Each has advantages: nominal groups allow in-depth discussion and rapid prioritisation but are typically conducted in smaller groups and may be more vulnerable to the influence of dominant voices. [94] Delphi surveys enable anonymous, iterative input from geographically diverse participants but require careful design, consensus definition, and interpretation. Consensus development meetings allow refinement and final agreement but depend on group dynamics and can be resource-intensive. [94]

The choice of method depends on the purpose of the exercise. While nominal group technique is well-suited to generating and exploring ideas, the Delphi method is often preferred for guideline development because it enables consensus to be obtained from a larger group of experts through a structured and iterative process done anonymously. [94, 95]

The Delphi survey is an established methodology to gather expert agreement on a given topic. [96] It allows experts from diverse backgrounds (such as patient representatives, members of the public, trial professionals, researchers, trial coordinators, statisticians) to engage in multiple rounds of feedback. After each round, a moderator analyses the data,

prepares feedback, and presents it to the panellists to consider for the next round. This process, called 'controlled feedback', allows panel members to get an insight into others' responses and an opportunity to reconsider their own position. Controlled feedback ensures that consensus is built gradually and thoughtfully. [97]

The repetitive and interactive survey rounds help gather valuable information and work towards achieving consensus. The anonymous nature of the participation allows individual members to contribute independently without concerns about direct confrontation or risk of inherent biases such as dominance or groupthink mentality. [97] Anonymous participation therefore supports honest and independent contributions while minimising bias and ensuring that diverse perspectives are considered. [97]

A consensus development meeting is a structured discussion where key stakeholders, such as experts, researchers, practitioners, and patient representatives, come together to review Delphi survey findings and finalise consensus on a set of items. [66] This meeting is typically conducted after the final Delphi round to resolve any remaining disagreements, refine ambiguous items, and ensure that the final outputs are meaningful, clear, and practical for implementation. [66]

Although Delphi methods and consensus meetings are commonly used in reporting guideline development, not all guideline projects use this approach because of practical challenges such as cost, time, geographical barriers, or concerns that face-to-face discussion may reduce anonymity and increase the influence of dominant individuals. [98] In some cases, guideline developers may rely on smaller expert panels, nominal group

techniques, or informal consensus processes, particularly where the scope of the guideline is narrow, revisions are minor, or resources are limited.

I used a combination of Delphi survey and consensus meeting methods, as this approach allowed broad participation from both PPI representatives and professional stakeholders across different backgrounds while also enabling structured discussion and final agreement on key reporting items (Chapter 4 and 5). The final consensus development meeting helped me bring together diverse expertise from both professionals and PPI representatives and allowed for in-depth discussion, which improved the credibility and internal validity of the final recommendations to reach 'closer to the truth'. [99] A recognised limitation of consensus meetings is that face-to-face discussion can introduce power imbalances or the influence of dominant individuals. [94] To minimise this risk, I used structured moderation and ensured equal representation of PPI representatives and professional participants to ensure that different perspectives were represented during discussions. I considered the consensus meeting particularly important for this project because the reporting guideline is intended for diverse user groups and needed to balance scientific accuracy with clarity and accessibility for patients and the public.

For a guideline intended for communication with patients and the public, usability testing is particularly important because checklist items need to be understandable and practical for both professional and non-professional users. I therefore incorporated pilot testing with both professionals and PPI representatives as the final step to identify areas requiring refinement and to assess whether the checklist could be applied consistently and meaningfully in practice (Chapter 6).

Established guidance documents, including the EQUATOR Network's recommendations for developing reporting guidelines, the SQUIRE guideline for quality improvement reporting, and the ARRIVE guideline for animal research, emphasise the value of testing draft guidance with intended users. [85, 90, 100] However, there is currently little formal guidance on how these tests should be designed, conducted, or evaluated. [67, 85, 90] As a result, pilot testing approaches vary considerably across reporting guideline projects, and there is no shared framework to support systematic and transparent evaluation.

Some studies rely on informal expert feedback or internal review, while others use more structured approaches such as cognitive interviews, retrospective application exercises, prospective implementation studies, usability testing, or surveys of intended users. [67, 90] Each approach has strengths and limitations. For example, cognitive interviews can explore how users interpret checklist items in depth, whereas retrospective application studies allow assessment of whether different users apply checklist items consistently. Prospective testing can provide insight into how guidance performs in real-world settings but may require greater time and resources. Most published reporting guidelines provide limited information about whether checklist items were tested with intended users before publication. Few describe the rationale for selecting particular pilot testing methods or the theoretical frameworks underpinning their evaluation approach. [67, 101]

Because this reporting guideline was intended for use by both professionals and non-professional audiences, I considered it important to use a structured pilot testing approach that evaluated not only the content of the checklist, but also how usable and

practical it would be in real-world settings. To guide this stage of the project, I drew on five complementary domains using established frameworks from usability research, implementation science, and health communication. I used 'Usability' frameworks to examine how easily and effectively the checklist could be used in practice, including concepts such as efficiency, effectiveness, and user satisfaction. [102] I drew on Sekhon et al.'s theoretical framework of acceptability to explore how appropriate and acceptable participants considered the checklist and whether they would be willing to use it in practice. [103] I also considered concepts of feasibility, applicability and readability, which are commonly used in implementation and intervention research to assess whether a tool can realistically be applied across different contexts, settings and diverse groups of users. [104, 105] Feasibility assesses whether an intervention can realistically be implemented within routine practice, while applicability considers whether it is relevant across different settings and contexts. [104, 105] Finally, readability evaluates how understandable the resulting summaries are for their intended audience. [105]

I selected these frameworks because they provided a structured way to evaluate the checklist beyond simple item agreement and allowed me to assess whether the reporting guideline was understandable, usable, and relevant for its intended audiences, particularly patients and members of the public.

Although reporting guidelines specify the minimum information that should be reported, a checklist alone may not always provide sufficient guidance on how individual items should be interpreted or applied in practice. Explanation and Elaboration documents are therefore developed alongside many reporting guidelines to explain the rationale for each

checklist item, provide methodological background, and illustrate good reporting using published examples. [66, 68] Major reporting guideline initiatives, including CONSORT and PRISMA, recommend using the E&E document alongside the checklist to promote more complete, transparent and consistent reporting. [62, 74, 106, 107]

For a reporting guideline intended to support communication with patients and the public, I considered an E&E document particularly important. Checklist items may require judgement regarding the level of detail, language and presentation appropriate for different audiences. A supporting guidance document therefore provides additional explanation and practical examples to help authors apply the reporting guideline consistently while retaining flexibility to adapt reports to different trial contexts and patient groups.

Following the recommendation of Moher et al., I developed the E&E document (Chapter 7) alongside the reporting guideline rather than after its completion. [66] This allowed findings from each stage of the development, including the qualitative study, Delphi survey, consensus meeting and pilot testing, to directly inform the explanations, recommendations and examples accompanying each checklist item.

Taken together, these considerations informed the overall methodological approach used throughout this thesis and shaped the design of the different stages of reporting guideline development as outlined in the following section.

1.8 Research outline

Aim:

The overall aim of this thesis was to develop a standardised reporting guideline that provides consensus-driven recommendations for sharing the results of randomised trials with patients and the public.

This was achieved through the following objectives:

1. To conduct a scoping review to identify and summarise existing guidance on sharing trial results with patients and the public (Chapter 2).
2. To conduct qualitative interviews and focus group discussions to understand what trial information should be shared with patients and the public and how it should be communicated effectively (Chapter 3).
3. To conduct a Delphi survey to gather consensus on the important elements of a reporting guideline for sharing trial results (Chapter 4).
4. To conduct a consensus meeting to discuss the Delphi findings and agree the content and structure of the draft reporting guideline (Chapter 5).
5. To synthesise findings into a comprehensive guideline, evaluate and refine it through pilot testing, and develop the accompanying E&E guidance (Chapters 6, 7).
6. To present the final reporting guideline, prepare it for publication, and consider its implications, dissemination, and future implementation (Chapters 7, 8).

Research approach

I followed a staged approach comprising several interrelated projects, each addressing a specific research objective. The projects built sequentially on one another, with findings from each informing the next stage of the research.

I describe each objective in separate chapters in this thesis (Chapters 2-7), detailing the methodology, findings, discussion, and limitations. The opening chapter in my thesis provides a detailed description of the research scope, objectives and the approach taken. The final chapter (Chapter 8) will bring all findings together and discuss the implications for the reporting guideline and future research.

After summarising my findings and outputs in the final chapter (Chapter 8), I reflect on the strengths and limitations of my approach, next steps, and the impact I hope my work will have on trial result reporting, patient and public involvement, and trials policy and regulations.

1.9 Patient and public involvement throughout my DPhil

NIHR defines public involvement in research as "research being carried out 'with' or 'by' members of the public rather than 'to,' 'about' or 'for' them". [108] Patient and public involvement sits at the heart of my DPhil as the objective of this study is to serve patients and the public by improving how the results of randomised trials are shared with them.

Meaningful PPI, however, is not always straightforward, and many early-career and doctoral researchers report challenges in implementing it effectively. [109, 110] Throughout

this DPhil, I learnt that meaningful involvement required balancing research objectives with the expectations and contributions of public partners, while remaining flexible about how and when their input was incorporated. I learned how to manage differing perspectives, resolve disagreements constructively, and, importantly, to step out of my "researcher" mindset and work with patient partners as equal contributors rather than external advisors. [111]

I was deeply moved when one patient representative shared the phrase "Nothing About Us Without Us", which captures the principle that underpins PPI in clinical research. [112] That conversation shaped how I approached collaboration with public partners throughout the research process rather than consulting them only at isolated stages.

PPI was incorporated from the earliest stages of the study. I first presented the study to the OPEN ARMS public engagement network within the Nuffield Department of Orthopaedics, Rheumatology and Musculoskeletal Sciences (NDORMS), University of Oxford on 26th February 2024. OPEN ARMS is a patient and public involvement and engagement network that supports collaboration between researchers and members of the public in musculoskeletal research. [113] A short survey conducted with the 15 attendees indicated unanimous support for the project and 87% expressed interest in contributing further.

Through OPEN ARMS, I joined the Student Patient Alliance (SPA), which pairs members of the public with DPhil students. Ms Clara de Martins kindly became my patient partner and provided ongoing feedback and insights throughout the research process. Several other

patient partners also generously supported the study by reviewing the study aims, contributing to the design and conduct of the qualitative study and Delphi process, and actively participating in interviews, focus groups, Delphi survey, consensus meeting, and pilot testing. Their involvement ensured that the resulting reporting guideline reflects the priorities and perspectives of its intended users.

As Clara reflected during focus group discussion 2,

"It is the connection you feel with others and being represented even amongst peers is so important. It gives us the confidence and the courage that we're not alone and we matter, and it doesn't matter who we are, what we look like…. What matters is that we're there and we're at the table. We brought our chair and we're here and that's what matters."

This collaboration highlighted the importance of co-production in this DPhil work, something I am deeply committed to, and served as a reminder of the value of including diverse voices to make research more relevant and accessible. Their presence also encouraged participants to engage more openly, knowing that PPI representatives were actively involved in shaping the study. Overall, it strengthened the project's inclusivity and responsiveness to participants' voices, which is ultimately the purpose of this work.

Summary

Having set the scene, I begin this thesis in the same way I began my research: by exploring whether there is a clear need for a reporting guideline for sharing trial results with patients and the public. In Chapter 2, I present the results of the scoping review I

conducted to identify existing guidance in this area and to examine its strengths and limitations. This review formed the foundation for the subsequent work in this thesis.

Chapter 2: A scoping review of existing guidance on sharing trial results with patients and the public

This chapter is based on the published article: **Choudhury S**, Collins GS, Albury C, de Beyer J, Hopewell S. A scoping review of guidance on sharing trial results with patients and the public finds inconsistent recommendations and limited methodological development. *Journal of Clinical Epidemiology*. 2026:112394. [114]

2.1 Background

A comprehensive review of the existing literature was an important first step in developing the reporting guideline. Before proposing new recommendations, I needed to understand what guidance already existed, its scope and limitations, and where important gaps remained. As the aim was to map the existing landscape rather than answer a narrowly defined research question, a scoping review was the most appropriate approach.

A scoping review is a type of evidence synthesis that uses a systematic approach to identify, examine, and synthesise the available literature on a particular topic. [115] Unlike a systematic review, which is designed to answer a focused question by synthesising evidence on a specific intervention or outcome, a scoping review is used to explore a broad topic where the evidence is diverse, scattered, or still developing. [91, 92, 115]

Additionally, a scoping review allows different types of evidence to be brought together, mapped, and examined to identify what is already known and where further work is

needed. This was particularly relevant to my research because guidance on sharing trial results is published in a variety of sources, including journal articles, regulatory documents, organisational guidance, and grey literature, rather than within a single body of evidence.

The findings of this review provided the evidence base for the subsequent stages of reporting guideline development. In addition to summarising the existing guidance, the review identified limitations in current recommendations and areas requiring further development. As I anticipated that little guidance would be available specifically for randomised trials, I broadened the scope to include guidance developed for other study designs such as observational studies, qualitative research, and systematic reviews. This allowed me to identify transferable principles while also highlighting the need for guidance tailored specifically to randomised trials.

2.1.1 Review question

"What guidance exists on sharing trial results with patients and the public”?

2.1.2 Objectives

The objectives of this scoping review were to:

1. Identify and describe existing guidance on sharing trial results with patients and the public.
2. Summarise recommendations on the content of result summaries.

3. Summarise recommendations on the dissemination of trial results to patients and the public.
4. Identify the intended audience for each guidance document.
5. Describe how the guidance documents were developed.
6. Examine whether diversity, inclusivity, and ethnicity were considered during guidance development.
7. Describe the role of PPI guidance development.
8. Generate candidate reporting items for the Delphi survey (Chapter 4).
9. Identify recommendations to inform the development of a high-quality reporting guideline.

2.2 Methods

2.2.1 Protocol and registration

The protocol is registered on the Open Science Framework (OSF) to support transparency and reproducibility. [116] I developed the protocol using established scoping review methodology, specifying the research questions, scope, inclusion criteria, and analysis plan before conducting the review. The protocol was structured using the PRISMA-ScR (Preferred Reporting Items for Systematic Reviews and Meta-Analyses extension for Scoping Reviews) reporting guideline, and the completed review is reported in accordance with PRISMA-ScR (Appendix 2.1). [117]

2.2.2 Terminology and eligibility criteria

Table 2.1 outlines the eligibility criteria using the PCC (Participants, concept and context) model.

Table 2.1: Terminology, inclusion and exclusion criteria

Category	Details
Participants	Patients, trial participants and the public. As described in Chapter 1, the terms patients and participants are used interchangeably in this scoping review.
Concept	I performed an initial literature search, which identified a shortage of resources specific to clinical trials. Consequently, I designed the protocol to extend the scope to include guidance applicable to any type of study design. This broader approach allowed for the capture of a wider range of practices and insights potentially relevant to clinical trials. This scoping review examined guidance reports, contents, presentation style recommendations, development processes, target audiences, publishers, utilisation, and limitations.
Context	This scoping review was not limited to any specific setting.
Inclusion Criteria	1. Any guidance on sharing study results with patients/participants and the public. 2. Any guidance or recommendations published in journals or found in the grey literature (for example, the guidance published by TransCelerate BioPharma in 2016) [118] 3. Guidance written in English. 4. Guidance involving humans only.
Exclusion Criteria	1. Guidance on reporting study results to clinicians, researchers, policy makers etc (e.g., the CONSORT Statement).[62]

In this scoping review, I included journal articles, opinion pieces, organisational reports, blog posts and literature reviews that matched the eligibility criteria. To be included, the documents had to explicitly provide guidance on sharing any type of study results to patients and the public, and specify the contents to be shared (the “what”) and how to represent the information somewhere within the text (i.e., not necessarily in the title or abstract).

Guidance that did not specify the contents to be shared was excluded from data extraction. I also excluded guidance intended for scientific audiences, generic recommendations on dissemination or plain language writing, and guidance relating to reporting clinical results (e.g., risk assessments or genetic test results) rather than overall study findings.

2.2.3 Search strategy

The initial literature search revealed limited availability of resources in the published literature and indexed journals. Therefore, alongside standard bibliographic databases, it was crucial to include unpublished or grey literature sources such as government websites and evidence-based agency reports into the search strategy.

I devised a multi-stage in-depth search strategy to ensure maximum coverage of potential sources. The approach began with a systematic search, complemented by a citation tracking stage, and finished with a thorough extensive grey literature search. Each step is described in detail below.

Stage 1: Systematic search

The search strategy for bibliographic databases was informed by an initial search of the Ovid MEDLINE® database, [119] which identified a few relevant articles. I used the keywords as presented in the titles, abstracts, and indexes of these articles as a basis to develop the full search strategy for two bibliographic databases. The search strategies for both databases were reviewed by two information specialists who reviewed the structure, terminology, and syntax of the search queries (Table 2.2 and Table 2.3).

First, I searched Ovid MEDLINE® [119] from 1946 to 12th March 2024. Second, I searched the Web of Science Core Collection, [120] covering records from 1900 to 12th March 2024, depending on the specific index. Both searches were conducted on 12th March 2024. No date limits were given as the goal was to include all potentially eligible records. At this stage, 1,303 records were screened, and 18 records met the eligibility criteria for inclusion in this review.

I included Web of Science in addition to Ovid MEDLINE® to improve the comprehensiveness of the search. Ovid MEDLINE® is one of the principal databases for biomedical and health research, [119] while Web of Science provides broader interdisciplinary coverage and indexes journals that may not be included in MEDLINE, as well as conference proceedings. [120] Searching multiple databases reduces the risk of missing relevant studies because no single database indexes all published literature, thereby improving the completeness of evidence identification. [121]

Table 2.2: Ovid MEDLINE® search strategy

(Ovid MEDLINE® Epub ahead of print, in-Process and other non-indexed citations, Ovid MEDLINE® Daily and Ovid MEDLINE®) 1946 to 12th March 2024

Date of search: 12th March 2024

#	Search Query	Results
1	(patient* or participant* or public).ti,ab,kw.	9631201
2	((communicat* or offer* or return* or feedback or shar* or disseminat* or provid* or receiv*) adj5 ("study result*" or "trial result*" or "clinical trial results" or "research results" or "study findings" or "trial findings" or "results of the stud*" or "results of the trial*" or "results of a clinical trial*" or "results of clinical trials" or "results of a study" or "results of stud*" or "findings of the study" or "findings of the trial" or summar* or "aggregate results")).mp.	67155
3	((recommendation* or guidance* or guideline*) adj7 (results or findings)).mp.	60867
4	1 and 2 and 3	697

Table 2.3: Web of Science Core Collection search strategy

Database: Web of Science Core Collection

Indexes and coverage: Each index covers different types of journals, conference proceedings and time periods as described below:

WOS.IC (1993–2024); WOS.CCR (1985–2024); WOS.SCI (1900–2024); WOS.AHCI (1975–2024); WOS.BHCI (2005–2024); WOS.BSCI (2005–2024); WOS.ESCI (2015–2024); WOS.ISTP (1990–2024); WOS.SSCI (1900–2024); WOS.ISSHP (1990–2024).

Date of search: 12th March 2024

#	Search Query	Results
1	ALL=((patient* or participant* or public))	11,231,568
2	TS=((communicat* or offer* or return* or feedback or shar* or disseminat* or provid* or receiv*) NEAR/5 ("study result*" or "trial result*" or "clinical trial results" or "research results" or "study findings" or "trial findings" or "results of the stud*" or "results of the trial*" or "results of a clinical trial*" or "results of clinical trials" or "results of a study" or "results of stud*" or "findings of the study" or "findings of the trial" or summar* or "aggregate results"))	77,498
3	TS=((recommendation* or guidance* or guideline*) NEAR/7 (results or findings))	121,690
4	#3 AND #2 AND #1	606

Stage 2: Citation tracking

Using the 18 articles identified in stage 1 as a starting point, additional relevant articles were explored in PubMed® between 13th April 2024 and 23rd May 2024. For each included article, I re-identified the record in PubMed® and screened reference lists (backward snowballing) and “cited by” lists (forward snowballing). I also used PubMed’s “Similar articles” feature to identify any further relevant studies.

At each step, the first ten results were screened, yielding an average of 30 additional records for each article retrieved in stage 1. Duplicates already identified in the initial search were excluded from further screening.

Stage 3: Grey literature search

To complement the database searches, I also performed an extensive grey literature search in multiple stages. The grey literature search was limited to reports published in English.

First, I conducted an advanced Google Scholar search employing a variety of search terms on 23rd May 2024, 30th May 2024, and 12th June 2024. The search terms were used as free text terms and searched in different combinations to ensure maximum coverage. The search engines, number of results screened and retrieved, and dates of each search are documented in Appendix 2.2.

I sorted the search results using the "Relevance" filter to place the more relevant articles first. After the search was conducted, I screened the first ten pages of the search results to identify relevant documents (approximately 100 records for each search). This number of pages was chosen to identify many of the most relevant hits while still maintaining a manageable amount to screen.

Second, I performed a Google search on 15th June 2024 using keywords such as "guidance + results + patients + public," and retained the first 100 results for further screening (Appendix 2.2).

Third, I hand-searched relevant organisational websites using each site's search function and combinations of keywords (e.g., "guidance", "results", "patients", "public"). Websites were identified through the database and grey literature searches, as well as my existing knowledge. The websites included government organisations (e.g., UK HRA), grant funding bodies (e.g., NIHR), research and policy centres (e.g., Multi-Regional Clinical Trials Center (MRCT) of Brigham and Women's Hospital and Harvard), charity organisations (e.g., Cancer Research UK), the EQUATOR Network, publishing groups (e.g., Taylor & Francis), patient participation groups (e.g., NIHR Biomedical Research Centre (BRC) Patient and Public Advisory Group), and workgroups of medical journal editors (Appendix 2.2).

Search results can be influenced by user behaviour; therefore, I used the same device across all sessions and conducted each search in one sitting with all top 100 links reviewed. As noted by Haddaway et al., while such searches may be less precise, they can improve the comprehensiveness of evidence identification when used alongside structured database searches. [122]

Following peer review in the *Journal of Clinical Epidemiology*, I reran the Google Scholar searches using revised syntax on 17th March 2026. I screened the first 100 results sorted by relevance. No additional eligible guidance documents were identified in this step beyond those already included in the review.

2.2.4 Study selection

The scoping review included documents written in English, published at any time, that provided guidance or recommendations on sharing study results with participants, patients, or the general public.

All records were imported into EndNote (v21), where duplicates were removed and screening was conducted. Screening was performed in two stages: (1) title/abstract screening and (2) full-text screening. I screened all identified records and assessed for eligibility using the title and abstract against the inclusion criteria followed by full text-screening for final inclusion in the review. My primary supervisor, Professor Sally Hopewell, independently verified the inclusion of records, with disagreements resolved through discussion and consensus. The search strategy and the inclusion process are summarised using the PRISMA flow diagram shown in Figure 2.1. [74]

2.2.5 Data extraction

Data were extracted using Microsoft Excel. I piloted the data extraction form on five articles containing guidance or recommendations on sharing trial or research results and subsequently refined to ensure all relevant information was captured. Table 2.4 summarises the data points collected.

Table 2.4: Data extraction form fields

- Title
- Source
    - Publisher and date of publication
    - Where is the guidance published? (e.g., government agency website, peer reviewed source)
    - Location: Where is the guidance developed? (e.g., UK, Canada)
- Applicable study types: Which study designs does the guidance cover? (e.g., clinical trials, observational studies, or all study designs)
- Content of the guidance:
    - Key points: what the report should include
    - Structure: format of report (e.g., lay summary), if template/toolkit included
    - Recommendations on presentation: writing style, readability, etc.
    - Recommendations on planning resources (e.g., budget)
- Dissemination:
    - Target audience (e.g., study participants, general public, or both)
    - Type of result: Individual or aggregate results
    - Timeline of reporting
    - How to disseminate
- Patient and public involvement:
    - Were patients and/or the public involved in developing the guidance?
    - Does the guidance recommend involving patient and public in creating the report?
- Development and evaluation:
    - How was the guidance developed (e.g., expert panel, consensus meeting)
    - Was the guidance evaluated?
    - Were diversity or inclusivity (e.g., ethnicity, culture, language, or underrepresented groups) considered during the development of the guidance

2.2.6 Data analysis and presentation of results

I collated, summarised, and analysed the data according to the key features of each guidance document. The data were characterised in the following themes and presented in tabular form:

- Characteristics of the guidance
- Recommendations on content and presentation
- Recommendations on timeline and dissemination
- Patient and public involvement in guidance development
- The development methods and, where applicable, evaluation of the guidance documents

2.2.7 Data quality

The PRISMA-ScR statement states that critical appraisal is not required for a scoping review, [117] and no recognised tool currently exists to assess the quality of reporting guidelines. As such, I did not perform a critical appraisal. However, to assess the rigor and relevance of the identified guidance documents, I performed a methodological appraisal examining the following key domains relevant to reporting practice:

- **Scope and purpose:** clarity of aims and target audience
- **Development methods:** whether systematic processes (e.g., literature reviews, expert consultation) supported the development
- **Stakeholder involvement and co-production:** involvement of patients, public, or participants in development
- **Content:** aspects of results reporting covered (e.g., individual vs summary results, format, 'what' to share, timing, and dissemination strategies)
- **Accessibility:** availability, clarity, and usability for non-specialist audiences

To improve transparency, I assessed each domain using a simple coding framework:

- **reported** (clearly described in the document),
- **unclear** (mentioned but lacking sufficient detail), or
- **not reported** (no information provided)

The full table is provided in Appendix 2.3. This appraisal helped assess the rigor and comprehensiveness of each guideline, highlighting variations in methodological approaches and the extent to which they incorporated diverse perspectives. By evaluating these aspects, I was able to identify strengths, gaps, and inconsistencies across guidelines, which informed the next steps in developing a more robust and inclusive reporting guideline.

2.3 Results

2.3.1 Search results

The scoping review identified 2,289 potential records (database searches n=1,703, citation tracking n=486, grey literature searches n=100). After title and abstract screening, 162 records underwent full-text review, and 24 were deemed eligible for data extraction and inclusion in this scoping review. The detailed search process is illustrated using the PRISMA flow diagram and shown in Figure 2.1. [74]

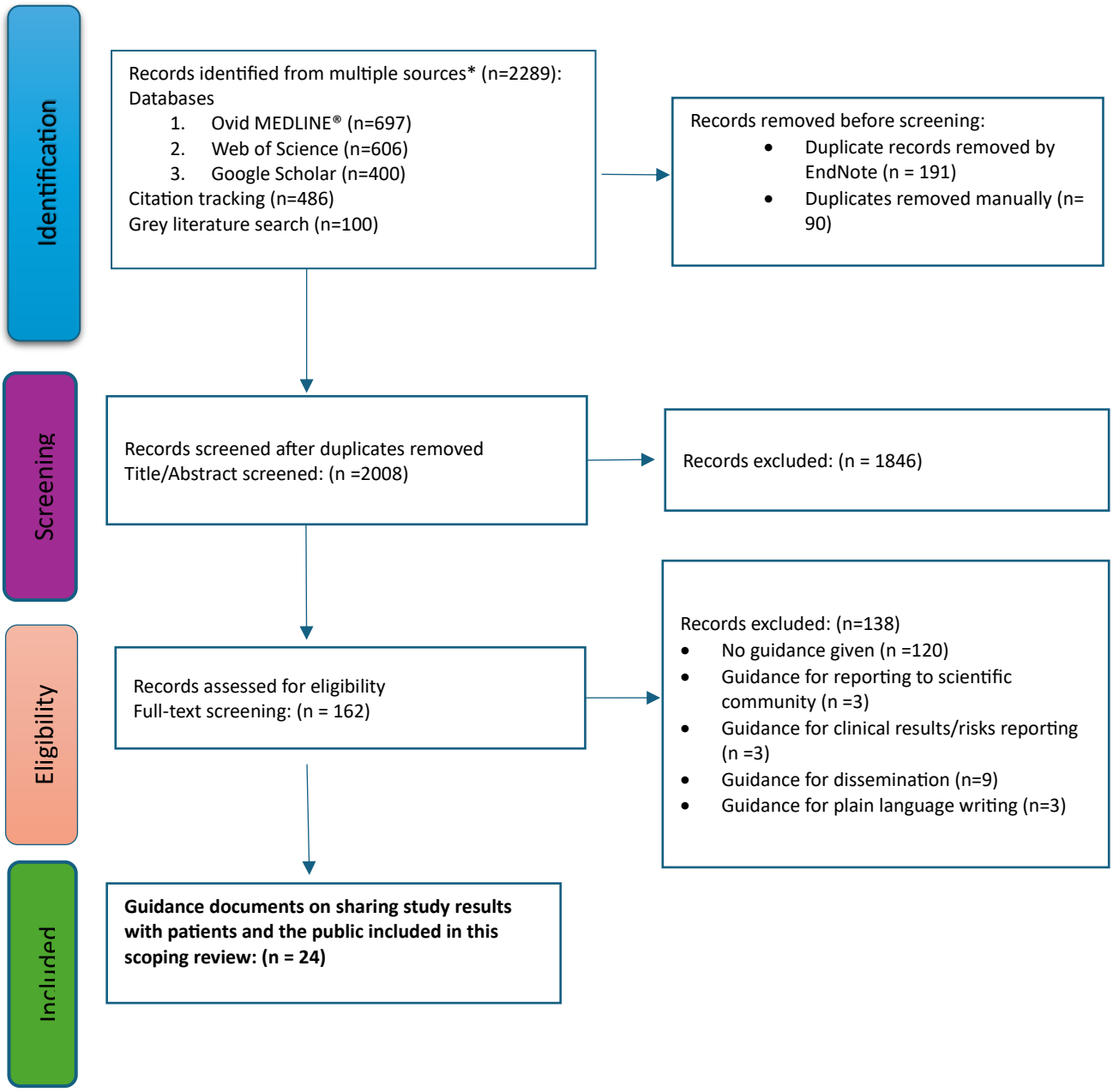


Figure 2.1: Flow chart of screened and included documents. *(Adapted from Prisma 2020 flow diagram for systematic reviews* [74]

2.3.2 Characteristics of the included reports of guidance for sharing study results

Of the 24 included guidance documents, ten applied broadly to any type of research study, [123-132] while nine focused on different clinical trial designs. [118, 133-140] A small number

of documents addressed systematic or evidence reviews (2) [141, 142], biospecimen studies (1) [143], biomonitoring studies (1) [144], and communication research (1) [145]. None were specifically designed for reporting results of randomised trials.

The 24 guidance documents were mostly published in North America and Europe, with an increase in publications observed over the last decade (Figure 2.2). Eight documents were peer-reviewed [123, 126, 128, 132, 133, 140, 144, 145]; others were published on websites of government bodies, research organisations, regulatory agencies, charities, publishers, or industry. Most documents addressed sharing summary results, two focused on individual participant results [143, 144], and one covered both individual and summary results [145]. In terms of the target audience, eight of the 24 guidance reports were directed at participants, nine aimed for sharing with the public, and eight targeted both groups.

One report was under review by the United States Food and Drug Administration (U.S. FDA) and not officially published yet (proposed guidance under 21 CFR 10.115(f)(3)). [137] A full summary of characteristics is provided in Table 2.5.

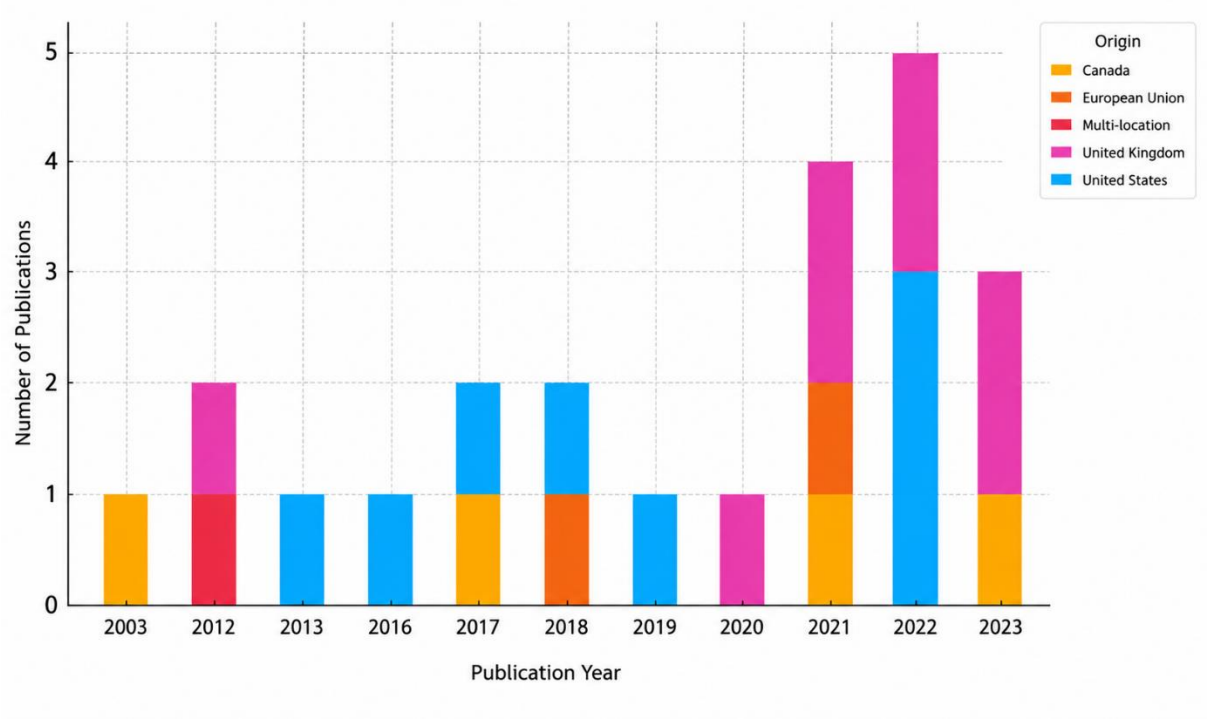


Figure 2.2: Geographical and temporal distribution of the included guidance documents. *Each bar represents the number of guidance documents published in a given year, grouped by geographical origin. Colours indicate Canada, the European Union, Multiple regions, the United Kingdom, and the United States.*

Note: *The draft guidance submitted to the United States Food and Drug Administration in 2017 had not been officially published and was therefore not included in this figure.*

Table 2.5: Characteristics of the included guidance documents for sharing study results with patients and/or the public

Report ID	Title of guidance	Source	Year	Location	Study type	Type of result	Target Audience (Participants/ General public)	Template/ toolkit provided?	Method of development reported?	Patients/ Public involved in developing guidance?	Ethnic diversity considered?
Arnstein et al. 2020 [123]	Patient involvement in preparing health research peer-reviewed publications or results summaries: a systematic review and evidence	Peer-reviewed journal	2020	UK	Any type of research study	Aggregate	Both	Yes	Yes	Yes	Not reported
Baba et al. 2023 [133]	Youth and family involvement in the development of a plain language trial results communication tool: CommuniKIDS	Peer-reviewed journal	2023	Canada	Paediatric trials	Aggregate	Participants	Yes	Yes, but not detailed	Yes	Not reported
Canadian Frailty Network 2017 [124]	Guidelines for writing a lay summary	Government agency website	2017	Canada	Any type of research study	Not specified	General public	Examples given	No	Not reported	Not reported
Clinical Trials Ontario 2021 [134]	Plain language result summaries template for participants	Clinical Trials organisation website	2021	Canada	Adult clinical trials	Aggregate	Participants	Yes	Yes, but not detailed	Yes	Not reported
Cochrane 2022 [141]	How to write a plain language summary of a Cochrane intervention review	Publishing agency	2022	UK	Cochrane reviews	Plain language summari-es of Cochrane reviews	General public	Yes	Yes, but not detailed	Yes	Not reported

Duke et al. 2012 [125]	How to write a lay summary	Charity organisations website	2012	UK	Any type of research study	Not applicable	General public	No	No	Not reported	Not reported
Dunagan et al. 2013 [144]	When pollution is personal: best practices for reporting results to participants in biomonitoring and personal exposure studies	Peer-reviewed journal	2013	USA	Biomonitoring studies	Individual	Participants	No	Yes	yes	Yes
European Commission 2018 [135]	Summaries of clinical trial results for laypersons	Regulatory organisation website	2018	European Union	Clinical trials	Aggregate	General public	Yes	No	Not reported	Not reported
European Commission 2021 [136]	Good lay summary practice (GLSP)	Regulatory organisation website	2021	European Union	Clinical trials	Aggregate	Both	Yes	Yes	Yes	Not reported
Fernandez et al. 2003 [126]	Informing study participants of research results: an ethical imperative	Peer-reviewed journal	2003	Canada	Any type of research study	Aggregate	Participants	No	No	Not reported	Not reported
Fernandez et al. 2012 [132]	Recommendations for the return of research results to study participants and guardians: a report From the Children's Oncology Group (COG)	Peer-reviewed journal	2012	Multi-national institute*	All COG-sponsored studies	Aggregate	Both	No	Yes	Not reported	Yes
Health Research Authority, 2021 [127]	Writing a plain language (lay) summary of your research findings	Government agency website	2021	UK	Any type of research study	Aggregate	General public	Provides links to further resources	No	Not reported	Not reported

Hintz and Dean. 2019 [145]	Best practices for returning research findings to participants: methodological and ethical considerations for communication researchers	Peer-reviewed journal	2019	USA	Communication research	Individual and aggregate	Participants	No	Yes	Not reported	Not reported
Knowles et al. 2022 [142]	Drawing in the experts! 10 recommendations for communicating research findings to patients and the public	Research organisation website	2022	UK	Evidence review output	Aggregate	Both	No	Yes, but not detailed	Yes	Not reported
MRCT FDA ,2017 [137]	*Draft FDA guidance on provision of plain language summaries*	*Not officially published yet*	*N/A*	*USA*	*Clinical trials*	*Aggregate*	*Both*	*In the appendix, a draft toolkit is suggested*	*No*	*Not reported*	*Not reported*
MRCT Center 2017** [138]	Return of aggregate results to participants guidance document v3.1	Government agency website	2017	USA	Clinical trials	Aggregate	Participants	yes	Yes	Not reported	Not reported
NASEM 2018*** [143]	Returning individual research Results to participants: guidance for a new research paradigm	Government agency website	2018	USA	Biospecimen studies	Individual	Participants	No	Yes	Yes	Not reported
Rosenberg et al. 2021 [128]	Open Pharma recommendations for plain language summaries (PLS) of peer-reviewed medical journal publications	Peer-reviewed journal	2021	UK	Any type of research study	Aggregate	General public	No	Yes	Yes	Not reported

Solovyeva et al. 2023 [139]	Toolkit for lay summary of early phase dose-finding clinical trial results	Charity organisations website	2023	UK	Early Phase dose-finding clinical trials	Aggregate	Both	yes	Yes	Yes	Not reported
Taylor & Francis 2023 [129]	Plain language summaries of publications (PLSPs) author guidelines for development, submission and publication	Publishing agency	2023	UK	Any type of research study	not applicable	Both	No	No	Not reported	Not reported
TransCelerate BioPharma 2016 [118]	Recommendations for drafting non-promotional lay summaries of clinical trial results.	TransCelerate BioPharma website	2016	USA	Clinical trials	Aggregate	Both	No	No	Not reported	Not reported
Vanderbilt Institute for Clinical and Translational Research 2022 (a) [131]	Guidelines for creating a public summary	Research organisation website	2022	USA	Any type of research study	Aggregate	General public	Yes	Not reported explicitly.****	Yes	Yes
Vanderbilt Institute for Clinical and Translational Research 2022 (b) [130]	Guidelines for creating a narrative summary	Research organisation website	2022	USA	Any type of research study	Aggregate	Participants	Yes	Not reported explicitly.****	Yes	Yes
Zimmerman 2022 [140]	Developing lay summaries and thank you notes in paediatric pragmatic clinical trials	Peer-reviewed journal	2022	USA	Pragmatic paediatric trials	Aggregate	Participants	No	Yes	Yes	Yes

Notes:

*(North America, Australia, New Zealand, and parts of Europe)

** Multi- Regional Clinical Trials Center of Brigham and Women's Hospital and Harvard

***National Academies of Sciences, Engineering, and Medicine, 2018

**** The dissemination research was found after further searching

*Note: **Not reported** indicates that no explicit information was identified in the guidance document. This does not necessarily mean that the activity was not undertaken.*

2.3.3 Suggested content for sharing study results:

The 24 guidance reports provided diverse recommendations on the content for sharing study results with patients and the public. Many gave little to no detail, some provided section headings, and a few offered detailed headings, subheadings, and example text. The guidance also varied on which items should be shared. Table 2.6 summarises these recommendations; detailed findings for each report are presented in Appendix 2.4.

Table 2.6: Suggested content for sharing results with patients and the public

Category	Key content items as suggested by the reports of guidance [Reference # (Report ID which contains the recommendation)]
Thank you	• To study participants, sites, trial teams and any other relevant contributors 118, 123, 127, 130-134, 136-139
Introduction	• General description of the risks and benefits of receiving results 125, 132
Background	• Primary goal, aims and objectives, research question 123-126, 128, 130-133, 135-138, 140-143, 145
General information about the study	• Title or trial name (formal and lay name), • Protocol number, investigator name(s), sponsor, funder, timescales, study start/completion dates, clinical trial identifier or registration/universal trial number • About the trial: (e.g., disease studied, intervention, goal and hypothesis, where and when, investigational medicinal products used, study phase/design • Optional diagram of protocol flow, number of arms, treatment per arm, and other pertinent information that is helpful to understand the results 123-128, 132-141
About the study methods	• Major interventions, such as randomisation • Any issues that necessitated changes to the trial 124, 127, 129-134, 139-142
Study participants	• General information to help readers check how similar they are to the study participants • Main inclusion/exclusion criteria of the trial • Number of participants: numbers overall and participants per arm • Age group breakdown and gender breakdown • A clear statement that the results apply to this population, and not any other population, and under these specific conditions 123, 127, 129, 131, 133-139, 142
Key result or outcome of the study	• Primary and secondary outcomes • If applicable, patient-reported outcomes • Short/long-term treatment effects • Implications for practice/research • A statement noting that no individual results are provided in this document • Potential impact of the results on the population under study/clinical care • Positive or negative findings • A statement that the summary includes the results of a single study and that multiple studies are used together to assess the risks and benefits of an FDA-regulated product • Any questions that weren't answered or that emerged due to the results • Level of uncertainty in the result validity

118, 123-145

Side effects	• Key side effects of the intervention • Most frequent, most serious, and/or unexpected side effects • Mention if unwanted effects were not reported • Additional link to the reported scientific results for a listing of additional safety information • Anticipated long-term effects and surveillance recommended, if any, for the participant • Additional sources of support to prevent possible harm resulting from the return of study findings, if applicable • Main challenges for patients with the treatment 126, 127, 133-141, 145
Next steps	• Information about follow-up studies, if available, and opportunities to be involved in future phases of the trial • What's next for the research (e.g., moving to phase 3 after phase 2, another study, publication, licensing) • Whether and when the intervention might be available after the study • If the experimental or standard arm will likely become the standard of the future • Next steps (e.g., publication, licensing) • Suggested follow-up plans, if any, reference to long-term follow-up guidelines • Frequency of follow-up and safety monitoring (on and off treatment) 123, 124, 127, 131-139, 143, 145
Patient engagement and community involvement	• Patient and public involvement and engagement (PPIE) in the design or the study delivery • Patient stories 127, 131, 133, 139, 142
Trial conclusions	• Conclusions and interpretations 123, 133
Shared decision-making prompt	• Highlight desirable action • How to discuss trial results with personal health care providers • A statement that patients should consult their physicians and/or study doctors with further questions about their individual care and should not make changes in the treatments based on the results of this study 118, 123, 133, 134, 137
Trial limitations	• Excluded populations • Limitations of the evidence, etc. 133, 134, 141, 145
Date	• Date of summary • Whether and when update may be expected • Defining when the findings became available for disclosure (i.e., when the peer review process was completed)

	123, 132, 136-139, 141, 145
Contact information	• Sponsor contact details 123, 137
Further information	• Signpost to further information • Link(s) to any publication(s), study website, institutional contacts 118, 123, 127, 130-140, 143, 145, 146
QR code	• Link to digital version of PLS, if applicable 128
Disclosures	• Drug approval status • Authorship and/or funding transparency • Data protection policy 123, 145

2.3.4 What are the recommendations for presenting the study results?

Of the 24 guidance documents, 23 documents provided recommendations on presenting results to patients and the public. Most recommended using plain language and avoiding jargon. Few emphasised the need to consider cultural differences and sociodemographic characteristics. Some suggested to offer multiple strategies to ensure accessibility for diverse audiences. A summary is provided in Table 2.7, with more detailed tables in Appendix 2.5.

Table 2.7: Recommendations for presentation of study results to patients and the public

Category	What are the recommendations on presenting study results?
Text structure and style	• Use text hierarchy (differentiation in text styles) to emphasise important information [123, 144] • Apply a "funnel" structure: (inverted pyramid writing style)[123, 135, 138, 142] • Keep font sizes readable (minimum of 12-point font)[123, 135, 138] • Open question headers: to engage readers[123] • Use active voice, non-technical language, and simple sentences. Provide lay definitions for technical terms. Present medical terms in brackets.[124, 125, 129, 131, 133-136, 138, 140, 141] • Use simple descriptive headings, subheadings, and bullet points. [123, 133, 135, 136, 138, 140, 141] • Use respectful everyday language, for example: people with (condition), not patients. Apply cultural sensitivity. [123-125, 127, 135, 136, 141, 143] • Provide simple, relevant examples when describing the research[123-125, 127, 135, 136, 141, 143] • Use bold text to add emphasis but do not use underlining, italics, fancy fonts, or all CAPS [135, 136, 138] • Keep paragraphs and sentences short (~20 words per sentence). Break up longer sentences for readability. [125, 127, 129, 131, 135, 136, 140, 141] • Use pronouns. Write in the first-person plural. [141]
Numeracy and data representation	• Use natural frequencies and percentages; avoid variable frequencies. Write numbers as numerals (1, 2, 3…) but avoid starting sentences with them. Do not use statistical terms.[123, 135, 136, 138, 141] • Avoid superlative and enthusiastic words. Use neutral, consistent language. [118, 127, 129, 136, 137] • Avoid stock photos; instead, use real images of the team or bespoke illustrations.[142] • Ensure clear label captions and meaningful scaling for graphs. [136]
Design and layout	• Use clear sections with colour blocks, divider lines, and white space to distinguish content. [123, 135, 136, 138, 141, 142] • Ensure sufficient contrast between text and background (e.g., black text on a white background). • If sharing electronically, save and share as a PDF.[133, 134] • Avoid using blue font for regular text to avoid confusion with hyperlinks.[133] • Use left-justified text. [136]
Engagement and accessibility	• Involve patients, patient representatives, or members of the public in the development and/or review of your summary/feedback plans. • Involve professionals with experience of writing in plain language for the public such as medical writers [124, 131, 138, 141, 142] • The summary should be in an accessible level of English and, when locally relevant, translated into additional languages.[132, 143] • Write for an international audience (avoid regional terms like "A&E" or "ER").[141] • Consider using suitable graphics, visuals, or videos to make summaries more accessible (e.g., video with closed captions)[123, 127, 133-136, 138, 140, 142-144]

Review and quality control	• Read the summary aloud to catch errors or awkward expressions [124] • Grammar and punctuation should be accurate, and spelling should follow appropriate conventions.[125] • Sentences should be phrased positively, rather than negatively [125] • A good and relevant title should be provided, and the first sentence should offer a concise introduction to the text.[125] • Text should be suitable for people with a low to average level of literacy. (~12 years/6th grade/8th grade). [129, 131, 135, 136, 140, 142, 144, 145] • Hyperlinks should be minimal.[135, 137, 140, 142] • Limited use of unnecessary imagery that does not enhance understanding (icons, logos, etc.)[135] • Do not assume any prior knowledge [127]

2.3.5 Patient and public involvement

Of the 24 guidance documents, 13 reported incorporating patient and public involvement to some extent during the development stage (e.g., discussions, consultations, or public workshops). Table 2.5 outlines if PPI input was taken during development of each guidance. Fourteen of the 24 guidance documents explicitly advocated for incorporating PPI at various stages of the result-sharing process ranging from input in the initial planning to final review and dissemination.

2.3.6 What are the recommendations for the timeline and dissemination of study results?

Of the 24 guidance documents, ten provided recommendations regarding the timing of sharing study results with patients and the public. Most recommended sharing results within 1 year of primary outcome completion, with shorter or longer timelines for specific study types (e.g., 6 months for paediatric trials). [132, 135-137] Taylor and Francis require PLSs to be

submitted within 2 years of the original article's publication. [129] Documents also recommended involving ethics boards and patient partners [133], clarifying timing in consent forms [126], and sharing results only after peer review. [145]

Regarding dissemination strategies, 13 documents offered varying recommendations, including making results publicly accessible (e.g., open access or public websites) [118, 127, 129, 132, 134, 139, 143] and using multiple formats such as digital platforms, printed materials, or in-person sessions. [126, 145] Findings should preferably be returned by researchers or delegates who have an ongoing relationship with the participants. [145] Direct communication is suggested in case of significant consequences anticipated, and participants should have the opportunity to ask questions even if the results are shared without personal interaction. [126] Participants should be given the choice to opt in/out of receiving trial results. [133]

Twelve documents provided toolkits or practical resources (e.g., checklists, templates) to support dissemination. [123, 124, 127, 130, 131, 133-139, 141] Seven recommended early planning and budgeting for dissemination during protocol development and grant applications. [118, 126, 129, 136, 140, 143, 145] Costs to consider include lay summary production, patient involvement, follow-up care, and translations. The distribution plan should be reviewed by the research ethics board [133]and discussed with community members. [144]

Only two documents emphasised tailoring dissemination approaches to participants' cultural needs, preferences, and logistical constraints. [136, 138] Detailed findings are presented in Appendix 2.6.

2.3.7 Development of the guidance

The methods used to develop the 24 guidance documents were often unclear or insufficiently reported. None of them reported adhering to the recommended steps for developing a reporting guideline. [66] For ten documents, no information on development methods could be identified; it is possible that they undertook similar steps but did not report them. Another ten documents provided detailed accounts of their development, and four offered little description. Thirteen documents reported involving PPI during development. Only five documents reported pilot testing before implementation and just four referenced considerations of diversity. A summary of reported development methods is presented in Table 2.8.

Table 2.8: Development methods reported by the guidance documents (n=14)

Report ID	Development method	Level of reporting	Reported diversity consideration	Reported pilot testing before implementation
Arnstein et al. 2020 [123]	Systematic review and "Plain Language Summary of Publications" workshop	Detailed	Not reported	No
Baba et al. 2023 [133]	Virtual workshops with paediatric researchers, healthcare professionals, youth and parents	Not detailed	Not reported	Yes
Cochrane 2022 [141]	Built on existing resources and expert input	Not detailed	Not reported	No
Dunagan et al. 2013 [144]	Multi-institute collaboration, literature review, interviews, and workshops	Detailed	Yes	Yes
European Commission 2021[136]	Multi-stakeholder approach with expert consultation and review	Detailed	Not reported	
Fernandez et al. 2012 [132]	Literature review and multidisciplinary discussions by a Return of Results Task force	Detailed	Yes	
Hintz and Dean [145]	Systematic literature review and expert opinion synthesis	Detailed	Not reported	
Knowles et al. [142]	Think aloud interviews and co-design workshop	Not detailed	Not reported	
MRCT Center,2017 [138]	Multi-step collaborative approach with diverse workgroup	Detailed	Not reported	Yes
NASEM, 2018 [143]	Expert committee with public input and workshops, interviews with community representatives and literature reviews	Detailed	Not reported	No
Rosenberg et al. 2021 [128]	Expert consultations followed by public discussion	Detailed	Not reported	
Solovyeva et al. 2023 [139]	Review of resources, expert discussions, and wider consultations from a formal PPIE working group	Detailed	Not reported	Yes
Vanderbilt Institute for	Focus groups and dissemination study	Not reported explicitly.	Yes	

Clinical and Translational Research (a, b) [130, 131]		Their dissemination research was found after further searching. [147, 148]		
Zimmerman 2022 [140]	Collaboration with science communication experts and qualitative study testing lay summaries	Detailed	Yes	Yes

2.3.8 Additional findings

During screening, I identified several documents describing the rationale and methods for sharing results with patients and the public (the "why" and "how"), but not the specific content to be reported (the "what"). Although these documents did not meet the inclusion criteria, their relevance to dissemination led me to include them as additional findings under “Dissemination” and “Plain language resources”.

Table 2.9 summarises resources supporting the planning and dissemination of research findings, including stakeholder engagement, communication planning, and ethical considerations.

Table 2.9: Dissemination resources

Title	Publisher	Summary of recommendations
Patient centred outcomes research institute (PCORI) dissemination and implementation framework [149]	Patient centered outcomes research institute	The document provides PCORI and its partners with actionable steps for dissemination and implementation of health and healthcare evidence
Implementation research toolkit [150]	Published by the WHO on behalf of the Special Programme for Research and Training in Tropical Diseases. Co-sponsored by the United Nations Children's Fund, the United Nations Development Programme, the World Bank, and the World Health organisation	Outlines steps for developing a comprehensive communication strategy.
Beyond scientific publication: strategies for disseminating research findings [151]	Yale Center for Clinical Investigation: CARE: Community Alliance for Research and Engagement	This document focuses on strategies for dissemination of findings to affected communities, participant agencies, health departments, researchers, policy makers, and health advocacy groups. It includes a dissemination planning worksheet and examples of dissemination products.
Exchanging knowledge: a research dissemination toolkit [152]	University of Regina, USA	Provides a toolkit for developing a community dissemination plan, offering tools for engaging with communities effectively in research dissemination.
Communicating your research - a toolkit [153]	The Health Foundation	A research communications toolkit focused on presenting findings clearly to engage different audiences.
Sharing research results with participants: an ethical discussion [146]	Centre for Global Development	A blog post that discusses the ethical considerations around sharing research results with participants and provide five key questions for deciding whether and how to share study results.
Return of aggregate results to study participants: facilitators, barriers, and recommendations [154]	*Contemporary Clinical Trials Communications. 2023;33:101136.* [154]	Provides recommendations on overcoming barriers and leveraging facilitators to return aggregate study results to participants, outlined considerations for reporting results to lay audiences

NIHR plain English summaries 2021 [155]	National Institute for Health Research UK	This provides guidance for researchers writing plain English summaries, and board and panel members including public reviewers. This is more applicable during the research application stage.
The SHOW RESPECT adaptable framework of considerations for planning how to share trial results with participants, based on qualitative findings from trial participants and site staff [156]	*Trials. 2024;25(1):467.*[156]	This paper describes the development of the SHOW RESPECT framework, which outlines key considerations for planning how to share trial results with participants. This framework is designed to be adaptable, helping researchers effectively communicate findings while taking into account participants' needs and perspectives.
What, how, when and who of trial results summaries for trial participants: stakeholder-informed guidance from the RECAP project	*BMJ Open. 2022;12(3):e057019.* [157]	Provides stakeholder-informed recommendations on what, when, how, and by whom trial results should be communicated to participants, developed through a mixed-methods and co-production approach.

Table 2.10 summarises plain language resources that provide practical guidance on improving readability, reducing jargon and communicating health information clearly to non-specialist audiences.

Table 2.10: Plain language resources

1. Federal plain language guidelines: official guidelines for the Plain Writing Act of 2010.[158]
2. PRISM Readability Toolkit[159]
3. The CDC Clear Communication Index.[160]
4. The Plain Language Summary Tool[161]
5. Five steps to plain language developed by the Centre for plain language.[162]
6. Everyday Words for Public Health Communication—by CDC.[163]
7. Going public: Writing About Research in Everyday Language. [164]
8. Plain Language Links: Tips, Tools and Tutorials.[165]
9. How to write medical information in plain English.[166]

2.4 Discussion

To my knowledge, this is the first scoping review to explore and identify existing guidance on sharing study results with patients, participants, and the public. I identified 24 guidance documents, which provided valuable insight into current practices and recommendations on the result-sharing process. The findings revealed a wide variability in the scope, quality, and specificity of the recommendations. Many documents lacked details on what information to share or how to tailor it for diverse audiences, and most had little or no focus on cultural sensitivity. Many did not report their development methods explicitly. Importantly, none were specifically designed for reporting the results of randomised trials with patients and the public, nor developed as reporting guidelines following established methodology. [66]

Identifying relevant guidance presented several methodological challenges. Much of the available guidance was published outside the peer-reviewed literature, often on organisational websites or embedded within broader dissemination frameworks, which can limit their visibility to researchers who are planning to share results. Even within published literature, inconsistent terminology including terms such as *sharing*, *returning*, *providing,* and *disseminating* results, as well as *patients*, *participants,* and *the public* made it difficult to develop a sensitive search strategy. The ubiquitousness of common keywords like “results”, “reporting”, and “patients” yielded a large volume of unrelated articles, complicating efforts to refine the search. To address this, I collaborated with my supervisors and two information specialists to design a multi-stage search strategy, combining systematic searches, citation tracking, and grey literature searches. This combination of bibliographic database and grey

literature searches maximised coverage of relevant sources, including those outside the traditional academic literature.

The inconsistency in terminology was also evident in the reviewed guidance reports, which presents a barrier to standardising the process of sharing results with patients and the public. The lack of standardised terminology in this evolving area is understandable but establishing consistent terminology should be a priority for future work.

A key finding was that most documents addressed how and why results should be communicated rather than what information should be included. Most documents were written for research dissemination more broadly and none were developed specifically for randomised trials. This is important because randomised trials present unique methodological, ethical, and regulatory challenges. Features such as randomisation, blinding, and complex statistical analyses can be difficult to explain in plain language, yet are essential for accurate interpretation. Existing guidelines typically address these issues only at a high level, lacking the nuanced guidance necessary to translate randomised trial results effectively for non-specialist audiences.

Recent regulatory developments further emphasise this gap. As described in Chapter 1, organisations such as the UK HRA and the European Union increasingly expect trial results to be shared in accessible language and within defined timelines. Only ten of the 24 guidance documents identified in this review provided recommendations on *when* results should be shared with patients and the public. This may reflect the fact that many of the guidance documents were developed before recent regulatory changes, which now specify timelines

for sharing trial results. However, these policies largely describe when results should be shared rather than what information should be shared or how it should be presented.

Just as the CONSORT statement provides guidance for reporting randomised trials to academic audiences, [62] there is a clear need for similar guidance aimed at reporting results of randomised trials to patients and the public. This distinction reinforces the need for the reporting guideline developed in this thesis, which complements existing regulatory requirements by providing recommendations on the content of patient-facing trial result summaries.

The methodological quality of the identified guidance documents also varied considerably. Of the 24 documents, 14 did not describe how recommendations had been developed, limiting transparency and making it difficult to judge the robustness of their recommendations.

Only five reported pilot testing before implementation, which improved some approaches, such as making the resource more relevant and user-friendly. [140] However, pilot testing was in most cases limited in scope, with small samples and narrow audiences. Best practice in guideline development recommends robust, iterative testing with diverse end-users to ensure clarity, usability, and impact. [167, 168]

Stakeholder involvement was similarly inconsistent. While around half of the guidance documents reported PPI input (e.g., consultations or workshops), the extent of involvement varied, and few demonstrated evidence of true co-production. [169] This represents a missed

opportunity, as stakeholder input enhances clarity and ensures alignment with the target audience's preferences. [169] It is possible that some development activities were undertaken but not reported explicitly.

Only four guidance documents referenced diversity considerations, and none sufficiently addressed cultural and linguistic factors or reported considering factors like religion, sexuality, or other cultural differences, despite their importance in sensitive result-sharing practices. Again, it is possible that these considerations were undertaken but not reported explicitly.

Most guidance originated from North America and Europe, with limited consideration of implementation in low- and middle-income settings. This is important because limited resources, infrastructure, and funding can create additional challenges for patient and public involvement and research dissemination in these contexts. [170]

Future guideline development should prioritise co-production, diversity, and robust pilot testing to ensure recommendations are relevant, culturally appropriate, and usable in practice.

This review has several limitations. Title and abstract screening and most data extraction were undertaken by a single reviewer, although my supervisor was involved in piloting the data charting form, reviewing full-text eligibility decisions, and discussing uncertainties throughout the review. The review was limited to English-language documents and, despite extensive grey literature searching, some relevant documents may not have been identified.

Despite these limitations, I am confident that the review achieved its primary aim of mapping the available guidance on sharing trial results with patients and the public. The consistency of findings across the included documents suggests that, while additional guidance may exist, it is unlikely to have substantially altered the overall conclusions or the subsequent development of the reporting guideline.

The findings from this review provided the methodological foundation for the remainder of this thesis. They informed the design of the qualitative interviews and focus groups described in Chapter 3, where stakeholders were asked to identify candidate reporting items from their perspectives. The findings also highlighted the importance of diversity considerations, co-production, transparent development methods, and pilot testing, principles that were subsequently incorporated throughout the qualitative study, Delphi survey, consensus meeting, and evaluation of the reporting guideline. In this way, the scoping review served not only to map the existing evidence but also to inform the methodological approach adopted throughout the subsequent stages of reporting guideline development.

Chapter 3: A qualitative interview and focus group study to investigate approaches for sharing trial results with adult patients and the public

This chapter is based on the article currently in press: Choudhury S, Albury C, Collins GS, de Beyer J, Hopewell S. Approaches to sharing trial results with adult patients and the public: a qualitative interview and focus group study. *Trials*. 2026. [171]

3.1 Background and rationale

Following the scoping review, the next stage of my research was to supplement the reporting items identified from existing guidance by exploring what additional information patients, public and trial professionals considered important when sharing trial results. Developing a reporting guideline requires candidate reporting items that reflect the priorities and information needs of both those who prepare trial result summaries and those who receive them. While previous studies have explored preferences for receiving trial results, uncertainty remained regarding what information should be included in a summary and how it should be communicated. More recently, the RECAP programme developed stakeholder-informed recommendations for sharing trial results with participants. [157] RECAP used Q-methodology to ask stakeholders to rank predefined content items and identified broad principles relating to what, when, how, and by whom results should be communicated, but did not offer a structured itemised guideline or specify the reporting items for inclusion in a trial results summary. [157]

Similar to RECAP, I drew on my scoping review (Chapter 2) findings to identify reporting priorities. However, I also sought to generate new reporting items directly from patients, public representatives and trial professionals. Together, these findings subsequently informed the generation of candidate items for the Delphi phase of the reporting guideline development (Chapter 4).

To achieve this, I conducted semi-structured interviews with trial professionals, patients and public representatives using an open-ended approach that allowed reporting items to emerge inductively from participants' experiences and priorities, rather than from a predefined list. Three focus groups were subsequently conducted to explore and refine the emerging themes.

In addition to identifying candidate reporting items, I explored stakeholder perspectives on communication strategies, barriers to implementation, and opportunities to improve the sharing of trial results. These findings informed both the development of the reporting guideline and the accompanying Explanation and Elaboration document (Chapter 7), while also identifying wider organisational and resource-related barriers that may influence implementation.

The relevant stakeholders are described in Table 3.1:

Table 3.1: Participants definition

Group	Definition
Group 1:	Researchers working in trials: Chief investigators, trial managers, statisticians, trial coordinators, etc.
Group 2:	Intended recipients of trial results: Members of the public and patient representatives.

Including trial professionals, patients and public participants enabled comparison of their perspectives on reporting priorities, communication preferences, and perceived implementation barriers, ensuring that the reporting guideline reflected the needs of both those preparing and those receiving trial result summaries.

3.1.1 Research question

"What key items should be included in a trial results report to effectively share results with patients and the public?"

3.1.2 Aim and objectives

Aim

To explore the perspectives and recommendations of trial professionals, patients, and members of the public on how trial results should be communicated, to inform the development of a reporting guideline for sharing trial results with patients and the public.

Primary objectives

1. Explore the perspectives, expectations, and preferences of trial professionals, patients and members of the public regarding the communication of trial results.
2. Identify key reporting items for inclusion in trial result summaries.
3. Generate candidate reporting items for the subsequent Delphi survey (Chapter 4).

Secondary objectives

1. Include a diverse range of stakeholders, including people from underrepresented communities, to address gaps identified in the scoping review.
2. Explore preferences for the format, structure, and presentation of trial result summaries.
3. Identify barriers and facilitators to sharing trial results with patients and the public.
4. Explore researchers' views on sharing trial results with participants.
5. Generate recommendations to support effective dissemination of trial results.

3.2 Methods

3.2.1 Protocol and registration

I registered the study protocol on OSF for transparency and reproducibility. [172] Reporting follows the 'Standards for Reporting Qualitative Research' (SRQR) guideline. [173] (Appendix 3.1)

The study was underpinned by a pragmatic approach that focused on practicality and usefulness: not only 'what is' but also 'what might be'. The aim was to gather insights on how to share trial results with patients and the public and identify solutions to inform the development of a reporting guideline. A pragmatic approach fits well within this narrative as actions and changes are the essence of pragmatist ontology, as opposed to interpretivism, which delves deeper into the subjective meanings behind a person's preferences and opinions. [174] The study received ethical approval from the University of Oxford Medical Sciences Interdivisional Research Ethics Committee (MS IDREC): reference no: R93417/RE001.

3.2.2 Sampling and participant identification

3.2.2.1 Sampling strategy

A major finding from the scoping review was that existing guidance on sharing trial results lacks sufficient consideration of cultural and linguistic diversity. Additionally, few of these guidelines have been co-produced with patients or the public, raising concerns about their relevance, accessibility, and inclusivity. To address this gap, I aimed to actively recruit participants from a broad range of backgrounds, including individuals from different professional roles within clinical research; patient and public participants from varying geographic regions, age, and gender groups; and speakers of multiple languages. I placed particular emphasis on including individuals from underrepresented and marginalised communities, such as ethnic minorities or people with lived experiences, to ensure that their perspectives were sought out.

I used a combination of purposive and snowball sampling strategy to recruit the participants. A purposive sample is widely used to get information-rich cases for in depth studies maximising the efficient use of limited resources. [175] I aimed for a maximum variation purposive sample to include cases that are purposefully as different from each other as possible and as such cover the widest range of perspectives. Researchers with a range of trial-related roles, including trial managers, chief investigators, statisticians, clinicians, researchers with expertise in trial methodology, and other trial professionals, were targeted, recognising that responsibility for result sharing is often unclear. I aimed to ensure representation across roles, with at least one participant from each job role and participants representing at least two separate institutions.

This diverse selection was primarily due to the lack of clarity on who is responsible for preparing the trial results report. Additionally, it was beneficial to gather the perceptions and preferences from different trialists' viewpoints in providing meaningful insights into the current reporting practices.

I also used snowball sampling to identify participants through mutual contacts and established networks that they engage with. Snowball sampling was particularly useful in recruiting participants from difficult-to-recruit underrepresented populations such as people with Asian or Black backgrounds.

3.2.2.2 Sample size

Sample size was informed by various factors, including the research design, complexity of the study, available resources, and the concept of information power, [176, 177] with data collection continuing until adequate information power was achieved for the developing themes.

Based on the five distinct aspects of information power, **[176]** a range of 10 to 15 individuals per stakeholder group was deemed sufficient for the purpose of the research (Table 3.2). This was also consistent with methodological guidance and similar qualitative studies. [157, 178]

Table 3.2: Aspects of information power and how they were considered

5 distinct aspects of information power	
Scope	The study had a relatively focused aim, concentrating on receiving or sharing trial results, although interviews covered various approaches to sharing results and potential impact and challenges associated with sharing. I continued data collection until sufficient scope was attained (comprehensive data coverage efforts were made to include participants from diverse background when I realised that only white British people were signing up for the study) and replication across participants was seen (common characteristics between data).[176, 177]
Specificity	The sample was purposefully specific, with Group 1 participants bringing highly relevant experiences to the study and Group 2 participants bringing high variability within the participant population.
Theory	As outlined in section 3.2.4, an established thematic framework model guided the analysis process.
Quality	I established a good rapport with the participants, generating high-quality dialogues, producing a rich dataset.
Analysis	I used a cross-case analysis strategy, examining data from different participants to identify shared patterns and ideas.

3.2.2.3 Eligibility criteria

- Aged 18 years and older
- Willing and able to give verbal informed consent
- Identifies as either a:
    - Researcher involved in a trial setting or
    - Member of the public or patient representative

3.2.3 Study activities

3.2.3.1 Recruitment period: May 2024-November 2024

I created advertisement materials to reach a wide range of people, including layman-friendly posters, network-specific mailshots, and social media posts (Figure 3.1). These were shared through research and PPI networks, clinical trial networks (e.g., the UK Trial Managers'

Network), local communities, religious groups (e.g., Islamic Society of Women in Oxford), diversity networks (e.g., the NIHR Diversity in Research Network), social media (LinkedIn, X), and personal and professional contacts. (Table 3.3)

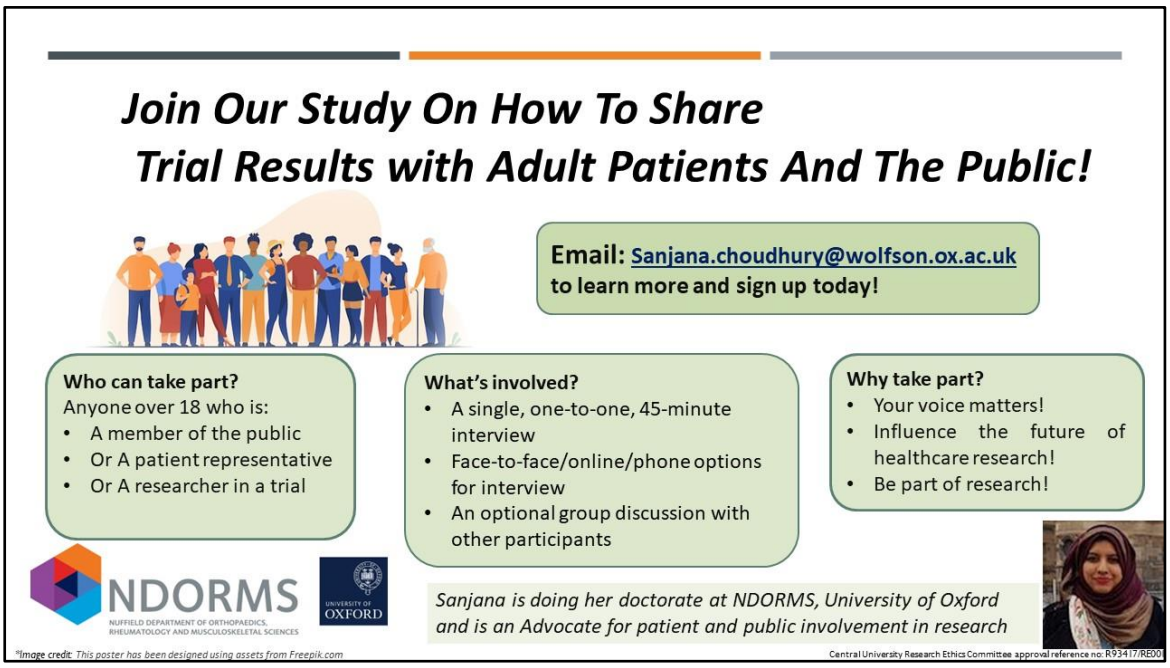


Figure 3.1: Poster used for advertisement in different platforms

Table 3.3: Recruitment pathways for study participants

Recruitment pathway	Details
Group 1: Trial professionals	
Trial networks	- UK Trial Manager's Network (UKTMN) - UK Clinical Research Collaboration (UKCRC) Registered Clinical Trials Unit - MRC-NIHR Trials Methodology Research Partnership groups - NIHR Oxford Biomedical Research Centre (BRC) - NIHR Centre for Engagement and Dissemination
Local trial units	- Oxford Clinical Trials Research Unit (OCTRU) - National Perinatal Epidemiology Unit (NPEU) - Diabetes Trials Unit (DTU) - Clinical Trial Service Unit (CTSU) - Surgical Intervention Trials Unit (SITU) - Nottingham Biomedical Research Centre PPI network
Known contacts	- Cambridge Clinical Trials Unit - Hertfordshire research group - Researcher and supervisor's personal networks
University network	- NDORMS Departmental Bulletin
Group 2: Patient representatives and members of the public	
Diversity networks website advertisement	- Oxford BRC, Diversity in Research Group - People in Research Group
Social media	- #OxfordPPI Twitter - Researcher's personal Twitter accounts
Religious and community groups	- Oxford Islamic Society Community of Women
Patient and public involvement networks	- Local PPI groups - NDORMS OpenArms PPI group - Be Part of Research-NIHR
Snowball sampling	- Personal contacts

3.2.3.2 Methods of data collection

I conducted 29 semi-structured one-to-one interviews over five months (first interview: 30th May 2024, Last interview: 22nd October 2024). The interviews were guided by a topic guide. I developed the guide based on existing literature and gaps identified in the scoping review

(Chapter 2), then refined and piloted with researchers and PPI representatives to ensure alignment with the study objectives (Appendix 3.2).

The guide was updated iteratively as new topics arose. For example, I added questions on whether receiving trial results would influence participation for Group 2 participants or whether Group 1 participants were receiving any training in plain language writing.

I chose semi-structured interviews as the primary data collection method because they offer a balance between flexibility and structure. While a set of predetermined questions guided the interviews, these questions were open-ended, allowing the conversation to flow naturally and giving participants the freedom to delve into topics of particular interest. This approach enabled a deeper exploration of key areas while ensuring that essential themes were consistently covered. In contrast to structured interviews, semi-structured interviews often help participants feel more at ease and open to share their thoughts; as a result, leading to richer data and insights. [179]

Interviews lasted an average of 45 minutes and were conducted in English. Participants chose their preferred interview mode (face-to-face, telephone, or online via Microsoft Teams) at a time and location convenient for them. Arrangements were made via email, where eligibility was confirmed, and a participant information sheet (PIS) (Appendix 3.3) was provided. The PIS provided a description of the study purpose and study activities, the benefits and risks of taking part, and how the data were to be handled. I obtained verbal consent for recording at the start of each interview, which was recorded by Microsoft Teams or encrypted Dictaphones.

I asked Group 1 participants about their experiences and views of result sharing, including the content and format of result reports and implementation challenges. Group 2 participants were asked about their preferences for receiving trial results, potential impacts, and the information they would find meaningful.

During their interviews, each participant was invited to attend a focus group discussion (FGD). In an FGD, members discuss a given topic in depth, sharing their opinions over a course of interaction with others. This process is conducted by a moderator. [180] Three synchronous online focus group discussions were conducted, each consisting of a mix of participants from both groups. Each FGD included five participants, a number that was chosen to encourage meaningful interaction while allowing everyone a chance to share their thoughts. The scheduling of the FGD was determined by the availability of the majority of interested participants. Each session lasted around an hour.

I chose a traditional qualitative design for the focus groups instead of a participatory approach, based on the intended outcome and level of participant involvement. This design was exploratory, seeking to understand subjective experiences without actively influencing the content, whereas participatory and co-production FGDs often aim for actionable outcomes, such as community interventions or service designs. [181] Focus groups were used to facilitate interactions between participants, hoping to uncover new insights and gather a range of perspectives. The focus groups also served as an opportunity to share findings from the interview analysis, providing a means to validate the results of the thematic analysis.

3.2.4 Methods of data analysis

I used a combined analytical approach, integrating the structured organisation of the Framework Method by Gale et al. [182] with the iterative and theory-generating processes of constant comparison by Corbin and Strauss. [183] The Framework Method provided a systematic approach for organising and managing the data, [182] while grounded theory techniques, including open and axial coding, supported exploration of relationships between codes and development of themes. [183] I chose Framework Method as, unlike other qualitative methods that are aligned with a particular epistemological approach, framework analysis is pragmatic, adaptable, and allows for the flexibility of using a combined approach.[182]

Data analysis followed the seven stages of the Framework Method: transcription, familiarisation, coding, developing a working analytical framework, applying the analytical framework, charting data into the framework matrix, and interpreting data.[182]

Stage 1: Transcription

Interviews were audio-recorded, transcribed verbatim, and imported into NVivo 12. Since content is of primary interest in this study and not how the dialogues were said, the conventions of dialogue transcriptions were not transcribed (e.g., pauses). I read and reviewed each transcript against the audio recording to identify any errors made during transcription. I also kept a diary during the interviews to write down any observations, notes, or thoughts, which supplemented the transcripts during the analysis.

Stage 2: Familiarisation with the interview

I familiarised myself with each interview by listening to the audio recording and reading the transcript alongside the accompanying field notes. This provided a good opportunity for me to be immersed in the data before coding commenced.

Stage 3: Coding

Coding was informed by Saldana's *'The coding manual for qualitative researchers*'. [184] I used a combined inductive and deductive approach to develop a thematic analytic framework.

I started with a set of *a priori* codes based on the topic guide (Appendix 3.4), while also leaving scope for important additions as the interviews progressed and new ideas developed; i.e., I inductively revised the coding frame as I iteratively read through the data using an open coding technique. *A priori* codes were content elements such as mandatory content of trial result report, result dissemination formats, etc. Participants' own words were used where more appropriate (*in vivo* coding). A master code list was maintained and updated as required.

Following initial coding, I used focused coding to identify the most conceptually important and frequently occurring codes, particularly those relating to the primary objective of identifying candidate reporting items for sharing trial results.

Finally, I used axial coding to find connections between different codes, allowing broader categories to emerge. Throughout the process, constant comparison was used to revisit each new code and compare it with previous ones, ensuring important patterns, differences, and relationships were captured. Constant comparison was also applied both within and across

transcripts to identify similarities, differences, and emerging patterns. [183, 185] Together, these methods added depth and richness to the analysis. [184]

Coding was undertaken by me and discussed regularly with my qualitative supervisor (Associate Professor Charlotte Albury). Any uncertainties were resolved through discussion and reference to the original recordings. Codes of similar content and characteristics were grouped into defined categories, which were then mapped by connections to explore concepts and develop themes, in a process similar to that illustrated in Figure 3.2.

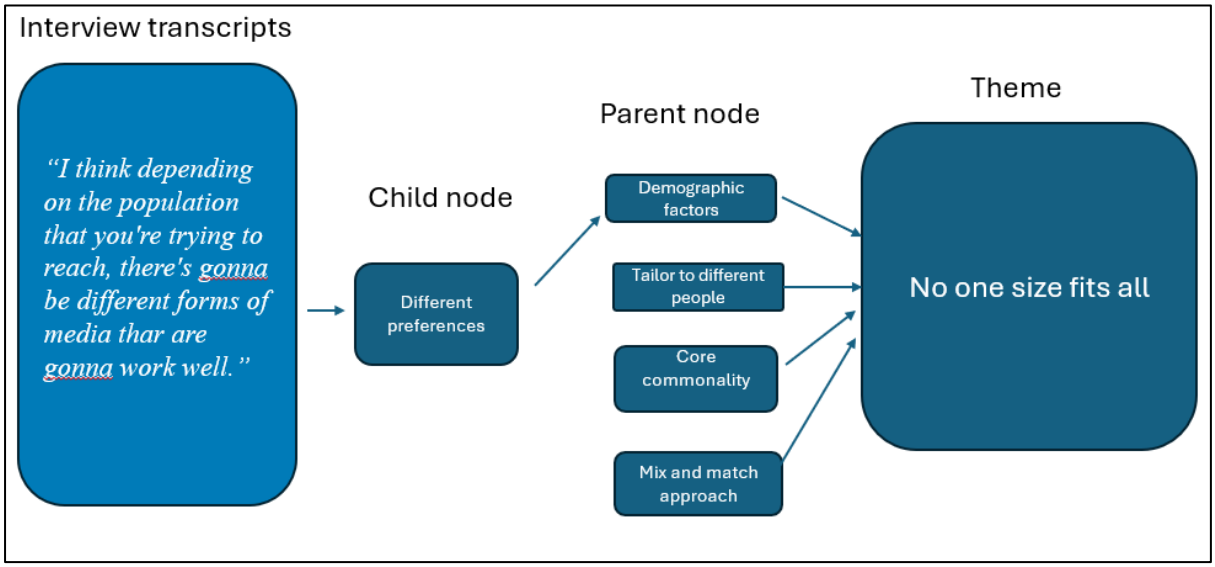


Figure 3.2: An example coding from the framework analysis of this study. *Developed using the streamlined codes to theory model by Saldana 2021)* [184]

Stage 4: Developing a working analytical framework

After the first five transcripts had been coded, related codes were organised into parent and child nodes to develop a working analytical framework. The framework underwent several iterations before being reviewed and agreed with my supervisors.

Stage 5: Applying the analytical framework

The analytical framework was applied to all remaining transcripts and refined iteratively as new concepts emerged. The framework reached finality when all transcripts had been coded completely (Appendix 3.4).

Stage 6: Charting data into the framework matrix

Data were charted into a framework matrix using Microsoft Excel. Summaries were organised by category and participant, while illustrative quotations were retained to support interpretation and reporting.

Stage 7: Interpreting the data

The completed framework matrix was used to interpret relationships between categories and develop six descriptive themes representing the findings. Data were presented narratively and supported by tables, figures, and illustrative quotations.

As the purpose of this study was to identify candidate reporting items and implementation considerations for subsequent reporting guideline development, data from researchers, patient representatives, and members of the public were analysed together rather than compared between stakeholder groups.

3.2.5 Reflexivity and data quality

It is not straightforward to assess the quality of a qualitative study, and there are several points to consider such as triangulation, reflexivity, fair dealing, and relevance. [186] Varpio et

al. critique the value of traditional member checking in qualitative research, in which participants review interview transcripts or researchers' interpretations to verify accuracy. [187] However, this approach can conflict with modern qualitative research practices, which recognise that researchers co-construct findings through their own interpretive lens. Additionally, the researcher comes to a conclusion after analysing the entire dataset, which a participant will not have access to. Seeking participant validation may therefore impose unnecessary restrictions, potentially limiting the depth of analysis. [187] Rather than undertaking formal member checking, I strengthened the trustworthiness of the findings through methodological triangulation, reflexive practice, regular discussions with supervisors, and by presenting the emerging interview themes during the focus groups, where participants were able to confirm, refine, and extend the developing interpretations.

Triangulation involves looking at a problem from different angles to determine whether different sources or methods produce consistent findings. [187] However, triangulation was used in this study as a means of enriching rather than validating data, as suggested by Varpio et al. [187] Interview findings were presented to focus group participants, allowing them to discuss, refine, and expand upon the emerging themes. Participants confirmed that the themes reflected their experiences while also contributing additional insights and clarifications. Comparing findings across interviews and focus groups further enhanced the depth and comprehensiveness of the analysis. The findings were also broadly consistent with those from the scoping review (Chapter 2) and previous research in this field, [156, 157] providing additional confidence in the interpretations.

Reflexivity was incorporated throughout the study to consider how my background, assumptions, and role as a researcher might influence the research process. [188, 189] I considered how my role might influence participants and developed the interview topic guide with sensitivity to their perspectives. The topic guide was piloted by researchers and patient representatives. Demographic questions were placed at the end of the interview to give participants greater control and comfort, and interviews were chosen according to their preference (home, workplace, or virtually). I positioned myself as a 'guest', adopting a back-seat role that allowed participants to set the pace and fostered authentic dialogue, acknowledging that the interviewer's presence and manner could shape participants' responses to some degree. This approach facilitated rapport and generated high-quality, in-depth data.

I maintained a reflective diary throughout the study to document methodological decisions, observations, and potential sources of researcher bias. Regular discussions with my supervisors provided opportunities to challenge developing interpretations, review coding decisions, and refine the analytical framework. These discussions supported ongoing reflexivity and helped ensure that interpretations remained grounded in the data.

Diversity within the sample was also considered an important aspect of data quality. I sought to include participants from a range of demographic, socioeconomic, and experiential backgrounds to capture multiple perspectives on sharing trial results. Detailed reporting of the study protocol, data collection, and analytical procedures further enhances transparency, allowing readers to judge the credibility and transferability of the findings.

3.2.6 Discontinuation/withdrawal of participants from study

One participant joined the study on two separate occasions but withdrew quickly each time upon realising there was no funding available for the research. This information had been clearly stated in both the PIS and email communications prior to both interviews. Following the established protocol, their record was deleted, and they were not included in the study's data analysis. This ensured that the integrity of the study was maintained while adhering to ethical guidelines regarding participant participation and data management.

3.3 Results

3.3.1 Characteristics of participants

I interviewed 29 participants (Group 1: researchers working in trials, *n* = 15; Group 2: members of the public and patient representatives, *n* = 14) and conducted 3 focus groups. (Table 3.4)

Table 3.4: Data collection methods

Methods	Group 1 participants	Group 2 participants	Total
Semi-structured interviews	15	14	29
Focus Group Discussion			
Focus Group 1 (25th October 2024)	2	3	5
Focus Group 2 (1st November 2024)	2	3	5
Focus Group 3 (5th November 2024)	2	3	5

Most participants originated from different areas of England, with one participant from Scotland, one participant from Wales, and one from Ireland. A summary of participant characteristics is provided in Table 3.5.

Table 3.5: Summary table of participant characteristics

Category	**No. of participants**	
Group	**Group 1 (n=15)**	**Group 2 (n=14)**
Sex		
Female	11	10
Male	4	4
Age		
21-30	3	3
31-40	1	3
41-50	7	0
51-60	4	2
61-70	0	2
71-80	0	4
Ethnicity		
White-British	12 (English-11, Scottish-1)	10 (English-9, Welsh-1)
White other	2 (Turkish-1, American-1)	0
Asian-Indian	1	1
Asian-Pakistani	0	2
Black-African	1	1
Current profession: Group 1		
Medical writer	2	NA
Clinical trial monitor lead	1	NA
Clinical trial coordinator	1	NA
Study delivery officer for Clinical Research Network (CRN)	1	NA
Senior trial manager	1	NA
PhD researcher/Junior qualitative researcher	1	NA
Intensive care research nurse	1	NA
Clinical trial manager	1	NA
Chief-investigator in clinical trials	1	NA
Professor of clinical trials	1	NA
PhD Student in clinical trials methodology	1	NA
Research trial manager	1	NA
Professor of clinical trials and medical statistics	1	NA
Senior researcher	1	NA
Lived experience/Special interest/Representative: Group 2		
Member of the public	NA	6

Member of autistic community	NA	2
Dementia	NA	2
PPI representative	NA	1
Diabetes	NA	1
Oesophageal cancer survivor	NA	1
Psychologist	NA	1
LGBTQ+ representative	NA	1

Overall, 72.4% of participants were female and 75.9% identified as White British. Participants from both groups represented a range of age groups and ethnic backgrounds, including Asian and Black ethnicities. Individual participant characteristics are presented in Table 3.6 and Table 3.7.

Table 3.6: Individual participant characteristics: Group 1

Group 1: Researchers working in trials

ID	Ethnicity	Age range	Sex	Current profession
A1	White-British	26-35	Female	Senior medical writer
A2	White-British	36-45	Female	Clinical trial monitor lead
A3	White-British	18-25	Female	Clinical trial coordinator
A4	White-British	56-65	Male	Principal medical writer
A5	White-British	46-55	Female	Study delivery officer
A6	White-Scottish	46-55	Female	Senior trial manager
A7	White-British	26-35	Female	Junior qualitative researcher
A8	White-British	56-65	Female	Intensive care research nurse
A9	White other-Turkish	26-35	Female	Clinical trial manager
A10	White-British	36-45	Male	Chief-investigator in clinical trials
A11	White-English	36-45	Male	Professor of clinical trials
A12	White-American	36-45	Female	PhD student in clinical trials methodology
A13	White-British	46-55	Female	Research trial manager
A14	White-British	36-45	Male	Professor of clinical trials and medical
A15	Asian-Indian	46-55	Female	Senior researcher

Table 3.7: Individual participant characteristics: Group 2

Group 2: Members of the public and patient representatives

ID	Ethnicity	Age range	Sex	Native language	Lived experience/Representative/ Special interest
B1	White-British	>65	Female	English	PPI representative
B2	White-British	>65	Male	English	Dementia
B3	White-British	46-55	Female	English	Autism, Long-term physical and mental health conditions
B4	White-Welsh	>65	Male	English	Dementia
B5	White-British	>65	Female	English	Diabetes
B6	White-British	56-65	Female	English	Oesophageal cancer
B7	White-British	56-65	Female	English	Psychology
B8	White-British	56-65	Male	English	Member of the public
B9	White-British	18-25	Male	English	Autism, Identifies as LGBTQ+
B10	White-British	18-25	Female	English	Member of the public
B11	Asian-Pakistani	36-45	Female	Urdu	Member of the public
B12	Asian-Indian	36-45	Female	Bengali	Member of the public
B13	Asian-Pakistani	26-35	Female	Urdu	Member of the public
B14	Black-African	18-25	Female	English	Member of the public

Socioeconomic diversity was assessed using Index of Multiple Deprivation (IMD) tenths, ranging from 1 (most deprived) to 10 (least deprived). The median was 9 for Group 1 and 8 for Group 2 (Figure 3.3). Participants were predominantly from less deprived areas, although more deprived communities were also represented.

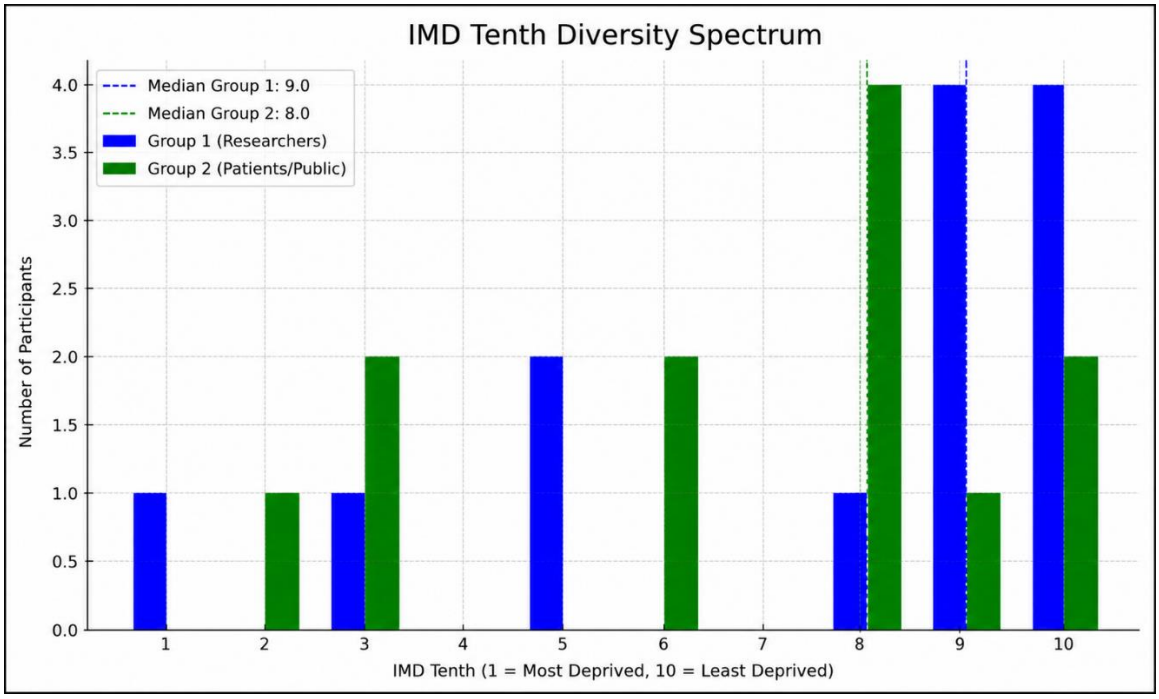


Figure 3.3: Socio-economic diversity by IMD tenth, showing participant distribution from 1 (most deprived) to 10 (least deprived). *The dashed line indicates the median IMD tenth (8 and 9) for Groups 2 and 1, respectively. Bars represent the number of participants within each tenth. Three participants were excluded because they lived outside England, and one declined to provide their postcode.*

Experiences with result-sharing

Group 1 participants (researchers) noted that in non-commercial settings, increased funding and a growing emphasis on PPI, especially after the COVID-19 pandemic, have helped raise awareness of the value of PPI in research. However, result sharing is not routine, and researchers often rely on personal judgment when deciding whether and how trial results should be shared with patients and the public.

In Group 1, four participants said they had shared trial results, three planned to do so, and two had no plans for dissemination. The formats used to share results included a lay summary, plain language abstract, short video or newsletter, and public dissemination event.

Dissemination planning varied: two participants (medical writers for commercial trials) followed the European Union Clinical Trials Regulation for trial result sharing and submitted a lay summary to the EU portal including the mandatory elements as outlined in the EU guidance Annex IV. [24] Four participants were at an early stage with no detailed plan, while two had established detailed dissemination strategies. Five participants reported having a PPI group in their trials.

Commercial trials typically have dedicated transparency teams and regulated templates to ensure consistency and reduce selection bias. While commercial sponsors are required to share summaries only with EU participants, some go beyond by making them publicly available. In contrast, less transparent companies may only share private links with participants, meeting regulatory requirements without embracing full transparency.

Within Group 2 (patients and members of the public), six participants had previous experience of taking part in research, including three in clinical trials. Only one participant had received results directly, while five received no feedback. Ten participants had experience of PPI activities, but only three had ever reviewed trial results, mostly as research papers.

3.3.2 Sharing trial results with patients and the public

I developed six descriptive themes to discuss the results (Figure 3.4):

1. No participants no trials – it is all about respect and recognition;
2. Results, clinical implications, and demography are the most meaningful items to report when sharing trial results;

3. Clarity, accessibility, and respect for the reader are important when presenting information;
4. No ‘one size fits all’ – communication strategy must be tailored;
5. Barriers to sharing trial results;
6. Areas of improvement for sharing trial results.



Figure 3.4: A summary of the overarching themes

Theme 1: 'No participants no trials' – it is all about respect and recognition

Motivations for sharing trial results

Participants from both groups described several reasons for sharing trial results, centred on the principles of respect and recognition for participants and the ethical and moral responsibility of researchers (Figure 3.5). Most importantly, participants should have the option to choose if they want to receive results, with their preferences regularly updated.

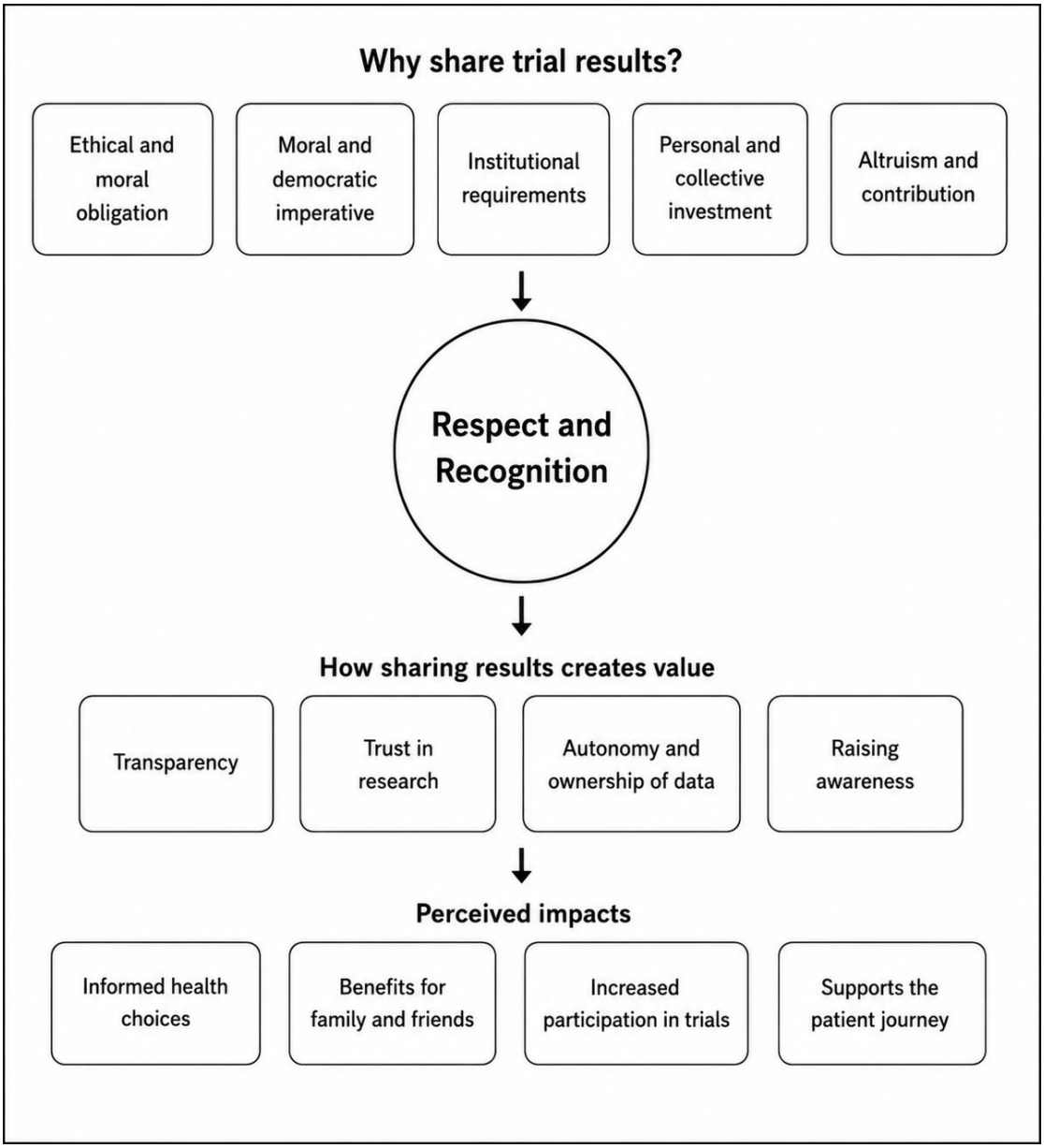


Figure 3.5: Conceptual framework illustrating participants' motivations for, and perceived value of, sharing trial results with patients and the public.

Many believed that sharing results could encourage future research participation, strengthen trust in research, promote transparency, and support informed health decisions. Participants also viewed result sharing as a way of acknowledging participants' contribution to research, raising public awareness, and enabling information to be shared with family and friends.

"But I think if people have committed, agreed to commit time to it, then it makes them feel a bit more special, makes them feel heard." (B1)

Impact on participants

Participants described both positive and potentially challenging impacts of receiving trial results. For many, it may bring a sense of closure and understanding, especially if the results offer insights into their health or compare their progress with others. There is a sense of pride and contribution to something bigger than themselves.

However, there is often an expectation that clinical trials will bring big advances in care, but when this isn't the case, it can be disappointing. Clear, thoughtful communication is therefore important to manage expectations and help participants understand what the results mean for them personally.

Sub-theme: Sharing negative results

Participants from both groups unanimously agreed that all results should be shared, whether positive or negative. Sharing negative results was viewed as essential for transparency, reducing research waste, and ensuring that knowledge gained from unsuccessful trials could inform future research.

PPI can guide the best approach to communicating potentially distressing results. Researchers need to be mindful and prepared to offer support if necessary. One researcher highlighted the importance of how negative findings are communicated:

"If somebody's taking part in research and you've had a negative trial, they might be a bit disappointed, but hopefully you could word your lay summary in a way that explains to them that even though the result hasn't shown anything, it has a value because it means we know not to keep repeating the same mistakes or to do that again." (A6)

3.3.3 Main aspects of sharing trial results with patients and the public

Theme 2: Results, clinical implications, and demography are the most meaningful items to report when sharing trial results

Participants from both groups most frequently identified trial results and their clinical implications as information that should be included in a results report. They wanted to understand the key message, what the study found, whether the intervention was beneficial, harmful, or showed no meaningful difference, and how the findings might improve a condition or quality of life. Many were also interested in whether the results might influence healthcare policy. Demographic information was also frequently mentioned, as participants wanted to judge whether the results were relevant to them. Many were curious about the trial's future direction: will there be a next phase, is there an opportunity to participate, and what is planned for the findings?

Another commonly mentioned item was a brief overview of the trial's aim and background. This is perhaps particularly important for long-running trials as participants may have forgotten details from the participant information sheet by the time they see the results. Having the aim and background would also help put things into perspective for members of the public.

However, are the most frequently mentioned items truly the most important? As Saldana suggests, is there any value in measuring a "qualitative mean," and does it truly enhance the analysis? [184] While identifying common themes is useful, I aimed to go beyond this by including less frequently mentioned items, which can provide valuable depth and nuance.

For example, 'Thank you' was not mentioned often by participants. Did they perhaps not view this item as important, or did they view saying thank you to be an automatic or expected gesture that does not need explicit mention or reinforcement? It is possible that participants may not feel the need to emphasise it because it feels like such a routine or ingrained part of communication.

"Well, that's a given, isn't it...You know you always say thank you. I mean simple 2 words. Simplest word." (B2)

When asked to distinguish between information that should be essential and information that could be optional, participants across both stakeholder groups recognised that not all items would be equally important in every context. While there was broad agreement on a core set of information that should be included in all trial result summaries, participants also felt that additional information could be included where relevant or where readers wished to access more detail. This was viewed as a practical way of balancing completeness with accessibility and accommodating different information needs.

In Table 3.8, I present a full list of items (non-ranked) suggested by participants, with supporting quotes. These items were derived inductively from participant suggestions from both groups. Similar or overlapping items were grouped together and duplicate suggestions

were removed. The resulting categories remained close to participants' original descriptions and were intended to provide a descriptive summary of the information they considered important to include in trial result summaries.

Table 3.8: Items suggested by participants (Group 1 and 2) for inclusion in trial result summaries

	Categories	Illustrative quotes
1	Results	*"What are the findings? I think that would be a key one."* (B7)
2	Clinical implications	*"The significance of the results from the trial. And how they might be implemented on the standard of care."* (A3)
3	Improvement of quality of life	*"It might also be very useful from a patient perspective to if the clinical trial that involve quality of life and things like that to see if we can present some results on that as well, and how being on the trial has affected quality."* (A3)
4	Changes to NHS policy	*"I guess implications for the NHS for our trials."* (A8)
5	Economic implication	*"I guess cost implications for the NHS maybe also interesting for the public as well."* (A8)
6	Comparison with other research	*"How it compares to what's known from before, you know other research as well."* (A15)
7	Generalisability	*"I would be interested to know how the sample met, because I know from the work I do that this samples are often not reflective of the population, let alone the population with diabetes."* (B5)
8	Demography	*"Interested in the demographics of the people involved, you know the other participants."* (B4)
9	Number of participants	*"How many people took part?"* (A5)
10	Aim and background	*"So, the purpose like why it was being done."* (B14)
11	Future direction	*"What is the next stage say from the outcome of this? Is there a paper being written to recommend a change in standard care?"* (A2)
12	Next steps	*"What are the next steps going forward?"* (B9)
13	Milestones (patient journey)	*"To make it interesting, maybe something about the people involved. You know the people, the researchers and some of the difficulties maybe they had and how they overcame them and make it a bit more of a story. But you know, people like a story, don't they?"* (B1)
14	Further information	*"And then their contact details if they need…If they would like more information or if they would like to discuss it with somebody else that would be handy as well."* (A5)

15	Publication details	*"Like it's…published or it is accessible for all the people like how can the normal people read that outcome?"* (B11)
16	Side effects	*"I guess if there were some serious adverse effects…. worth knowing. I mean, I tend to want the good news."* (B8)
17	Thank you	*"I definitely want to feel like my input was valued and like my time was respected…definitely like a thank you for the people that are actually involved- would be great because I think a lot of the time that's kind of forgotten."* (B9)
18	Strengths and limitations of the findings	*"So, I think there should be accessible communication about the strengths and limitations of findings. What can we be more sure of? What are we less sure of, regarding the findings? What are the certainties? What is the uncertainty?"* (B3)
19	How to talk with healthcare providers about the results	*"I think using as simple English as possible and very clear, so that people can decide whether how relevant it is to them and then also like referencing it back to talk to your GP if you have any further questions."* (B13)
20	Logistics	*"I've not specifically said it, but you would usually say who funded it…You would want to mention the Institute and maybe the Chief investigator name as well."* (A6)
21	Methodology	*"Methodology-I would be interested in, especially if it could be summarised."* (B10)
22	What could be done better	*"I think it's really important to be honest about… What could have we done better in the trial?"* (B9)
23	Ethics approval details	*"Uh, yes, I would expect to see that very much…I would want to have that reassurance that ethically this has been approved."* (B7)
24	Frequently asked questions	*"Maybe there's like a frequently asked questions…. that could be interesting because eventually people might still be asking that in the future after the trial, so, that might be interesting."* (A9)

Theme 3: Clarity, accessibility and respect for the reader are important when presenting information

Participants offered varied insights into how best to present information, emphasising clarity, accessibility, and respect for the reader. Responses from the two groups highlighted different priorities, reflecting their unique perspectives and needs. Researchers highlighted the importance of using appropriate and respectful language, whereas patients and members of the public prioritised plain language, brevity, and empathy.

Subtheme: Simplicity is key

This subtheme relates to the principle of ‘"less is more," highlighting the value of clear and concise communication. Academic writing is often inaccessible and intimidating. When the target audience is the general public, a balance must be struck between sufficient detail and clarity.

“I think it needs to be easily accessible so that you can just flick to it straight away.” (B5)

Patients and members of the public favoured short, jargon-free sections with clear headings, executive summaries, and white space. However, participants also shared insights about not compromising the integrity of the report to make it more accessible. Some expressed feeling insulted when information was oversimplified, emphasising that they, as laypeople, should be treated as capable of understanding complex concepts.

“Just because we are lay people and people on the street, we we've still got brains in our heads, and we can work things out.” (B2)

When dealing with technical terms, some participants suggested including a glossary. However, there was a preference for in-text definitions or footnotes rather than requiring readers to consult a separate document.

Balanced use of visuals

Responses varied when it came to visuals as the level of interpretation varies between people. Some found graphs and visuals helpful for understanding complex information quickly, while others preferred text or worried that visuals might clutter or reduce professionalism.

“I think visual only if they're actually really necessary, if you're just getting results for me…Yeah, I don't see any particular need to consider the aesthetics of it.” (B10)

Some researchers expressed concern over the risk of unnecessarily lengthening the document with too many visuals.

“So, if I'm talking about a theme, for example, I could put a quote in front to illustrate that. But as soon as you do that in a lay summary, it becomes ridiculously long.” (A7)

Infographics were noted by many as a preferred middle ground, offering a balance of text and visuals, although it can be expensive to develop a meaningful one.

Framework approach

Some researchers described using a structured, question-and-answer format when sharing trial results. They felt this approach improved accessibility by guiding readers through the summary while allowing them to focus on the information most relevant to them.

“We use the leading questions as headings; that seems to make it a bit more accessible. So, they can just focus on what they want because they might already know the hypothesis and aim.” (A4)

PPI review

Participants shared that PPI partners can offer unique perspectives, often identifying the most impactful and practical information to include, helping to keep the content focused and useful. However, PPI involvement shouldn’t just be a final-stage review; it should be a continuous part of the process, integrated from the very start.

Translations

Translation was considered important to reduce health inequalities for non-native speakers, with suggestions for written, audio, and video formats. However, cost and quality of translations were noted as challenges. Free tools like Google Translate are often unreliable, and many non-commercial trials lack funding for professional services. Artificial intelligence (AI) tools can help with lowering cost, but human review will be essential in maintaining quality and accuracy. [190]

In Focus Group 1, participants discussed whether the value of translation justifies the cost. One researcher noted that much of the research contact is usually in English and questioned the impact of translating only some documents. They added that there is limited evidence to suggest that translation alone significantly boosts recruitment.

Length of the report

Participants noted that language should take priority over length, while others highlighted the need for a balance, stressing the need for brevity, especially for public engagement. Some participants in Group 2 noted that attention span is shorter for older people, and the report should be flexible in length. People with learning differences such as autism and ADHD may find lengthy documents difficult to read.

"I struggle with things that are very long to read because of my autism and my ADHD." (B9)

Researchers also raised concerns about the potential for misunderstanding when more information is provided.

"I do suppose it is slightly double edged. More information that leads to more potential of misunderstanding or raising concerns." (A14)

Sub-theme: Timing of sharing trial results

The timing of sharing trial results is often delayed due to sponsor approvals, additional reports, or changes in trial teams. Researchers generally felt that participants should receive results first before journal publication, but acknowledged that peer review frequently takes precedence, delaying direct communication.

Researchers often felt a sense of urgency to share results while fresh and felt that waiting too long could reduce enthusiasm. However, patients and the public had mixed opinions: some wanted to be the first to know the results, while others valued peer review for credibility. A possible solution is simultaneous sharing, although this can be challenging, as journals may impose embargoes or funders may have confidentiality agreements in place. Timing is especially important for groundbreaking results and are likely to influence policy or practice. In commercial trials, proprietary concerns also add complexity. Regardless, it was considered essential for trial participants to have a clear expectation of when they would receive results.

Theme 4: No 'one size fits all' – communication strategy must be tailored

It is essential to recognise that people respond to different ways of presenting information and that there is no one-size-fits-all approach. Preferences depend on personal learning styles, age, culture, and access to technology.

"British people over here…maybe they like to read…But in Asian countries...it's my personal [opinion], might not apply to everybody.. that they want to watch or [listen to] audio." (B12)

Subtheme: Formats and their trade-offs

Participants discussed a range of formats that can be used to share results, noting that each had distinct advantages or limitations.

- **Audio:** valued by people with visual impairments or low literacy. However, some found phone calls intrusive, worried about accents and clarity, and felt calls could be easily missed.
- **Digital media (emails, PDFs, videos):** praised for being convenient, mobile-friendly, and environmentally friendly, However, some raised concerns about digital exclusion for those without internet access or devices. Videos drew mixed reactions: some welcomed them as engaging, while others preferred written reports.

  "I think like sustainability wise an e-mail makes more sense." (B10)
- **Social media:** recognised as a powerful tool for engagement and reach, though participants worried about credibility, navigation difficulties, and data privacy issues.

  "I'm on the fence with social media." (B2)
- **Interactive sessions (webinars, Q&A events, podcasts)**: provides two-way communication and trust through clinician involvement, but poses challenges around affordability, scheduling, and anxiety for some participants.

Offering multiple formats was seen as an ideal solution. But limited funding, especially in non-commercial trials, often constrains these options. A well-rounded PPI team, with broad representation, can help ensure that communication strategies are inclusive and impactful.

Theme 5: Barriers to sharing results

Group 1 participants (researchers) identified a wide range of barriers that complicate or delay the sharing of trial results with patients and the public.

Lack of guidance and consistency

Participants felt that the absence of clear guidance poses a major challenge to sharing. Terminology such as “lay summary,” “plain language summary,” and “patient summary” are used inconsistently, creating confusion. Clear standardised templates and guidance are not available to standardise language and practices across the field. This finding aligns with the findings from the scoping review (Chapter 2).

“We just worked as a group. We weren't following any guidance, to my recollection about it, to be honest.” (A14)

Legal and regulatory barriers

Legal requirements to share results are limited, particularly in the UK and USA, where dissemination to participants has historically not been mandated. However, since this study was conducted, the UK has introduced a new regulation that requires trial sponsors to offer a summary of trial results of investigational medicinal products to participants within 12 months of trial completion (*Medicines for Human Use (Clinical Trials) (Amendment) Regulations 2025)*. [22] Industry trialists worried that sharing results could be misconstrued as marketing. Embargoes from journals or funders, intellectual property concerns, and data protection restrictions (e.g., reliance on NHS-only software) further complicate timely dissemination.

Practical and logistical barriers

Resource constraints were a recurring concern, particularly for non-commercial trials with limited budgets. Large trials face the additional challenge of disseminating results to thousands of participants. Staff turnover in long-running studies can also disrupt continuity.

Cultural and institutional barriers

Researchers noted that lay summaries were often treated as a low priority at an institutional level. The skills, time, and expertise needed to produce high-quality lay summaries were often underestimated, with limited training or support provided. At an individual level, some participants described a lack of confidence in writing lay summaries, recognising that this requires specific communication skills to avoid misinterpretation.

Communication and engagement barriers

Translating complex data into an accessible lay summary was seen as challenging. Researchers observed that trial results rarely feature in mainstream media, while digital literacy barriers limit access for some groups. Trials face competition for attention from more engaging media on participants' devices, and results can feel disconnected from everyday concerns.

Timing and continuity barriers

Delays in disseminating results were felt to undermine momentum, reducing motivation for research teams and weakening participants’ sense of connection to the study.

"Publications will take months, years, sometimes, so it'd be really hard for me as a clinician to say, well, I know the results, but I can't tell you until this arbitrary process is done. Even though these results are directly related to you." (A12)

Theme 6: Areas of improvement for sharing trial results

Participants identified several opportunities to strengthen how trial results are communicated.

Guideline availability and awareness

Participants called for regulatory bodies to standardise terminology for lay summaries and offer consistent templates. Medical writers shared that they typically followed EU CTR Article 537 [24] and shared their awareness of the "Good Lay Summary Practice" (GLSP) guideline. [136] However, they noted that while GLSP provides structure, it is lengthy and lacks practical advice with limited inclusivity. One participant noted that the guidance was written a few years ago and there is a clear need to update them.

In contrast, NHS and non-commercial researchers shared that they were often unaware of formal guidelines for creating lay summaries, instead relying on personal judgment. A standardised reporting guideline with an evolving checklist was widely supported as a potential solution that could address many of the challenges in preparing a PLS for trial results. Such a framework would provide clarity and consistency, ensuring that all summaries meet a baseline standard while allowing flexibility for specific trial needs.

"*So, if there was some, you know, guidance to make it easier, you know, uh, you could do that."* (A13)

Funders and organisational support

Researchers noted that funders are now prioritising results dissemination, which is acting as fuel for academic, non-commercial trials. Journals can also contribute to dissemination efforts by mandating a public engagement section.

Early planning and budgeting

Participants suggested that dissemination should be planned from the outset and built into the protocol and funding applications to ensure sufficient time, staffing, and resources for sharing results. Budgets should cover PPI activities, plain language writing, design, digital tools, legal requirements, and maintaining participant contact details. Dissemination roles should be defined from the start, with chief investigators supported by trial managers and coordinators. Participants noted that PPI involvement is essential to ensure results are presented clearly and respectfully.

As trial results are typically shared through local hospital teams rather than the central trial team, participants recommended discussing dissemination during site initiation visits and incorporating responsibilities into site agreements. They suggested that Clinical Trials Units (CTUs) could support local sites by preparing and tailoring dissemination materials, recognising that local teams often lack the time and resources to develop them independently. Oversight from Trial Management Groups and Trial Steering Committees was also considered important to ensure dissemination plans were implemented and trial results shared responsibly.

Aligning results reports with participant-facing materials

Participants noted that results reports should mirror the language and terminology used in the PIS, which trial participants are already familiar with. Including a statement in consent forms about whether and how results will be shared was seen as a way to ensure accountability.

Diversity and representation

Diversity in research is essential for meaningful outcomes. Trust issues, rooted in societal inequalities like anti-Blackness, anti-immigrant sentiments, and Islamophobia, often prevent participation. Participants called for inclusive trial design and recruitment strategies tailored to underrepresented groups. Staff from minority backgrounds can bridge cultural gaps and help recruit participants from diverse communities. For example, I was able to reach into the Women's Islamic community of Oxford, being a member of this community.

Accessibility must go beyond physical barriers, recognising invisible disabilities and the intersectionality of marginalised identities. Creating safe, welcoming environments where all participants feel valued was seen as key to genuine engagement.

"I'm also someone from that [Autistic] community… It's about kind of the environment and the atmosphere that's created and which I think was done really well.

And I think that kind of gave me the opportunity to contribute because it's kind of the first time I've done anything like this because I've always thought like, I don't know if my opinions [are] really going to be valued…You kind of allowed that time and that space... And I think

that's what kind of encouraged me to stay and not just feel completely overwhelmed straight away. So, I'd just like to say thank you for that." (B9)

Identify the audience

Participants urged researchers to consider who needs the results most, including patients, carers, clinicians, policymakers, family members, and charities:

"But it's also thinking well, who's got most to gain. And who are the hardest to reach?" (A11)

Participants cautioned that an additional layer of complexity arises around sharing results with family members if the trial participant has passed away, which is more likely in certain trials, such as those related to cancer, palliative care, or intensive care. Determining how to handle this ethically and compassionately is challenging: should consent be obtained beforehand and, if so, who gets to make that decision? These questions require careful consideration, balancing respect for patient privacy with the needs of grieving families who may find closure or insight in the trial's findings.

Audience considerations also affect the tone and terminology used. For instance, terms like "relapsing MS" might be familiar to multiple sclerosis patients but need explanation for general readers. Tailoring the communication style can improve comprehension and engagement across diverse groups.

Engaging the public

Participants recognised that trial evidence is not part of mainstream conversation and is often overshadowed by sensational posts on social media.

"If, like, the voice from the trial is overshadowed by more sensational stuff on TikTok, then it's not in that space, then that's a problem, because people…they wouldn't read the paper. They wouldn't get the message." (B13)

Participants encouraged researchers to use social media creatively and professionally, partner with charities, and host community events to improve reach. They felt these approaches could increase awareness of trials, improve dissemination to diverse populations and encourage future participation.

Dedicated trial websites and dashboards were seen as helpful resources, with the caveat that they require maintenance and good search visibility to be effective. For large trials, community engagement events, press releases and media coverage, as successfully demonstrated during COVID-19 trials, were also considered valuable when individual result sharing is not feasible.

A selection of illustrative quotations supporting each theme is presented in Table 3.9.

Table 3.9: Illustrative quotes per theme and categories

Themes	Categories	Illustrative quotes
No participants no trial – It is all about respect and recognition	Gratitude and sense of pride	*"Yeah, some pride in that you've contributed to this, you've helped create. This wasn't possible without your data."* (A1) *"Which is, you know, a bit of a slap in the face, really. It is almost like, well, you are not considered quite well, although you took part in the Trial, you are not considered as important as publishing your results."* (B6)
	Ethical and moral obligation	*"But also, actually for good research conduct practice and for good use of research findings that is always conducted."* (A11)
	Altruism and contribution	*"I mean, the patient has done this because they're interested in and the not only their own future prognosis but also that of other people with the condition, done it out of an altruistic [reason]."* (B1)
	Impact participation in trials	*"I think the more that you can do to engage with people and different ways of engaging people, the greater your chance of securing large numbers to the trials."* (B7)
	Patient journey	*"They might not remember that they were in a trial, or if they do remember, they don't remember the details.* *So, sometimes it is interesting for them as well, and it can help them put together their ITU journey...and actually going back to things and revisiting can actually be really helpful because it is a very stressful period of time when they might not remember things and then they're fitting it all together later."* (A8)
	Informed health choices	*Well, I take things quite seriously. So, I think I would really reflect on it...kind of…it would help me make decisions about health in the future or like choosing medication… it would be important."* (B13)
	Institutional requirements	*"So, in every clinical trial, we plan to do that. Partly, because of the requirements of a funder's perspective, and the expectation from a funder's perspective."* (A11)
Main items to share	Results	*"I just want the outcome of the research and that would do for me."* (B2)
	Clinical implications	*"What effects the trial results have had in changing anything you know; I mentioned NHS and I mentioned treatments. You know what impact it has."* (B7)
	Aim and background	*"What was this trial about?"* (A1)
	Future direction	*"Is there a paper being written to recommend a change in standard care?"* (A2)

Clarity, accessibility and accessibility and respect for the reader are important when presenting information	Simplicity is key	*"Putting it in language that people can understand, …not just the people who are doing it.* *And … you know the general public, otherwise they the whole time they're gonna be thinking you know what's going on behind all these all these clouds and mirrors and everything that they're putting up for us. Yeah."* (B6)
	Self-sufficient	*"Ideally, the report should be self-sufficient on its own."* (B1)
	Affordability on digital content	*"And definitely you have to do more than one way... like you say to cover all bases, and I mean obviously you got the elder population, which actually more of them are using computers and emails now, but you are you know you may have some that still aren't, or you know people that can't afford."* (A13)
	Academic writing	*"It is very hard to unlearn making everything sound very intelligent."* (B1)
	Clear language	*"And I think if the language and the mode is not clear, then you can't pique the interest and you can't have the impact that you are trying to achieve, yeah."* (A11)
	Broken into small paragraphs	*"Break it down to different sections, like clearly signposting more. Each bit means what."* (B10)
	Regional language convention	*"In America one could think that was absolutely fine, but it I don't know if you are sending that out in this country, I don't think the science should be communicated quite like that, but it is probably a personal thing."* (A4)
	Visual memory	*"Yeah, yeah, it is good for your visual memory because I know. So, it is stuck into my memory…just because of that animation."* (B11)
	Numeric presentation	*"But if it is to get, say, that we found that 70 people that had this, then 25 people had this, then no, it is better as a diagram or chart or something, yeah."* (B6)
	Balanced use of visuals and text	*"I think a balance of both. You know infographics. That's the thing about infographics, that's a mix of visuals and text.* *So where possible you communicate what you can visually with infographics, then you use text for the parts you can't."* (B3)
	Preference for digital media	*"We don't, we don't communicate with each other with like letters. A lot of this information that's shared is digital."* (B13)
No 'one size fits all'-communication strategy must be tailored	Tailoring strategy	*"Tailoring it to the particular research question and population is really important."* (A11)
	Offering multiple formats	*"There's really no excuse anymore for not being able to develop fully accessible, you know, dissemination products, whether it be you know the videos, or it be some kind of literature product.* *There are so many options available to people these days."* (A12)

Barriers to sharing results	Lack of guidance and inconsistency	*"We just worked as a group.* *We weren't following any guidance, to my recollection about it, to be honest."* (A14)
	Funding issues	*"I don't think there's ever going to be funding for it. "* (A2)
	Staff turnover	"*Probably the trouble is in research, when you move from job to job, your kind of if a study is going for 25 years, you'll perhaps be there at the beginning or at the end or in the middle.* *But because of staff changes, you don't always see a study all the way through."* (A5)
	Timing issues	"*Publications will take months, years, sometimes, so it'd be it'd be really hard for me as a clinician to say, well, I know the results, but I can't tell you until this arbitrary process is done.* *Even though these results are directly related to you."* (A12)
Areas of improvement for sharing trial results	Clear regulation is required	*"Having clear, clear guidance from regulators about what's acceptable and what's not."* (A1)
	Right to opt in or out	*I think it should be compulsory for the researcher to give you the option of having the result."* (B4)
	Early planning and budgeting	*"And I think the important thing is to think at the start, because if you if you know how you are wanting to disseminate you, incorporate that right at the start in your ethics application.* *And because if you haven't got ethics approval, you can't contact them at the end."* (A6)
	Diversity and representation in clinical trials	*"and having the staff to conduct the trial.* *Who can I mean...That's another thing that doesn't get talked about enough is that the people who do the research can't access groups because they just don't have. Uh.* *The social cultural characteristics to be able to enter and gain trust for different communities so they have to change the staff mix."* (A6)
	Identify the audience	*"But it is also thinking well, who's got most to gain. And who are the hardest to reach? And can we try to get the easy to reach people, but also the harder to reach people as well equally."* (A11)
	Public sharing	*"if, like, the voice from the trial is overshadowed by more sensational stuff on TikTok, then it is not in that space, then that's a problem, because people…they wouldn't read the paper. They wouldn't get the message…"* (B13)

3.4 Discussion

In this Chapter, I described semi-structured interviews and focus group discussions conducted with researchers, patients, and members of the public to gather their perspectives on sharing trial results with patients and the public, priorities for reporting, preferences for communication, barriers to implementation, and potential areas of improvement. Researchers and the general public have traditionally been separated out of fear of power dynamics. In this study, however, I deliberately brought both groups together through individual interviews and mixed focus groups to encourage richer discussion and a more comprehensive understanding of the issues.

Participants identified both what information should be shared and how it should be presented. Unlike most guidance development approaches identified in the scoping review, which asked stakeholders to evaluate or rank predefined reporting items, I asked participants to generate reporting items inductively from their own experiences and priorities. Many reporting priorities aligned with previous studies of participant preferences [157] and with the findings of the scoping review (Chapter 2). Participants also identified additional reporting items that were rarely or not represented in existing guidance, including items such as comparison with existing research, economic implications, changes to healthcare policy, strengths and limitations, and milestones in the patient journey. These findings suggest that open-ended qualitative inquiry can identify reporting items that are important to intended audiences but may not emerge through approaches based on predefined candidate items. These reporting items were subsequently taken forward into the Delphi survey for further evaluation (Chapter 4).

Participants also emphasised that trial results should be communicated in ways that are meaningful, understandable, and respectful of participants' contributions to research. Although previous studies have noted that concerns about the psychological impact of negative findings may discourage result sharing, [8] participants overwhelmingly expressed a desire to receive results regardless of outcome, provided they were communicated sensitively. Similar findings were reported in recent literature, where participants described result sharing as important for trust, transparency, and feeling valued. [13, 16, 157]

Participants emphasised the importance of inclusive communication. Both this study and the scoping review (Chapter 2) highlighted the lack of guidance on cultural and linguistic diversity in trial result dissemination. Addressing this gap is essential to ensure that results reach, and are meaningful to, diverse communities. Consequently, I prioritised diverse recruitment throughout this study and the subsequent stages of the reporting guideline development.

Participants expressed a preference for flexibility in how trial results are communicated, recognising that individuals differ in their information needs and preferred modes of communication. While offering multiple dissemination formats may improve accessibility and engagement, it also has practical implications for trial teams in terms of time, resources, and infrastructure. A layered communication model, where all participants receive a concise summary of the key findings with opportunities to access additional information if desired, may provide a practical compromise. These findings suggested the importance of

distinguishing between core items that should be routinely reported and additional items that can be adapted according to context and audience.

I also observed that industry trials are often driven by the need to comply with regulatory frameworks like the EU CTR, [24] while non-commercial trials depend more on researchers' passion and organisational commitment to share results. The former has clear mandates for results dissemination, while the latter may lack formal structures, making the role of researchers' commitment crucial. Although recent UK legislation may help establish more consistent expectations across both sectors, implementation is likely to require organisational commitment alongside regulatory requirements.

Across stakeholder groups, there was strong support for a more consistent approach to communicating trial results. Participants recognised the challenge of presenting complex scientific information in plain language while maintaining accuracy and repeatedly highlighted the need for practical guidance, institutional support, and clear dissemination processes. Similar barriers, including limited time, resources, uncertainty regarding responsibility, and lack of organisational support, have also been reported previously.[13, 157] Consistent with Bagita-Vangana et al., my findings suggest that ethical commitment alone is insufficient to ensure routine dissemination in practice. [13]

Several aspects of the study strengthened confidence in these findings. Unlike many reporting guideline development studies, which involve stakeholders primarily during later consensus stages, I sought stakeholder input before candidate reporting items had been generated, allowing participants to identify reporting priorities inductively from their own

experiences. This reduced the likelihood of overlooking issues that may not have been identified through the literature alone. Purposeful recruitment also resulted in a diverse participant group, with approximately one quarter identifying as belonging to a non-White ethnic group, and representation across different regions of the UK, socioeconomic backgrounds and lived experiences. My patient partner expressed her happiness at seeing two members from autistic communities participating in this study. As a member of that community herself, she felt positively represented, an experience she mentioned doesn't happen often.

Including both trial professionals and intended recipients of trial results also enabled comparison of perspectives across stakeholder groups, strengthening the relevance of the findings for reporting guideline development. Combining individual interviews with mixed focus groups further strengthened the study by allowing participants to challenge, refine, and build upon each other's perspectives, generating insights that may not have emerged from interviews alone. [180, 191, 192]

The study design also strengthened the credibility of the findings. Participants expressed a high level of satisfaction with the study's flexibility to take part online, by telephone, or face-to-face at a time and place of their choosing. The online approach also offered additional benefits, such as easier access for geographically dispersed participants, greater scheduling flexibility, and potentially enhanced comfort for participants sharing from familiar environments.

This study also has several limitations. The absence of dedicated funding meant that participants could not be reimbursed for their time, which may have reduced participation and limited the diversity of perspectives obtained. Although the sample size was appropriate for qualitative research, it may not capture the full range of stakeholder perspectives. Participants were recruited exclusively from the UK, and their views were therefore shaped by the UK healthcare and research context. Consequently, some findings may not transfer directly to countries with different regulatory environments, research infrastructures, or cultural expectations. Recognising this limitation, I purposively recruited international stakeholders in the subsequent phases of the reporting guideline development. Finally, although reflexive practices were embedded throughout data collection and analysis, qualitative interpretation is inevitably shaped by the researcher's perspectives and experiences.

Overall, this study identified reporting items and implementation considerations that stakeholders considered important when sharing trial results with patients and the public. Together with findings from the scoping review, these informed the candidate reporting items subsequently evaluated through the international Delphi survey described in Chapter 4.

Chapter 4: Identifying core reporting items through a Delphi survey

4.1 Introduction

In Chapter 2, I examined existing guidance through a scoping review and identified that while several guidance documents exist, there is a lack of evidence-based co-produced reporting guidelines for sharing results of randomised trials with patients and the public in a clear and consistent way. In Chapter 3, by conducting qualitative interviews and focus groups, I explored what different stakeholders, including trial professionals and patient and public representatives, considered important to communicate when sharing trial results. Together, these chapters highlighted both the gaps in current guidance and the priorities of those who would prepare or receive trial result summaries.

The next step was to bring these findings together and move towards developing a structured reporting guideline. To do this, it was necessary to reach agreement on which items should be considered essential when sharing trial results with patients and the public. The guidelines identified in the scoping review suggested a list of potential items to report, while qualitative study participants provided further input on which items would be meaningful to be reported.

Drawing on the findings from the scoping review, qualitative study, and relevant reporting frameworks such as CONSORT, [62] I generated a preliminary list of potential checklist items. Additional items were included based on insights from published literature and practical considerations identified during study development. However, developing a list of potential

items was only the starting point; agreement across stakeholders was needed to determine which of these should be prioritised and how they should be classified. This chapter describes a Delphi survey, which I conducted to achieve consensus on the key items to include in the reporting guideline checklist for sharing the results of randomised trials with patients and the public.

4.1.1 Objectives

Primary objective:

1. To conduct a Delphi survey to reach consensus on the reporting items for inclusion in a checklist for sharing results of randomised trials with patients and the public.

Secondary objectives

1. To rank and prioritise candidate reporting items through successive Delphi rounds.
2. To involve a diverse range of stakeholders, including trial professionals, researchers, patients and the public, clinicians, guideline developers, and policymakers.
3. To document participant feedback and how it informed the development of the checklist transparently .

4.2 Methods

4.2.1 Protocol and ethics approval

The Delphi protocol for this study is registered on the OSF. [193] Ethical approval was granted by the Central University Research Ethics Committee at the University of Oxford (MS IDREC – 1149364).

4.2.2 Selection of potential items for the Delphi survey

The potential Delphi survey items were gathered from three key sources:

1. **Scoping review findings** – A list of recommendations from existing guidance on what content should be shared with participants was developed during the scoping review (Table 2.6, Chapter 2). (35 potential items)
2. **Qualitative study findings** – Interviews and focus groups with members of the public, patient representatives, and trial professionals identified a list of meaningful items to share (Table 3.9, Chapter 3). (24 potential items, some overlapping with the scoping review items)
3. **Additional items** – Additional items were included based on insights from existing literature, personal experience, and practical considerations identified during study development. (9 potential items)

I removed duplicates, resulting in a list of 55 potential items, and grouped them under seven themes. The complete list of items and their sources (scoping review, qualitative study, or additional items) is presented in Table 4.1. The red highlighted cells indicate items that were

either rejected or merged with other items during preparation of the candidate item list for the Delphi survey.

These items then went through several rounds of review and refinement. PPI input played an important role at this stage. Two PPI members reviewed the draft list of potential items and provided detailed feedback on both language and layout, with the aim of making the Delphi survey easier for patients and members of the public to understand and complete.

Their feedback led to several concrete changes. For example, the item originally described as "*Acknowledging contribution*" was revised to "*Thank participants for taking part in the trial*" to make its meaning more explicit. For the item relating to the primary outcome, PPI contributors suggested referring to "*Main findings*" in the description, which was felt to be more intuitive for non-specialist audiences.

PPI feedback also informed the terminology used throughout the survey. The term "*Adverse events*" was replaced with "*Side effects*" following discussion that this wording would be more familiar and easier to understand from a patient perspective. These changes were made to reduce technical barriers and support meaningful participation by patient and public contributors in the Delphi process.

After this iterative process, **45 items** were finalised for inclusion in the first round of the Delphi survey.

Table 4.1: Sources of potential Delphi items across them

Key: Y = identified from source; grey = not identified; red rows = removed/merged before the Delphi survey

Themes	Description	Scoping review	Interviews PPI	Interviews Professionals	Additional items
1. Thank You					
Trial participants	Thank trial participants for taking part in the trial	Y	Y	Y	
Trial team	Thank trial sites, trial teams, and other contributors for their role in the trial	Y			
2. Background					
Benefits/risks of receiving results	Potential benefits and risks for the trial participants of receiving the trial results. (e.g., "We are sharing these results with you because understanding them helps you see how your participation has contributed to research." or "Some people may find some results unexpected or difficult to process, especially if they had personal hopes for the outcome. If you have any questions or concerns after reading the results, support and further information are available.")	Y			
Objective	Objective (purpose) of the trial (e.g., what did the trial want to find out)	Y	Y	Y	
Trial purpose	Primary goals and research questions of the trial	Y	Y	Y	
Health condition	Description of the health condition being studied	Y		Y	
Rationale	Rationale (the reason) behind choosing a randomised trial design (A randomised trial is a trial where participants are assigned by chance to different groups to compare treatments or interventions)				Y
3. Methods					
3.1 General information about the trial					
Title or trial name	Identification as a randomised trial	Y			
Protocol changes	Any issues that changed the protocol/trial plan; difficulties encountered	Y	Y		
Trial duration	Trial start and completion dates	Y			
Trial journey	Any notable events or issues that happened during the trial, (if applicable) (e.g., if the trial was stopped early for any reason or if there was a breakthrough finding)	Y	Y		

3.2 Trial participants					
Eligibility criteria	Inclusion and exclusion criteria for the trial participants	Y			
Number of participants	Number of participants included in the trial	Y	Y	Y	
Demographics	Age, sex, and/or gender of the trial participants	Y	Y	Y	
	Diversity of the trial participants (e.g., ethnicity, religion, language, income, education, geographic location, disability, or other health conditions)		Y		
Population applicability	A clear statement that the results apply to this population, not any other population, under these specific conditions	Y			
Follow-up participants	Who the follow-up participants will be, if applicable		Y		
Settings and location	Where the participants were recruited from in the trial			Y	
3.3 Intervention(s)	Intervention(s) for each group and what was it compared with (An intervention is a specific action or treatment that is being tested in the trial. This can be e.g., a new medication, surgery or lifestyle changes. Sometimes more than one intervention is evaluated.)	Y			
3.4 Randomisation, blinding, and analysis					
Randomisation	How the participants were allocated to the intervention(s) in the trial (e.g., who received the treatment being tested and who received a placebo (a dummy treatment), or a different treatment)	Y		Y	Y
Blinding	Whether the trial participants, care givers, or trial team knew which intervention(s) the participants received (e.g., if the trial participants knew whether they got the treatment or the placebo / different treatment)				Y
Methodological limitations	Any uncertainties or limitations specific to the randomisation process				Y
	Use of placebo control, equipoise				Y

Ethical considerations specific to randomisation	Information on how participants were informed about the randomisation process				Y
Analysis	Statistical methods used to analyse the trial data				Y
3.5 Patient engagement and community involvement					
Patient and public involvement and engagement	Whether and how patients and/or the public helped in the design and delivery of the trial (e.g., if patients and/or the public helped to plan and run the trial)	Y	Y		
Patient and public involvement and engagement	Feedback on what the participants experienced in different trial arms (e.g., side effects, treatment burden)				Y
4. Results					
4.1 Outcomes					
Main findings	A summary of the primary outcome results (The primary outcome of a trial is the main result that the trial is aiming to investigate, e.g., if the treatment worked)		Y	Y	
All findings	All other outcomes assessed in the trial (Secondary outcomes are additional results that are measured in a trial to gain more information, even though they are not the main focus of the trial)	Y			
Significance of results (main)	Explanation of the statistical significance of the primary outcome result		Y	Y	
Significance of results (all)	Explanation of the statistical significance of all outcome results				Y
Positive or negative findings	Include an interpretation as to whether these are positive or negative findings	Y			
4.2 Adverse events					
Side effects	Main adverse events experienced by the trial participants during the trial (Adverse events in a trial are any unwanted or unexpected health problems that occur during the trial, whether or not they are directly caused by the intervention(s) being tested)	Y	Y	Y	

Long-term effects	State anticipated long-term effects and surveillance recommended, if any, for the participant and sources of support links	Y			
Follow-up plan	Suggested follow-up plans, (if applicable) (Post-trial follow-up involves monitoring trial participants' health after a trial has ended to understand the long-term effects and safety of the treatment)	Y			
5. Conclusion					
Interpretation	General interpretation of the trial results (e.g., what do the results mean)	Y			
Generalisability	How applicable the trial results are to the broader general population, beyond the specific context of the trial (e.g., if the trial results are relevant to most people with the condition, not just those who took part in the trial)	Y	Y		
5.1 Implications					
Clinical practice	How the intervention(s) may improve the health condition and its effectiveness	Y	Y	Y	
Healthcare policy	Whether and when the intervention(s) might be available after the trial (e.g., if the NHS will include it in their policy)		Y	Y	
Economic implications	Cost-effectiveness of the intervention(s) tested (e.g., if the new treatment is cheaper than the current treatment)		Y	Y	
Comparison	How the trial results compare with current treatment options and existing research		Y	Y	
Media coverage	Significance of the trial's impact on public interest and media attention (e.g., if the trial was publicised in the news)			Y	
5.2 Limitations					
Strengths and limitations	Strength and limitation of the trial results (e.g., provide a statement such as "The summary result reflects the results of a single trial, and multiple trials are sometimes needed to assess benefits and risks of new medicines or treatments")	Y	Y	Y	
	A statement that the summary includes the results of a single trial and that multiple trials are used together	Y			
Uncertainty	Any unanswered questions or emerging questions from the trial results	Y			
5.3 Future direction					

Next steps	Next steps for the trial (e.g., licensing of the medicine or treatment, publication)	Y	Y	Y	
Future studies	Opportunities for involvement in future studies	Y	Y	Y	
Will the intervention be available	Whether and when the intervention might be available after the trial	Y			
Unanswered questions	Unanswered questions or emerging questions from results	Y			
6. Discussing the trial results with healthcare providers					
Direction of questions	How the trial participants can discuss the trial results with health care providers to make informed health choices (e.g., provide a statement such as “You may wish to share these results with your doctor”)	Y	Y	Y	
	Highlight desirable action	Y			
	Advise the trial participants to consult healthcare providers before making any changes in their treatment plan based on the trial results	Y			
7. Additional information					
Accessibility	How the trial participants can get more information (e.g., provide a QR code to a digital version of the patient information)	Y	Y	Y	
Publication details	Where and when the trial report will be published	Y	Y		
Drug approval status	Current approval status of the treatment or intervention(s) studied in the trial (e.g., whether it is approved or waiting for regulatory review)	Y			
Funding	Who funded the trial	Y		Y	
Data protection policy	How the data of the trial participants will be protected	Y			
Hospital site details	Where the participant was recruited			Y	
Ethics approval	Details about the ethical approval of the trial and the ethics committee		Y		
Frequently Asked Questions	A section providing answers to common questions patients and/or the public may have about the trial, its results, or the next steps.			Y	

4.2.3 Participant identification and recruitment for Delphi survey

Who were the participants:

I recruited participants from both the UK and internationally to ensure diverse perspectives, with a strong emphasis on ensuring representation from PPI groups.

Three self-identifying groups of participants took part in the Delphi survey :

1. Trial/research professionals
    - Researchers with expertise in trial design and methodology, such as trial methodologists, trial managers, chief investigators, clinicians, statisticians, and epidemiologists
    - Assessors and approvers of trials, such as regulatory agencies and research ethics committee members
    - Commissioners of trial research grants, such as funders
    - Potential beneficiaries and users of the reporting guideline, such as journal editors, medical writers, peer reviewers, and clinical guideline developers
    - Authors of published reporting guidelines
2. Patient representatives
3. Members of the public

I analysed the responses from each of these three groups separately to give equal representation and to ensure that every group carried equal weight in determining whether an item reached agreement.

Eligibility criteria

Participants had to be over 18 years of age and fall under the definition of at least one of the participant groups outlined above.

Recruitment

Potential Delphi participants were identified from a distribution list developed with my supervisors, drawing on established research and trial networks, existing collaborations, professional research societies, guideline development networks such as EQUATOR Network, and international trial units (Appendix 4.1). I also invited journal editors and medical writers with experience in publishing plain-language summaries.

I invited professionals with diverse roles and from a range of settings (including academic, industry, and policy contexts) to take part in the Delphi survey. Participants were purposively selected to ensure geographical and professional diversity across key stakeholder groups, including trial managers, clinicians, statisticians, epidemiologists, methodologists, ethicists, journal editors, professional medical writers, funders, policymakers, healthcare professionals, and healthcare regulators.

I also reached out to my personal and professional contacts in Asia (Bangladesh, India, Thailand) and Australia. My supervisors helped me to reach contacts across Europe, Africa, and North America. I also invited authors of the guidance documents identified in the scoping review (Chapter 2) and participants of the qualitative study (Chapter 3) and requested them to spread by word of mouth.

To recruit patient and public representatives, I reached out to established PPI networks, local and international community contacts, charities, and community organisations (Appendix 4.1). I made a conscious effort to promote inclusivity and diversity, including the recruitment of participants from ethnic minority and underrepresented groups, and those with lived experience of health conditions or learning disabilities.

I prepared recruitment materials in different formats, including email invitations, professional mailing lists, flyers, posters, and network mailshots, adapted to the requirements of the individual networks I reached out to. Figure 4.1 shows an example flyer that I shared at multiple community engagement events. I printed out the flyer and posters and distributed them around academic departments, trial conferences, primary care / general practice settings, PPI events, and religious and social gathering places. I also created social media materials for X and LinkedIn, which were shared by my supervisors and me.

Snowball sampling was used to identify additional eligible participants, with several PPI participants sharing study information within their own networks. For example, one PPI expert circulated the study through the Deep End PPI Group, a GP-based PPI network working with practices serving highly deprived communities in the UK.

Interested individuals could express interest using the contact details provided in recruitment materials or access the survey directly via a link included in the advertisements. The recruitment period ran from 9th May 2025 to 27th August 2025.

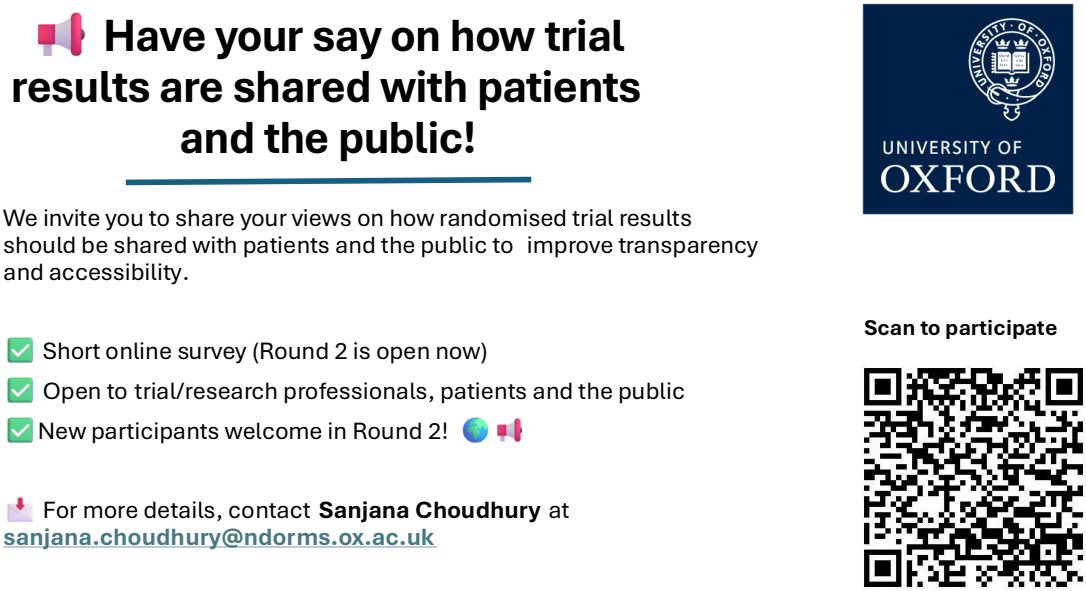


Figure 4.1: An example of advertisement material for the Delphi survey

Sample size

Previous research suggested that a minimum sample size of 60 to 80 participants in multistakeholder Delphi surveys provides a high level of replicability (≥80%) of results.[194] However, the minimum number of participants in a Delphi study can vary depending on the study's purpose, scope, and desired diversity of perspectives. For example, 292 participants were invited to Round 1 of the Delphi survey during the development of the TRIPOD+AI reporting guideline for reporting studies that develop a prediction model or evaluate its performance using artificial intelligence and machine learning. [195] During the 2025 update of CONSORT, 317 participants took part in the Delphi. [62] During the development of the CONSORT extension: CONSORT guideline for reporting scientific abstracts of randomised trials, 109 participants were invited to take part in the Delphi. [196]

For this study, I aimed to recruit a minimum of 100 participants, with no fixed upper limit. This target was intended to ensure representation from a broad range of stakeholder groups, including trial professionals and patient and public representatives, and broad geographical representation. The decision was informed by the supervisory team's previous experience of conducting and participating in Delphi surveys, as well as by the scale of comparable reporting guideline developments.

Approach

The Delphi survey was conducted using Online Surveys, access provided via the University of Oxford. [197] In all rounds, the survey remained open for at least three weeks, with a reminder email sent one week before the closing date of the round. Informed consent from participants were obtained on the survey platform, where a link to the PIS was also provided (Appendix 4.2). The PIS described the study and its eligibility criteria, process, and timeline. Participants were given the choice to withdraw at any time. Participants did not know the identities of other individuals completing the Delphi survey, nor did they know the specific responses that any individual provided. Participants could opt to be acknowledged by name for their contribution (Appendix 4.3).

4.2.4 Delphi survey rounds

Design

The Delphi process involved three rounds, in which participants independently ranked proposed checklist items. I asked participants to rate the importance of different types of information that could be shared with patients and the public when reporting the results of a randomised trial. The aim was to find out what people think is most important and useful

to include, which would help to decide the content of the reporting guideline checklist. Each survey round took around 10-15 minutes to complete. After each round, structured feedback summarising the group's responses were shared to help panellists reflect on the opinions of others and refine their views in the subsequent round.

Executive committee:

An executive committee was established for the Delphi survey and the subsequent consensus meeting (Chapter 5). This committee consisted of me, my supervisors, and four PPI representatives. I coordinated and oversaw the Delphi survey, with guidance and oversight from the executive committee.

Procedure for reaching consensus/structure of the survey

In the Delphi survey, participants were asked to rate each potential checklist item on a 5-point Likert scale to indicate the level of agreement with its inclusion in the reporting guideline checklist. This approach is consistent with previous reporting guideline development studies, including the CONSORT update methodology, and provides a balance between sufficient discrimination and ease of use for participants.[198]

1 = Not important at all

2 = Slightly important

3 = Moderately important

4 = Important

5 = Very important

Participants were asked to consider the following guiding principles when reviewing items for inclusion in the reporting guideline checklist:

a. **Easy to understand** – Will including this item help make trial results clearer and simpler for patients and the public?

b. **Useful and relevant** – Is this something patients and the public would find important to know?

c. **Works for most trials** – Can this item apply to almost all randomised trials, regardless of their design and setting? (For trial professionals to consider)

d. **Essential information** – Is this one of the key things needed to explain trial results properly and meaningfully?

At the start of each round, information about the study rationale, aims and methods of the Delphi survey, and use of participant data was provided. Consent was obtained from the participants, and they were required to confirm that they were 18 years old or over. In rounds 2 and 3, summary results of previous rounds were displayed. Participants also had the option to provide comments to explain their decision or suggest wording changes in a free-text box. Additionally, a free-text box was available at the end of the survey for participants to propose additional checklist items. I compiled suggestions made during each round and reviewed them to be considered for inclusion in subsequent rounds.

User testing

The Delphi survey underwent multiple rounds of user testing prior to launch. Testing involved individuals familiar with trial reporting and reporting guidelines, as well as PPI

representatives. For each testing round, I conducted iterative reviews independently, with my supervisory team, and with PPI representatives.

PPI representatives involved across testing rounds included Carolyn Newbert (CN, Rounds 1 and 2), Amy Wizard-Ponter (AWP, Rounds 1–3), Mohammad Sayeem (MS, Rounds 1 and 3), and Karen Williams (KW, Round 3). Permission was sought and obtained from the PPI representatives to formally acknowledge their contribution to this research in my thesis.

PPI input focused on clarity, layout, accessibility, and overall usability of the survey for patient and public respondents. Feedback during Round 2 of the Delphi survey was particularly influential in refining how results were presented. I asked PPI representatives to comment on the clarity of summary rating tables and the presentation of items that had not reached consensus. For example, I sought views on whether displaying results for three stakeholder groups alongside an overall percentage was clear, and whether non-consensus items were best presented as a single list or broken down by theme.

CN noted that the overall tone of the survey was welcoming and easy to navigate. She felt the summary rating tables were clear and not overwhelming, but highlighted that she was more interested in group-specific results than the overall percentage.

AWP provided detailed feedback on consistency and readability. She felt that Round 1 results were generally clear and appreciated the repeated structure across pages, noting that this consistency supported understanding. However, she suggested that tables displaying new items should be larger, with clearer fonts and improved colour contrast, as some text

appeared small and difficult to read. These layout issues were subsequently corrected. In the final round of testing, KW described the survey as *"very accessible, easy to understand and follow"* and did not suggest further amendments, indicating that earlier revisions had addressed key usability concerns.

Delphi rounds, consensus definition and handling of near-threshold items

The Delphi survey ran across three rounds. At the end of each round, I downloaded the survey data as an Excel file and analysed them. Round 1 was open from 9th May 2025 until 17th June 2025.

In **Round 1,** I pre-specified 'consensus' as ≥80% of participants in **all three stakeholder groups** (trial/research professionals, patient representatives, and members of the public) rating an item as important or very important (score 4 or 5). After analysing responses from Round 1, I noticed that this strict criterion resulted in many items not reaching consensus, including some that showed strong support in two of the three groups. Ahead of **Round 2,** and following discussion with my supervisors, I pragmatically revised the consensus definition to **≥80% in at least two of the three stakeholder groups**. This was done primarily to help reduce the number of items carried forward into Round 3 and minimise participant burden, while still maintaining a reasonable standard of agreement. This also helped ensure representation across the three stakeholder groups.

Many Delphi studies use variable thresholds across rounds or combine quantitative and qualitative steps to refine consensus. [199, 200] Setting strict ≥80% consensus for final inclusion maintains rigor, however, the relaxed thresholds for re-rating balanced feasibility and

inclusiveness. This was also made transparent and clear to the Delphi panel when the summary results were displayed.

Round 2 of the survey was open from 1st July 2025 until 22nd July 2025. Participants from Round 1 were invited to take part in Round 2, alongside any new participants invited to ensure stakeholder balance. A summary of the anonymised group ratings from Round 1 was provided. Participants were asked to rate each item again, including new items suggested in Round 1, while considering the structured feedback from the previous round to inform their responses. Items that had reached 'consensus' were presented for information purposes only, with no voting required, but a free-text box was provided for any additional comments.

Round 3 of the Delphi went live on 4th August 2025 and was open until 27th August 2025. All individuals who were invited to participate in Rounds 1 and 2 were invited again to participate in the Round 3, unless they had requested not to receive further invitations. Round 3 was designed to follow on from the results of Rounds 1 and 2. A large number of items had not reached consensus after Round 2. To reduce participant burden and avoid survey fatigue, I adopted a two-part approach in Round 3.

- First, I identified items that were close to reaching consensus, defined as having received a rating of 4 or 5 from **at least 60% of participants in all three stakeholder groups** (trial professionals, patient representatives, and members of the public). These items were carried forward for re-rating in Round 3 using the same 5-point Likert scale. Focusing on items that already showed moderate agreement (≥60% in all groups) targeted the most promising items while respecting participants' time.

- Second, I presented the remaining items in a list. Rather than asking participants to rate these again, I provided an open-text comment box. Participants were invited to share any thoughts on whether these items should still be considered for inclusion, or to explain their reasoning.

4.2.5 Analysis of Delphi survey results

Comparison between stakeholder groups

Separate analyses were conducted for (1) researchers/professionals involved in trials, (2) PPI representatives and (3) members of the public. This approach ensured that the perspectives of professionals, patients, and the public were distinctly represented.

Quantitative analysis

The characteristics and demographics of Delphi respondents from each round were summarised. Item scores were summarised for the three stakeholder groups separately, including percentages across the rating categories. Results from all survey rounds were reviewed and discussed by the executive committee.

Qualitative analysis

Participant comments from all Delphi rounds were extracted and uploaded to NVivo 12. I analysed the comments thematically, initially coding them deductively according to the seven pre-specified item themes, with separate nodes created for each theme. Within these nodes, I reviewed comments inductively to identify common issues, including suggestions for clarification, concerns about feasibility, requests for additional items, and recommendations for rewording.

I used memos to summarise key points for each item, reviewed suggested modifications and proposed new items, and discussed them with my supervisors to inform item revision between rounds.

Withdrawal of participation

Participants were reassured that they were free to withdraw at any point, and they could stop the survey if they chose to do so. If a participant withdrew, no new information was collected from them. However, any data that had already been collected and stored in previous survey rounds were kept and used in the final study analyses. This was clarified in the PIS.

Data management

All data were captured electronically using the online Delphi survey tool approved by the University of Oxford Information Security Team. All data were securely stored, anonymised when possible, and handled in accordance with data protection regulations (e.g., GDPR) and University of Oxford policies. Survey data was downloaded from the online survey provider and transferred electronically to storage in password-protected Excel files on encrypted computers within the University network. Access to the data were restricted to me.

4.3 Results

4.3.1 Selection of items for Delphi

Figure 4.2 outlines a summary of how I developed and selected the 45 items which were rated in the Delphi.

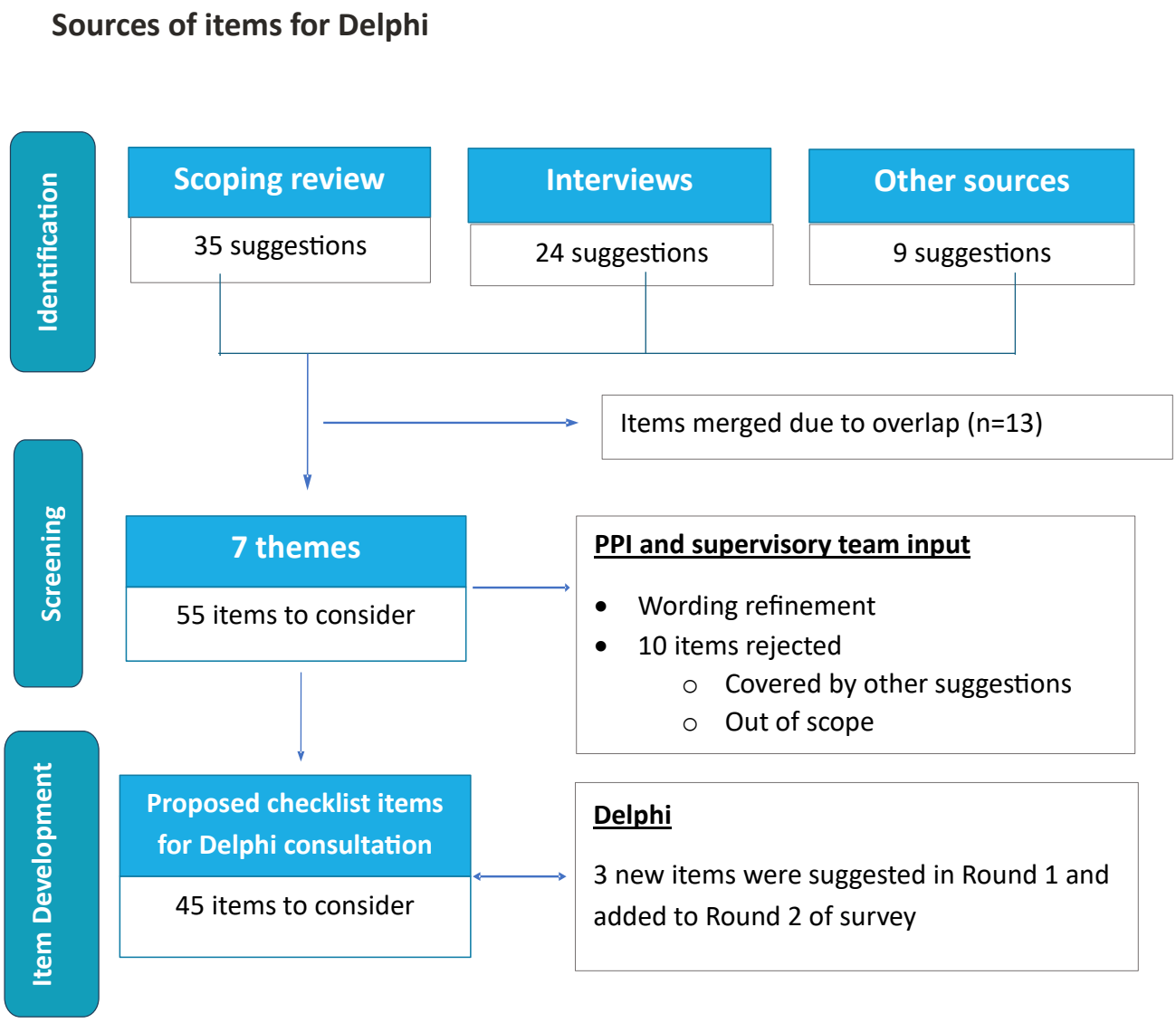


Figure 4.2: Sources of potential items for Delphi

4.3.2 Flow of rounds

A summary of the three Delphi rounds is presented in Figure 4.3.

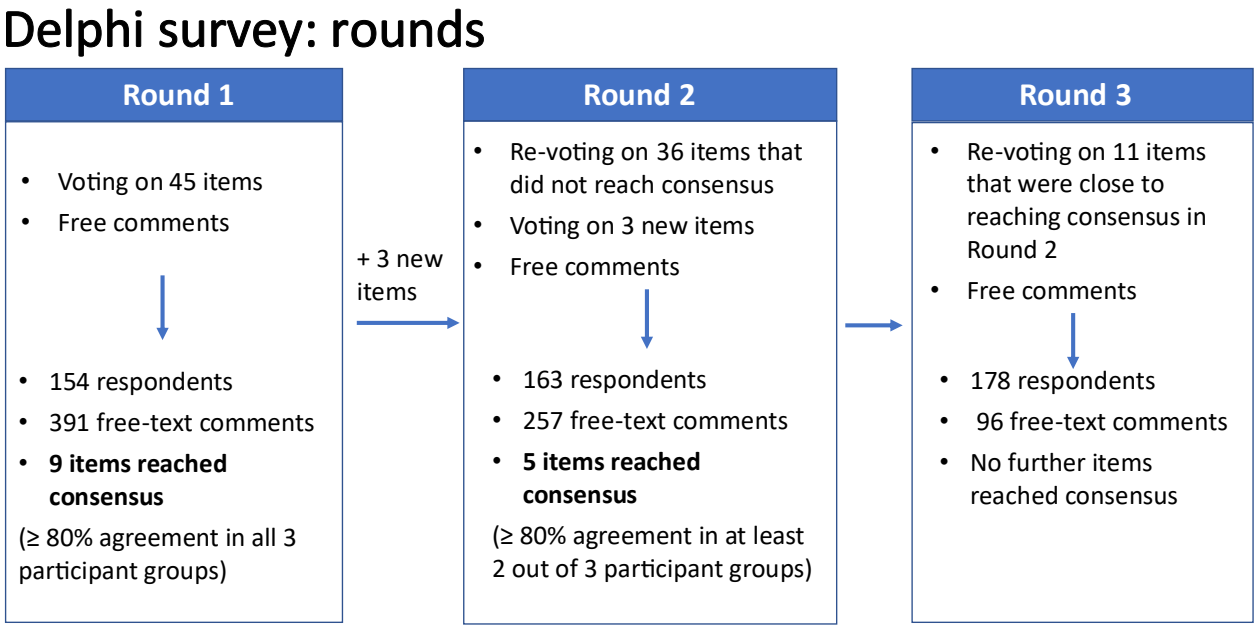


Figure 4.3: Flow of the Delphi survey rounds

4.3.3 Participant characteristics

A total of 154 participants completed Round 1, increasing to 163 in Round 2 and 178 in Round 3. A total of 103 (66.9% overall retention) participants completed all three rounds of the Delphi survey, indicating good retention and sustained engagement across rounds.

Across all rounds, trial and research professionals formed the largest stakeholder group, increasing from 44% (n=67/154) in Round 1 to 58% (n=94/163) in Round 2, and 61% (n=108/178) in Round 3. Patient representatives accounted for 29% (n=45/154) of participants in Round 1, with similar proportions in subsequent rounds (21%; n=35/163 in Round 2 and 22%; n=34/178 in Round 3). Members of the public represented 27% (n=42/154) of participants in Round 1, decreasing to 21% (n=34/163) in Round 2 and 17% (n=31/178) in Round 3.

The gender distribution remained broadly consistent across rounds, with 69% (n=105/154) of participants in Round 1, 73% (n=119/163) in Round 2, and 72% (n=129/178) in Round 3 identifying as women. Age distributions across the three rounds were also similar, with most participants aged between 26 and 65 years, and representation from younger and older age groups. Detailed respondent characteristics are shown in Table 4.2.

A broad range of end user roles were represented in all rounds, including patient representatives, trial professionals, members of the public, clinicians, systematic reviewers, statisticians/methodologists/epidemiologists, regulatory agency/ethics specialists, guideline developers, journal editors, medical communication specialists, funders, and other roles (e.g., admin, R&D experiences).

Participants came from 16 countries and covered a wide range of ethnic backgrounds, including those identifying as White (British, Irish, European, Australian, Canadian), Asian or Asian British (Bangladeshi, Chinese, Indian, Pakistani, Turkish), Black or Black British (African and Caribbean), mixed ethnic backgrounds and other ethnic groups such as Arab and Jewish.

Table 4.2: Characteristics of the Delphi participants, categorised by rounds

Category	Number of participants (%)		
	Round 1	**Round 2**	**Round 3**
Overall number	154	163	178
Stakeholder group			
Trial/research professional	67 (44%)	94 (58%)	108 (61%)
Patient representative	45 (29%)	35 (21%)	39 (22%)
Member of the public	42 (27%)	34 (21%)	31 (17%)
Gender			
Man	48 (31%)	42 (26%)	48 (27%)
Woman	105 (69%)	119 (73%)	129 (72%)
Prefer not to answer	0 (0%)	1 (1%)	1 (1%)
Age (years)			
18-25	1 (1%)	1 (1%)	2 (1%)
26-35	29 (19%)	38 (23%)	23 (13%)
36-45	35 (23%)	39 (24%)	48 (27%)
46-55	33 (21%)	35 (21%)	43 (24%)
56-65	17 (11%)	17 (10%)	20 (11%)
>65	36 (23%)	30 (18%)	37 (21%)
Prefer not to answer	3 (2%)	3 (2%)	5 (3%)
Ethnicity			
White British	97 (63%)	100 (61%)	131 (74%)
White European	8 (5%)	12 (7%)	10 (6%)
White other	9 (6%)	6 (4%)	5 (3%)
Asian/Asian British	24 (16%)	27 (17%)	15 (8%)
Black/African/Caribbean/Black British	5 (3%)	5 (3%)	7 (4%)
Mixed/Multiple ethnic groups	6 (4%)	7 (4%)	5 (3%)
Other ethnic groups (Arab, Jewish, Turkish)	4 (3%)	4 (2%)	4 (2%)
Not reported	1 (1%)	2 (1%)	1 (1%)
Native language			
English	120 (78%)	124 (76%)	153 (86%)
Bengali	17 (11%)	19 (12%)	8 (4%)
Dutch	3 (2%)	1 (0.7%)	1 (0.6%)
Chinese	2 (1%)	2 (1%)	1 (0.6%)
French	2 (1%)	3 (2%)	3 (2%)
Portuguese	2 (1%)	1 (0.7%)	1 (0.6%)
Polish	1 (0.7%)	2 (1%)	1 (0.6%)
Other (Arabic, German, Hausa, Italian, Kikuyu, Japanese,	6 (3%)	9 (6%)	9 (5%)

Spanish, Turkish, Urdu, Russian, Kazakh, Welsh)			
Region of residence			
UK	109 (71%)	122 (75%)	147 (83%)
Europe (excluding UK)	3 (2%)	4 (2%)	3 (2%)
Asia	14 (9%)	9 (6%)	7 (4%)
North America	26 (17%)	23 (14%)	18 (10%)
Africa	1 (1%)	3 (2%)	2 (1%)
Oceania	1 (1%)	1 (1%)	1 (1%)
Not reported	0 (0%)	1 (1%)	0 (0%)
Years involved in trials			
More than 10 years	53 (34%)	64 (40%)	79 (45%)
6-10 years	20 (13%)	28 (17%)	31 (18%)
1-5 years	36 (23%)	42 (26%)	41 (23%)
Less than 1 year	8 (5%)	1 (1%)	5 (3%)
Not applicable	37 (24%)	26 (16%)	21 (12%)
Main employment sector			
Academic	63 (41%)	87 (55%)	91 (54%)
Charity	12 (8%)	6 (4%)	4 (2%)
Industry	6 (4%)	8 (5%)	7 (4%)
Not applicable	54 (36%)	41 (26%)	41 (25%)
Other (e.g., NHS, retired)	17 (11%)	17 (10%)	24 (14%)

Note: Percentages may not total 100% due to rounding.

4.3.4 Delphi ratings

Round 1

Items reaching consensus in Round 1

Table 4.3 shows the list of 45 items included in Round 1 of the Delphi survey along with the percentage of people who rated the item as important or very important **(scores of 4 or 5),** shown separately for each participant group. For example, if an item shows 30% in the 'patient representative' column, then 30% of people in that group rated the item as **important or very important** to include when sharing trial results.

In Round 1, nine items reached consensus (highlighted in green in Table 4.3). These nine items met the 80% threshold in **all three stakeholder groups** and were not rated again in Round 2.

Table 4.3: Ratings of Delphi items in Round 1

Item	Trial/ research professional (n=67) %	Patient representative (n=45) %	Member of the public (n=42) %
Item 1. Trial participants: Thank the participants for taking part in the trial	**94%**	**80%**	**90%**
Item 2. Trial team: Thank trial sites, trial teams, and other contributors for their role in the trial	**60%**	**69%**	**81%**
Item 3. Benefits/risks of receiving results: Potential benefits and risks for the trial participants of receiving the trial results	**75%**	**78%**	**79%**
Item 4. Objective: Objective(purpose) of the trial	**97%**	**98%**	**90%**
Item 5. Health condition: Description of the health condition being studied	**79%**	**87%**	**95%**
Item 6. Rationale: Rationale (the reason) behind choosing a randomised trial design	**61%**	**73%**	**71%**
Item 7. Title or trial name: Identification as a randomised trial	**66%**	**64%**	**62%**
Item 8. Trial duration: Trial start and completion dates	**45%**	**62%**	**64%**
Item 9. Trial journey: Any notable events or issues that happened during the trial (if applicable)	**79%**	**78%**	**76%**
Item 10. Eligibility criteria: Inclusion and exclusion criteria for the trial participants	**61%**	**69%**	**79%**
Item 11. Number of participants: Number of participants included in the trial	**66%**	**64%**	**69%**
Item 12a. Demographics: Age, sex, and/or gender of the trial participants	**55%**	**62%**	**67%**
Item 12b. Demographics: Diversity of the trial participants	**51%**	**69%**	**64%**
Item 13. Settings and location: Where the trial participants were recruited from	**51%**	**42%**	**43%**
Item 14. Intervention(s): Intervention(s) for each group and what they were compared with	**93%**	**93%**	**88%**
Item 15. Randomisation: How the participants were allocated to the intervention(s) in the trial	**54%**	**58%**	**60%**
Item 16. Blinding: whether the trial participants, care givers, or trial team knew which intervention(s) the participants received	**58%**	**64%**	**71%**
Item 17. Analysis: Statistical methods used to analyse the trial data	**18%**	**40%**	**45%**

Item 18. Patient and public involvement and engagement: Whether and how patients and/or the public helped in the design and delivery of the trial	**67%**	**78%**	**64%**
Item 19. Main findings: A summary of the primary outcome results	**99%**	**98%**	**95%**
Item 20. All findings: All other outcomes assessed in the trial	**67%**	**60%**	**64%**
Item 21. Significance of main results: Explanation of the statistical significance of the primary outcome results	**84%**	**84%**	**88%**
Item 22. Significance of all results: Explanation of the statistical significance of all outcome results	**52%**	**60%**	**69%**
Item 23. Side effects: Main adverse events experienced by the trial participants during the trial	**81%**	**91%**	**74%**
Item 24. Follow-up plan: Suggested follow-up plans (if applicable)	**78%**	**91%**	**90%**
Item 25. Interpretation: General interpretation of the trial results	**91%**	**93%**	**88%**
Item 26. Generalisability: How applicable are the trial results to the broader general population beyond the specific context of the trial	**94%**	**93%**	**83%**
Item 27. Clinical practice: How the intervention(s) may improve the health condition and the effectiveness of the intervention(s)	**91%**	**91%**	**86%**
Item 28. Healthcare policy: Whether and when the intervention(s) might be available after the trial	**76%**	**87%**	**90%**
Item 29. Economic implications: Cost-effectiveness of the intervention(s) tested	**55%**	**60%**	**62%**
Item 30. Comparison: How the trial results compare with current treatment options and existing research	**90%**	**80%**	**79%**
Item 31. Media coverage: Significance of the trial's impact on public interest and media attention	**33%**	**33%**	**31%**
Item 32. Strengths and limitations: Strengths and limitations of the trial results	**69%**	**73%**	**71%**
Item 33. Uncertainty: Any unanswered questions or emerging questions from the trial results	**72%**	**67%**	**62%**
Item 34. Next steps: Next steps for the trial	**72%**	**76%**	**74%**
Item 35. Future studies: Opportunities for involvement in future studies	**66%**	**69%**	**62%**
Item 36a. Direction of questions: How the trial participants can discuss the trial results with	**72%**	**69%**	**69%**

health care providers to make informed health choices			
Item 36b. Direction of questions: Advise the trial participants to consult healthcare providers before making any changes in their treatment plan based on the trial results	**90%**	**84%**	**83%**
Item 37. Accessibility: How the trial participants can get more information	**81%**	**73%**	**83%**
Item 38. Publication details: Where and when the trial report will be published	**63%**	**76%**	**57%**
Item 39. Drug approval status: Current approval status of the treatment or intervention(s) studied in the trial	**79%**	**76%**	**67%**
Item 40. Funding: Who funded the trial	**64%**	**56%**	**45%**
Item 41. Data protection policy: How the data of the trial participants will be protected	**69%**	**82%**	**81%**
Item 42. Ethics approval: Details about the ethical approval of the trial and the ethics committee	**57%**	**71%**	**74%**
Item 43. Frequently Asked Questions: A section providing answers to common questions patients and/or the public may have about the trial, its results, or the next steps	**73%**	**78%**	**67%**

New items

During the Delphi rounds, participants reviewed and provided feedback on items in each round, with the option to suggest additional items. Any newly suggested items were assessed and, if deemed appropriate, included in the subsequent Delphi round. In this process, three new items were added after Round 1:

1. Trial registry record
2. Post-trial contact information
3. Conflicts of interest (if applicable)

Round 2

In Round 2, participants were asked to vote again on the 36 items from Round 1 that did not reach consensus, plus the three new items suggested by Delphi participants. In Round 2, an item reached consensus or agreement if **at least two out of the three participant groups** had 80% or more people rating it as important or very important. Table 4.4 shows the results from Round 2 items and the percentage of people who rated the item as important or very important (scores of 4 or 5), shown separately for each participant group. Five items reached consensus in Round 2 and were not rated again in Round 3 (highlighted in green).

Table 4.4: Ratings of Delphi items in Round 2

Items	Trial/research professional (n=94) %	Patient representative (n=35) %	Member of the public (n=34) %
Item 2. Trial team: Thank trial sites, trial teams, and other contributors for their role in the trial	56%	49%	56%
Item 3. Benefits/risks of receiving results: Potential benefits and risks for the trial participants of receiving the trial results	62%	66%	76%
Item 5. Health condition: Description of the health condition being studied	89%	77%	97%
Item 6. Rationale: Rationale (the reason) behind choosing a randomised trial design	41%	66%	62%
Item 7. Title or Trial name: Identification as a randomised trial	51%	40%	56%
Item 8. Trial duration: Trial start and completion dates	43%	34%	53%
Item 9. Trial journey: Any notable events or issues that happened during the trial (if applicable)	68%	77%	68%
Item 10. Eligibility criteria: Inclusion and exclusion criteria for the trial participants	61%	71%	74%
Item 11. Number of participants: Number of participants included in the trial	73%	77%	65%
Item 12a. Demographics: Age, sex, and/or gender of the trial participants	62%	69%	65%
Item 12b. Demographics: Diversity of the trial participants	55%	66%	68%
Item 13. Settings and location: Where the trial participants were recruited from	39%	46%	29%

Item 15. Randomisation: How the participants were allocated to the intervention(s) in the trial	50%	60%	50%
Item 16. Blinding: whether the trial participants, care givers, or trial team knew which intervention(s) the participants received	53%	66%	62%
Item 17. Analysis: Statistical methods used to analyse the trial data	16%	46%	47%
Item 18. Patient and public Involvement and engagement: Whether and how patients and/or the public helped in the design and delivery of the trial	70%	74%	50%
Item 20. All findings: All other outcomes assessed in the trial	47%	63%	44%
Item 22. Significance of all results: Explanation of the statistical significance of all outcome results	52%	71%	71%
Item 23. Side effects: Main adverse events experienced by the trial participants during the trial	86%	97%	91%
Item 24. Follow-up plan: Suggested follow-up plans (if applicable)	73%	91%	88%
Item 28. Healthcare policy: Whether and when the intervention(s) might be available after the trial	83%	80%	82%
Item 29. Economic implications: Cost-effectiveness of the intervention(s) tested	47%	51%	76%
Item 30. Comparison: How the trial results compare with current treatment options and existing research	87%	91%	88%
Item 31. Media coverage: Significance of the trial's impact on public interest and media attention	17%	23%	32%
Item 32. Strengths and limitations: Strengths and limitations of the trial results	68%	71%	71%
Item 33. Uncertainty: Any unanswered questions or emerging questions from the trial results	57%	77%	56%
Item 34. Next steps: Next steps for the trial	68%	83%	71%
Item 35. Future studies: Opportunities for involvement in future studies	50%	60%	59%
Item 36a. Direction of questions: How the trial participants can discuss the trial results with health care providers to make informed health choices	56%	60%	71%
Item 37. Accessibility: How the trial participants can get more information	77%	66%	74%
Item 38. Publication details: Where and when the trial report will be published	39%	43%	41%
Item 39. Drug approval status: Current approval status of the treatment or intervention(s) studied in the trial	73%	80%	68%
Item 40. Funding: Who funded the trial	51%	54%	50%
Item 41. Data protection policy: How the data of the trial participants will be protected	68%	60%	76%
Item 42. Ethics approval: Details about the ethical approval of the trial and the ethics committee	49%	54%	56%
Item 43. Frequently Asked Questions: A section providing answers to common questions patients and/or the public may have about the trial, its results, or the next steps	62%	66%	79%

Item 44. Trial registry record: Details about the trial registration	44%	26%	41%
Item 45. Post-trial contact information: Contact information for the trial team after the trial has ended	63%	46%	59%
Item 46. Conflicts of interest: Disclosing any conflicts of interest related to the trial (If applicable)	53%	66%	71%

Round 3

In Round 3, participants ranked 11 items that were close to reaching consensus in Round 2 (defined as having received a rating of 4 or 5 from at least 60% of participants in all three stakeholder groups). However, none of the items reached consensus threshold in Round 3. These 11 items were carried forward to the consensus meeting (Chapter 5) for further discussion. These items and the percentage of people who rated the item as important or very important (scores of 4 or 5), shown separately for each participant group, are presented in Table 4.5.

In Round 3, participants were also invited to provide open-text comments on the remaining 23 items that did not reach moderate consensus. Substantive feedback was received supporting the inclusion of two of these items, and they were therefore carried forward to the consensus meeting discussion (Chapter 5). These two items are:

1. Item 12b. Demographics: Diversity of the trial participants
2. Item 18. Patient and public involvement and engagement: Whether and how patients and/or the public helped in the design and delivery of the trial

Table 4.5: Ratings of Delphi items in Round 3

Item	Trial/research professional (n=108) %	Patient representative (n=39) %	Member of the public (n=31) %
Item 3. Benefits/risks of receiving results: Potential benefits and risks for the trial participants of receiving the trial results	56%	72%	71%
Item 9. Trial journey: Any notable events or issues that happened during the trial (if applicable)	69%	72%	55%
Item 10. Eligibility criteria: Inclusion and exclusion criteria for the trial participants	52%	69%	65%
Item 11. Number of participants: Number of participants included in the trial	62%	64%	55%
Item 12a. Demographics: Age, sex, and/or gender of the trial participants	57%	54%	68%
Item 32. Strengths and limitations: Strengths and limitations of the trial results	74%	74%	74%
Item 34. Next steps: Next steps for the trial	71%	77%	68%
Item 37. Accessibility: How the trial participants can get more information	77%	77%	65%
Item 39. Drug approval status: Current approval status of the treatment or intervention(s) studied in the trial	61%	72%	65%
Item 41. Data protection policy: How the data of the trial participants will be protected	53%	46%	74%
Item 43. Frequently Asked Questions: A section providing answers to common questions patients and/or the public may have about the trial, its results, or the next steps	62%	72%	58%

4.3.5 Qualitative feedback across Delphi rounds

Across the three Delphi rounds, participants provided extensive free-text feedback alongside quantitative ratings (391 comments in Round 1, 257 in Round 2, and 96 in Round 3). The comments provided insights into the reasoning behind ratings, clarified areas of disagreement, and informed refinement of items between rounds and discussion at the consensus meeting. I developed the following themes after analysing the qualitative feedback.

Recognition, respect, and the purpose of thanking in result summaries

Across all rounds, participants consistently emphasised the importance of acknowledging contributions to trials as a matter of respect and trust. In Round 1, comments focused on how thanking trial participants reinforced feelings of being valued, improved experiences of taking part in research, and supported future willingness to participate.

In later rounds, feedback became more nuanced, with some participants distinguishing between the *importance of expressing appreciation* and whether this needed to be explicitly included within a constrained results summary. As one patient representative commented: *“I think that there are two questions embedded here: "How important is it to thank people?" (very important) and "How important is it to use up precious words of the lay summary to say that you have done so?" (not important at all). I fear that you are asking the second of these questions while respondents are answering the first!”*

Providing context without overload

Comments across rounds highlighted the importance of background information in helping participants interpret results in relation to the original purpose of the trial. Participants emphasised that explaining *why* a trial was designed in a particular way (e.g., randomisation) could help foster understanding and appreciation of research, provided this was done in accessible language.

At the same time, participants repeatedly cautioned against excessive technical detail. Many noted the difficulty of prioritising items within a limited word count and expressed concern that overly long summaries could undermine accessibility. Suggestions included combining

related methodological items, focusing on core principles (such as fairness and robustness), and avoiding detailed descriptions of technical processes. As one patient representative shared:

"Item 15 - we already know it is an RCT, so randomisation is implicit. Knowing exactly how the randomisation was achieved (spin a coin, next off the stack, whatever) is not important at all for the lay summary."

Participants also highlighted the importance of clearly presenting eligibility and demographic information in a way that was meaningful rather than exhaustive, with some noting that reporting on participant diversity could support transparency and accountability.

Interpreting results, uncertainty, and avoiding overstatement: realism

Across the Delphi rounds, many participants commented on the difficulty of presenting trial results in plain language, particularly when explaining statistical concepts to non-technical audiences.

Statistical significance was frequently described as poorly understood, with contributors instead emphasising the value of explaining results in concrete terms, such as how many people experienced benefits or harms. As a patient representative noted,

"Statistical significance means little to the public, but plain language summaries of how many people improved and how many didn't and how that is defined is valuable."

Participants also raised concerns about the potential for results to be overinterpreted or presented in a promotional way. There was strong agreement that findings should be

communicated proportionately, with clear acknowledgement of uncertainty and without creating unrealistic expectations. Several contributors, including trial professionals, highlighted the importance of distinguishing between clinical and statistical significance and of presenting adverse reactions with appropriate context to avoid unnecessary alarm. As one trial professional explained,

“Generally, we want to answer: why are these results important, what do they mean, and what happens next? It’s important to be open about adverse events, but also not to cause people to worry unnecessarily.”

Participants across stakeholder groups also cautioned against overstating impacts on clinical practice, policy, or economics when such outcomes were uncertain or dependent on future research and funding. One trial professional commented,

“The trial would be of little benefit if comparison with existing interventions was not given. Strengths and limitations should be spelt out because so many clinical trials are not well designed and the public should be aware of 'hype'.”

In later rounds, participants highlighted the importance of tailoring discussions of next steps to context and jurisdiction, noting that economic and policy implications varied across healthcare systems. As a patient representative noted,

“Item 28 (Healthcare policy) would have to be specific to the geographical context so how can you mandate this so that it will include everyone who reads the report? Same for Item 29 (economic implications) - health technology assessments vary from jurisdiction to jurisdiction even within same countries.”

Supporting dialogue with healthcare providers

Comments relating to sharing results with healthcare providers reflected tensions between patient empowerment and safety. Many participants felt that guidance was needed to support discussions with clinicians, particularly when results might prompt questions about treatment changes. However, participants also expressed concern about placing undue responsibility on patients, given variable access to healthcare providers and the potential for clinicians to be unfamiliar with emerging evidence.

Participants suggested that guidance should be framed sensitively, avoid prescriptive language, and take account of practical constraints, including delays in care and differences in professional roles. These discussions informed refinement of items relating to post-trial communication and safety. As one patient representative shared,

"As a patient, we have to advocate for ourselves when we're often least able to and going to the doctor or other health professional can be so stressful even if they are kind and compassionate. Some doctors/health professionals get angry or frustrated when patients bring them research… Also, I know it makes sense and is a bit of a cya to say consult with your healthcare provider before making any changes, but in reality, that is not always possible. It could be weeks or months before you can get into a provider, and some changes that make sense based on current research may not have trickled down to the provider yet, so they may be resistant to change. There is a balance here between patient safety and paternalism."

Suggestions for modification and new items

In addition to commenting on existing items, participants suggested a range of modifications and potential new items. These suggestions included recommendations to minimise information overload, adopt layered approaches to result sharing, distinguish more clearly between summaries intended for trial participants and those aimed at the general public, and clarify expectations around post-trial contact.

These qualitative insights were considered alongside quantitative ratings and were used to inform item refinement between rounds, structured discussion at the consensus meeting (Chapter 5), and development of the E&E document (Chapter 7).

4.3.6 Summary of Delphi outcomes and items progressing to consensus

Based on the quantitative ratings and qualitative feedback across the three Delphi rounds, a subset of items was identified to be taken forward to the expert consensus meeting (Chapter 5) for final discussion and classification. These included the 14 items that had reached consensus in Rounds 1 and 2, and 13 items that had not reached consensus but had generated substantial discussion or divergent views. These 13 items were selected from:

- 11 items that had moderate agreement across the three participant groups and were close to reaching consensus (the items rated in Round 3)
- 2 items that raised substantial comments

Table 4.6 summarises the items progressing to the consensus meeting.

Table 4.6: Final Delphi items for discussion in the consensus meeting, broken down by themes

Theme	Item
Consensus items	
Thank you	1. Trial participants: Thank the participants for taking part in the trial
Background	2. Objective: Objective(purpose) of the trial
	3. Health condition: Description of the health condition being studied
Methods	4. Intervention(s): Intervention(s) for each group and what they were compared with
Results	5. Main findings: A summary of the primary outcome results
	6. Significance of main results: Explanation of the statistical significance of the primary outcome results
	7. Side effects: Main adverse events experienced by the trial participants during the trial
	8. Follow-up plan: Suggested follow-up plans (if applicable)
Conclusion	9. Interpretation: General interpretation of the trial results
	10. Generalisability: How applicable are the trial results to the broader general population beyond the specific context of the trial
	11. Clinical practice: How the intervention(s) may improve the health condition and the effectiveness of the intervention(s)
	12. Healthcare policy: Whether and when the intervention(s) might be available after the trial
	13. Comparison: How the trial results compare with current treatment options and existing research
Discussing the trial results with healthcare providers	14. Direction of questions: Advise the trial participants to consult healthcare providers before making any changes in their treatment plan based on the trial results
No consensus items	
Background	1. Benefits/risks of receiving results: Potential benefits and risks for the trial participants of receiving the trial results
Methods	2. Trial journey: Any notable events or issues that happened during the trial (if applicable)
	3. Eligibility criteria: Inclusion and exclusion criteria for the trial participants
	4. Number of participants: Number of participants included in the trial
	5. Demographics: Age, sex, and/or gender of the trial participants
	6. Demographics: Diversity of the trial participants (e.g., ethnicity, religion, language, income, location, health conditions) **(Substantial comments from Delphi)**
	7. Patient and public involvement and engagement: Whether and how patients and/or the public helped in the design and delivery of the trial **(Substantial comments from Delphi)**
Conclusion	8. Strengths and limitations: Strengths and limitations of the trial results
	9. Next steps: Next steps for the trial (e.g., licensing of the medication, publication)
Additional information	10. Accessibility: How the trial participants can get more information
	11. Drug approval status: Current approval status of the treatment or intervention(s) studied in the trial

12. Data protection policy: How the data of the trial participants will be protected
13. Frequently Asked Questions: A section providing answers to common questions patients and/or the public may have about the trial, its results, or the next steps

4.4 Discussion

Delphi surveys are a valuable tool for reaching agreement among a group of experts. I conducted three rounds of Delphi survey by engaging stakeholders who made judgements on the content of the reporting guideline checklist. Due to the nature of a Delphi, which is both quantitative and qualitative, conducting the survey allowed me to delve deeper into the complex insights of representative stakeholders while still reaching group consensus. [201] The flexible nature of the Delphi allowed me to interact simultaneously with stakeholders who are experienced and trained in this field and with patient and public representatives who the guideline ultimately aims to serve. [200]

A high-quality Delphi study should include diverse perspectives and experiences. [202] When designing the survey, I emphasised engaging a diverse panel of experts, including patients, and public representatives, trial professionals, researchers, clinicians, guideline developers, and policymakers to ensure the guideline reflects a wide range of perspectives rooted in real-world opinions. Based on the findings from the scoping review and interview study, I aimed to work on the gaps present in existing guidance documents. By advertising in diverse international networks, professional groups, and PPI networks, I sought to achieve diversity in terms of subject expertise, geography, ethnicity, language, lived experience, and age

ranges. Participants covered a wide range of roles from academic, charity, and industry sectors with many cumulative years of experience in trials.

As described in the results section, the Delphi achieved broad international representation, with participants from 16 countries, although stakeholders from South America and Africa were underrepresented. Approximately 29% participants reported a non-white ethnicity, and 22% participants reported a native language other than English, which helped improve the diversity in opinions and ratings.

Reflecting on the development of the Delphi survey, PPI input shaped not only the wording of individual items but also how I approached the survey as a whole. Reviewing their feedback made me realise how easily technical language that feels routine to trialists can create barriers to engagement for patients and members of the public. Acting on this feedback led me to favour clarity and familiarity over technical precision where appropriate. This process reinforced the importance of designing a reporting guideline that is accessible from the outset, rather than attempting to 'translate' technical concepts at a later stage.

Another strength of the Delphi was the scope of the stakeholder's input. Recent guidance on Delphi studies highlights the importance of reporting panel composition and handling stakeholder differences transparently. [203] A recent systematic review of 100 Delphi studies that included "lifeworld experts" (i.e., patients and members of the public) found that their perspectives were rarely analysed separately from professional experts. [204] In only 26% of studies were results presented by stakeholder group, and in just 14% was feedback provided by group during the Delphi process. The review noted that differences in judgement

between expert groups were seldom explored or reflected upon, despite evidence that patients and professionals often prioritise different issues.

My decision to analyse groups separately was therefore intended to give equal weight to PPI and professional perspectives and to make explicit where agreement or disagreement varied between stakeholder groups. I separated out not only professionals from PPI, but also patients from public representatives, as PPI voices can overshadow public voices. During the interview and focus group stage (Chapter 3), I noticed patient representatives often have experience in research and are familiar with technical terms. What they find valuable may differ from what a member of the public may find valuable. Doing separate analysis for the three groups provided confidence to each group that their voices were not being drowned. This may have also helped to reduce attrition, which is an important issue in Delphi surveys that may lead to overestimation of the level of consensus reached. [205]

The open-text comments from the Delphi survey were helpful in several ways. Taken together, the qualitative feedback across the Delphi rounds highlighted areas of strong agreement, as well as tensions between clarity, feasibility, and the risk of information overload. Reflecting on this process, I became increasingly aware of the need to balance what participants and the public felt was important to know with what trial teams felt able to communicate clearly within practical constraints.

Preparing summaries of these comments for subsequent rounds and for the consensus meeting (Chapter 5) required judgement about how to represent diverse perspectives without privileging any single group. This stage reinforced the value of combining

quantitative ratings with qualitative insight, as it was often the free-text feedback, particularly from PPI representatives, that provided the context needed to interpret scores and guide meaningful discussion during the consensus meeting. The comments provided similar value to the results from the interview study, adding overall strength and alignment with what people find valuable. The qualitative feedback also informed the content and structure of the E&E document (Chapter 7), ensuring that explanations and examples reflected issues raised by participants.

I also used flexible criteria for reaching consensus to avoid loss of potentially critical items. For Round 3 of the Delphi survey and the consensus meeting (Chapter 5), I chose items reaching ≥60% agreement across *all* stakeholder groups as it indicated a baseline level of shared importance without meeting the stricter ≥80% consensus threshold. This criterion ensured that items with reasonable cross-group support were retained for further consideration rather than prematurely discarded, which aligned with the iterative nature of Delphi methodology.

The Delphi findings highlighted some important differences between stakeholder priorities and what is commonly recommended in the existing literature. Several guidance documents identified in the scoping review (Chapter 2) suggested including items such as demographics and participant characteristics, discussion of next steps, and PPIE. However, these items did not consistently reach consensus in the Delphi survey. Rather than excluding them outright, they were taken forward to the consensus meeting (Chapter 5) for further discussion, recognising their prominence in existing guidance and their potential value for transparency.

It is possible that existing guidance reflects the views of a relatively small group of authors or expert committees, rather than being grounded in broad multistakeholder consultation.

Interestingly, items relating to interpretation, clinical implications, generalisability, and comparison with existing research were rated highly across stakeholder groups, despite being less consistently emphasised in the existing guidance documents. This suggests that participants placed more importance on helping readers understand what the results mean in practice and how they fit within the broader evidence base. Taken together, these findings support the need for a reporting checklist that is shaped not only by existing written guidance, but also by the perspectives of those who design, conduct, and receive trial results.

The Delphi method, while useful for bringing together diverse perspectives, has a few limitations. Participants are purposively selected rather than randomly sampled, meaning the findings may not represent all possible views. [206] The results also depend on the expertise of panel members and their willingness to engage thoughtfully with the process. [202, 207] For feasibility reasons, participants in Rounds 2 and 3 were shown summary ratings but not qualitative comments from earlier rounds, which may have limited the added value of subsequent rounds by restricting insight into the reasoning behind others' ratings.

These limitations were considered when interpreting the findings, and items that remained uncertain or contested were taken forward to the consensus meeting described in Chapter 5 for further discussion and clarification.

Chapter 5: Consensus development meeting and provisional checklist development

5.1 Introduction

In Chapter 4, I described the Delphi survey, which was conducted to achieve consensus on the key items to include when sharing the results of randomised trials with patients and the public. The agreed items formed the foundation of the reporting guideline checklist, which was refined during an online consensus development meeting, convened on 20th October 2025.

A consensus development meeting is a structured discussion where key stakeholders, such as experts, researchers, practitioners, and patient representatives, come together to review Delphi survey findings and finalise consensus on a set of items. [66] This meeting is typically conducted after the final Delphi round to resolve any remaining disagreements, refine ambiguous items, and ensure that the final outputs are meaningful, clear, and practical for implementation. [66]

While the Delphi process described in Chapter 4 helped achieve convergence of opinions, some items still had borderline agreement or required further clarification. A consensus meeting allowed for in-depth discussion to address these uncertainties and agree on the content of the resulting checklist. Bringing together diverse perspectives (e.g., researchers, trial professionals, patient representatives, and members of the public) ensured that the final recommendations are comprehensive, inclusive, and acceptable to all relevant groups.

5.1.1 Objectives

Primary objective:

1. To convene a consensus meeting to agree the content of the reporting guideline checklist.

Secondary objectives

1. To involve a diverse range of stakeholders, including researchers, clinicians, patients and the public, guideline developers, and policymakers.
2. To document participant feedback and how it informed the development of the checklist transparently.
3. To synthesise the consensus meeting findings into a draft checklist for pilot testing.

5.2 Methods

5.2.1 Overview

The Delphi survey results (Chapter 4) were presented and discussed at a half-day online expert consensus meeting conducted via Microsoft Teams, on 20th October 2025, attended by 23 international participants representing the different stakeholder groups included in the Delphi. During the meeting, each checklist item was discussed and agreement sought. I used an anonymous poll via Microsoft Teams to help establish the level of support for items where the discussion indicated differing opinions; these polls were advisory and no formal consensus threshold was specified. Voting related to agreement of concepts, not necessarily specific wording of individual items. The meeting was audio recorded and transcribed verbatim.

5.2.2 Consensus meeting participants

Moher et al. recommended to keep the size of the meeting to a maximum of 30 participants as larger participation may disrupt the spontaneous flow of discussion and interaction among participants. [66] They also suggested that participants be chosen from a range of expertise that reflects the particular guidance under consideration. [66] I developed a list of potential participants that deliberately reflected a wide range of stakeholder perspectives, including trial professionals (chief investigators and trial managers), reporting guideline specialists, PPI experts, members of the public, methodologists and epidemiologists, medical writers, journal editors, statisticians, and systematic reviewers.

Similarly to the Delphi, I sought to include participants from diverse geographical regions, including Europe, Asia, North America, and Africa, to capture variation in trial conduct, reporting practices, and research cultures internationally. This was a deliberate methodological choice, informed by findings from the scoping review, which showed that existing guidance documents rarely account for geographic diversity or variation in practice and often lack meaningful engagement with PPI groups. Addressing both of these gaps was a key aim of the guideline development process, to ensure that the resulting checklist would be relevant and usable across diverse global settings.

My supervisors reviewed the draft list of potential participants and supported its refinement, particularly by suggesting additional contacts where I had difficulty identifying suitable individuals. I contacted international trial networks, PPI groups, and journal editors to identify and invite appropriate participants for the consensus meeting. I also invited selected

PPI representatives and members of the public who had participated in the Delphi survey, had provided particularly insightful feedback, and had expressed interest in further involvement.

I am a strong advocate for recognising and reimbursing PPI contributions. However, despite exploring multiple avenues, I was unable to secure funding to support PPI involvement in the Delphi survey or interview study. For the consensus meeting, I made a further proactive effort to obtain funding specifically to support PPI participation. I contacted several charitable organisations, including the British Heart Foundation, [208] Kidney Research UK, [209] Age UK, [210] and Open Arms; [113] however, none of them were able to provide any support in PPI reimbursement. I also applied for the Oxford University Public and Community Engagement with Research strategy (PCER) funding, although this application was unsuccessful. Ultimately, I was successful in securing funding through the NIHR School for Primary Care Research (SPCR) PPI scheme within the Nuffield Department of Primary Care Health Sciences (NDPCHS). After reviewing the application, the allocated funding was increased from £250 to £500, which felt like positive recognition of the project's value. I used this funding to recognise and reimburse the contributions of PPI members who participated in the consensus meeting.

Throughout my thesis, I prioritised balanced representation between professionals and PPI representatives. The final list of invitees comprised ten professionals, six PPI experts, and three members of the public. All but one of those invited (a trial professional) were able to attend, resulting in 23 participants in the meeting, including my supervisors and myself

(Appendix 5.1). Participants were from six countries (the UK, USA, Denmark, Nigeria, Australia and France), representing diverse practices and expertise.

I prepared pre-reading materials and sent them to participants two weeks before the consensus meeting (Appendix 5.2). The pre-reading material contained a summary of the project rationale, the aim and structure of the consensus meeting, and a list of the Delphi items that would be discussed in the meeting. I also held three preparation sessions with participants who were PPI representatives and members of the public to explain the meeting scope, structure, and decision process ahead of the meeting.

5.2.3 Meeting agenda

I began the meeting by providing an overview of the thesis and summarising the findings from the scoping review, qualitative interviews, focus groups, and Delphi survey. I explained the purpose of the consensus meeting and the process for reaching consensus. The main meeting focus was to finalise and agree on the content of the reporting guideline checklist. Findings from the qualitative study and Delphi survey indicated that some reporting items were considered essential, whereas others were viewed as context-dependent. The meeting therefore focused on finalising the reporting guideline by distinguishing between:

- **Minimum essential reporting items** that should always be included when sharing results of randomised trials with patients and the public.
- **Additional reporting items** that may be included where appropriate, depending on the context or audience.

The meeting lasted four hours, with three ten-minute breaks scheduled throughout. It was recorded, and I obtained consent from participants in advance. I later used the recording to review the discussions and clarify any points when summarising the meeting.

The meeting was organised into sessions, which were facilitated by my supervisors and me. For each item discussed at the meeting, a summary of the Delphi ratings along with key comments from Delphi participants was presented. We then opened the floor for discussion and invited everyone to share their views. Participants also used the chat function to share their opinions. I extracted the chat information and added them to the meeting notes.

We discussed:

1. 14 items that reached consensus in the Delphi (Table 5.1)
2. Items that did not reach consensus in the Delphi:

34 items did not reach consensus (agreement) in the Delphi. Since our time was limited, **we focused on discussing 13 high-priority items**. (Table 5.2) These 13 items were selected from:

- 11 items that had moderate agreement across the three participant groups, were close to reaching consensus, and were rated in Round 3;
- 2 items that raised numerous comments across Delphi rounds

Table 5.1: Items that reached consensus in the Delphi, broken down by themes

Theme	Item	Consensus reached in	Trial/ research professional (R1, n=67; R2, n=94) %	Patient representative (R1, n=45; R2, n=35) %	Member of the public (R1, n=42; R2, n=34) %
Thank you	Trial participants: Thank the participants for taking part in the trial	Round 1	94%	80%	90%
Background	Objective: Objective(purpose) of the trial	Round 1	97%	98%	90%
	Health condition: Description of the health condition being studied	Round 2	89%	77%	97%
Methods	Intervention(s): Intervention(s) for each group and what they were compared with	Round 1	93%	93%	88%
Results	Main findings: A summary of the primary outcome results	Round 1	99%	98%	95%
	Significance of main results: Explanation of the statistical significance of the primary outcome results	Round 1	84%	84%	88%
	Side effects: Main adverse events experienced by the trial participants during the trial	Round 2	86%	97%	91%
	Follow-up plan: Suggested follow-up plans (if applicable)	Round 2	73%	91%	88%
Conclusion	Interpretation: General interpretation of the trial results	Round 1	91%	93%	88%
	Generalisability: How applicable are the trial results to the broader general population beyond	Round 1	94%	93%	83%

	the specific context of the trial				
	Clinical practice: How the intervention(s) may improve the health condition and the effectiveness of the intervention(s)	Round 1	91%	91%	86%
	Healthcare policy: Whether and when the intervention(s) might be available after the trial	Round 2	83%	80%	82%
	Comparison: How the trial results compare with current treatment options and existing research	Round 2	87%	91%	88%
Discussing the trial results with healthcare providers	Direction of questions: Advise the trial participants to consult healthcare providers before making any changes in their treatment plan based on the trial results	Round 1	90%	84%	83%

Table 5.2: Items that did not reach consensus in the Delphi and discussed at the consensus meeting

Theme	Item	Round 2 ratings		
		Trial/research professional (n=94) %	Patient representative (n=35) %	Member of the public (n=34) %
Background	1. Benefits/risks of receiving results: Potential benefits and risks for the trial participants of receiving the trial results	62%	66%	76%
Methods	2. Trial journey: Any notable events or issues that happened during the trial (if applicable)	68%	77%	68%
	3. Eligibility criteria: Inclusion and exclusion criteria for the trial participants	61%	71%	74%
	4. Number of participants: Number of participants included in the trial	73%	77%	65%
	5. Demographics: Age, sex, and/or gender of the trial participants	62%	69%	65%
	6. Demographics: Diversity of the trial participants (e.g., ethnicity, religion, language, income, location, health conditions)	55%	66%	68%
	7. Patient and public Involvement and engagement: Whether and how patients and/or the public helped in the design and delivery of the trial	70%	74%	50%
Conclusion	8. Strengths and limitations: Strengths and limitations of the trial results	68%	71%	71%
	9. Next steps: Next steps for the trial (e.g., licensing of the medication, publication)	68%	83%	71%
Additional information	10. Accessibility: How the trial participants can get more information	77%	66%	74%
	11. Drug approval status: Current approval status of the treatment or intervention(s) studied in the trial	73%	80%	68%

12. Data protection policy: How the data of the trial participants will be protected	68%	60%	76%
13. Frequently Asked Questions: A section providing answers to common questions patients and/or the public may have about the trial, its results, or the next steps	62%	66%	79%

5.2.4 Checklist writing and revision

Following the consensus meeting and the decisions described in the Results section 5.3.1, I summarised the meeting discussion and poll results. I then held a dedicated in-person writing meeting with my supervisors on 27th October 2025 to refine the format and wording of each checklist item. I drafted v0.1 of the checklist based on the Delphi results, consensus meeting discussions, and writing group meeting discussions. I circulated this draft version to consensus meeting participants on 5th November 2025 to confirm whether it accurately reflected the group's consensus or required further clarification.

Participants of the consensus meeting reviewed and provided feedback on the content, phrasing, and structure of the checklist items. Revision was open for two weeks. I summarised their feedback, revised the items accordingly, and held further follow-up meetings with my supervisors. The resulting checklist was then taken forward for pilot testing (Chapter 6).

5.3 Results

5.3.1 Summary of consensus meeting decisions

During the consensus meeting, we discussed each checklist item in detail, with particular attention given to items that had generated substantial comments or mixed views during the Delphi survey. Overall, participants were broadly supportive of items that had reached consensus in the Delphi, but discussions frequently focused on issues of practicality and feasibility of reporting items in real-world settings. Where discussion was not conclusive, items were decided through a live poll.

For each item discussed, participants considered whether it should be removed, merged with another item, or retained and classified as an **essential item** (to be reported in all cases) or an **additional item** (to be reported where relevant). A summary of decisions and poll results for each item is provided in Table 5.3.

Table 5.3: Summary of consensus meeting decisions

Item	Delphi results	Consensus meeting	Decision	Rationale for the decision
Trial participants: Thank the participants for taking part in the trial	Consensus	Context-dependent; concerns about word limits in journals. Suitable for letters to participants **Poll results:** Mandatory: 62% Additional: 28% Do not include: 10%	Include as an 'Additional item'	Acknowledgement was strongly supported on ethical grounds, but is not always feasible or appropriate in all formats (e.g., journals). Retained as an additional item, with guidance that it is essential for participant-directed communications and recommended elsewhere where space allows.
Benefits/risks of receiving results: Potential benefits and risks for the trial participants of receiving the trial results	No consensus	**Poll results:** Additional: 15% Do not include: 85%	Do not include	Outside the scope of reporting trial results. Providing participants with a choice to receive results addresses ethical considerations without needing a separate checklist item.
Objective: Objective (purpose of the trial)	Consensus	Provide guidance in E&E on how much detail is needed for reporting	Include as an 'Essential item'	Understanding the purpose of the trial was consistently viewed as critical for interpreting results.
Health condition: Description of the health condition being studied	Consensus	Provide guidance in E&E on how much detail is needed for reporting	Include as an 'Essential item'	Essential for interpreting relevance of results and avoiding misinterpretation, particularly for public and participant audiences.
Trial journey: Any notable events or issues that happened during the trial (if applicable) (e.g., if the trial was	No consensus	**Poll results:** Additional: 52% Do not include 48%	Do not include	Outside the scope of reporting trial results. Such information may be reported on an ad hoc basis in publications or summaries but does not

stopped early for any reason or if there was a breakthrough finding)				warrant inclusion in the core reporting checklist.
Eligibility criteria: Inclusion and exclusion criteria for the trial participants	No consensus	Merge with demographics; request summary level data only **<u>Poll results:</u>** Mandatory: 15% Merge with demographics: 79% Additional: 5%	Include as an 'Essential item'	Participants felt omission could limit understanding of who the results apply to. Retained as a separate essential item to preserve clarity.
Number of participants: Number of participants in the trial	No consensus	Suggested to merge with other items	Include as an 'Essential item'	Viewed as fundamental for transparency and interpretation of results. Retained as a distinct essential item.
Demographics: Age, sex and/or gender of the trial participants	No consensus	Important, suggested to merge, add ethnicity	Include as an 'Essential item'	Core demographic information was considered necessary to support understanding of applicability.
Demographics: Diversity of the trial participants (e.g., ethnicity, religion, language, income, education, geographic location, disability, or other health conditions)	No consensus	**<u>Poll results:</u>** Mandatory: 33% Additional: 50%	Do not include apart from 'ethnicity'	Comprehensive diversity data are not always collected. CONSORT also does not require reporting beyond key demographics. Ethnicity has been included in the essential Demographics item, while other diversity factors are mentioned in the E&E as illustrative examples of good practice.
Intervention(s): Intervention(s) for each group and	Consensus	Important to give context	Include as an 'Essential item'	Necessary to understand what was tested and how results should be interpreted.

what they were compared with				
Patient and public involvement and engagement: Whether and how patients and/or the public helped in the design and delivery of the trial	No consensus	Mixed views; concern about perceived research value **<u>Poll results:</u>** Mandatory: 33% Additional: 16% Do not include: 50%	Include as an Additional item	Strongly valued, but not always applicable in all summaries. Retained as additional, with explanatory guidance in the E&E.
Main findings: A summary of the primary outcome results	Consensus	Strong support; add explanation of why not all outcomes in E&E	Include as an 'Essential item'	Central to communicating trial results. Guidance added to E&E to clarify why not all outcomes need to be reported.
Significance of main results: Explanation of the statistical significance of the primary outcome results	Consensus	Replace with clinical significance	Replace with clinical significance	Statistical terminology was seen as potentially misleading. Emphasis on clinical relevance better supports interpretation for patient and public audiences.
Side effects: Main adverse events experienced by the trial participants during the trial	Consensus	Clarify scope and terminology; Include a glossary in E&E	Include as an 'Essential item'	Considered critical for informed interpretation. Wording clarified to include any important adverse (or unexpected) events experienced by trial participants, with definitions supported in the E&E.
Follow-up plan: Suggested follow-up plans (if applicable)	Consensus	Clarify applicability situations in the E&E **<u>Poll results:</u>** Mandatory: 10% Additional: 90%	Include as an 'Additional item'	Important for participants but not always applicable.
Interpretation: General interpretation of	Consensus	Merge with clinical implications	Merged with Clinical	Interpretation and clinical implications were considered

the trial results, (e.g., what do the results mean)			implications (Essential)	inseparable for public understanding.
Generalisability: How applicable are the trial results to the broader general population beyond the specific context of the trial	Consensus	Merge with strengths and limitation	Merged with Strengths and limitations (Essential)	Generalisability and strengths/limitations both relate to interpreting trial results in context. CONSORT (Items 29–30) treats limitations and applicability together, and merging them reduces redundancy while encouraging a balanced, clear discussion of both reliability and relevance.
Clinical practice: How the intervention(s) may improve the health condition and the effectiveness of the intervention(s)	Consensus	Reword to clinical implications and merge with interpretation	Merged into Clinical implications (Essential)	Clinical practice is not the appropriate term, as clinical practice is not based on a single trial. Clinical significance is more relevant in terms of results interpretation
Healthcare policy: Whether and when the intervention(s) might be available after the trial	Consensus	Can be speculative; takes years **<u>Poll results:</u>** Mandatory: 5% Additional: 80% Do not include: 15%	Merged with Next steps (Additional)	Policy impacts are rarely immediate or within researchers' control. Retained as part of broader discussion of next steps.
Comparison: How the trial results compare with current treatment options and existing research	Consensus	Keep the item but define scope Comparison with existing research is easy, but comparison with all existing treatment options is challenging	Include as an Additional item (reworded)	Reworded to focus on how findings relate to existing research, without requiring formal assessment of overall evidence impact.

Strengths and limitations: Strengths and limitations of the trial results	No consensus	Merge with generalisability	Merged with Generalisability (Essential)	Absence of limitations was seen as risking over-interpretation. Merged item supports transparent and proportionate reporting.
Next steps: Next steps for the trial	No consensus	**Poll results:** Mandatory: 10% Additional: 75% Do not include: 15%	Include as an Additional item	Valuable for understanding how findings fit into ongoing research, but not always applicable.
Direction of questions: Advise the trial participants to consult healthcare providers before making any changes in their treatment plan based on the trial results	Consensus	More suitable for direct reporting to participants. Not for journals. Explanatory text could be useful for shared decision making	Include as an Additional item (renamed Advisory statement)	Important for participant safety in some contexts, but not universally appropriate. Retained with flexible guidance.
Accessibility: How the trial participants can get more information	No consensus	**Poll results:** Mandatory: 22% Additional: 61% Do not include: 17%	Include as an 'Additional item' (renamed Further information)	This item can help interested participants get more information, include where word limit permits.
Drug approval status: Current approval status of the treatment or intervention(s) studied in the trial (e.g., whether it is approved or waiting for regulatory review)	No consensus	**Poll results:** Additional item: 12% Do not include: 88%	Do not include	Outside the scope of reporting trial results. Best addressed in informed consent and regulatory documents.
Data protection policy: How the data of the trial participants will be protected	No consensus	**Poll results:** Do not include: 100%	Do not include	Outside the scope of reporting trial results. Best addressed in informed consent and

				data management documentation.
Frequently Asked Questions: A section providing answers to common questions patients and/or the public may have about the trial, its results, or the next steps	No consensus	**<u>Poll results:</u>** Additional item: 5% Do not include: 95%	Do not include	This is a communication tool rather than a reporting requirement. The content is better addressed within the summary itself rather than as a separate checklist item.

Among the fourteen items that reached consensus in the Delphi survey, seven were agreed to be essential items. Three items were retained as additional items: '*Thank trial participants for taking part in the trial'*, '*Follow-up plan'*, 'and *'Direction of questions: Advise the trial participants to consult healthcare providers before making any changes in their treatment plan based on the trial results'.* The third item was renamed *'Advisory statement'* for clarity. These items were recognised as important but not always feasible or relevant in every context.

Some items were modified following discussion. The item '*Explanation of statistical significance*' was replaced with '*Clinical implications*', reflecting concerns that statistical terminology alone may be misleading or unhelpful for patient and public audiences. The item '*Clinical practice'* was renamed '*Clinical implications*' and merged with '*Interpretation of results*', with a focus on explaining whether observed differences were meaningful in real-world terms. As one participant noted:

"I was just wondering about framing it in terms of clinical relevance or importance…because sometimes you know there's statistical difference, but the difference actually is not very

meaningful in the sort of real-world impact on a patient, whether there's some way to think about framing it in those sorts of terms."

There was considerable discussion on the item '*Healthcare policy*'. Participants expressed concerns that findings from a single trial are unlikely to directly influence healthcare policy. As a result, this item was merged with '*Next steps*' and retained as an additional item.

The item '*Comparison'* was renamed '*Existing research'* and retained as an additional item, allowing trial results to be contextualised without requiring authors to assess their formal impact on the wider evidence base.

The item '*Strengths and limitations'* was merged with '*Generalisability'*. Participants agreed that without some discussion of limitations, results could easily be misinterpreted or overstated, and therefore this merged item was classified as essential.

Of the thirteen '*no consensus'* items discussed at the meeting, three items were initially agreed to be merged and kept as essential items: '*Eligibility criteria'*, '*Number of participants'*, and '*Demographics (age, sex, and/or gender)'*. Participants felt that omission of these elements could limit transparency and understanding of who the results applied to. However, after several discussion with my supervisors, we decided that these three items were not to be merged, rather to be kept as stand-alone essential items as each captures distinct information and serves a different purpose. Combining them into a single item could increase the risk that one or more elements would be overlooked or not reported.

The items '*Patient and public involvement and engagement'*, and '*Accessibility (how participants can obtain further information)'* were retained as additional but not essential items. These were seen as valuable, particularly from a PPI perspective, but not always applicable in all dissemination contexts. The item '*Accessibility'* was reworded to '*Further information'* to better reflect its intent.

Five items were removed entirely following discussion: '*Benefits/risks of receiving results*', '*Trial journey*', '*Drug approval status*', '*Data protection policy*', and '*Frequently Asked Questions*'.

Based on the combined findings from the Delphi survey and the consensus meeting, I consolidated the work into a draft reporting guideline checklist comprising **ten essential items** (to be reported in all cases) and **seven additional items** (to be reported where relevant and space requirements allow), supported by an accompanying Explanation and Elaboration document (Chapter 7) to guide proportionate and context-appropriate reporting.

5.3.2 Checklist revision

The draft checklist was circulated to consensus meeting participants for further review, and 64 comments were received. Feedback focused primarily on clarification of scope, alignment with existing reporting standards, and improving consistency and usability across different dissemination contexts (e.g., results directed at participants, journal publication, or regulatory reports).

Several comments related to the item '*Side effects*', particularly around its scope and terminology. Participants discussed whether the item should focus solely on harms or more broadly include unintended or unexpected effects associated with the intervention. One participant noted that the relevant information would vary across studies and therefore supported a broad definition that could capture both known and unexpected effects. Others suggested aligning terminology with the CONSORT 2025 statement. [62] At this stage, the item remained as *'Side effects'*, but the discussion highlighted the need to consider appropriate terminology when refining the checklist during pilot testing.

For the item '*Thank you*', participants revisited whether this should be considered essential. Suggestions included retaining the item as essential for participant-directed communications with a very brief acknowledgement or keeping it as an additional item with clear guidance that it is strongly recommended where space allows.

Feedback on items '*Follow-up plan*' and '*Next steps*' highlighted the need to clarify the distinction between these items. Participants suggested reframing the follow-up item to focus specifically on follow-up with trial participants, while noting that broader next steps, such as policy or practice implications, may be beyond the control of individual trial teams.

For the item '*Comparison with existing research*', participants cautioned against wording that implied formal assessment of a trial's impact on the entire evidence base. It was agreed that the item should instead support a simple explanation of how the findings relate to what was already known.

Finally, comments on the items '*Advisory statement*' and '*Further information*' focused on broadening their applicability beyond trial participants alone. Revised wording was suggested to refer more generally to readers, including guidance on consulting healthcare providers and on where further information about the trial or related resources could be found.

These comments were reviewed and incorporated into revisions to item wording and accompanying guidance, helping to refine the checklist before finalisation.

5.3.3 Draft reporting guideline checklist v0.1

The following section presents the resulting checklist and describes how essential and additional items were organised to support clear and meaningful sharing of trial results with patients and the public. In the next chapter (Chapter 6), I describe how the draft checklist was pilot-tested and further refined to produce the final version.

Essential items

The ten essential items represent the minimum reporting requirements and should be included in all summaries of trial results, regardless of audience or format, to support transparency, completeness, and clear communication of the results. (Table 5.4) The items are not prioritised or ranked; they are presented in a logical sequence to guide reporting.

Table 5.4: Draft checklist: Essential items

Theme/item	No	Checklist item description	Reported (Y/N)
Background			
Objective	1	Main objective of the trial	_____
Health condition or area of focus	2	Description of the health condition or broader area addressed by the trial	_____
Methods			
Interventions	3	Interventions for each group and what they were compared with	_____
Summary of eligibility criteria	4	Key inclusion and exclusion criteria for participation in the trial	_____
Results			
Number of participants	5	Number of participants included in the trial	_____
Demographics	6	Key participant demographics (e.g., age, ethnicity, sex, and/or gender)	_____
Main findings	7	Summary of the primary outcome results of the trial	_____
Side effects	8	Any important adverse (or unexpected) events experienced by trial participants	_____
Conclusion			
Interpretation	9	Interpretation of the trial results, noting potential clinical implications	_____
Strengths and limitations	10	Strengths and limitations of the trial, including factors that may influence the interpretation or generalisability of the results	_____

Additional items (where applicable)

The seven additional items should be included where relevant and feasible, considering the needs of the intended audience and any constraints such as word limits (Table 5.5). While these items are strongly recommended for participant-facing materials, they add valuable context to other public summaries, such as journal plain language summaries, website content, or reports for regulatory organisations where word limits and format allow.

Some items apply only in certain situations (for example, when long-term follow-up is planned), so authors should consider including each item wherever it is relevant and feasible, while recognising that not all items will be appropriate or possible in every format. For journal publications, inclusion may be constrained by word limits, so authors should prioritise the items that are most relevant to their intended audience while maintaining transparency.

Table 5.5: Draft checklist: Additional items

Theme/item	No	Checklist item description	Applicability (Who/where this may be relevant)	Reported (Y/N)
Thank you				
Trial participants	11	Thank participants for taking part in the trial	Trial participants, Trial/sponsor websites	_____
Methods				
Patient and public involvement and engagement	12	Whether and how patients and/or the public helped in the design and delivery of the trial	Trial participants, Members of the public, Journal plain language summary (PLS), Trial/sponsor website	_____
Results				
Follow-up plan	13	Any plans for long-term follow-up of trial participants after the trial has ended	Trial participants, Trial/sponsor website	_____
Conclusion				
Existing research	14	How the trial results compare with existing evidence (e.g., systematic reviews and other trials)	Trial participants, Members of the public, Journal PLS, Trial/sponsor website, Trial registry, Regulatory agency report	_____
Next steps	15	Next steps for the trial (e.g., publication, licensing of the medicine or treatment, or integration into healthcare policy)	Trial participants, Members of the public, Journal PLS, Trial/sponsor website, Trial registry, Regulatory agency report	
Discussing the trial results with healthcare providers				
Advisory statement	16	Statement advising the reader to consult their healthcare provider before making any changes to their treatment based on the trial results	Trial participants, Members of the public, Trial/sponsor website	_____
Additional information				
Further information	17	Where more information about the trial results or related resources can be found	Trial participants, Members of the public, Trial/sponsor website	_____

5.4 Discussion

The outcomes of the consensus meeting formed the basis of the draft reporting guideline checklist that was taken forward for pilot testing (Chapter 6). Decisions made during the meeting, informed by both the quantitative Delphi results and qualitative discussion during the consensus meeting, shaped the final structure of the reporting guideline. The consensus meeting allowed for nuanced debate, clarification, and potential compromise that could not be captured by numeric thresholds alone.

As with the Delphi survey, I aimed to bring together a diverse group of participants for the consensus meeting to reflect a broad range of real-world perspectives. I invited not only professionals and PPI representatives, but also members of the public, so that each group would be represented. This was particularly important, as most trial participants are not PPI representatives, and the reporting guideline is intended to serve all audiences. Conducting the meeting online made it possible to include participants from different countries and time zones, which strengthened the diversity of perspectives in the panel. At the same time, it required careful planning to manage differences in availability and time commitment. The meeting was scheduled to maximise overlap across regions, and materials were circulated in advance to support informed discussion. [99] In addition, I held three preparation sessions with patient representatives and public participants beforehand, to ensure they felt confident with the content and structure of the meeting and were able to contribute meaningfully during the discussion. [1, 211]

Reflecting on the consensus meeting, this stage highlighted the value of bringing diverse perspectives together to move beyond numerical agreement and consider practical implications. Discussions often revealed tensions between what patients and the public considered important to know and what trial teams felt was feasible to communicate clearly. Facilitating these conversations required careful judgement to ensure that patient and public perspectives were not lost when weighed against concerns about burden or practicality. This process reinforced my awareness of how consensus in guideline development is not solely about agreement, but about negotiating balance and proportion across different stakeholder priorities.

The tensions observed during the consensus meeting were consistent with challenges described in the wider literature on co-production with multistakeholder engagement. [1, 2, 212] Studies have noted that bringing together professionals and patient or public representatives can surface differences in priorities and create tension in power dynamics. [2, 94] There is also evidence that without deliberate facilitation and transparent reporting, certain voices may dominate discussions and minority perspectives may be diluted within aggregate consensus scores. [99, 213] Reflecting on this literature helped me prepare adequately for the consensus meeting. I provided a supportive environment with structured facilitation, explicit decision rules, and separate consideration of stakeholder perspectives, which ultimately helped contextualise the discussions and reinforced the importance of meaningful engagement from all parties.

While the Delphi survey provided an important foundation for item prioritisation, decisions made during the consensus meeting did not always align exactly with the quantitative Delphi

results. This was a deliberate and transparent part of the process. During the consensus meeting, we sought to balance the consensus items from the Delphi against keeping the guideline useful and practical so that it is not burdensome to trialists. Some items that had reached Delphi consensus were reconsidered, refined, or reclassified in the meeting, where participants felt they would be difficult to report clearly, risked over-interpretation, or were unlikely to be applicable across contexts. Meeting participants raised concerns about items that are difficult to report, such as '*Healthcare policy*' and raised concerns about word limit constraints that are often associated with trial result summaries. The opposite also happened; for example, the item '*Patient and public involvement*' did not receive very high ratings in the Delphi, but received numerous substantial comments urging the importance of including this item. This was discussed in detail, and the item was retained by the consensus meeting participants. We decided on the critical content of the checklist, a minimum set of items necessary to explain the results of the randomised trial to patients and the public, with an additional set that may be valuable depending on context.

These decisions were informed by in-depth discussion among a diverse group of stakeholders with extensive experience in trial design, reporting, and PPI representation. Although this meant that judgement was exercised beyond numerical consensus alone, the process was undertaken reflexively and transparently, with explicit consideration of how each item contributed to the overall purpose of the guideline. In this sense, the consensus meeting acted as a necessary interpretive stage, allowing alignment between the research aims, the realities of trial reporting, and the needs of patient and public audiences.

This approach reflects the importance of methodological coherence, whereby decisions across stages of research remain conceptually aligned rather than mechanically driven by a single method. [214] Just as reflexive thematic analysis requires thoughtful engagement with data rather than procedural rule-following, guideline development benefits from deliberative judgement that considers how different elements of the process fit together. [215] By combining Delphi consensus with structured discussion and reflexive decision-making, the resulting checklist aimed to balance inclusivity of perspectives with clarity, feasibility, and transparency.

A key limitation of this process is that, despite efforts to balance stakeholder perspectives, some decisions made at the consensus meeting relied on judgement beyond Delphi ratings alone. The views of those present at the meeting may have carried more weight than those of participants who contributed only through the Delphi survey. In addition, practical considerations such as word limits, reporting burden, and feasibility influenced how items were classified or merged, which may not fully reflect the priorities of all stakeholder groups. These limitations were considered throughout the process and are acknowledged as part of the trade-off between inclusivity and producing a usable reporting guideline.
The qualitative feedback from the consensus meeting also informed the content and structure of the E&E (Chapter 7), ensuring that explanations and examples reflected issues raised by participants.

The next stage of this work involved pilot testing the draft checklist in real-world settings, which is described in Chapter 6.

Chapter 6: Refining the draft reporting guideline through extensive pilot testing

6.1 Introduction

Pilot testing is a critical but frequently omitted step in the development of reporting guidelines. [101] The scoping review (Chapter 2) findings showed that most guidance documents did not report any form of pilot testing before publication. When pilot testing was mentioned, it was often described briefly and without methodological detail. This gap is notable given that reporting guidelines are intended for practical use by diverse users, and their clarity, feasibility, and usability directly influence whether they are adopted and applied as intended.

This chapter describes how I pilot-tested the draft reporting guideline checklist for sharing results of randomised trials with patients and the public. The aim of this stage was to assess how well the checklist worked in practice before finalising it. I focused on five key domains: usability, clarity, feasibility, applicability, and acceptability in real-world settings. These concepts are commonly used when evaluating complex interventions and tools, and I drew on established frameworks to guide their use in this chapter. [102, 103] The rationale for selecting these evaluation domains and the theoretical frameworks underpinning them is described in Chapter 1. Brief definitions are provided below to aid interpretation of the findings.

Usability refers to how easily and effectively the checklist can be used to produce a trial results summary. I drew on established usability frameworks (Figure 6.1), which define

usability in terms of effectiveness, efficiency, and user satisfaction within a given context. [102]

Acceptability refers to the extent to which users consider the checklist appropriate and are willing to use it in practice, informed by the theoretical framework of acceptability of Sekhon et al., which considers users' perceptions, responses, and engagement with an intervention. [103]

I also considered **feasibility**, defined as whether the checklist can realistically be applied within the time, resource, and expertise constraints of routine trial reporting. [104]

Applicability relates to whether the checklist is relevant across different types of trials and reporting contexts, reflecting considerations of external validity and transferability in health research. [104, 105] Finally, **readability** refers to how understandable the resulting summaries are for patients and members of the public, drawing on principles of plain language and health literacy. [105]

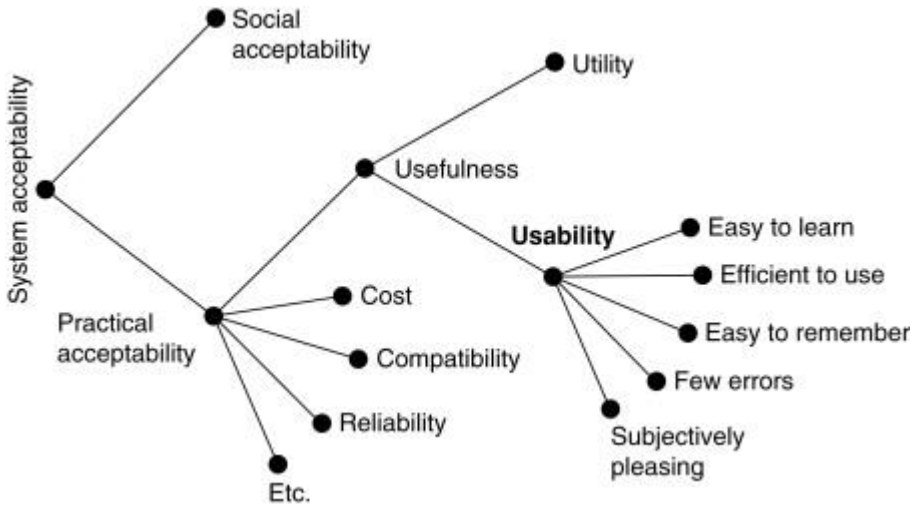


Figure 6.1: Usability framework. *Reproduced from "User experience re-mastered: your guide to getting the right design".* [102]

6.1.1 Scope of pilot testing

I piloted the checklist using reports of randomised trials from a range of designs and contexts. These included randomised trials of investigational medicinal products and non-drug trials, blinded and unblinded trials, surgical and complex intervention trials, and trials involving underrepresented groups. This broad scope was chosen to ensure that the checklist is relevant and adaptable across the diversity of trials for which patient- and public-facing results are produced.

6.1.2 Objectives

The objectives of the pilot testing were:

1. To evaluate the usability of the checklist, including the distinction between minimum essential and additional reporting items.
2. To examine the feasibility of using the checklist in real-world trial reporting.
3. To explore the applicability of the checklist across different types of trials and reporting contexts.
4. To identify areas of ambiguity, duplication, or missing content to inform further refinement.
5. To assess the clarity and readability of the checklist items and resulting summaries for patients and the public

6.2 Methods

6.2.1 Overview of the pilot testing

The pilot testing protocol was registered on OSF. [216] I evaluated the draft checklist using a structured three-phase approach. The evaluation progressed from initial testing by me as the lead researcher, to testing by its intended users, and finally to assessment of the resulting summaries by patients and the public. This approach recognised that the checklist is a practical tool for those preparing trial result summaries (e.g., chief investigators, trial managers, trial coordinators, medical writers, and patient partners), whereas the summaries it produces are intended for patients and the public.

This design reflects a methodological distinction between evaluating the tool and evaluating its outputs. Usability, feasibility, applicability, and acceptability were assessed with the intended users of the checklist (trial professionals and medical writers), focusing on how easily and realistically the checklist could be applied in practice. In parallel, the clarity and readability of the resulting summaries were assessed with patients and members of the public. This approach was informed by reader-focused evaluation methods, which emphasise assessing how well a text works for its intended audience rather than relying only on expert judgement. [217]

The aim was to refine the checklist iteratively by identifying issues with content, wording, usability, feasibility, and output quality before finalising the guideline. Findings from each phase were reviewed and used to revise the checklist before moving on to the next stage. Figure 6.2 illustrates the overall flow of the pilot testing process.

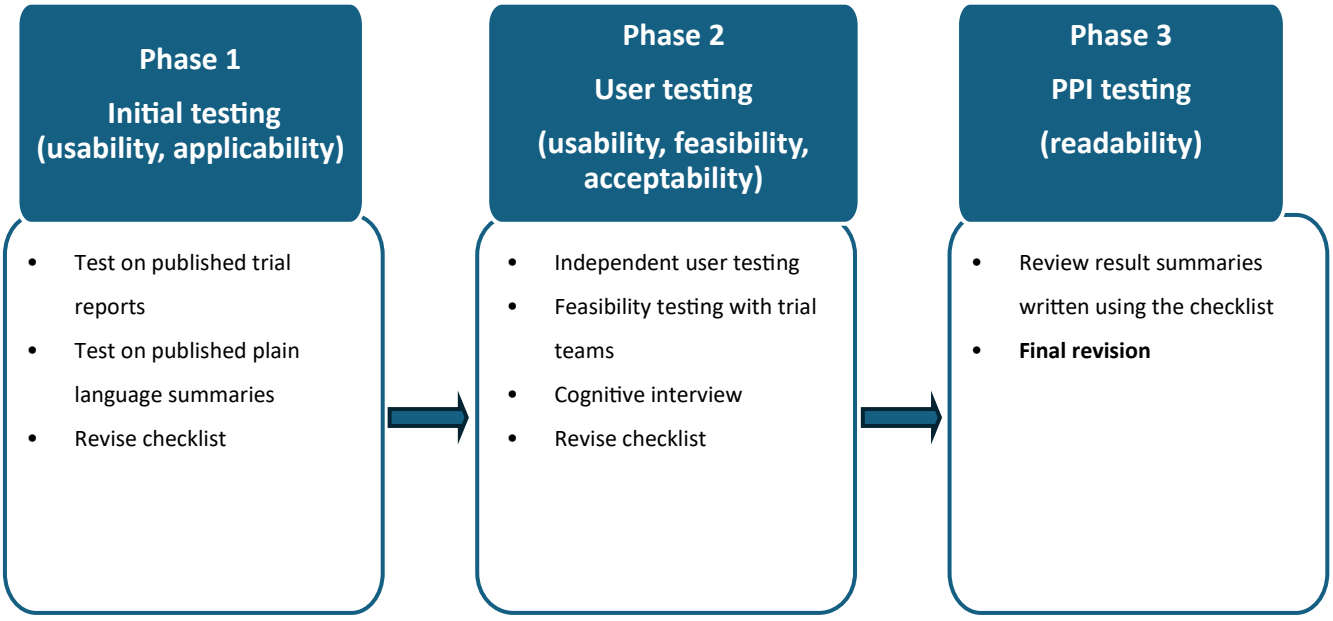


Figure 6.2: A flowchart displaying the phases of the pilot testing

6.2.2 Phase 1: Initial testing

This section describes Phase 1 of the pilot testing, which focused on my direct application of the checklist to assess whether it captured essential reporting content and could be used within realistic publishing constraints. This phase consisted of two components:

a. applying the checklist to write PLSs from published randomised trial reports

b. applying the checklist to existing PLSs to compare their content against the checklist

Phase 1a: Applying the checklist to published randomised trial reports

I applied the draft checklist to write result summaries of a selection of completed and publicly available randomised trials. I identified trials through publicly accessible registries, including ClinicalTrials.gov, the International Standard Randomised Controlled Trial Number (ISRCTN) registry, and the WHO International Clinical Trials Registry Platform (ICTRP).

On each registry, I applied filters to identify completed randomised trials with available results (Table 6.1). From the eligible trials, I purposively selected ten trials to maximise variation in characteristics relevant to the intended use of the checklist. I sought diversity in intervention type (drug and non-drug), study design (blinded and unblinded), clinical specialty (e.g., surgical and behavioural), reporting context, and availability of results (registry results alone or registry results accompanied by a journal publication). Where multiple trials met the same selection criteria, one was chosen at random. This approach enabled the checklist to be evaluated across a range of trial designs and reporting contexts likely to be encountered in practice. Selection continued until the sample included examples representing each of these characteristics. For each selected trial, I identified the registry record and any associated results publications and used these as the source material for checklist application.

Table 6.1: Search queries across registries

Registry/website	Search query
ClinicalTrials.gov	Filter: Intervention/treatment: 'randomised controlled trial' Study type: Interventional Study results: With results
ICTRP	Search term: 'randomized controlled trial' Phase: all With 'results only'-selected
ISRCTN	Search term: 'randomised' Study status: completed Results status: with results

To support interpretation of findings, I reviewed journal policies on PLS word limits. I identified examples of journals that accept but do not require PLS and journals that mandate them. Word limits varied widely, typically ranging from 150 to 400 words (Table 6.2). This

review helped contextualise the practical constraints under which the checklist would be used.

Table 6.2. Example publishers/journals that publish plain language summaries

Publishers/journals	Word limit	PLS submission requirement
SAGE Publications-most journals	300 words	Encouraged
Taylor & Francis	250 words	Encouraged
American Geophysical Union (AGU)	200 words	Encouraged
Science Societies Journals	150 words	Encouraged
eLife	~400 words	Encouraged
Journal of Clinical Epidemiology	specific word limit not provided	Encouraged
Research Involvement and Engagement	250 words	Required
Therapeutic Advances in Drug Safety	Title 50 words, summary: 300 words	Required
BMJ Open	specific word limit not provided	Required
PLoS ONE	no word count but suggested 150-200 words	Required
Journal of Comparative Effectiveness Research	120-250 words PLS abstract	Required

Using the checklist, I produced two types of summaries for each trial: a word-restricted summary of around 300 words and a non-word-restricted summary. This allowed me to explore how the checklist performed under realistic reporting constraints (such as journal word limits) and to identify which items were most difficult to report within shorter word limits. It also enabled me to assess whether both the minimum essential items and the additional items could be applied appropriately in practice. Throughout this process, I recorded detailed notes on the usability of individual checklist items, challenges with wording or interpretation, overlap between items, and any content gaps.

Phase 1b: Applying the checklist to published PLSs

I then compared the checklist contents to a purposive sample of published PLSs. I chose summaries published by journals (e.g., *BMJ* journals), funders' reports (e.g., NIHR Open Research), and industry sources such as pharmaceutical company websites (e.g., PLSs published on Pfizer website [218]). I iteratively reviewed available summaries and selected eight to maximise variation in source, format and presentation style. The sample included text-based, web-based, and infographic-style summaries from different organisations. Eight provided sufficient variation for this initial checklist testing without duplicating similar examples. Where multiple summaries met the same characteristics, I selected one without preference.

For each summary, I checked if the checklist items were reported or not. I coded each checklist item as *Present, Partly present, Not present, or Not applicable*. I summarised the findings in a results table to identify common reporting practices and frequent omissions.

6.2.3 Phase 2: User testing

I designed Phase 2 to test the checklist with professionals from a wide range of expertise and settings. The aim was to assess whether the checklist was feasible, usable, applicable, and acceptable in real-world contexts, and to explore how different users interpreted the items. I was particularly interested in whether experience, background, or professional role influenced understanding of the checklist and how the checklist was applied in practice to produce outputs in professional contexts. I used a stepwise approach to user testing

combining independent use, real-world application, and in-depth user testing via cognitive interviews.

My experience applying the checklist during Phase 1 highlighted that some items would benefit from additional explanation and guidance. To explore how the level of detail influenced usability, I developed three versions of the checklist:

- **Concise version** (Appendix 6.1)
- **Expanded version** (including an additional 'lay item description' column to provide further explanation) (Appendix 6.2)
- **Expanded 'Merged' version** (a combination of the concise and expanded formats) (Appendix 6.3)

All three versions were shared with participants in advance of pilot testing. Participants were asked to select their preferred version, use it to prepare a trial results summary, and explain the reasons for their choice, to better understand how different formats supported or hindered use in practice.

Sample size

I used a purposive sample to include participants with a range of roles and experiences relevant to trial reporting. Participants varied in their:

- professional roles (e.g., trial manager, medical writer, researcher, patient and public representative),
- years of experience in trials or health research,
- familiarity with writing or reviewing trial summaries, and

- prior exposure to reporting guidelines or networks (e.g., CONSORT, EQUATOR). [62, 65]

This variation was important because users with different backgrounds may interpret checklist items differently and encounter different challenges when applying them. [69] I anticipated that those with less experience in trial reporting or without prior exposure to reporting guidelines might find some items less clear or more difficult to apply, while more experienced users might focus on completeness and feasibility in professional contexts.

The sample size for this phase was pragmatic and shaped by time and resource constraints, as well as the iterative nature of the pilot testing. Across the three stages, I included 14 participants in total. As argued in usability research, relatively small samples are often sufficient to identify the majority of usability issues and areas of misunderstanding. [219] In Chapter 3, I introduced information power as a concept to guide sample size in qualitative research, and I drew upon it again in pilot testing. [176]

Using the concept of information power, I aimed to maximise the relevance and richness of data from each participant rather than achieve a large sample. This was supported by selecting participants with direct experience of trial reporting and by using methods designed to elicit detailed feedback (e.g., independent application, real-time use, and think-aloud interviews). I continued pilot testing until no new information was coming up (replication across participants was seen) and sufficient scope was attained by including participants from diverse sectors of commercial and non-commercial backgrounds. [176]

Although modest in absolute terms, this level of pilot testing is relatively extensive compared with common practice in reporting guideline development. In my scoping review (Chapter 2) of the literature, I found that few guidelines (n=5 out of 24) reported conducting evaluation and that it involved limited or informal feedback rather than structured, multi-stage pilot testing with end users. A review of 262 reporting guidelines indexed in the EQUATOR Network database in 2023 found out that only 23.3% reporting guidelines reported conducting pilot testing before dissemination. [67] Against this background, I anticipated that this sample would be sufficient to identify key issues in clarity, interpretation, and feasibility, and to support meaningful refinement of the checklist.

Participant recruitment

The recruitment period ran from 1st December 2025 to 30th April 2026. I invited participants through a combination of established networks and direct contacts. Potential participants were identified through research and trial networks including existing collaborations, clinical trials networks (e.g., UK Trial Manager's Network), medical writing organisations (e.g., European Medical Writers Association (EMWA), MedSciComms), and guideline development networks (e.g., EQUATOR Network). A non-exhaustive list of networks contacted is provided in Appendix 6.4.

I aimed to include individuals with a range of roles, including trial managers, medical writers, chief investigators, and PPI representatives, across academic, industry, and policy settings. I also contacted participants from earlier phases (qualitative study, Delphi survey, and consensus meeting) and asked them to share the invitation within their networks. Recruitment was supported through targeted emails, word of mouth, and online promotion

(e.g., flyers, posters, and social media posts tailored to specific platforms). An example from a LinkedIn advertisement posted by the EMWA is shown in Figure 6.3.

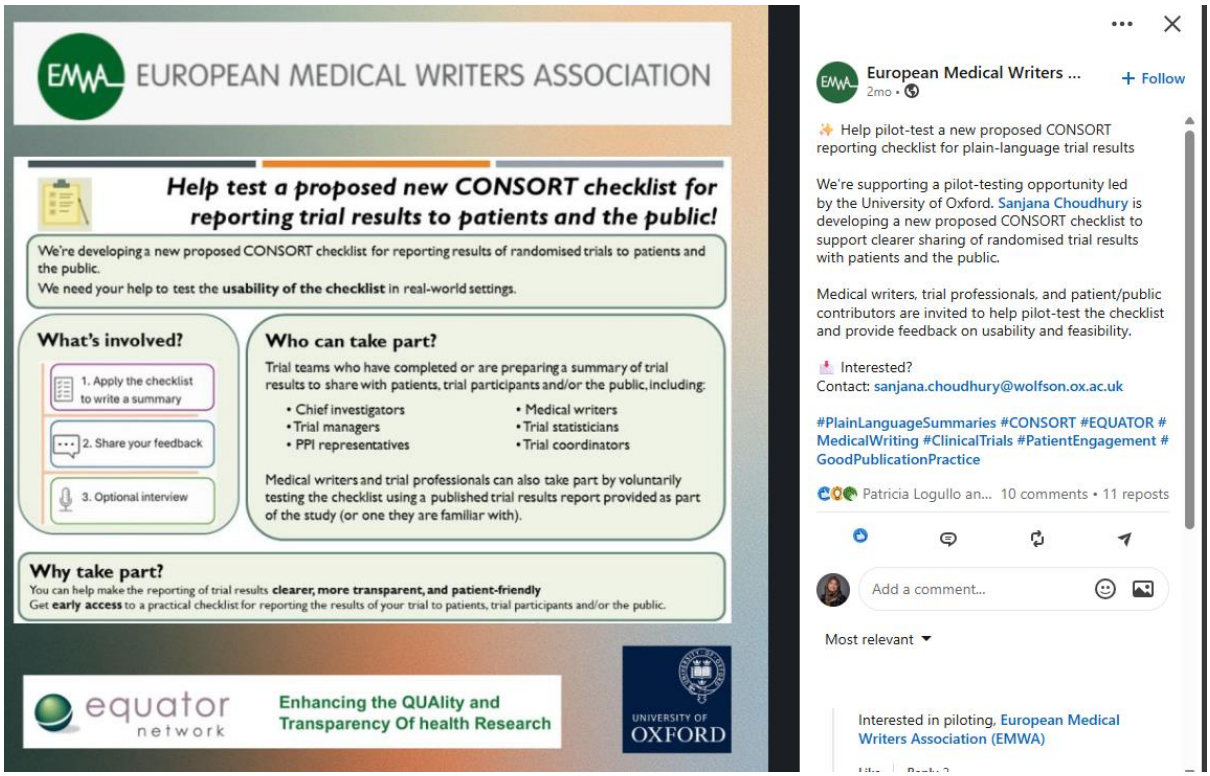


Figure 6.3: Example advertisement by the recruitment networks. *Screenshot taken from LinkedIn post shared by the European Medical Writer's Association in support of the pilot testing*

Stages of user testing

Phase 2a. Independent user testing

I invited experienced professionals (e.g., trial managers, medical writers, PPI leads) to independently apply the checklist to published trial reports and prepare results summaries (a short version of ~ 300 words and an unrestricted version). Participants were provided with the trial registry record and, where available, links to the published journal article (Appendix 6.5). Ten participants took part and provided structured feedback on the checklist's clarity, completeness, and usability.

Phase 2b. Feasibility testing with trial teams

I invited trial teams who were preparing for dissemination of results to use the checklist in real time. Two teams took part: one retrospectively applied the checklist to a plain language summary they were developing and provided informal feedback, while the other used the checklist prospectively to develop a summary alongside a journal article under review and provided structured feedback.

Phase 2c. One-to-one "think-aloud" sessions (cognitive interview)

I conducted one-to-one think-aloud sessions with two participants (23rd February 2026 and 20th April 2026). They applied the checklist to draft a short trial results summary and verbalised their thought process in my presence. During these sessions, I noted points where participants hesitated, interpreted items differently, or found wording unclear. The sessions were recorded with consent taken from the participants. I wrote a short thematic summary after each of these sessions with example quotes. The participants also provided structured feedback.

Feedback collection

All participants were asked to provide feedback through a structured form (Appendix 6.6). All but one participant provided formal feedback. The form included Likert-scale ratings and open-text responses.

User testing focused on how well the checklist functioned in practice, rather than on participants' personal preferences. I aimed to ensure that feedback reflected how the checklist was used, rather than whether participants simply liked its format. For example,

instead of asking general questions such as *"Do you like the format of the checklist?"*, the questions were framed around specific domains such as *usability* and *clarity*. Participants were asked questions such as *"How useful was the checklist for deciding what to include?"*, to understand how the checklist supported decision-making during summary writing. Feedback was requested on the set of predefined domains described in Table 6.3.

Table 6.3: Domains of pilot testing feedback: user testing

Domain	Measures collected
Usability and feasibility	Ease of use, time required, usefulness of the checklist (e.g., How useful was the checklist for deciding what to include)
Clarity	Understanding of items, confusing terms, scope of the checklist (e.g., How clear was it to understand when and for whom this checklist should be used)
Acceptability	Likelihood of future use (e.g., how likely are you to use the checklist in future)
Completeness	Missing, repetitive or redundant items, (e.g., if the checklist covered everything needed to report the trial results)
Qualitative feedback	Open-text comments on wording and content, (e.g., suggestions for improvement)

Analysis

Quantitative data (Likert-scale responses) were summarised descriptively. Qualitative data (open-text feedback and think-aloud transcripts) were analysed thematically to identify issues with wording, missing items, interpretation, and feasibility. Findings from each stage were synthesised and compared iteratively and used to inform revisions to the checklist to improve clarity, logical flow, and overall usability, while maintaining sufficient detail. I also noted items that needed further guidance for highlighting in the E&E (Chapter 7).

6.2.4 Phase 3: Readability and accessibility testing with patient and public representatives

In Phase 3, I worked with patient and public representatives to assess whether summaries produced using the checklist were clear, engaging, understandable and meaningful to non-specialist audiences, ensuring that the outputs remained grounded in the needs of end users.

Participants were purposively selected from those previously involved in the project who had expressed interest in further participation. I invited five PPI representatives and provided them trial results summaries developed during Phase 2 (both short and long versions) and asked them to review the summaries against the checklist. I used the remaining funding from the NIHR School for Primary Care Research (SPCR) award to offer each participant a £20 Amazon voucher in recognition of their time.

Feedback was collected using a short-structured form with the option to provide additional comments (Appendix 6.6). PPI feedback focused on the aspects of readability described in Table 6.4. Findings from this phase informed the final revisions to the checklist and the accompanying E&E (Chapter 7).

Table 6.4: Domains of pilot testing feedback: PPI

Area	Example	Response Format
Clarity	How clear was the summary?	1–5 Likert
Relevance	Did the information feel relevant to you as a reader?	1–5 Likert
Readability	Did you find any parts unclear or confusing?	Open text
Completeness	Did the summary cover everything you needed to understand the trial results? Did you expect any topics to be included that are not covered by the checklist? If yes, what was missing?	1–5 Likert and open text
Open comments	Any other comments or suggestions to improve the checklist (e.g., wording, order, format, examples)?	Free text

6.2.5 Use of AI

There is growing interest in using generative AI to produce PLSs of clinical research. Studies have shown that AI tools can significantly and meaningfully improve both the readability and completeness of trial summaries. [220] As an illustrative application, I explored whether a generative AI tool can correctly apply the checklist to create PLSs. This was intended to demonstrate potential use of the checklist as an assessment framework, rather than to evaluate the performance of AI-generated summaries. The aim was to show how the checklist can be used as an assessment framework, e.g., *'can GPT help me write a PLS using the checklist?'*

I used ChatGPT (OpenAI) accessed through the University of Oxford workspace, selected one example trial publication, and asked ChatGPT to produce a PLS by applying the checklist. I tested multiple prompts to explore how prompt wording influenced the structure, completeness, and readability of the generated summaries. Examples of prompts included:

- *"Write a PLS of this trial results report using the checklist within 300 words."*
- *"Write a PLS of this trial results report using the checklist with no word limit."*
- *"Write a PLS ensuring that all essential checklist items are reported."*
- *"Write a PLS for patients and the public based on the attached trial article, following the checklist recommendations."*

The summaries produced were reviewed against the checklist to assess whether key reporting items had been addressed.

6.3 Results

6.3.1 Phase 1: Initial testing

Phase 1a: Application of the checklist to published randomised trials

In Phase 1a, I applied the draft checklist to ten completed randomised trials identified from trial registries and associated publications. The ten selected trials represented a range of intervention types, study designs and reporting formats. These included drug and non-drug trials, surgical and behavioural trials, blinded and unblinded trials, and trials with results reported through registry-records alone as well as those with accompanying journal publications. Appendix 6.7 details the source materials and essential and additional checklist items that could be reported for each test.

Across all ten trials, it was possible to produce summaries that included **all essential checklist items (items 1–10)** when relevant information was available in the source materials. This was consistent across trial types and sources, indicating that the essential

items were broadly applicable and feasible to implement in practice. I observed that item '*Strengths and limitations*' was the most difficult to report within shorter word limits, noting that additional guidance is required for this item in the E&E (Chapter 7).

I also found that the order of two checklist items could be improved. The item '*Health condition*' was moved before the item '*Objective'* to provide context before introducing the purpose of the trial, resulting in a more logical flow.

However, the reporting of **additional items (items 11–17)** was strongly influenced by word limits. When summaries were restricted to approximately 300 words, only a small subset of additional items could usually be included, most commonly a thank-you statement, an advisory statement, and limited information on next steps or further information. Under more restrictive word limits (150–200 words), inclusion of additional items was often not feasible without compromising essential content. In some cases, such short word limits also made it difficult to meaningfully report all essential items. In contrast, when no word limit was applied, all additional items could be incorporated across trials where relevant information was available.

This pattern was observed consistently across trial types, suggesting that constraints were primarily driven by summary length rather than trial design or intervention type. These findings informed refinements to the checklist structure and suggested that a word limit of approximately 300 words provides a better balance between completeness and brevity than more restrictive limits of 150–200 words.

Phase 1b: Application of the checklist to published PLSs

In Phase 1b, I applied the checklist to eight purposively selected PLSs representing a range of publishers, dissemination settings, and reporting formats, including journal, funder, and industry-produced summaries. The summaries varied considerably in structure, length, and intended audience.

Most summaries consistently reported the items *'Health condition', 'Objective', 'Interventions',* and *'Main findings'.* Information on '*Participant numbers*' and *'Side effects'* was also commonly included, although often with limited detail. In contrast, several checklist items were frequently missing or only partly addressed. These included *'Strengths and limitations*', *'Patient and public involvement and engagement'*, *'Follow-up plans', 'Advisory statements',* and '*Next steps'*. '*Demographic information'* was inconsistently reported, and '*Interpretation'* of results was sometimes limited to descriptive statements without contextual explanation (Table 6.5, Detailed table in Appendix 6.7).

Overall, this analysis highlighted substantial variation in current practice and demonstrated that many elements valued by patients and the public are not routinely reported. These findings reinforced the need for explicit guidance and structured reporting to support more complete and consistent communication of trial results.

Table 6.5: Presence of checklist items across published plain language summaries (n=8)

Checklist item	Present n (%)	Partly present n (%)	Not present n (%)	Not applicable n (%)
Essential items				
1. Health condition	8 (100%)	0	0	0
2. Objective	8 (100%)	0	0	0
3. Interventions	8 (100%)	0	0	0
4. Summary of eligibility criteria	6 (75%)	2 (25%)	0	0
5. Number of participants	8 (100%)	0	0	0
6. Demographics	7 (87.5%)	1 (12.5%)	0	0
7. Main findings	8 (100%)	0	0	0
8. Side effects	7 (87.5%)	1 (12.5%)	0	0
9. Interpretation	7 (87.5%)	1 (12.5%)	0	0
10. Strengths and limitations	2 (25%)	3 (37.5%)	3 (37.5%)	0
Additional items				
11. Thank you	6 (75%)	0	2 (25%)	0
12. Patient and public involvement and engagement	2 (25%)	0	6 (75%)	0
13. Follow-up plan	1 (12.5%)	0	0	7 (87.5%)
14. Existing research	3 (37.5%)	2 (25%)	3 (37.5%)	0
15. Next steps	3 (37.5%)	1 (12.5%)	4 (50%)	0
16. Advisory statement	2 (25%)	0	6 (75%)	0
17. Further information	6 (75%)	0	1 (12.5%)	1 (12.5%)

Note:

"Partly present" indicates that the item was mentioned but incompletely reported or lacked sufficient detail.

"Not applicable" indicates that the item was not relevant to the context of the summary.

How phase 1 findings informed checklist refinement and phase 2 design

Based on findings from Phase 1, I refined the draft checklist. I swapped the order of the items describing the *'Health condition'* and trial *'Objective'* to improve logical flow. I also found that word limits of 150–200 words were often insufficient to report essential information clearly and meaningfully. A target word limit of approximately 300 words appeared more feasible for producing comprehensive yet understandable summaries. These refinements formed the basis of the checklist taken forward to Phase 2.

As I noticed that some checklist items required further explanation to support consistent interpretation, I developed three alternative checklist formats: a concise version (Appendix 6.1), an expanded version with explanatory text (Appendix 6.2), and a merged version combining both approaches (Appendix 6.3), for evaluation by intended users in the next phase of pilot testing.

6.3.2 Phase 2: User testing

Phase 1 identified initial content issues and informed preliminary revisions. The refined checklist was then tested by external experts and trial teams to assess its usability and feasibility under real-world conditions.

Participant characteristics

Thirteen individuals provided formal feedback across the three stages of pilot testing: independent user testing (n=10), think-aloud interviews (n=2), and prospective feasibility testing with a trial team (n=1). Participants represented a range of roles, including trial managers, medical writers, researchers, and patient and public representatives, across

different clinical areas and settings (Table 6.6). A second trial team participated retrospectively by applying the checklist to a plain language summary they were already developing and providing informal feedback.

Table 6.6: Participant demographics: Phase 2

ID	Stage	Role	Field / trial type	Years of experience	Experience with trial summaries	Experience with reporting guidelines
1	Independent	Medical writer, PPI representative	General	6	Writing	Yes
2	Independent	DPhil student; former communications specialist	Translational health science, public health	7 (2 in trials)	Writing	No
3	Independent	Trial project manager; PPIE officer	Oncology (adult and paediatric)	7	Writing	No
4	Independent	Trial manager; Researcher	Surgical sciences	4	Writing	Yes
5	Independent	Researcher	Infectious disease	10	Writing	Yes
6	Independent	Medical writer; QA/GCP auditor	Phase trials; BA/BE studies	18	Reviewing	Yes
7	Independent	Medical writer	Pharmacology	>15	Writing	No
8	Independent	Researcher	Oral medicine	22	Writing	Yes
9	Independent	Medical writer	Biotech; RCTs; economic evaluations	22	Writing	Yes
10	Independent	Marketing professional	Health and policy communications	1	None	No
11	Think-aloud	Researcher	Mental health and addiction	5	Writing	Yes
12	Think-aloud	Trial manager	AI trials	7	No	Yes
13	Trial team	Medical writer	Clinical research	9	Writing	Yes

Participants had between 1 and 22 years of experience in trials or health research. Most had prior experience writing or reviewing trial summaries, and around half reported familiarity

with EQUATOR [65] or reporting guidelines such as CONSORT. [62] The sample included participants from academic, clinical, and industry backgrounds, as well as individuals with international experience.

Feedback from user testing

Quantitative feedback

Quantitative feedback from participants indicated that the checklist performed well across all domains, with generally positive ratings for clarity, usability, completeness, and acceptability. Participants took around 1-2 hours to complete writing a summary using the checklist.

Overall, the checklist was considered clear in its purpose and scope. Nine participants rated it as *very clear*, three as *quite clear*, and one as *moderately clear* in terms of understanding when and for whom it should be used.

In terms of usability, participants reported that the checklist was generally easy to apply when writing a summary. Five participants rated it as *very easy* to use, seven as *quite easy*, and one as *moderately easy*, indicating that the checklist could be applied with relatively low effort in practice. The checklist was also viewed as useful for guiding content selection. Eight participants rated it as *very useful*, with smaller numbers rating it as *quite useful* (n=1), *moderately useful* (n=3), or *slightly useful* (n=1). This suggests that the checklist supported decision-making for most users, although a few participants found it less helpful.

Regarding completeness, most participants felt that the checklist covered the necessary information to report trial results. Seven participants *strongly agreed* and three *agreed* with this statement, while two participants *disagreed* and one was neutral, indicating some remaining gaps or differing expectations.

Finally, participants expressed a high level of acceptability, with most indicating they would use the checklist in the future. Six participants rated themselves as *very likely* to use the checklist, six as *quite likely*, and one as *moderately likely*. This suggests that the checklist was generally well received and considered relevant for future use.

Feedback from trial teams: Feasibility

Feedback from trial teams was broadly consistent with the findings from the wider user testing. One trial team applied the checklist prospectively while preparing a patient-facing summary for an ongoing study. Overall, they found the checklist valuable and feasible to use. The team reported that several additional items ('*Patient and public involvement and engagement', 'Follow-up plan', 'Next steps'* and '*Advisory statement'*) were not applicable to their study, while the item *'Existing research'* would have been useful to include but was difficult to accommodate within the available word count. Suggestions for additional content included clearer reporting of study objectives and timeframes, guidance on titles, reporting of randomisation and distinguishing between participants enrolled and participants analysed.

A second trial team retrospectively reviewed the checklist against a patient-facing summary they were already developing. The team considered the checklist sensible and broadly

aligned with their reporting approach. However, they highlighted challenges in communicating the item *'Strengths and limitations'* in a concise and understandable way for patients and families. They also questioned the level of demographic detail requested, noting that reporting multiple demographic characteristics may be difficult within the space constraints of a patient-facing summary.

Qualitative feedback and refinement of the checklist

Qualitative feedback helped to explain the quantitative ratings and identified areas where refinements were needed to improve clarity, usability, and practical application.

"The checklist covered the key topics needed to understand the trial and its results in plain language." (Participant 4)

There were suggestions to combine certain items (e.g., '*Objective'* with '*Health condition'*, or participant-related items). However, I decided to retain these as separate items, as they represent distinct pieces of information that support clarity and completeness in reporting.

A recurring issue in the pilot testing was that some participants (n=3) found it difficult to complete certain items when using the example trial reports provided, particularly when relying on registry data alone. Items such as '*Interpretation*' and '*Strengths and limitations*' required access to more detailed information than what was available in the source materials. As one participant noted:

"Using the example given (KARMA-Dep Trial) I struggled to find eligibility but that is not an issue with the checklist. Number 10 is difficult for me to complete without the trial in more depth, but on one of our own trials it would be easier" (Participant 3)

This was considered a limitation of the pilot testing setup rather than of the checklist itself, as trial teams would typically have full access to their study data in real-world use.

Pilot testing highlighted uncertainty around the level of detail required for several items, such as which adverse events to report or how much information to include on eligibility criteria. Many participants asked for more specific guidance on what should be included. While I have added further examples and clarification in the E&E document (Chapter 7), I did not define a fixed level of detail for these items. From a methodological perspective, I felt it was important to avoid over-specifying content in a way that might not be appropriate across different trials. In practice, the level of detail will need to be determined by individual trial teams, drawing on clinical judgement and, where appropriate, input from PPI representatives. This reflects the reality that the relevance of certain information depends on the trial topic, the audience, and practical constraints such as word limits. More broadly, this highlights a limitation of rigid checklists, as overly prescriptive guidance can reduce flexibility and make it harder to produce summaries that are both accurate and meaningful in real-world settings.

Pilot testing also highlighted tension between technical accuracy and patient-friendly language, particularly for the item on adverse events. Some participants noted that while *'Side effects'* is more familiar to patients and the public, it does not fully capture the scope of '*Adverse events'* as used in trial reporting. [221] This issue was also raised in the consensus meeting discussion. I had chosen to use the term '*Side effects'* based on PPI feedback at that time, where it was consistently preferred for clarity and familiarity. However, feedback from

trial professionals at the pilot testing stage raised concerns about potential loss of precision. Upon studying further, I concluded that the checklist is intended to be used by professionals and therefore technical accuracy is needed. In response, I revised the checklist to change the item name from *'Side effects'* to '*Adverse events*', while allowing flexibility in how this is presented in summaries. In the expanded version and the E&E (Chapter 7), I suggested using a patient-friendly phrasing (e.g., *"What were the side effects?"*) in the output, while ensuring that the content reflects the underlying adverse event data. This approach reflects a deliberate balance between technical accuracy and accessibility. More broadly, it illustrates the need to support translation between professional terminology and patient-facing language, rather than prioritising one at the expense of the other.

Pilot feedback also identified missing contextual information, particularly around when and where the trial was conducted. Although the item '*Trial setting'* had not been retained following the Delphi process as it received consistently low ratings in Rounds 1 and 2, pilot participants felt this information was important for interpreting the results. In response, I expanded the participant-related checklist item 'Summary of eligibility criteria' to include both eligibility criteria and trial setting by separating it into two sub-items: a. '*Participant: Key inclusion and exclusion criteria for participation in the trial*' and b. '*Trial setting: When and where the trial was conducted*'.

Some participants commented on the order of items in the checklist. The checklist was not intended to prescribe a fixed structure, but rather a logical flow when applying it. In response, I clarified within the checklist itself and the E&E (Chapter 7) that items can be reordered when writing summaries. Minor adjustments were also made to improve flow,

including swapping the order of the items *'Summary of eligibility criteria'* and '*Interventions'* to better reflect how summaries are typically structured.

Finally, refinements were made to improve clarity and completeness, including updating the item *'Number of participants'* to distinguish between the number included in the trial and the number analysed.

Regarding the different checklist formats, participants expressed varying preferences between the concise version and the merged version (which combined the concise checklist with expanded 'Lay header' guidance). These differences appeared to reflect individual preferences and levels of familiarity with PLS writing. Participants who were more comfortable working with concise reporting tools tended to favour the concise version because of its brevity and ease of use, particularly when working within word limits.

"I used the original simple version (v0.3). I chose this because it was concise and easy to follow within the 300-word limit." (Participant 11)

In contrast, many participants preferred the merged version because the additional prompts and question-and-answer format provided clearer guidance on communicating information in plain language.

"I have chosen the 'merged version'. I liked the simplicity and the question-and-answer format as it guides/reminds the writer to write in a very 'lay person' manner and by crafting the response based on the questions the writer is more likely to achieve this." (Participant 5)

As both formats addressed different user preferences, I retained the concise checklist alongside the merged version (hereafter referred to as the 'Expanded checklist'). This approach is consistent with reporting guidelines such as CONSORT, [62] which provide both a concise checklist and an expanded checklist to support users with different levels of experience and detail.

6.3.3 Phase 3: Readability and accessibility testing with patient and public representatives

I invited five PPI representatives to review the summaries written using the checklist during phase 2. Participants were all over 56 years old (Table 6.7). All but one participant was female. All of them had prior experience with plain language summaries.

Table 6.7: Participant demographics: Phase 3

ID	Age range	Sex	Lived experience/expertise/special interest:	Prior experience with PLSs
1	65+	Female	Expertise: Chartered psychologist	Yes
2	56-65	Female	Lived experience: Oesophageal cancer and atrial fibrillation	Yes
3	65+	Female	Expertise: Plain language advocate, English language specialist	Yes
4	65+	Female	Lived experience: Various conditions, including Type 2 Diabetes	Yes
5	65+	Male	Lived experience: Chronic pain; patient advocate	Yes

Feedback from PPI representatives

PPI representatives provided detailed feedback on both the readability of the pilot summaries and the content of the checklist. Overall, participants found the summaries generally clear, relevant, and understandable, particularly where plain language explanations

and structured headings were used. Participants identified some areas where the checklist could be strengthened. One recurring theme was the need to include information about funding sources or sponsor details. One participant noted:

"As a PWLE [People with lived experience] reader, knowing who paid for and who wrote a summary changes how I weigh it." (PPI participant 5)

In response to this feedback, I revised the item '*Further information*' to include: '*More information about the trial (e.g., trial registration, sources of funding, trial website link) or where related resources can be found.'*

PPI participants also commented on the item '*Strengths and limitations'* and suggested stronger emphasis on reporting generalisability and applicability of findings. Participants highlighted that demographic information alone may not help readers understand whether findings apply to them personally. In response, I provided additional guidance and examples within the E&E (Chapter 7). However, I decided not to expand the *'Strength and limitations'* item further within the checklist itself, as the purpose of the checklist is to support transparent reporting rather than provide personalised interpretation of findings. Over-specifying applicability criteria may also make reporting impractical, particularly where evidence is limited, and interpretation of clinical relevance would still require discussion between patients and healthcare professionals.

Some participants also suggested additional items to be included in the checklist, such as economic evaluation of trial findings and whether patients or members of the public contributed to writing or reviewing the summary. However, the economic evaluation item

had previously been considered during the Delphi process and did not reach consensus for inclusion. Regarding public involvement in summary development, I considered this to be covered within the item '*Patient and public involvement and engagement in the design and delivery of the trial'.*

Many comments related to writing style, structure, and presentation rather than checklist content itself. Participants suggested using clearer headings, bullet points, shorter sentences, stronger signposting within conclusions, and additional explanations of technical concepts and study methods. Others highlighted the importance of helping readers interpret numerical findings and tables, rather than simply presenting data. These comments informed the development of the E&E (Chapter 7). One participant suggested the inclusion of an audience-focused matrix to help users identify which checklist items may be most applicable across different summary formats and audiences. I therefore developed a matrix to guide authors on item applicability as an additional feature within the E&E (Chapter 7).

Similarly to the user testing, some comments highlighted information that participants expected to see in the summaries but which was unavailable in the original trial publications used during pilot testing, such as ethnicity data and patient involvement in trial design. These observations were considered limitations of the source materials and the pilot testing setup rather than deficiencies of the checklist itself. Nevertheless, they reinforced the importance of transparency when information is unavailable.

6.3.4 Use of AI

I asked ChatGPT to write PLSs using the checklist. I observed that prompt wording influenced the extent to which checklist items were incorporated. More specific prompts, particularly those emphasising inclusion of “all essential checklist items,” generally produced more complete summaries, whereas shorter prompts sometimes omitted contextual or methodological details. I also noticed that ChatGPT tended to omit or oversimplify items like limitations, uncertainty, or advisory statements.

This exercise demonstrated the potential utility of the checklist as a structured framework to guide AI-assisted drafting of lay summaries. For example, users could use prompts such as *“Can GPT help me write a PLS using this checklist?”* to generate an initial draft that can subsequently be reviewed and refined by researchers, patient partners, or medical writers. Human oversight will remain essential to ensure that AI-generated lay summaries are accurate, understandable, and appropriately tailored to the intended audience. [190] The exercise also highlighted the importance of prompt engineering, where small modifications in wording may substantially affect the quality and completeness of outputs.

To illustrate these findings, below I present an example summary generated by ChatGPT. This is followed by an assessment highlighting limitations, use of technical language, areas requiring human judgement, and opportunities for refinement of the summary.

Example 1: PLS of trial results produced by ChatGPT.

Prompt: *Write a plain language summary of this trial results report using the checklist within 300 words. (A link to the trial publication was provided and the checklist was uploaded to the system)*

Output summary is presented in Table 6.8.

Table 6.8: AI generated plain language summary

AI-generated text[1]
Background and Objective This study looked at whether eating two larger meals per day (breakfast and lunch) is more effective than eating six smaller meals per day for people with type 2 diabetes who are following *a calorie-restricted diet*[2]. The main goal was to compare the effects on body weight, liver fat, blood sugar control, insulin sensitivity, and *pancreatic beta-cell function*[2]. **Methods** Participants were randomly assigned to follow both eating patterns in a *crossover design*[2]. Each eating pattern lasted 12 weeks and provided the same number of calories and similar *nutrient content*[2,4]. Eligible participants were adults aged 30–70 years with type 2 diabetes treated with oral diabetes medications, a body mass index (BMI) of 27–50 kg/m², and HbA1c levels between 6% and 11.8%.[3] The study was done in Prague, Czech Republic. **Results** A total of 54 participants (men and women) were included in the analysis.[5] Both meal patterns led to weight loss and improvements in metabolic health. However, the two-meal regimen resulted in greater reductions in body weight, liver fat, fasting blood glucose, *C-peptide, and glucagon levels*[2], and greater improvements in insulin sensitivity than the six-meal regimen. No adverse events or important side effects were reported. **Conclusion and Interpretation** The findings suggest that, for people with type 2 diabetes following a calorie-restricted diet, eating a larger breakfast and lunch may provide greater health benefits than spreading the same calories across six smaller meals. These results may help inform dietary advice for diabetes management, although larger studies are needed to confirm the findings.[3] **Strengths and Limitations** Strengths include the randomised crossover design and detailed metabolic measurements. Limitations include the relatively small sample size, single-centre setting, short follow-up period, and inclusion only of people using oral diabetes medications, which may limit generalisability.[3] **Additional Information** Thank you to all participants for taking part in this research. The publication does not report patient or public involvement in study design, nor any plans for long-term follow-up.[6] The findings challenge the common recommendation of eating many small meals and add to evidence supporting meal timing as an important factor in diabetes management.[3] Readers should consult their healthcare provider before making changes to their diet or diabetes treatment. More information is available in the published study and ClinicalTrials.gov record (NCT01277471).

Annotations are indicated using superscript numbers within the summary and correspond to the explanations below.

1. The summary is 375 words, which exceeds the 300 word limit given.
2. Many jargon terms are used without explanation (*italicised*).
3. In many instances, language is not easy to understand.
4. Some important information, such as a clear description of the intervention in the methods section, was not presented. The method section could instead read:

   'Participants were in the study for 24 weeks. For 12 weeks, they followed either a six-meal pattern (three meals and three snacks) or a two-meal pattern consisting of breakfast and lunch eaten earlier in the day. They then switched to the other pattern for a further 12 weeks. Both diets provided the same total calories and nutrients.'

5. GPT omitted item 6: *Demographics*, which provides important context for patients. The gender and age breakdown could readily have been included in the results section during human review:

   'Fifty-four adults with type 2 diabetes took part, including 29 men and 25 women aged 30 to 70 years.'

6. The statement 'The publication does not report patient or public involvement in study design, nor any plans for long-term follow-up.' (Additional information) should not have been included in the summary output.

Overall, ChatGPT produced a reasonable first draft and included most of the checklist items. However, it would require considerable human review before it could be shared with patients and the public.

6.3.5 Refinement and finalisation of the checklist

After careful consideration of the pilot testing feedback and consolidating the revisions, I finalised two versions of the reporting guideline checklist: 1. Concise checklist 2. Expanded checklist. The final versions of the checklist are presented in Chapter 7, alongside the E&E guidance. Table 6.9 summarises the revisions made to individual checklist items following pilot testing.

Table 6.9: Summary of checklist revisions following pilot testing

Checklist item	Summary of feedback (across phases)	Action
Essential items		
Item 1. Objective: Main objective of the trial	No major issues	Swap order with item 2
Item 2. Health condition or area of focus: Description of the health condition or broader area addressed by the trial	No major issues	Swap order with item 1
Item 3. Interventions: Interventions for each group and what they were compared with	No major issues	Swap order with item 4
Item 4. Summary of eligibility criteria: Key inclusion and exclusion criteria for participation in the trial	More information about the trial setting is needed. Item is revised and expanded.	Swap order with item 3 Item revised to Item 3 Participants: • 3a. Summary of eligibility criteria • 3b. Settings: when and where the trial was conducted
Item 5. Number of participants: Number of participants included in the trial	Item is revised to include number analysed in the trial	Item revised to: Item 5: Number of participants: Number of participants included in the trial and number of participants analysed
Item 6. Demographics: Key participant demographics (e.g., age, ethnicity, sex, and/or gender)	No major issues. Provide detailed guidance in E&E for	No changes in the checklist

	meaningful reporting.	
Item 7. Main findings: Summary of the primary outcome results of the trial	No major issues	No changes in the checklist
Item 8. Side effects: Any important adverse (or unexpected) events experienced by trial participants	Item name needs to be revised for technical accuracy. Provide detailed guidance in E&E for meaningful reporting.	Item revised to: Item 8. Adverse events: Any important adverse (or unexpected) events experienced by trial participants
Item 9. Interpretation: Interpretation of the trial results, noting potential clinical implications	No major issues	No changes in the checklist
Item 10. Strengths and limitations: Strengths and limitations of the trial, including factors that may influence the interpretation or generalisability of the results	No major issues. Provide detailed guidance in E&E for meaningful reporting.	No changes in the checklist
Additional items		
Item 11. Trial participants: Thank participants for taking part in the trial	No major issues	No changes in the checklist
Item 12. Patient and public involvement and engagement: Whether and how patients and/or the public helped in the design and delivery of the trial	No major issues	No changes in the checklist
Item 13. Follow-up plan: Any plans for long-term follow-up of trial participants after the trial has ended	No major issues	No changes in the checklist
Item 14. Existing research: How the trial results compare with existing evidence (e.g., systematic reviews and other trials)	No major issues	No changes in the checklist
Item 15. Next steps: Next steps for the trial (e.g., publication, licensing of the medicine or treatment, or integration into healthcare policy)	No major issues	No changes in the checklist
Item 16. Advisory statement: Statement advising the reader to consult their healthcare provider	No major issues	No changes in the checklist

before making any changes to their treatment based on the trial results		
Item 17. Further information Where more information about the trial results or related resources can be found	Item revised to include funder/sponsor details.	Item revised to: Item 17. Further information: More information about the trial (e.g., trial registration, sources of funding, trial website link) or where related resources can be found

6.4 Discussion

Pilot testing provided important evidence to support refinement of the checklist and demonstrated how the guidance functions in practice across different user groups and contexts. I incorporated multiple complementary approaches, including independent user testing, real-time testing by trial teams, cognitive interviews, testing with existing PLSs, PPI feedback, and an exploratory AI proof-of-concept exercise. Together, these approaches enabled identification of practical issues and a formal evaluation of the checklist.

Evaluation methods may serve either a verifying or troubleshooting function. [222] Verifying approaches aim to provide overall judgements about quality and are generally quantitative, whereas troubleshooting approaches seek to identify specific user problems through qualitative and exploratory methods. [222] The pilot testing served both functions, examining how users interpreted checklist items, where misunderstandings or implementation difficulties occurred, and whether the checklist could realistically support the development of useful lay summaries.

Participants highlighted areas where terminology was unclear, instructions were too broad or overly prescriptive, and additional examples or explanations were needed. This process identified ambiguities that may not have emerged through quantitative feedback alone and

informed refinements to item wording, structure, and supporting guidance. Where participants requested greater specificity about the level of detail to report, I avoided prescribing fixed requirements that may not apply across trials. Instead, I incorporated further clarification and examples into the E&E (Chapter 7), while allowing trial teams to use clinical judgement and PPI input according to the trial, audience, and practical constraints.

Cognitive interviews were particularly valuable for exploring understanding, interpretation, and wording issues associated with individual checklist items. Using publicly available trial reports (Appendix 6.5) also made the pilot process transparent and potentially replicable, enabling future researchers to test or compare the checklist using the same materials. The exercise also identified instances where checklist expectations were difficult to meet because the source summary or publicly available trial report lacked sufficient detail. I considered this a limitation of the hypothetical pilot testing setup rather than the checklist itself, as trial teams in real-world settings would typically have access to the full study data and reporting materials.

Real-time testing with trial teams preparing or reviewing patient-facing summaries provided further insight into feasibility and applicability. Unlike retrospective testing using published summaries, this approach allowed me to examine how the checklist was used during summary development and highlighted practical considerations such as word limits and applicability of individual items, and identified areas where additional guidance or clarification was needed. It also demonstrated how the checklist could function as a practical writing aid integrated into the summary development process. This real-time application

highlighted operational considerations that may not emerge through hypothetical exercises alone.

PPI feedback was essential in ensuring that the checklist supported the development of summaries that are understandable, relevant, and meaningful for patients and the public, rather than simply satisfying academic or professional expectations. PPI representatives provided perspectives on readability and clarity that differed in important ways from researcher-focused feedback, strengthening the checklist's practical relevance for its intended audience.

Pilot testing also highlighted that users may benefit from different checklist versions or formats depending on their experience and writing context. Some participants preferred the concise checklist because it was easier to apply within strict word limits, while others favoured the expanded version containing additional prompts and explanatory guidance. These findings suggest that flexibility in presentation may improve usability across different contexts. A concise checklist may suit experienced writers familiar with lay communication principles, whereas expanded guidance may better support novice users or multidisciplinary teams less experienced in writing for public audiences.

The exploratory AI exercise demonstrated another potential application of the checklist as a practical assessment and drafting framework. This exercise was intentionally presented as a proof of concept rather than a formal evaluation of AI-generated summaries. The aim was to explore whether a generative AI tool could use the checklist to produce a PLS. The exercise illustrated that AI-generated summaries remain dependent on several factors, including the

quality and clarity of underlying trial reporting, human-defined standards for what information should be included, and careful oversight to ensure accuracy, transparency, and trustworthiness for patient audiences. In this context, the checklist provides the foundational content framework that both AI tools and human writers could follow. No conclusions can be drawn regarding the performance, reliability, or superiority of AI-generated summaries from this exercise, and the findings are not generalisable. Future studies could explore whether AI tools can consistently generate summaries that adhere to the checklist, how patients and the public perceive AI-generated compared with human-written summaries, and the role of co-production and human oversight when AI tools are used in PLS development.

Overall, pilot testing provided important insight into how the checklist performed in practice and highlighted areas where further refinement was needed. Quantitative ratings indicated that the checklist was generally clear, usable, and acceptable, while qualitative feedback directly informed revisions to item wording, organisation, and explanatory guidance.

Reflecting on this process, pilot testing was not simply a final validation step, but an essential stage in shaping the checklist into a practical and usable tool. It enabled me to move beyond the theoretical agreement achieved during earlier development phases and better understand how the checklist was interpreted and applied by intended users, as well as how resulting summaries were received by patients and the public. The final version of the checklist therefore reflects not only evidence generated through the scoping review, qualitative study, and Delphi consensus process, but also practical considerations identified

through real-world application and user feedback. I present the final versions of the checklist alongside accompanying E&E guidance in the next chapter (Chapter 7).

Chapter 7: Final reporting guideline checklist and accompanying Explanation and Elaboration (E&E) guidance

7.1 Introduction

In this chapter, I present the final reporting guideline resulting from the development and pilot testing described in the previous chapters. I present two versions of the checklist that include the same items but different amounts of descriptive information: a **concise checklist**, containing only the reporting items, and an **expanded checklist**, which includes additional prompts and explanatory guidance. I then present the accompanying E&E guidance, developed alongside the reporting guideline to support understanding and implementation of the checklist items.

The E&E aims to support the use, understanding, and consistent application of the reporting guideline. It aims to help authors prepare clearer, more complete, and more transparent reports of randomised trial results for patients and the public. The E&E was informed by evidence and feedback gathered throughout the development process. This included notes and observations from the qualitative interviews and focus groups (Chapter 3), comments and suggestions from the Delphi survey (Chapter 4), discussions during the consensus meeting (Chapter 5), feedback from pilot testing (Chapter 6), and established literature where available. Pilot testing was particularly valuable in identifying checklist items that users found difficult to interpret or report. For example, participants highlighted challenges in reporting strengths and limitations in a balanced and responsible way without introducing

"spin". [223] These findings helped identify where further guidance and examples were needed, while retaining flexibility for different trials, audiences, and contexts.

Rationale for developing E&E guidance

A reporting guideline provides recommendations about the minimum information that should be included when reporting a research study. [64] However, a checklist alone may not always be sufficient to help users understand exactly what information should be reported or how items should be interpreted in practice. Some checklist items can be broad or open to interpretation, particularly for authors who are unfamiliar with reporting guidelines. Writers may also experience difficulties when writing results reports for a diverse group of audience such as patients, participants, carers, and members of the public. E&E documents are designed to address this problem by providing additional guidance alongside the checklist. They explain why each item is important, provide the scientific or methodological rationale for its inclusion, and give practical examples of good reporting from published studies. [66, 68]

Moher et al. emphasised the importance of developing an E&E document alongside the reporting guideline itself, arguing that simply presenting a checklist may appear overly brief or unsupported without detailed explanation and rationale. [66] Leading reporting guideline initiatives such as CONSORT and PRISMA strongly recommend using the E&E document alongside the checklist statement. [62, 74, 106, 107] Developing and publishing an E&E simultaneously alongside the reporting guideline is recommended to explain checklist items and provide examples of good reporting, which will enhance the usability of the reporting guideline. [66, 68]

E&E guidance can help improve understanding and use of reporting guidelines by reducing confusion, supporting more consistent interpretation of checklist items, and helping authors apply reporting recommendations more effectively. [62, 66] They can also support peer reviewers and journal editors by promoting more standardised interpretation of reporting requirements.

I aimed to develop the E&E alongside the reporting guideline rather than as a later stage of the project. Developing both documents simultaneously allowed insights from consensus discussions and pilot testing to directly inform the guidance and examples included within the E&E. This approach also helped ensure that the reporting guideline was ready for dissemination and practical use following completion of the development process.

7.2 Final reporting guideline checklist: items to include when sharing results of randomised trials with patients and the public

This checklist has been developed to guide reporting of results of randomised trials to trial participants, patients, and the public. It supports the preparation of PLSs across a range of formats, such as feedback letters to participants, summaries published on trial or organisational websites, summaries published in journals, result summaries posted on trial registries, and other public-facing materials (for example leaflets, infographics, blogs, or short reports). Information can be presented in text, tables, figures, or other suitable formats, and does not need to be confined to a single section. The checklist is not designed to guide the writing of a full scientific article but complements existing reporting guidelines

such as CONSORT by focusing specifically on the patient- and public-facing communication of trial results. [62]

The checklist includes ten essential items and seven additional items and is organised into two sections. The checklist follows a logical reporting sequence but does not prescribe the structure or order of the final summary. Authors may present the information in a different order, depending on the reporting format and intended audience. Users are encouraged to consult the explanation and elaboration guidance alongside this checklist for further detail on the rationale, scope, and use of the items. There are two versions of the checklist: 1. Concise checklist and 2. Expanded checklist, which are described below.

7.2.1 Concise checklist

Essential items

The ten essential items represent the minimum reporting requirements and should be included in all summaries of trial results, regardless of audience or format, to support transparency, completeness, and clear communication(Table 7.1). The items are not prioritised or ranked; they are presented in a logical sequence to guide reporting.

Table 7.1: Concise checklist: Essential items

Theme/item	No	Checklist item description	Reported (Y/N)
Background			
Health condition or area of focus	1	Description of the health condition or broader area addressed by the trial	_____
Objective	2	Main objective of the trial	_____
Methods			
Participants	3a	Summary of eligibility criteria: Key inclusion and exclusion criteria for participation in the trial	_____
	3b	Settings: When and where the trial was conducted	
Interventions	4	Interventions for each group and what they were compared with	_____
Results			
Number of participants	5	Number of participants included in the trial and number of participants analysed	_____
Demographics	6	Key participant demographics (e.g., age, ethnicity, sex, and/or gender)	_____
Main findings	7	Summary of the primary outcome results of the trial	_____
Adverse events	8	Any important adverse (or unexpected) events experienced by trial participants	_____
Conclusion			
Interpretation	9	Interpretation of the trial results, noting potential clinical implications	_____
Strengths and limitations	10	Strengths and limitations of the trial, including factors that may influence the interpretation or generalisability of the results	_____

Additional items (where applicable)

The additional items should be included where relevant and feasible, considering the needs of the intended audience and any constraints such as word limits (Table 7.2). While these items are strongly recommended for participant-facing materials, they add valuable context to other public summaries, such as journal PLSs, website content, or reports for regulatory organisations where word limits and format allow.

Some items apply only in certain situations (for example, when long-term follow-up is planned), so authors should consider including each item wherever it is relevant and feasible, while recognising that not all items will be appropriate or possible in every format. For journal publications, inclusion may be constrained by word limits, so authors should prioritise the items that are most relevant to their intended audience while maintaining transparency.

Table 7.2: Concise checklist: Additional items

Theme/item	No	Checklist item description	Applicability (Who/where this may be relevant)	Reported (Y/N)
Thank you				
Trial participants	11	Thank participants for taking part in the trial	Trial participants, Trial/sponsor websites	_____
Methods				
Patient and public involvement and engagement	12	Whether and how patients and/or the public helped in the design and delivery of the trial	Trial participants, Members of the public, Trial/sponsor website, Journal PLS	_____
Results				
Follow-up plan	13	Any plans for long-term follow-up of trial participants after the trial has ended	Trial participants, Trial/sponsor website	_____
Conclusion				
Existing research	14	How the trial results compare with existing evidence (e.g., systematic reviews and other trials)	Trial participants, Members of the public, Trial/sponsor website, Journal PLS, Trial registry, Regulatory agency report	_____
Next steps	15	Next steps for the trial (e.g., publication, licensing of the medicine or treatment, or integration into healthcare policy)	Trial participants, Members of the public, Trial/sponsor website, Journal PLS, Trial registry, Regulatory agency report	
Discussing the trial results with healthcare providers				
Advisory statement	16	Statement advising the reader to consult their healthcare provider before making any changes to their treatment based on the trial results	Trial participants, Members of the public, Trial/sponsor website	_____
Additional information				
Further information	17	More information about the trial (e.g., trial registration, sources of funding, trial website link) or where related resources can be found	Trial participants, Members of the public, Trial/sponsor website	_____

7.2.2 Expanded checklist

The expanded checklist contains the same reporting items as the concise checklist but includes brief prompts and key implementation guidance alongside each item. It is intended as a practical alternative to the concise checklist, allowing users to access the most important explanatory information without needing to refer to the full E&E guidance. Users seeking more detailed rationale, worked examples, or further guidance should refer to the E&E.

Essential items

The ten essential items represent the minimum reporting requirements and should be included in all summaries of trial results, regardless of audience or format, to support transparency, completeness, and clear communication (Table 7.3). The items are not prioritised or ranked; they are presented in a logical sequence to guide reporting.

Instructions for use:

If word limit is not an issue, consider presenting the results in a **question-and-answer format**, using the **lay headers** as section titles or guiding questions. While this is optional, it can help make the summary more engaging and easier to follow for patients and the public, while ensuring all key information is clearly addressed.

Table 7.3: Expanded checklist: Essential items

Theme/item	No	Checklist item description	Reported (Y/N)
Background			
Health condition or area of focus	1	Description of the health condition or broader area addressed by the trial **Lay header:** *What did we study*? • Provide a brief description of the condition, disease, or health issue addressed by the trial, including why it is important to patients or the public.	
Objective	2	Main objective of the trial **Lay header:** *What did we want to find out?* • State, in plain language, the main question the trial aimed to answer.	
Methods			
Participants	3a	Summary of eligibility criteria: Key inclusion and exclusion criteria for participation in the trial **Lay header:** *Who could take part in the trial?* • Summarise who could and could not take part, highlighting the main criteria e.g., age range, clinical diagnosis, or key health factors. You do not need to list every inclusion or exclusion criterion. Include only those most relevant for understanding who the trial results apply to.	
	3b	Settings: When and where the trial was conducted **Lay header:** *When and where did the trial take place?* • Summarise when and where the trial took place, including the countries and healthcare settings involved.	
Interventions	4	Interventions for each group and what they were compared with **Lay header:** *What did we do?* • Describe what treatments, tests, or actions participants received in each group and what these were compared against. • Focus on the essential features that distinguish the experimental intervention from the comparison.	
Results			
Number of participants	5	Number of participants included in the trial and number of participants analysed **Lay header:** *How many people took part?* • Report the number of participants included in the trial or analysis, and, where relevant, how many were in each group.	
Demographics	6	Key participant demographics (e.g., age, ethnicity, sex, and/or gender)	

		Lay header: *Who were the participants?* • At minimum, age, ethnicity, sex, and/or gender should be reported where collected. • If additional diversity data were collected (e.g., income, socio-economic status, language, or other relevant factors), report those as well.
Main findings	7	Summary of the primary outcome results of the trial **Lay header:** *What did we find out?* • Summarise the main results for the primary outcome of the trial. • Focus on what the results mean for patients (e.g., whether the new treatment worked better, the same, or worse than the comparison). • Avoid technical or statistical terms and use clear comparisons.
Adverse events	8	Any important adverse (or unexpected) events experienced by trial participants **Lay header:** *Were there any side effects?* • Summarise the main or frequent adverse events and refer readers to further guidance if applicable. • Clarify how common or serious they were using language understandable to non-specialists. • If no adverse events were identified, this should be stated.
Conclusion		
Interpretation	9	Interpretation of the trial results, noting potential clinical implications **Lay header:** *What do the results mean?* • Briefly explain what the results mean in real-world terms. • Provide a balanced interpretation of the findings, relating them to possible clinical relevance without exaggeration.
Strengths and limitations	10	Strengths and limitations of the trial, including factors that may influence the interpretation or generalisability of the results **Lay header:** *How confident can we be in these results?* Or *how could we have improved this research?* • Acknowledge key strengths (e.g., large sample size or diverse participants) and limitations (e.g., short duration or small numbers) to help readers interpret the findings appropriately. • Explain how relevant the findings are to the broader patient population or real-world settings. • Avoid overstating the generalisability of the findings to prevent misleading conclusions.

Additional items (where applicable)

The additional items should be included where relevant and feasible, considering the needs of the intended audience and any constraints such as word limits (Table 7.4). While these items are strongly recommended for participant-facing materials, they add valuable context to other public summaries, such as journal PLSs, website content, or reports for regulatory organisations where word limits and format allow.

Some items apply only in certain situations (for example, when long-term follow-up is planned), so authors should consider including each item wherever it is relevant and feasible, while recognising that not all items will be appropriate or possible in every format. For journal publications, inclusion may be constrained by word limits, so authors should prioritise the items that are most relevant to their intended audience while maintaining transparency.

Instructions for use:

If word limit is not an issue, consider presenting the results in a **question-and-answer format**, using the **lay headers** as section titles or guiding questions. While this is optional, it can help make the summary more engaging and easier to follow for patients and the public, while ensuring all key information is clearly addressed.

Table 7.4: Expanded checklist: Additional items

Theme/item	No	Checklist item description	Applicability (Who/where this may be relevant)	Reported (Y/N)
Thank you				
Trial participants	11	Thank participants for taking part in the trial **Lay header:** *Thank you!* • Acknowledge and thank the trial participants for their time and contribution.	Trial participants, Trial/sponsor websites	
Methods				
Patient and public involvement and engagement	12	Whether and how patients and/or the public helped in the design and delivery of the trial **Lay header:** *What patient and public involvement was there in the trial?* • Briefly report whether patients and / or the public were involved in the design or conduct of the trial, and describe their role (e.g., reviewing trial materials or advising on recruitment).	Trial participants, Members of the public, Trial/sponsor websites, Journal PLS	
Results				
Follow-up plan	13	Any plans for long-term follow-up of trial participants after the trial has ended **Lay header:** *Will there be any follow-up?* • Explain whether participants will be followed up after the trial, for how long, and what this means for them.	Trial participants, Trial/sponsor website	
Conclusion				
Existing research	14	How the trial results compare with existing evidence (e.g., systematic reviews and other trials) **Lay header:** *How do these results compare with other research?* • Summarise how the trial findings relate to previous studies or what is already known about the topic. • Highlight whether the results support, contradict, or add new insights compared with existing evidence, without going into exhaustive detail.	Trial participants, Members of the public, Trial/sponsor website, Journal PLS, Trial registry, Regulatory agency report	
Next steps	15	Next steps for the trial (e.g., publication, licensing of medicine or treatment, or integration into healthcare policy) **Lay header:** *What happens next?*	Trial participants, Members of the public, Trial/sponsor website, Journal	

		• Briefly describe any activities following the trial, if planned or known. • This could include publication of results, further research, regulatory review, or potential changes in healthcare practice or policy.	PLS, Trial registry, Regulatory agency report
Discussing the trial results with healthcare providers			
Advisory statement	16	Statement advising the reader to consult their healthcare provider before making any changes to their treatment based on the trial results **Lay header:** *Discussing the trial results with your doctor* • Include a short statement advising readers not to alter their treatment plan based on the trial results without consulting their healthcare provider first. • If possible, provide guidance on questions they may wish to discuss with their doctor.	Trial participants, Members of the public, Trial/sponsor website
Additional information			
Further information	17	More information about the trial (e.g., trial registration, sources of funding, trial website link) or where related resources can be found **Lay header:** *Where can you find more information?* • Provide clear directions on where readers can learn more (e.g., links to websites, trial registries, or contact details for investigators).	Trial participants, Members of the public, Trial/sponsor website

7.3 Explanation and elaboration

I developed the E&E following the structure used in explanatory papers for reporting guidelines such as CONSORT and CONSORT for Abstracts. [107, 196] For each checklist item, I present the item, provide an explanation describing the rationale for including the item and, where possible, discuss the evidence for the item, guidance on how it can be reported, and include examples of good reporting. The guidance presented here draws on findings from the scoping review, qualitative study, Delphi survey, consensus meeting, pilot testing (Chapters 2-6), and established literature.

7.3.1 General guidance for reporting trial results to patients and the public

Throughout the development process, participants highlighted that good communication of trial results depends not only on *what* information is reported, but also *how* it is presented. A substantial proportion of feedback related to writing style, structure, readability, and interpretation rather than the checklist items themselves. Participants emphasised the importance of using:

- clear headings,
- shorter sentences and shorter words,
- bullet points,
- plain language,
- stronger signposting within summaries, particularly in sections explaining conclusions or key findings.

Participants also noted that technical concepts, study methods, and statistical terms often require additional explanation when reporting to patient and public audiences and that simply presenting numerical findings or tables is often insufficient. Readers may need support interpreting what the results mean in practice, including understanding the size, importance, uncertainty, and relevance of findings.

Participants also highlighted the importance of maintaining consistency between different reporting formats. For example, shorter summaries should accurately reflect the findings and context presented in longer reports and should not omit important information or soften negative findings. This is particularly relevant where trial results may be communicated across multiple formats and audiences, including trial participants, public websites, journal summaries, trial registries, and regulatory reports.

Audience applicability matrix

Not all additional items will apply equally across all reporting formats or audiences. Different audiences may require different levels of detail, language, or presentation depending on the context. To support practical use of the reporting guideline, I developed an audience applicability matrix as a quick visual guide to help authors identify which checklist items are most relevant for different audiences and reporting formats (Table 7.5).

Table 7.5: Audience-applicability matrix

Checklist item	Trial participants	Members of the public	Trial/sponsor website	Journal PLS	Result posted on trial registry	Result posted on regulatory report
Item 11. Thank you	✓	Optional	✓	Optional	Optional	×
Item 12. Patient and public involvement and engagement	✓	✓	✓	✓	Optional	Optional
Item 13. Follow-up plan	✓	×	✓	×	Optional	Optional
Item 14. Existing research	✓	✓	✓	✓	✓	✓
Item 15. Next steps	✓	✓	✓	✓	✓	✓
Item 16. Advisory statement	✓	✓	✓	Optional	×	×
Item 17. Further information	✓	✓	✓	×	×	×

Communicating uncertainty and avoiding spin

Participants involved in the consensus meeting and pilot testing of this guideline consistently emphasised the importance of balanced and trustworthy communication of trial results. When reporting findings, authors should avoid "spin", language that overstates the certainty, importance, or applicability of the results. [136, 138] Instead, they should use neutral non-promotional language that accurately reflects the evidence, acknowledges uncertainty where appropriate, and avoids making recommendations that are not supported by the study findings. [118, 223] Table 7.6 provides examples of language that can help authors communicate results clearly while avoiding unintentional spin.

Table 7.6: Examples of language for communicating uncertainty and avoiding spin

Use when describing...	**Preferred wording**	**Avoid**
Findings	suggests, may reduce, may improve, was associated with Example: *"These results suggest that the treatment may help reduce symptoms."*	proves, demonstrates, works, was effective Example: *"The treatment was effective in reducing symptoms."*
Implications	could help inform, may be relevant to, has potential to Example: *"If confirmed in larger studies, this could help inform future care decisions."*	will change practice, should be used, confirms benefit Example: *"Clinicians should start using this treatment."*
Uncertainty	results should be interpreted with caution, further research is needed Example: *"The study was small, so the findings should be interpreted with caution."*	definitively shows, confirms, provides clear evidence Example: *"The study shows clear evidence that…"*
Policy relevance	may inform future discussions, could contribute to future policy Example: *"These findings may be useful for discussions about healthcare priorities."*	requires policy change, shows that change is needed Example: *"This study proves the need for new policy."*

7.3.2 Explanation and elaboration

The explanation and elaboration guidance is organised into two sections. The first presents guidance for the ten essential checklist items, which represent the minimum information that should be included when communicating trial results to patients and the public. The second presents the seven additional items, which provide supplementary information that may be included where relevant or feasible.

Essential items

Essential item 1. Health condition or area of focus: Description of the health condition or broader area addressed by the trial

Lay header: *What did we study?*

Explanation

A brief description of the condition, disease, or health issue being studied helps readers understand the purpose and relevance of the trial before the results are presented. [224] Patients and the public come to research with varying levels of health literacy. A foundational description establishes why the trial was necessary and what specific health challenge it aimed to address. Authors should briefly describe the condition in plain language and explain why it matters to patients, the public, or healthcare. [141, 225]

Rather than just naming a diagnosis, the description should capture how the condition affects people or healthcare delivery, ensuring the societal or personal value of the research is clear from the outset. Technical medical terms should either be avoided or immediately paired with a plain-language definition. [136]

Example

"Ovarian cancer is the name for cancer that originates in the ovary, which is the female reproductive organ that produces eggs and sex hormones. Ovarian cancer is a major cause of cancer death in women. Epithelial ovarian cancer is the most common type of ovarian cancer, and it originates in the cells that cover the outer surface of the ovary.

Researchers are looking for treatments for ovarian cancer. Avelumab is a medicine that may work by targeting a protein called "Programmed Death-Ligand 1" (PD-L1) found on the cancer cell. PD-L1 is involved in the body's immune system response to cancer." [218]

Essential item 2: Objective: Main objective of the trial

Lay header: *What did we want to find out?*

Explanation

This item refers to the trial's main objective, that is, the primary objective or main research question the trial was designed to answer. It helps readers understand the purpose of the research and provides context for interpreting the results presented later in the report.

Patients and members of the public may not be familiar with research terminology such as "primary objective" or "primary outcome". Authors should therefore focus on explaining, in plain language, what the researchers wanted to find out and why this question was important. [226] The objective should be specific enough to help readers understand the aim of the trial but should avoid unnecessary methodological or technical detail.

Where word limits allow, authors may briefly explain the rationale for the trial. This involves explaining the current gap in knowledge, such as a complete lack of evidence, conflicting data, or the need to confirm existing findings.

Where appropriate, authors may describe the treatments, interventions, or approaches being compared and the outcome of interest. If more than one objective is addressed, the primary objective (i.e., based on the prespecified primary outcome) should be indicated so that it is consistent with the results reported later in the summary. [136, 196]

Example

"For women with newly diagnosed advanced ovarian cancer, the standard treatment includes a combination of chemotherapy and surgery. Chemotherapy is often used after surgery to kill any cancer cells that might remain. It can also be used before surgery. This approach is usually effective, but in many cases the cancer comes back. The main goal of this study was to determine if adding a new drug (avelumab) both during and/or after standard chemotherapy treatment would increase the amount of time it takes for ovarian cancer to worsen (progress). The study also evaluated the overall safety of avelumab alone or in combination with standard chemotherapy." [218]

Essential item 3a: Summary of eligibility criteria: Key inclusion and exclusion criteria for participation in the trial

Lay header: *Who could take part in the trial?*

Explanation

This item describes who could and could not take part in the trial. It helps readers understand the characteristics of the participants and whether the results may be relevant to themselves, their family members, or other groups of people.

Trial protocols often contain extensive lists of inclusion and exclusion criteria. However, patient-facing summaries should focus on the most important criteria needed to understand who participated in the study. [133, 136] Authors do not need to report every eligibility criterion. Instead, they should highlight key factors such as age range, clinical diagnosis, demographic factors, previous treatments, or other characteristics that influenced who could take part. [135] This context is essential for readers to evaluate the applicability of the findings.

Example

"The study included adult women with advanced epithelial ovarian cancer that had spread beyond the pelvis or throughout the body who had not yet received treatment for their advanced cancer. Patients in this study must have had a surgery to remove as much cancer as possible." [218]

Essential item 3b. Settings: When and where the trial was conducted

Lay header: *When and where did the trial take place?*

Explanation

This item provides context about the setting of the trial. Knowing when and where a study took place can help readers understand the healthcare systems, countries, or clinical settings in which the results were generated. [136] This may help them judge whether the findings are relevant to their own setting or circumstances.

Authors should provide a brief description of the locations where participants were recruited and the time period during which the study was conducted. The level of detail should be appropriate for the reporting format and audience. For example, it may be sufficient to state the countries involved, the type of healthcare setting, and the years during which the trial took place.

Example

"This study took place from November 2009 to November 2021 in the following countries: Australia, Canada, Czech Republic, Israel, New Zealand, Poland, Portugal, Russia, Thailand, United Kingdom, and the United States." [227]

Essential item 4. Interventions: Interventions for each group and what they were compared with

Lay header: *What did we do?*

Explanation

This item describes what interventions participants received during the trial and what these were compared against (e.g., standard care, placebo). It helps readers understand what was being tested and how the comparison was made. [138] Without this information, it can be difficult to interpret the results or understand what the findings mean in practice.

Authors should briefly describe the treatments, tests, procedures, or actions received by participants in each study group. [139] The description should focus on the key features that distinguish the intervention from the comparison group rather than providing detailed

technical information. When describing investigational products and comparators, the language should be non-promotional. [118, 136]

Clear descriptions of the interventions help patients and the public understand what participation involved and what the findings relate to. Where relevant, authors should explain terms such as placebo, standard care, or usual treatment in plain language.

Example

"*Eligible patients were assigned to 1 of 3 treatment groups:*

- *Group A (335 patients): Platinum-based chemotherapy with no maintenance treatment*
- *Group B (332 patients): Platinum-based chemotherapy followed by avelumab maintenance treatment*
- *Group C (331 patients): Platinum-based chemotherapy given together with avelumab, then followed by avelumab maintenance treatment*

Patients were assigned to each group by chance. Putting people into groups by chance is called randomization. This helps make it more likely that the groups will be more even to compare." [218]

Essential item 5. Number of participants: Number of participants included in the trial and number of participants analysed

Lay header: *How many people took part?*

Explanation

This item describes how many people took part in the trial and where relevant, how many participants were analysed. Knowing how many people took part helps readers understand

the scale of the trial and gauge the strength of the evidence. This also provides context for interpreting the findings.

Authors should clearly state the total number of participants enrolled in the trial and how they were distributed across the study groups. Crucially, the summary must also report the number of participants included in the analysis. [133] Discrepancies between the number of people who started a trial and those who finished it can introduce bias or alter the reliability of the conclusions and therefore should be presented clearly. [136] Detailed participant flow information can be reported if appropriate, but readers should be able to understand how many people contributed to the final results.

Example

"A total of 262 patients joined the study, and 145 patients completed the study." [227]

Essential item 6: Demographics: Key participant demographics (e.g., age, ethnicity, sex, and/or gender)

Lay header: *Who were the participants?*

Explanation

This item describes the characteristics of the people who took part in the trial. Information about participant demographics helps readers understand the applicability of the results and who was represented in the research. This information is vital for patients and the public to assess whether the results may be relevant to people like themselves, their families, or their specific communities.

At a minimum, authors should report age, ethnicity, sex, and/or gender of the participants where these data were collected. [138] Depending on the focus of the trial, authors should also highlight other relevant demographic or social characteristics that might influence health outcomes or access to care such as socioeconomic status, education, language, disability, or geographic location. [135]

Authors do not need to report every characteristic collected during the trial. Rather than reproducing an exhaustive baseline characteristics table, they should select the factors most relevant to understanding the study's makeup and who the findings may apply to. [135] All demographic data must be presented using respectful, inclusive, and easy-to-understand language.

Example

"59 patients joined the study and 29 patients completed the study... There were more girls (51%) than boys (49%) in the study. Patient ages ranged from 6 to 19 with an average age of 15 years. Most of the patients were White (88%) and 2% of all patients identified as Hispanic or Latino." [228]

The summary this example is taken from also includes participant breakdown by country of participation and a pie chart illustrating the ethnicity distribution of the trial participants.

Essential item 7. Main findings: Summary of the primary outcome results of the trial

Lay header: *What did we find out?*

Explanation

This item presents the main findings of the trial and should clearly answer the question described in the trial objective. For patients and the public, this is the most critical section of the report because it reveals whether the intervention worked as intended. [140, 225] Clearly explaining the main findings helps readers understand what the study found and why the results are important. [141]

Most trials have several outcomes, such as primary and secondary outcomes. The primary outcome is the pre-specified main outcome that the trial is designed to assess and directly relates to the trial's primary objective. [136, 138] While trials often track numerous secondary outcomes, reporting too many can overwhelm lay summaries and lead readers to place undue emphasis on exploratory findings that may lack statistical power. [136] Authors may choose to present secondary outcomes if they have direct relevance or interest to patients. Where detailed information on trial results is available elsewhere, authors may provide a brief summary and direct readers to additional sources.

Findings should be described in plain language and framed in a way that helps readers understand whether the intervention performed better than, worse than, or similarly to the comparison group. Authors should describe what the results mean for participants rather than simply presenting numbers or statistical results. [141] Technical statistical terms, such as p-values or confidence intervals, are usually unnecessary unless accompanied by a clear explanation. [135]

Where appropriate, numerical results may be included, but these should be presented in a way that supports interpretation rather than requiring readers to interpret the data themselves.

Example

"Did DOR/ISL (100 mg/0.75 mg) work as well as the standard ART to lower the amount of HIV-1 in the body?

Researchers learned that DOR/ISL worked about as well as the standard ART to lower the amount of HIV-1 in the body. To learn this, researchers looked at the number of people whose HIV-1 viral load went down to less than 50 copies at 11 months of treatment. Viral load is the number of copies of a virus in a small amount of blood (1 millilitre or mL). A lower viral load may suggest an ART is working.

The table below shows the number of people who had an HIV-1 viral load of less than 50 copies at 11 months..." [229]

Essential item 8. Adverse events: Any important adverse (or unexpected) events experienced by trial participants

Lay header: *Were there any side effects?*

Explanation:

Most randomised trials have unintended or unexpected events as well as intended and beneficial events. Patients and members of the public need balanced information about both the benefits and harms of a treatment to understand the overall findings of a trial. Information about adverse events is essential for balanced reporting and helps readers weigh the potential risks of an intervention against its benefits. [226]

Authors should summarise the most important or most common adverse events reported during the trial and explain how frequently they occurred. These should be described in plain language, avoiding technical medical terminology where possible and put into context. [139] If no important adverse events were identified, this should be clearly stated. [230] Where detailed information on adverse events is available elsewhere, authors may provide a brief summary and direct readers to additional sources. [133]

The lay header uses the term "*side effects"* because it is familiar to many patients and members of the public as reported during the development process and also in previous guidance documents. [135, 138] Using familiar headers may help readers quickly identify information about potential harms. However, the header is intended as a navigation aid rather than a technical definition. Authors should ensure that the terminology used accurately reflects the data being reported. Where events are not known to be related to the intervention, terms such as "*adverse events"* or "*health problems reported during the trial"* may be more appropriate.

Example

"Side effects are unwanted medical events that were considered by the study doctor to be at least possibly related to the study treatment. A side effect is serious if it leads to death, is life-threatening, puts a patient in the hospital, keeps a patient in the hospital for a long time, or causes a disability that lasts a long time. 5.1% of patients (3 patients) had serious side effects during the study. No patients stopped taking the study treatment because of side effects during the study. No patients died during the study due to serious side effects.

33.9% of patients (20 patients) had side effects during the study. The most common side effect was shingles (painful, blistering rash caused by a virus).” [228]

The summary this example is taken from also includes detailed tables summarising serious side effects and common side effects.

Essential item 9. Interpretation: Interpretation of the trial results, noting potential clinical implications

Lay header: *What do the results mean?*

Explanation:

Patients and members of the public want to understand not only what a trial found, but also what the findings may mean for patients, healthcare, or future research. This is perhaps one of the most important items for patients and the public as it provides an opportunity to place the results in context and explain their potential relevance.

Authors should provide a balanced interpretation of the findings using plain language. A balanced interpretation helps readers understand the significance of the findings while maintaining trust and avoiding misleading or exaggerated conclusions. [223]

The interpretation should reflect the results reported in the trial and avoid overstating their importance or certainty. [225] It should be clear when findings are preliminary, uncertain, or require confirmation in future studies. Where appropriate, authors may briefly explain how the results relate to current care or contribute to the existing evidence base. [135] Authors may

combine this item with item 8 to state the results first and then describe their implications in the same section.

Particular care should be taken to avoid "spin" – presenting results as more positive, certain, or widely applicable than is justified by the evidence. [223] Statements implying that an intervention should be adopted in practice based on a single study should generally be avoided. Authors should reinforce that the results reflect the outcome of one single trial and that other trials may show different results. [136]

Balanced communication enhances trust and supports informed understanding. Examples of wording that can help communicate uncertainty and avoid overstating results are provided in Table 7.6.

Good practice

When describing clinical or policy implications:

- **Be accurate, not promotional.** Use balanced and neutral language.
- **Acknowledge uncertainty.** Make it clear if findings are preliminary, exploratory, or based on limited data.
- **Refer to the broader context.** Indicate that results contribute to rather than replace existing evidence.
- **Avoid prescriptive language.** Avoid making recommendations that readers, clinicians, or policymakers *should* take specific action based on one study.
- **Use plain, neutral language.** Words such as “may,” “could,” and “suggests” convey appropriate caution.

When drafting or reviewing a PLS:

- Ask: *Does this section describe what the findings mean without claiming more than the data support?*
- Seek PPI feedback on whether the language feels trustworthy or overstated.

Example 1 provides a brief interpretation of the findings, whereas Example 2 provides a more detailed explanation of their potential implications. Authors should adapt the level of detail according to the reporting format and any applicable word or space constraints.

Example 1

"The study helped researchers learn more about long-term treatment with adalimumab in young patients with UC. The study showed that treatment with adalimumab was overall safe and well tolerated by patients in this study. This summary only shows the results from this study, which may be different from the results of other studies." [228]

Example 2

"Based on all these results:

The researchers have decided that the combination of avelumab and axitinib may help to extend progression-free survival more than treatment with sunitinib. The researchers have decided that these results were not likely due to chance. The median overall survival was longer for participants who took avelumab with axitinib than for participants who took sunitinib. However, the researchers believe that this difference could have been the result of

chance. This means that the results did not show that avelumab plus axitinib was any better than sunitinib at extending overall survival.

This does not mean that everyone in this study had these results. This is a summary of just some of the main results of this study. Other studies may have different results." [231]

Essential item 10. Strengths and limitations: Strengths and limitations of the trial, including factors that may influence the interpretation or generalisability of the results

Lay header: *How confident can we be in these results?*

Or

How could we have improved this research?

Explanation

This item helps readers understand how much confidence they can place in the trial findings. All studies have strengths and limitations, and reporting both supports balanced, transparent, and trustworthy communication of results. [225]

Authors should briefly describe the most important strengths of the trial, such as a large sample size, diverse study population, or robust study design. They should also acknowledge key limitations that may affect the interpretation of the findings, such as a short follow-up period, missing data, or a study population that may not fully represent all patients who could receive the intervention.

This item also provides an opportunity to explain whether the findings are likely to apply to people outside the study population. Authors should avoid assuming that results apply equally to all patient groups and should clearly describe any factors that may limit the

broader applicability of the findings. Care should be taken to discuss generalisability in a balanced way to prevent misleading conclusions. When discussing strengths, limitations, and generalisability, authors should avoid language that overstates confidence in the findings. [225] Examples of neutral and cautious wording are provided in Table 7.6.

In particular, authors may find it difficult to discuss limitations and generalisability without unintentionally introducing overly positive framing or "spin". [223] Strengths should not be presented as proof that the findings are universally applicable, and limitations should not be dismissed or overlooked. Authors should clearly explain any factors that may affect confidence in the results or their relevance to wider patient populations. [126] Where appropriate, they should acknowledge uncertainty and avoid making claims about groups or settings that were not represented in the study. A balanced discussion of strengths, limitations, and generalisability can help readers understand both the value of the findings and their boundaries.

Example

Published examples of describing the strengths and limitations of a study in patient-facing trial summaries are uncommon. One published summary states:

“How could we have improved this research?

➢ Researchers only collected data for up to 12 months− Patients did not report any changes after that point

➢ More patient visits with researchers could have provided more data− This could have improved the accuracy of results.” [232]

This example attempts to describe study limitations in plain language. However, the distinction between explaining a limitation and suggesting improvements for future research is not always clear. Readers may therefore find it difficult to understand how these limitations should influence interpretation of the results.

Given the limited availability of published examples, the templates below illustrate possible approaches to reporting strengths and limitations in plain language. The aim is not to provide a detailed methodological critique but to briefly explain one or two key strengths or limitations that are most relevant to interpreting the findings.

Template A: Reporting a strength

*"A strength of this study is that [**Insert what the study did well,** e.g., a lot of people from different hospitals took part]. This means that [**Insert why this matters,** e.g., the findings are more likely to reflect what happens in routine healthcare]."*

Template B: Reporting a limitation

*"One limitation of this study is that [**insert the limitation,** e.g., only adults under 60 years of age took part]. This means that [**insert the implication,** e.g., we do not know whether the findings also apply to children or older adults]."*

Additional items

Additional item 11. Trial participants: Thank participants for taking part in the trial

Lay header: *Thank you!*

Explanation

Participants make trials possible. This item recognises the time, effort, and commitment of the individuals who took part in the research. Thanking participants demonstrates respect for their contribution and reinforces the importance of participant involvement in clinical research. [157] It also reflects good practice in patient-centred research communication.

A simple statement of thanks can help participants feel valued and respected, particularly when trial results are being shared directly with those who took part in the study. [140] This acknowledgement should be sincere, concise, and appropriate for the intended audience.

Authors may choose to include this statement at the beginning or end of the summary. Where appropriate, they may also acknowledge the contribution participants have made to future patients and healthcare research.

Example

"AbbVie wants to thank all the patients for their time and effort that went into making this study possible. Clinical study participation helps advance science!" [227]

Additional item 12. Patient and public involvement and engagement: Whether and how patients and/or the public helped in the design and delivery of the trial

Lay header: *What patient and public involvement was there in the trial?*

Explanation

This item describes whether patients and the public contributed to the planning, conduct, or dissemination of the trial. Patient and public involvement is increasingly recognised as an

important part of health research and can help ensure that research addresses questions and outcomes that are relevant to patients and communities. [110] Reporting patient and public involvement promotes transparency, recognises their contribution as research partners, and may also be of interest to patients and public readers. [226, 233]

Authors should briefly describe any involvement activities that took place across the lifecycle of the trial, such as helping to identify research priorities, reviewing participant information materials, advising on recruitment strategies, contributing to study oversight, or helping interpret and communicate the results. [225] If patients or members of the public contributed to writing or reviewing the trial results summary, this should also be reported. The level of detail should be proportionate to the reporting format. A short description is usually sufficient to help readers understand how patients and the public contributed to the research.

Example

Published examples of reporting patient and public involvement within trial result summaries remain limited despite searching multiple avenues. PPI is more commonly reported in trial protocols, grant applications or research publications using reporting guidelines such as GRIPP2. [233] An example of wording used in an AbbVie plain language summary is:

"This summary was reviewed for readability by a patient advocacy group." [227]

While this statement acknowledges patient involvement, it provides little detail on how patients contributed. Where possible, authors should provide a more meaningful

description, unless limited by word or space constraints. The worked example below provides one possible approach to reporting this item in a patient-facing trial results summary. This example follows principles from the GRIPP2 reporting guidance, which recommends describing the aims, methods, and impact of patient and public involvement in research. [233]

"Patients helped review participant information materials and provided advice on recruitment and study design. Patient representatives also reviewed this trial results summary to help ensure it was clear and easy to understand."

Additional item 13. Follow-up plan: Any plans for long-term follow-up of trial participants after the trial has ended

Lay header: *Will there be any follow-up?*

Explanation

Participants should know if follow-up is planned to collect additional information about longer-term benefits, risks, or health outcomes. This item helps to understand whether the research will continue beyond the initial study period and what this may mean for participants.

Authors should briefly describe whether any follow-up is planned, how long it is expected to continue, and the purpose of the follow-up. [139, 145] Where relevant, authors may explain whether participants will be contacted again, asked to attend further visits, complete questionnaires, or have their health records reviewed. The description should focus on

information most relevant to participants and avoid unnecessary procedural or technical detail.

Example

"After trial treatment: About 1 and a half months after a person took their last dose of ART, they went to the trial site for a health check." [234]

Additional item 14. Existing research: How the trial results compare with existing evidence (e.g., systematic reviews and other trials)

Lay header: *How do these results compare with other research?*

Explanation

Patients and members of the public may assume that a single trial provides a definitive answer to a research question. However, healthcare decisions are usually informed by the totality of evidence rather than one study alone. [235] Providing context about existing research helps readers understand the significance of the findings and how they contribute to the wider body of evidence. It also reinforces that scientific knowledge develops over time through multiple studies rather than a single trial. [236]

Authors should briefly describe whether the findings are consistent with previous research, differ from earlier studies, or provide new information. [126] The aim is not to provide a detailed literature review, but to help readers understand how the trial fits within existing knowledge. [225] Where appropriate, authors may explain whether the results strengthen confidence in an intervention, raise new questions, or suggest areas for further research.

Descriptions should be balanced and avoid implying that a single trial has settled a scientific question.

Example

Published examples of comparing trial results with existing evidence within patient-facing trial summaries remain limited. One published plain language summary briefly explains how the findings informed subsequent research:

"The results from this trial may help researchers learn more about DOR/ISL (100 mg/0.75 mg). Trials for DOR/ISL (100 mg/0.75 mg) were stopped due to decreases in lymphocytes (a type of white blood cell). New trials of a lower dose DOR/ISL (100 mg/0.25 mg) are ongoing." [229]

While this provides useful context by explaining how the findings influenced future research, it does not explicitly describe how the results compare with existing evidence. Where possible, authors should briefly explain whether the findings support, differ from, or add to existing knowledge, unless limited by word or space constraints. This can help patients and the public understand that scientific knowledge develops through multiple studies rather than a single trial. The example that follows illustrates one possible approach to reporting this information in a patient-facing trial results summary.

"Previous studies have shown that this treatment can improve symptoms. This study found similar results and adds to the existing evidence by including a larger and more diverse group of participants."

Additional item 15. Next steps: Next steps for the trial (e.g., publication, licensing of medicine or treatment, or integration into healthcare policy)

Lay header: *What happens next?*

Explanation

Patients and members of the public are often interested in what will happen after the trial ends and how the findings may be used. This item provides information about any planned activities following the completion of the trial and helps readers understand how the research may contribute to future knowledge, healthcare, or policy.

Authors should briefly describe any known next steps in non-promotional language, such as publication of the results, additional research, long-term follow-up studies, regulatory review, or consideration by healthcare organisations and policymakers. [133] Where appropriate, authors may explain that decisions about licensing, clinical practice, or policy typically require consideration of evidence from multiple studies rather than a single trial. [136] It also reinforces that research is often part of a larger process of evidence generation and decision-making. If no further activities are planned or known at the time of reporting, this should be stated.

Example

"Are future studies planned?

Argenx stopped the follow-up safety study, ARGX-113-2010, in participants with BP because efgartigimod did not result in significantly more symptom-free participants than placebo in this study (ARGX-113-2009). No new studies are planned to learn about efgartigimod for the treatment of patients with BP." [237]

Additional item 16. Advisory statement: Statement advising the reader to consult their healthcare provider before making any changes to their treatment based on the trial results

Lay header: *Discussing the trial results with your doctor*

Explanation

Patients and members of the public may read trial results and wonder whether the findings apply to their own health situation. However, the results of a single trial should not be used to make individual treatment decisions without professional medical advice. Factors such as a person's medical history, current treatments, preferences, and overall health need to be considered when making healthcare decisions. [238] This statement helps ensure that readers understand the limitations of applying trial findings to individual healthcare decisions and promotes safe, informed discussions with healthcare professionals.

Authors should include a brief statement encouraging readers to discuss any questions about the trial findings with their healthcare provider before making changes to their treatment or care. [137] Where appropriate, authors may also suggest topics that readers could discuss with their doctor, such as whether the treatment studied may be relevant to them or whether the findings are likely to affect their care. [133]

The advisory statement should be clear, supportive, and non-alarming. It should encourage informed conversations between patients and healthcare professionals without discouraging interest in the research findings.

Example

"This trial summary:

• Does not replace your healthcare professional's advice. You should always talk to a healthcare professional about any treatment decisions

• Is not a recommendation of how to use the trial medicine

• Does not give advice on how to prescribe the trial medicine" [234]

Additional item 17. Further information: More information about the trial (e.g., trial registration, sources of funding, trial website link) or where related resources can be found

Lay header: *Where can you find more information?*

Explanation

Patients and members of the public may wish to learn more about the trial after reading the summary. Some readers may want additional information about the study methods, detailed results, related publications, similar trials conducted, or future research. [225] Providing clear directions to further information supports transparency and allows readers to explore topics in greater depth if they wish.

Authors should provide links or references to relevant resources where available, such as journal publications, trial registries, sponsor websites, or other publicly accessible sources of information. [135] Where appropriate, a contact point for questions or feedback may also be provided. [139] Information should be presented clearly and in a way that is easy for readers to access. [139]

Authors should consider that readers may have different levels of interest and health literacy. [136] Providing further information allows the summary itself to remain concise while ensuring that more detailed resources are available for those who want them.

Example

"Title of Study	*Open-Label Continuation Treatment Study with Levodopa-Carbidopa Intestinal Gel in Subjects with Advanced Parkinson's Disease and Severe Motor Fluctuations Who Have Exhibited a Persistent and Positive Effect to Treatment in Previous Studies*
Protocol number	*S187.3.005*
Clinicaltrials.gov	*NCT00660673 https://clinicaltrials.gov/ct2/show/NCT00660673?term=NCT00660673&draw=2&rank=1*
EudraCT	*2008-001329-33 https://www.clinicaltrialsregister.eu/ctr-search/search?query=2008-001329-33*
Study sponsor	*AbbVie, Inc. Phone: +1 800-633-9110 https://www.abbvie.com/contactus.html"* [227]

7.4 Discussion

In this chapter, I presented the final reporting guideline and the accompanying E&E guidance. A challenge during the development of this reporting guideline was balancing brevity with comprehensiveness. However, feedback throughout the development process indicated that users often needed additional support on how to report certain items,

particularly those relating to interpretation, strengths and limitations, side effects, and communication of uncertainty. For this reason, I retained two versions of the checklist: a concise version containing the core reporting items and an expanded version that includes the core content of the explanation and elaboration guidance in shorter format (e.g., suggested lay headers and brief guidance to support implementation). Keeping both versions allows flexibility, as different users and organisations may have different reporting needs, levels of experience, and space constraints. The E&E provides further explanation, practical examples, and additional context for users seeking more detailed guidance on applying the checklist in practice.

The E&E was developed alongside the reporting guideline and was informed by findings from every stage of the project. Feedback from the qualitative study, Delphi survey, consensus meeting, and pilot testing helped identify areas where users needed additional support. While participants generally agreed on what information should be included in trial result summaries, many highlighted challenges around how that information should be communicated to patients and the public. Feedback from pilot testing showed that some checklist items, particularly interpretation, strengths and limitations, and generalisability, were difficult to report clearly and consistently. As a result, these areas received additional attention within the E&E guidance.

Unlike some reporting guideline E&E documents, which focus heavily on the methodological evidence supporting individual checklist items, this E&E focuses primarily on practical guidance for communicating trial results. This reflects the purpose of the guideline and the needs of its intended users. The guidance draws on published literature, but also on

extensive input from patients, members of the public, trialists, clinicians, regulators, and communication professionals. The inclusion of suggested lay headers, additional guidance on “avoiding spin”, and the audience applicability matrix were direct responses to stakeholder feedback and were designed to improve usability and navigation.

It is also important to recognise that many patient-facing trial result formats are subject to word or space restrictions. For example, PLSs published alongside journal articles often have strict word limits, making it difficult to report every checklist item in detail. For this reason, the essential checklist items represent the minimum information that should be included to describe the results of randomised trials. Where space is limited, authors may need to prioritise key information and provide additional details elsewhere. Additional item 17, ‘*Further information*’, offers one way of addressing this challenge by directing readers to more comprehensive reports, publications, trial registries, or other sources where they can access further information about the study and its findings.

Another challenge during the development of the E&E was identifying published examples for every checklist item. While examples were available for most items, there were few examples of items relating to reporting patient and public involvement (Item 12) or comparing findings with existing evidence (Item 14) within patient-facing trial summaries. In these cases, illustrative examples were developed based on stakeholder feedback and established guidance such as GRIPP2. [233] This highlights both the novelty of the reporting guideline and the limited guidance currently available for reporting trial results to patients and the public.

Overall, I see the E&E document as an important companion to the reporting guideline. The checklist describes what information should be reported, while the E&E provides practical support on how to report it. Together, they aim to improve the clarity, completeness, and accessibility of trial result summaries for patients and the public. Future work should evaluate how the guideline and E&E are used in practice and whether they improve the quality and consistency of patient-facing trial result communications.

Chapter 8: Discussion and conclusion

8.1 Chapter overview

In this final chapter, I summarise the findings from each stage of the thesis and reflect on its overall output: a reporting guideline for sharing the results of randomised trials with patients and the public. I discuss how the guideline was developed, what I learnt throughout the process, and the strengths and limitations of the work. I also discuss plans for publication, dissemination, and implementation, as well as the implications for practice and future research.

8.2 Summary of findings and reflections

The aim of this DPhil was to develop a reporting guideline to support the sharing of results of randomised trials with patients and the public. My intention was to create a practical tool to support those responsible for preparing patient-facing trial result summaries, including trial teams, chief investigators, trial managers, medical writers, sponsors, and patient partners, in identifying the minimum information that should be communicated. I believe that providing a structured framework will improve the consistency and quality of trial result summaries and, ultimately, make research findings more accessible and meaningful to patients and the public.

In Chapter 1, I reviewed the policy and regulatory landscape relating to trial transparency and result sharing. Across many countries, including the UK, there is a clear shift towards greater transparency, but most initiatives focus on making results available rather than making them understandable. [21, 22, 24, 26, 29, 34, 37, 239] Much of the information currently

available through trial registries and scientific publications remains highly technical and difficult for non-specialist audiences to interpret. This reinforced the need for a reporting guideline specifically designed to support patient- and public-facing communication.

Chapters 2–7 described the steps I followed to develop the reporting guideline. I began the empirical work with a scoping review (Chapter 2). My aim was not only to identify whether guidance already existed, but also to understand its strengths and limitations. I identified 24 documents containing recommendations on sharing research results with patients and the public but found no reporting guideline developed specifically for randomised trials. Many of the documents had limited visibility, unclear development methods, little evidence of co-production, and minimal consideration of diversity and inclusivity. Only a small number had been pilot-tested before publication. These findings directly informed the design of the subsequent stages of the research. They highlighted the importance of involving multiple stakeholder groups, considering inclusivity from the outset, and ensuring that any new guidance was practically tested before publication.

The qualitative study (Chapter 3) allowed me to move beyond the literature and understand how different stakeholders viewed the sharing of trial results. Over a series of interviews and focus groups with trial professionals, patients and members of the public, I explored what information people considered important and why. This stage gave me a much deeper understanding of the topic that could not have been obtained through the scoping review of the literature alone. It helped me understand not only which items stakeholders prioritised, but also the reasoning behind those preferences. Those insights were particularly valuable

during later stages of guideline development, where I was able to draw on participants' perspectives when discussing and refining checklist items.

One of the most memorable moments of the project occurred when I sought ethics approval for the qualitative study. I was initially told that the work appeared to be a PPI activity and therefore did not require ethics review. I found myself arguing that it was, in fact, research. The experience highlighted the continuing uncertainty around the boundaries between patient involvement and research about patient involvement, a distinction that remains poorly understood in many settings. [111]

Building on the findings of the scoping review, I made a conscious effort to recruit participants from a range of ethnic minorities and underrepresented groups, including people with lived experience or learning disabilities. Participants identified a range of information they considered important in trial result summaries and highlighted barriers to effective result sharing, including the absence of clear guidance, uncertainty around regulatory expectations, and limited resources for inclusive communication. Many participants felt that a standardised framework could help improve current practice.

Using findings from the scoping review and qualitative study, I developed a long list of candidate reporting items, which were refined through three rounds of a Delphi survey (Chapter 4). Again, I made a conscious effort to recruit participants from a range of professional backgrounds, ethnic minority groups, and individuals with lived experience. Conducting the Delphi survey was a valuable learning experience. Having never led a Delphi study before, I had to learn how to design, manage, and analyse the process while balancing

the views and needs of a large and diverse stakeholder group. PPI input was particularly valuable in this stage to help me design a survey that was easy to access for patient and public members. One of the most interesting aspects of the Delphi process was seeing where opinions converged and where they differed between the different stakeholder groups. Patients and public participants often prioritised information that helped them understand the relevance of the findings to themselves, whereas trial professionals were more likely to focus on feasibility and practical considerations. The Delphi process provided a structured way of bringing these perspectives together and ensuring that no single group dominated the development of the checklist.

Although the Delphi survey helped identify areas of agreement, several items remained borderline or generated uncertainty. A consensus meeting (Chapter 5) allowed for in-depth discussion to address these issues in greater depth and agree on the final content of the reporting guideline. Bringing together diverse perspectives (e.g., trial professionals, patient representatives, medical writers, methodologists, and public members) ensured that the final recommendations are practical, widely accepted, and reflect different points of view.

Participants frequently agreed on the value of including particular information but differed on how much detail was appropriate and whether it could be realistically communicated within the constraints of a patient-facing summary. In practice, these constraints are often determined by journal or publisher requirements. Many journals that publish plain language summaries impose word limits, commonly 150 to 400 words (Table 6.2, Chapter 6), requiring authors to balance completeness with brevity. Consensus meeting discussions often revealed tensions between what patients and the public considered important to know and

what trial teams felt was feasible to communicate clearly while remaining within these limits. This ultimately informed the distinction between essential and additional checklist items, allowing authors to prioritise key information when space is restricted while providing flexibility to include additional content where word limits permit.

Facilitating these discussions required careful judgement to ensure that patient and public perspectives were not lost when weighed against concerns about burden or practicality. Reflecting on this stage, I realised that consensus is not simply about achieving agreement. It is also about understanding different perspectives, negotiating compromises, and ensuring that the final recommendations remain both useful and practical. The consensus meeting ultimately strengthened the checklist by allowing participants to explain their reasoning, challenge assumptions, and refine items that might otherwise have been interpreted differently by different stakeholder groups.

Chapter 6 described the pilot testing process. I wanted to move beyond theoretical agreement and understand whether the checklist would work in practice. The checklist was tested in several stages, with revisions made after each round of feedback. I first applied the checklist myself to published trial reports and existing plain language summaries to assess its applicability across different contexts and trial designs. This was followed by real-world testing with trial professionals and medical writers, including cognitive interviews to understand how users interpreted and applied the checklist. The final stage involved readability testing with patient and public representatives, who reviewed summaries written using the checklist and provided feedback on clarity, relevance and readability.

Reflecting on this process, pilot testing proved to be much more than a final validation exercise. It played a key role in shaping the checklist into a practical and usable tool. It allowed me to identify issues that had not emerged during earlier stages and provided insight into how the checklist would function in real-world settings. The final version of the guideline therefore reflects not only the evidence generated through the scoping review, qualitative study, Delphi survey, and consensus meeting, but also the practical lessons learned through implementation and user feedback.

In Chapter 7, I presented the E&E guidance to support implementation of the reporting guideline. While the checklist identifies the minimum information that should be reported, the E&E provides additional explanation, examples, and practical guidance for each item. The content of the E&E was informed by findings from the scoping review, qualitative study, Delphi survey, consensus meeting, pilot testing and established literature. It was developed to address areas where users required additional clarification, provide worked examples, and support consistent interpretation of the checklist across different reporting contexts.

Developing the E&E reinforced that a checklist alone is unlikely to be sufficient to improve reporting practice. Reporting guideline developers have long recognised that authors and editors need more than a list of reporting items; they also require the rationale behind each recommendation, practical guidance, and examples of good reporting. [66, 68, 69] Recent research also suggests that many authors engage with reporting guidelines only at the point of manuscript submission, often using the checklist in isolation without referring to the accompanying E&E. This may contribute to the perception that reporting guidelines are rigid or burdensome, rather than practical tools to support good reporting. [240] For this reason,

established reporting guidelines such as CONSORT, PRISMA, and SPIRIT are accompanied by E&E documents to support consistent interpretation and implementation. [106, 107, 241] Moher et al. further recommend that reporting guidelines and their E&E documents should be published simultaneously to maximise dissemination and uptake. [66] Following this established approach, I developed the E&E alongside the reporting guideline to provide practical guidance, worked examples, and the rationale behind each reporting item.

Several of the items, particularly those relating to strengths and limitations, participant demographics, and contextual information, require judgement when applied in practice. Rather than prescribing a fixed level of detail that may not suit every trial, the E&E provides guidance while allowing flexibility according to the trial, audience, and reporting context.

One of the key reflections from this work is that there is no single format for sharing trial results with patients and the public. Organisations currently use a wide range of approaches, including PLSs published in journals, summaries on trial websites, regulatory reports, visual summaries, and interactive online formats. The intention of this reporting guideline is not to prescribe how information should be presented. Rather, it seeks to define the minimum essential information that should be shared regardless of format, setting, or delivery method. By focusing on content rather than presentation, the guideline is designed to be flexible enough to support a range of dissemination approaches while promoting greater consistency and transparency in what is reported.

8.3 Strengths of the research

One of the main strengths of this research is that the reporting guideline was developed using an established and rigorous methodology, drawing on multiple sources of evidence and stakeholder input. [66, 67, 85] Rather than relying solely on expert opinion, the guideline was informed by a scoping review, qualitative interviews and focus groups, a three-round Delphi survey, a consensus meeting, and extensive pilot testing. Each stage built on the findings of the previous stage, ensuring that the final recommendations were grounded in both evidence and stakeholder experience.

Unlike many reporting guideline development studies, which involve stakeholders primarily during later consensus stages to evaluate a list of predefined items, [67] I sought stakeholder perspectives before candidate reporting items had been generated. This open-ended qualitative approach allowed participants to identify reporting priorities inductively from their own experiences, reducing the likelihood of overlooking issues that may not have emerged from the literature alone.

Another strength was the breadth of stakeholder involvement throughout the project. The Delphi survey included trial researchers, clinicians, statisticians, trial managers, funders, journal editors, medical writers, methodologists, policymakers, patient representatives and members of the public. To ensure that no single stakeholder group dominated decision-making, Delphi analyses were conducted separately by stakeholder group. This approach gave equal weight to different perspectives and ensured that agreement was not driven solely by the largest group of participants.

Patient and public involvement was embedded throughout every stage of the research, from the qualitative study to the Delphi survey, consensus meeting and pilot testing. Looking back, one of the most important lessons from this DPhil was the value of meaningful partnership rather than tokenistic involvement. Involving patients and members of the public throughout the research process required additional time and flexibility, but it strengthened both the quality of the discussions and the relevance of the final guideline. It also challenged me to think beyond what researchers typically consider important and to consider how information is interpreted by those without specialist knowledge.

I also made a conscious effort to recruit participants from diverse backgrounds. Delphi participants represented 16 countries, a wide range of professional roles and lived experiences, with 29% identifying as belonging to a non-White ethnic group and 22% reporting a first language other than English. Although South America and Africa remained underrepresented, the study achieved broader international representation than is often seen in reporting guideline development studies. [67] Given the intended audience of the guideline, incorporating diverse perspectives was essential to ensure that the recommendations were relevant, acceptable and applicable across different settings. [67]

A further strength was the extensive pilot testing undertaken before finalising the guideline. Rather than relying on a single form of testing, I used multiple complementary approaches, including retrospective application of the checklist to published trial reports and plain language summaries, independent user testing, feasibility testing with trial teams, cognitive interviews, PPI feedback, and exploratory assessment of AI-assisted summary generation.

Together, these approaches provided valuable insight into the usability, feasibility, clarity, and acceptability of the checklist. They also enabled practical issues to be identified and addressed before publication.

Finally, this research was conducted at a time of increasing international attention to transparency and communication of trial results. [21, 22, 24, 26, 29, 34, 37, 239] While regulatory initiatives have created new expectations around sharing trial results with patients and the public, there remains little practical guidance on how this should be done. By combining evidence synthesis, stakeholder engagement, consensus methods, and practical testing, this thesis addresses an important gap and provides a reporting guideline that is both evidence-informed and developed with its intended users in mind.

8.4 Limitations of the research

The following limitations should be considered when interpreting the findings and the resulting reporting guideline.

Participation in the qualitative study, Delphi survey, consensus meeting, and pilot testing was voluntary. As a result, participants were self-selected and may have had a greater interest in trial transparency, patient involvement, or research communication than the wider populations they represent. Although I sought to recruit a diverse range of stakeholders, the views captured may not fully reflect those of all trial professionals, patients, or members of the public.

The Delphi process itself has recognised limitations. Participants are purposively selected rather than randomly sampled, and the findings are therefore dependent on the composition of the panel and the perspectives represented. [206] The quality of the output also depends on participants engaging thoughtfully with the process and completing multiple survey rounds. [202, 207] For practical reasons, participants in Delphi Rounds 2 and 3 were shown summary ratings from previous rounds but not the accompanying qualitative comments. While this reduced the burden on participants, it may have limited opportunities for respondents to understand the reasoning behind others' ratings and reconsider their own views in light of those explanations.

Although the Delphi survey provided a structured approach for reaching consensus, not all decisions were based solely on Delphi ratings. Some items required further discussion during the consensus meeting, particularly where ratings were borderline or where practical considerations needed to be taken into account. As a result, the views of participants attending the consensus meeting may have had greater influence on the final wording and classification of some items than those of participants who contributed only through the Delphi survey. Practical considerations such as word limits, reporting burden, and feasibility also influenced decisions about the structure of the checklist and the distinction between essential and additional items. These decisions were necessary to produce a usable guideline but may not fully reflect the preferences of every stakeholder group.

A further limitation relates to representation. Although participants were recruited from a range of countries, ethnic backgrounds, stakeholder groups, and levels of experience, some

regions remained underrepresented, particularly South America and Africa. The guideline therefore reflects the perspectives of a broad but not fully global group of stakeholders.

The pilot testing phase also had some limitations. While I used multiple approaches to evaluate the checklist, including user testing, cognitive interviews, trial team feedback, and readability assessment by patients and public representatives, the number of participants involved in some stages was relatively small. The findings therefore provide valuable insight into usability and feasibility but cannot guarantee that all future users will interpret or apply the checklist in the same way.

Finally, meaningful PPIE requires adequate funding to recognise and reimburse contributors for their time and expertise. During the qualitative study and the Delphi, I was unable to reimburse patient and public participants because no dedicated funding was available. Looking back, this was a limitation of the study and reflects a wider challenge faced by many doctoral researchers undertaking PPI work. [109, 110] As the project progressed, I made a conscious effort to secure funding for subsequent stages. This proved much more difficult than I had anticipated. Although my doctoral research was supported by a Clarendon Scholarship, the research itself was unfunded and there was no specific funding for PPI activities. Whilst many NIHR-funded studies include dedicated budgets for PPI, very few funding opportunities were available to support doctoral research projects like mine. I approached several charities and applied to the Oxford University PCER scheme, but these applications were unsuccessful, and I was often advised to seek support from my funder despite no PPI budget having been allocated. I was fortunate to receive support through the OPEN ARMS Student Patient Alliance programme, which enabled me to work with a patient

partner, and I later secured funding through the NIHR School for Primary Care Research PPI scheme to reimburse contributors who participated in the consensus meeting. This experience reinforced the importance of planning and resourcing meaningful involvement from the outset of research projects and highlighted the need for more accessible funding opportunities for doctoral researchers undertaking co-produced research.

Taken together, these limitations reflect the practical challenges of developing a consensus-based reporting guideline while ensuring broad stakeholder involvement, and were considered throughout the interpretation of findings and refinement of the final guideline.

8.5 Publication, dissemination, and implementation strategy

The first public output from this work will be the thesis itself, which will be made openly available through the Oxford University Research Archive (ORA). Open access is particularly important for reporting guidelines because their value depends on their accessibility and use. [67] If reporting guidelines are hidden behind paywalls or restrictive licences, they cannot be used to their full potential. [67, 69] Researchers, trial teams, patient partners, and public representatives should be able to access, use, and share the guideline freely without facing financial or administrative barriers.

Alongside the thesis, the scoping review has now been published in an open-access journal [114], and the qualitative study is in press in *Trials*. [171] I am also preparing the main reporting guideline manuscript for submission to an open-access journal, together with the accompanying E&E. Publishing these outputs separately will allow readers to understand not

only the final recommendations but also the evidence, stakeholder perspectives, and development process that informed them.

Publication alone is unlikely to be sufficient to change practice. Previous reporting guidelines have shown that awareness and uptake require active dissemination and implementation efforts. [69, 76] I therefore intend to promote the guideline through a range of academic, professional, and public-facing channels. Dissemination of this work has already begun and will continue alongside publication of the guideline. To date, I have presented findings from this research at academic, methodological, and public engagement events, as summarised in section 8.9, helping to raise awareness of the need for improved communication of trial results with patients and the public. Further dissemination is planned through major upcoming international meetings, including oral presentations accepted at the International Clinical Trials Methodology Conference (ICTMC) 2026 [242] and the Cochrane Colloquium 2026. [243]

Alongside conference presentations, dissemination will build on the professional networks established throughout this DPhil. During recruitment for the various stages, I developed relationships with a wide range of organisations involved in clinical trials, reporting methodology, patient and public involvement, and research communication. These included UK clinical trials units, the UKTMN, [244] the MRC-NIHR Trials Methodology Research Partnership, [245] the Society for Clinical Trials, [246] the SPIRIT-CONSORT executive group, [247] the EQUATOR Network, [65] journal editors, medical writers' organisations such as the EMWA, [248] and international research networks across Europe, North America, Asia, and Australia.

Following publication, I will continue working with these organisations, together with the NIHR, the HRA, journals, publishers, funders, CTUs, and patient organisations, to promote awareness and uptake of the guideline. As organisations that already support good research practice, they are well placed to encourage wider implementation among researchers and trial teams.

This reporting guideline has been developed as a proposed CONSORT extension for the CONSORT 2025 statement, [62] and members of the CONSORT group have contributed methodological expertise throughout its development. This connection helps ensure consistency with established reporting guideline methods and provides a potential route for future dissemination and endorsement. As with other CONSORT extensions, endorsement by journals will be an important longer-term goal. [84]

An important next step will be to engage with journals that already publish PLSs or patient-facing trial summaries, such as *Research Involvement and Engagement*, *Pain and Therapy*, and journals within the Springer Nature, BMC, Wiley, SAGE, and Taylor & Francis portfolios. [48, 49] I will seek opportunities for endorsement, inclusion of the guideline within author instructions and reviewer guidance, and integration into editorial and peer-review processes. Even where formal endorsement is not immediately achieved, promotion through journal websites, newsletters, editorials, webinars, and professional networks may help increase awareness and encourage routine use of the guideline within the trials community.

Patient and public audiences are an equally important part of the dissemination strategy. I have developed and presented PLSs, infographics, visual posters, and interactive

presentations at multiple patient and community engagement events. For example, at the Oxford University PCER conference in 2026, [249] I presented the reporting guideline through a poster and facilitated a public engagement activity comparing trial summaries written before and after applying the checklist. Participants were invited to discuss their preferences and share their views on the importance of this work. The feedback was overwhelmingly positive, with many commenting on the value of making trial results easier to understand and the importance of improving transparency and accountability in health research. These interactions reinforced the relevance of the guideline beyond academic and professional audiences and highlighted the strong public interest in accessible communication of research findings.

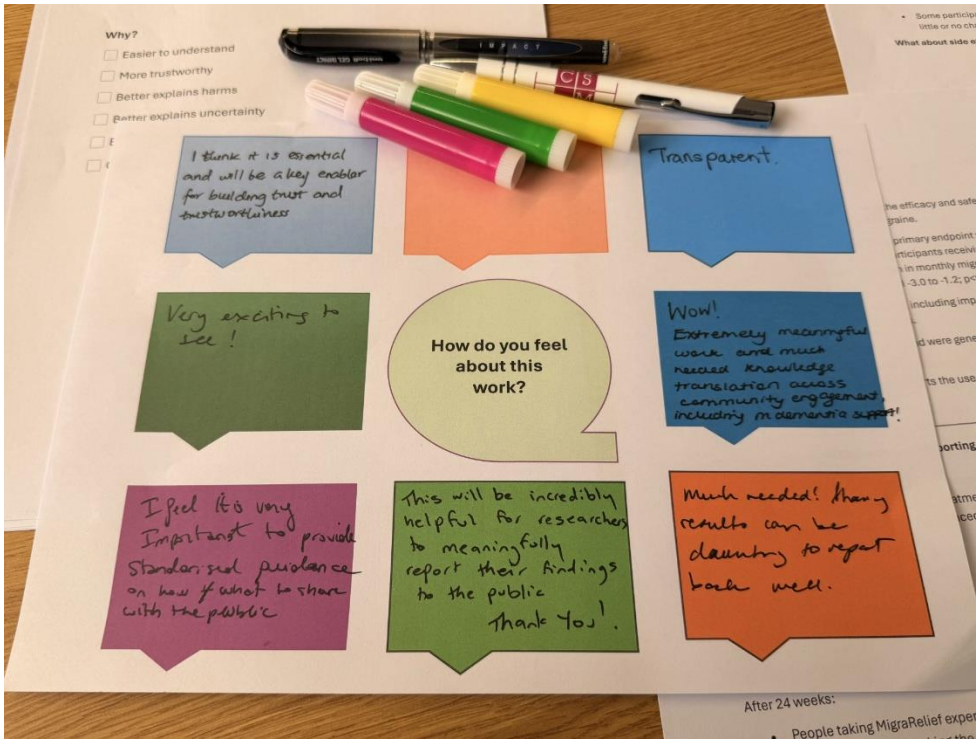


Figure 8.1: Feedback received from attendees of the Public and Community Engagement with Research Conference 2026

Digital dissemination will complement these activities. The guideline will be promoted through EQUATOR Network, ORA, professional networks, and social media platforms such as LinkedIn and X. Together, these approaches aim to reach researchers, trial professionals, patient partners, and members of the public who may not encounter the guideline through traditional academic routes.

Successful implementation will require more than simply making the guideline available. Training and support materials may help users apply the recommendations consistently. [69] Potential implementation activities include webinars, conference workshops, checklist templates, worked examples, training materials, and presentations aimed at trial managers, methodologists, and medical writers. Through professional CTUs, trial networks, and societies such as the UKTMN [244] and the Society for Clinical Trials, [246] I hope to support adoption of the guideline within routine trial practice. In the longer term, I would welcome opportunities to continue this work beyond my doctorate, including evaluating uptake of the guideline, developing implementation resources, and working with journals, funders, and research organisations to support wider adoption.

8.6 Implications for practice

The primary aim of this research was to develop a practical reporting guideline that can support researchers, trial teams, medical writers, and patient partners when sharing trial results with patients and the public. The findings suggest that such guidance is both needed and welcomed by potential users. Participants consistently identified a lack of clear

standards as a barrier to current practice, and many felt that a structured framework would improve the consistency and quality of trial result summaries.

In practice, the checklist provides a starting point for deciding what information should be included when sharing trial results with non-specialist audiences. Rather than requiring authors to decide independently what information patients and the public may find important, the guideline offers a consensus-based set of recommendations developed with input from multiple stakeholder groups. This may help reduce variation in reporting and improve the completeness and transparency of trial result summaries. Better communication of trial results has the potential to support informed healthcare decisions and strengthen public trust in research.

The pilot testing also highlighted that different users may require different levels of support. Some participants preferred the concise checklist because it was easier to apply within existing reporting workflows and word limits. Others preferred the version containing additional prompts and explanatory guidance. This suggests that a flexible approach to implementation may be beneficial. Experienced communicators may prefer a concise checklist, whereas researchers and trial teams with less experience of public-facing communication may benefit from additional examples and guidance provided in the E&E.

The findings also have implications for journals, funders, regulators, and research organisations. Endorsing and promoting the use of the guideline may help establish clearer expectations around the communication of trial results to patients and the public. As seen with other reporting guidelines, publication alone is unlikely to change reporting practices.

[69, 76, 84] Active implementation through journal policies, funder expectations, training, and professional guidance is likely to be necessary if the recommendations are to become part of routine practice. [69, 76, 84]

8.7 Implications for future work

This research represents an important first step, but further work will be needed to ensure implementation and to evaluate the long-term impact of the guideline. One priority will be to assess whether use of the checklist leads to measurable improvements in the completeness, clarity, and accessibility of patient-facing trial summaries. Future studies could compare summaries written with and without the guideline and explore how different audiences interpret and use the information provided. Research could also examine how authors, trial teams, and other users apply the checklist in practice, including whether they find it useful, which items they find most helpful or challenging, and whether the accompanying E&E supports consistent implementation.

Research is also needed to understand how best to support implementation. Experience from other reporting guidelines and relevant research suggests that dissemination alone rarely changes behaviour. [69, 76, 250] Future work should therefore evaluate strategies such as journal endorsement, funder requirements, training programmes, and integration into editorial and peer-review processes. Understanding which implementation approaches are most effective will be important if the guideline is to achieve widespread adoption.

The emergence of AI presents another area for future investigation. My exploratory testing suggested that AI tools may be able to assist with drafting trial summaries when guided by a structured checklist. However, substantial human oversight remained necessary. Future studies could explore whether AI tools can consistently generate summaries that adhere to the guideline, how patients and the public perceive AI-generated compared with human-written summaries, and what level of human review is required to ensure accuracy, readability, and trustworthiness.

I do not believe there is a single perfect way to communicate trial results. Different audiences, settings, technologies, and communication preferences will continue to evolve. For this reason, I view the reporting guideline as a living resource rather than a fixed product. Future updates should continue periodically to incorporate new evidence, user feedback, and emerging perspectives to ensure that the guideline remains relevant and useful to authors, patients, the public, journal editors, and peer reviewers.

8.8 Conclusion

As researchers continue to navigate the complexities of sharing trial results, it is essential to foster an environment where sharing trial results is viewed as an opportunity for improvement rather than something to be avoided. This is especially important in the context of randomised trials, which can be inherently complex, and where the need for clear, transparent, and thoughtful communication is paramount.

This thesis set out to address an important gap in randomised trial reporting: the absence of a structured, evidence-based approach to sharing trial results with patients and the public. Through a programme of work involving evidence synthesis, qualitative research, consensus methods, and practical testing, I developed a reporting guideline specifically designed for this purpose. The development of this guideline reinforced my belief that dissemination is not simply an optional activity that occurs after a trial has finished. Sharing results is part of the ethical responsibility researchers have to those who contribute their time, data, and trust to research. By ensuring that trial results are shared transparently and inclusively, we can build trust, encourage wider participation, and ultimately improve the quality and impact of clinical research.

I did not set out to create a perfect reporting guideline, because I do not believe such a thing exists. Communication needs vary across audiences and contexts, and these needs will continue to evolve. Instead, my aim was to develop guidance that is evidence-informed, practical, and responsive to the needs of its intended users. The guideline presented in this thesis should therefore be viewed as a foundation that can continue to develop as new evidence and experiences emerge.

One of the participants in the qualitative study reflected on their experience of taking part in this research:

“I'm also someone from that (Autistic) community… “It's about kind of the environment and the atmosphere that's created and just which I think was done really well. And I think that kind of gave me the opportunity to contribute because I've kind of its kind of the first time

I've done anything like this because I've always thought like, I don't know if my opinions really going to be valued…

You kind of allowed that time and that space to become more accessible. And I think that's what kind of encouraged me to stay and not just feel completely overwhelmed straight away. So, I'd just like to say thank you for that."

This comment has stayed with me throughout the DPhil. Although it was made in relation to participation in the research itself, it also captures the broader motivation behind this work. Patients and members of the public can only benefit from research findings if those findings are communicated in ways that are accessible, understandable, and relevant to them.

Ultimately, I hope this reporting guideline helps create that space. Not by simplifying science, but by making it easier for people to engage with, understand, and use research findings. If research is conducted with the aim of improving people's lives, then the results should be shared in a way that allows those people to understand and benefit from them.

8.9 Research outputs and achievements associated with this thesis

Publications:

- **Choudhury S,** Collins GS, Albury C, de Beyer J, Hopewell S. A scoping review of guidance on sharing trial results with patients and the public finds inconsistent recommendations and limited methodological development. *Journal of Clinical Epidemiology*. 2026:112394. [114]
- **Choudhury S,** Albury C, Collins GS, de Beyer J, Hopewell S. Approaches to sharing trial results with adult patients and the public: a qualitative interview and focus group study. *Trials*. 2026. (In press) [171]

Awards and prizes

- Clarendon scholarship (2023 – 2026)
- Medical Sciences Graduate School Studentship (2023 – 2026)
- Botnar Institute Student Symposium (BISS) presentation prize 2024
- BISS poster prize 2026
- NDORMS/NDPCHS Primary Care day poster prize 2025
- NIHR School for Primary Care Research (SPCR) PPI Scheme: Funding 2025 – 2026

Poster presentations

- Community Connections with Research: Oxford University Public and Community Engagement with Research strategy (PCER) event 2025
- NDORMS/NDPCHS Primary Care Showcase day 2025
- Oxford University Public and Community Engagement with Research strategy (PCER) conference 2026
- BISS 2026

Oral presentations

- SITU-NDORMS seminar presentation 2024
- Clarendon community engagement event 2025
- Oxfordshire Community Health and the Humanities (MEDHAM TORCH) event 2025
- ICTMC 2026 (Abstract accepted)
- Cochrane Colloquium 2026 (Abstract accepted)

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Appendices

Appendix 2.1: PRISMA-ScR checklist

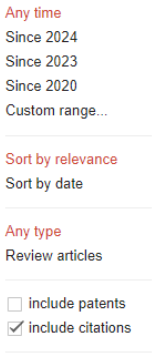
Preferred Reporting Items for Systematic reviews and Meta-Analyses extension for Scoping Reviews (PRISMA-ScR) Checklist

SECTION	ITEM	PRISMA-ScR CHECKLIST ITEM	REPORTED ON PAGE #
TITLE			
Title	1	Identify the report as a scoping review.	33
ABSTRACT			
Structured summary	2	Provide a structured summary that includes (as applicable): background, objectives, eligibility criteria, sources of evidence, charting methods, results, and conclusions that relate to the review questions and objectives.	N/A
INTRODUCTION			
Rationale	3	Describe the rationale for the review in the context of what is already known. Explain why the review questions/objectives lend themselves to a scoping review approach.	33-34
Objectives	4	Provide an explicit statement of the questions and objectives being addressed with reference to their key elements (e.g., population or participants, concepts, and context) or other relevant key elements used to conceptualize the review questions and/or objectives.	34
METHODS			
Protocol and registration	5	Indicate whether a review protocol exists; state if and where it can be accessed (e.g., a Web address); and if available, provide registration information, including the registration number.	35
Eligibility criteria	6	Specify characteristics of the sources of evidence used as eligibility criteria (e.g., years considered, language, and publication status), and provide a rationale.	36
Information sources*	7	Describe all information sources in the search (e.g., databases with dates of coverage and contact with authors to identify additional sources), as well as the date the most recent search was executed.	37-42
Search	8	Present the full electronic search strategy for at least 1 database, including any limits used, such that it could be repeated.	37-42
Selection of sources of evidence†	9	State the process for selecting sources of evidence (i.e., screening and eligibility) included in the scoping review.	43
Data charting process‡	10	Describe the methods of charting data from the included sources of evidence (e.g., calibrated forms or forms that have been tested by the team before their use, and whether data charting was done independently or in duplicate) and any processes for obtaining and confirming data from investigators.	43-45
Data items	11	List and define all variables for which data were sought and any assumptions and simplifications made.	44

SECTION	ITEM	PRISMA-ScR CHECKLIST ITEM	REPORTED ON PAGE #
Critical appraisal of individual sources of evidence§	12	If done, provide a rationale for conducting a critical appraisal of included sources of evidence; describe the methods used and how this information was used in any data synthesis (if appropriate).	45-46
Synthesis of results	13	Describe the methods of handling and summarizing the data that were charted.	44-45
RESULTS			
Selection of sources of evidence	14	Give numbers of sources of evidence screened, assessed for eligibility, and included in the review, with reasons for exclusions at each stage, ideally using a flow diagram.	46-47
Characteristics of sources of evidence	15	For each source of evidence, present characteristics for which data were charted and provide the citations.	47-53
Critical appraisal within sources of evidence	16	If done, present data on critical appraisal of included sources of evidence (see item 12).	326
Results of individual sources of evidence	17	For each included source of evidence, present the relevant data that were charted that relate to the review questions and objectives.	330-385
Synthesis of results	18	Summarize and/or present the charting results as they relate to the review questions and objectives.	54-65
DISCUSSION			
Summary of evidence	19	Summarize the main results (including an overview of concepts, themes, and types of evidence available), link to the review questions and objectives, and consider the relevance to key groups.	66-70
Limitations	20	Discuss the limitations of the scoping review process.	69-70
Conclusions	21	Provide a general interpretation of the results with respect to the review questions and objectives, as well as potential implications and/or next steps.	70
FUNDING			
Funding	22	Describe sources of funding for the included sources of evidence, as well as sources of funding for the scoping review. Describe the role of the funders of the scoping review.	N/A

Appendix 2.2: Grey literature search strategy

Google Scholar: Custom Google Scholar Search engines



# Search	# results	# results screened (~title/abstract)	# New potentially relevant records, full text screened	Included in the review	Date of search
1 Guidance + +shar*+ (Trial or study) + return+ result + (Patient or public or participant)	~8510	100	10	0	23rd May 2024
2 Guidance + Trial+ report + result + (Patient or public or participant)	~17,800	100	4	0	23rd May 2024
3 guideline + plain language summary + result+ (patient or participant or public) + trials	~17,800	100	2	0	30th May 2024
4 sharing or returning + result + research + (patient or participant or public)	~1,94,000	100	10	3	12th June 2024

Google Scholar sensitivity searches (post-peer review)

# Search	# results	# results screened (~title/abstract)	# New potentially relevant records, full text screened	Included in the review	Date of search
1 Guidance+(share OR shared OR sharing)+(Trial OR study) + return+ result + (Patient OR public OR participant)	17,700	100	8	0	17th March 2026
2 sharing OR returning+result+research+(patient OR participant OR public)	71	58	4	0	17th March 2026

Google search

# Search	# results	# results screened (~title/abstract)	# New potentially relevant records, full text screened	Included in the review	Date of search
sharing + results + with + research + participants	~348,000,000	100	10	4	15th June 2024

List of organisational websites searched during scoping review-grey literature stage:

Organisation / Website	Type of organisation	URL	Date of search
Health Research Authority (HRA)	Government / Regulator	https://www.hra.nhs.uk/	15th June 2024
National Institute for Health and Care Research (NIHR)	Funder	https://www.nihr.ac.uk/	15th June 2024
Be Part of Research (NIHR)	Patient participation group	https://bepartofresearch.nihr.ac.uk/	15th June 2024
Cancer Research UK	Charity	https://www.cancerresearchuk.org/	16th June 2024
PCORI patient centered outcomes research institute	Funder / Research institute	https://www.pcori.org/	16th June 2024
Multi-Regional Clinical Trials Center (Brigham and Women's Hospital and Harvard)	Research and policy centre	https://mrctcenter.org/	16th June 2024
OPEN ARMS (NDORMS)	Patient/public partnership group	https://www.ndorms.ox.ac.uk/open-arms	17th June 2024
EQUATOR Network	Reporting standards network	https://www.equator-network.org/	17th June 2024
Cochrane	Publishing / Research collaboration	https://www.cochrane.org/	18th June 2024
Taylor & Francis Group	Publisher	https://taylorandfrancis.com/	18th June 2024
Committee on Publication Ethics (COPE)	Editorial workgroup	https://publicationethics.org/	19th June 2024
International Committee of Medical Journal Editors (ICMJE)	Editorial workgroup	https://www.icmje.org/	19th June 2024
Federal plain language guidelines	Government agency website	https://www.plainlanguage.gov/guidelines/	19th June 2024
World Health Organization (WHO) – ICTRP	Global health body / Trial registry	https://www.who.int/clinical-trials-registry-platform	20th June 2024
U.S. National Institutes of	Registry / Research body	https://clinicaltrials.gov/	20th June 2024

Health – ClinicalTrials.gov			
European Medicines Agency (EMA)	Regulator	https://www.ema.europa.eu/	21st June 2024
U.S. Food and Drug Administration (FDA)	Regulator	https://www.fda.gov/	21st June 2024
UK Research and Innovation (UKRI)	National funder	https://www.ukri.org/	22nd June 2024
Wellcome Trust	Charity / Research funder	https://wellcome.org/	22nd June 2024
World Medical Association	Professional body	https://www.wma.net/	23rd June 2024
Centre for plain language	Plain language advocates	https://centerforplainlanguage.org/learning-training/five-steps-plain-language/	23rd June 2024
Plain English Campaign	Charity organisations website	https://www.plainenglish.co.uk/medical-information.html	23rd June 2024
The Health Foundation	Charity organisations website	https://reader.health.org.uk/s2-communicating-research-results/1-introduction#effective-ways-to-present-research-findings	23rd June 2024
Knowledge Mobilisation Alliance	Blogpost	https://kmalliance.co.uk/drawing-in-the-experts/	23rd June 2024
Centre for Global Development	Charity organisation	https://www.cgdev.org/blog/sharing-research-results-participants-ethical-discussion	23rd June 2024
Alberta Health and Wellness	Government health organisation	http://www.health.alberta.ca/initiatives/AHTDP-reviews.html	24th June 2024
Intellectus consulting	Private consultancy	https://www.statisticssolutions.com/how-to-share-your-research-findings-with-participants-and-stakeholders/	24th June 2024
Health Quality Council of Alberta (HQCA)	Provincial health quality agency	http://hqca.ca/studies-and-reviews/completed-reviews/	24th June 2024
Institute of Health Economics (IHE	Independent research institute / health economics think tank	http://www.ihe.ca/index.php?/publications	24th June 2024
Manitoba Centre for Health Policy (MCHP).	University-affiliated health policy research centre	http://mchp-appserv.cpe.umanitoba.ca/deliverablesList.html	24th June 2024
University of British Columbia. Centre for Health Services and Policy Research	Academic research centre	http://chspr.ubc.ca/publications/	25th June 2024
McMaster University, McMaster Health Forum. Health Systems Evidence	Academic research centre	http://www.healthsystemsevidence.org	25th June 2024
National Center for Biotechnology Information	Government organisation	http://www.ncbi.nlm.nih.gov/books	25th June 2024
TRIP database	Independent evidence-	http://www.tripdatabase.com	25th June 2024

	based research database		
University of York (CRD). Centre for Reviews and Dissemination	Academic evidence synthesis centre	http://www.crd.york.ac.uk/crdweb/SearchPage.asp	25th June 2024
World Health Organisation Global Health Observatory	International health organisation / data repository	http://www.who.int/gho/en/	25th June 2024
Canadian Medical Association (CMA)	National professional medical association	https/www.cma.ca/affiliates-associated-societies-and-observer-organizations	27th June 2024
Lund University Libraries	Academic library / institutional repository	http://www.doaj.org/	27th June 2024
Canadian Agency for Drugs and Technologies in Health (CADTH) – Rx for Change	National health technology assessment agency	http://www.cadth.ca/resources/rx-for-change/database/browse	27th June 2024
Registered Nurses' Association of Ontario (RNAO) – Publications and Resources	Professional nursing association	http://rnao.ca/resources	27th June 2024
University of Queensland	Academic institution	http://www.otseeker.com/	28th June 2024
INAHTA Secretariat – International Network of Agencies for Health Technology Assessment (INAHTA)	International research network	http://www.inahta.org/publications/	28th June 2024
WHO Regional Office for Europe – Health Evidence Network (WHO HEN)	International health organisation / evidence network	http://www.euro.who.int/en/what-we-do/data-and-evidence/health-evidence-network-hen/publications/by-keyword	28th June 2024
Department of Health and Human Services (HHS) – Clinical Trials Registration and Results Information Submission	U.S. government department / regulatory body	http://mchp-appserv.cpe.umanitoba.ca/deliverablesList.html	28th June 2024
NIHR INVOLVE – Plain English Summaries	UK national research funder (patient and public involvement initiative)	http://www.ihe.ca/index.php?/publications	1st July 2024
NIHR INVOLVE – Make it Clear	UK national research funder (patient and public involvement initiative)	http://hqca.ca/studies-and-reviews/completed-reviews/	1st July 2024

Cochrane – Standards for Reporting of Plain Language Summaries (PLEACS)	Research collaboration / publishing group	https://www.federalregister.gov/documents/2016/09/21/2016-22129/clinicaltrials-registration-and-results-informationsubmission	1st July 2024
Simply Put: A Guide for Creating Easy-to-Understand Materials	U.S. government publication (CDC / HHS)	https://www.invo.org.uk/resource-centre/plainenglish-summaries/	1st July 2024
Plain English Campaign – Guide to Design and Layout	Nonprofit advocacy organisation	https://www.invo.org.uk/makeitclear/	1st July 2024
Bristol-Myers Squibb – The Universal Patient Language	Pharmaceutical company	https://methods.cochrane.org/sites/default/files/public/uploads/PLEACS_0.pdf	1st July 2024
National Center for Health Marketing, Centers for Disease Control and Prevention – Plain Language Thesaurus for Health Communications	U.S. government public health agency	Centers for Disease Control and Prevention. https://www.cdc.gov/healthliteracy/pdf/Simply_Put.pdf. 3d edition April 2009.	1st July 2024
Duke M., Patients Participate! Project – How to Write a Lay Summary (Digital Curation Centre)	Academic / research communication initiative	http://www.plainenglish.co.uk/design-andlayout.html.	1st July 2024
European Federation of Pharmaceutical Industries and Associations (EFPIA) – Reflection Paper on Layperson Summaries	Industry association	https://www.upl.org/	2nd July 2024
Salita JT. Writing for lay audiences: a challenge for scientists	Journal article	https://www.orau.gov/hsc/HealthCommWorks/MessageMappingGuide/resources/CDC%20Plain%20Language%20Thesaurus%20for%20Health%20Communication.pdf.	2nd July 2024
Cancer Research UK – Style Guide for Health and Patient Information Pages	Charity / research organisation	http://www.dcc.ac.uk/resources/how-guides/write-lay-summary.	2nd July 2024
Chapman, S. Blogshots – Making Evidence Short and Shareable for Social Media (Evidently Cochrane)	Blog article / research communication platform	https://www.efpia.eu/media/25661/reflectionpaper-efpia-guiding-principles-on-laypersonsummary.pdf.	2nd July 2024
Schriver, K.	Journal article	*Medical Writing*. 2015;24(4):183-189. https://journal.emwa.org/writing-for-layaudiences/writing-for-lay-audiences-achallenge-	2nd July 2024

		for-scientists/.	
Centers for Disease Control and Prevention (CDC) – Everyday Words for Public Health Communication	U.S. government public health agency	https://www.cancerresearchuk.org/aboutcancer/about-our-information/style-guide	2nd July 2024
European Patients' Academy on Therapeutic Innovation (EUPATI)	Patient education and advocacy organisation	http://www.evidentlycochrane.net/blogshotsmaking-evidence-social-media/.	2nd July 2024
Plain Language Summaries in Medicine and Health Journals (Taylor & Francis)	Academic publisher / editorial guidance	Plain language in the US gains momentum: 1940–2015. *IEEE Trans Prof Comm.* 2017;60(4)343-383	2nd July 2024
Canadian Medical Association (CMA)	National professional medical association	https://www.cdc.gov/other/pdf/everydaywordsforpublichealthcommunication.pdf	3rd July 2024
Lund University Libraries	Academic library / institutional repository	https://www.eupati.eu/glossary-terms	3rd July 2024
Canadian Agency for Drugs and Technologies in Health (CADTH) – Rx for Change	National health technology assessment agency	https://htai.org/wp-content/uploads/2018/02/PCISG-Resource-ENGLISH-PatientandConsumerGlossary-Oct09.pdf	3rd July 2024
Registered Nurses' Association of Ontario (RNAO) – Publications and Resources	Professional nursing association	https://files.taylorandfrancis.com/journals-welcome-pls-plsps-11-apr-2024.pdf	3rd July 2024
Plain language summaries of publications of company-sponsored medical research: what key questions do we need to address?	Journal article	https://www.tandfonline.com/doi/full/10.1080/03007995.2021.1997221	3rd July 2024
Plain Language Summaries of Publications (PLSPs) Author Guidelines for Development, Submission and Publication	Publishing group	https://authorservices.taylorandfrancis.com/wp-content/uploads/2024/04/V9-PLSP-Guidelines-for-Authors-UPDATE-22-Mar-2024.pdf	3rd July 2024
Plain Language Summaries published by Taylor and Francis	Publishing group	https://www.tandfonline.com/topic/article-features/plain-language-summary	3rd July 2024

Appendix 2.3: Data quality matrix

Report ID	Scope clarified?	Development methods: reported?	Diversity considerations: reported?	Stakeholder involvement: Did it report patient and public involvement during development?	Content: Template or toolkit given?	Content: Timing and dissemination strategies suggested?	Accessibility: Where is it published?
Arnstein et al. 2020 [123]	Yes	Reported	Not reported	Yes	Yes	Not reported	Peer-reviewed journal
Baba et al. 2023 [133]	Yes	Unclear (Not detailed)	Not reported	Yes	Yes	Reported	Peer-reviewed journal
Canadian Frailty Network 2017 [124]	No	Not reported	Not reported	Not reported	Examples given	Not reported	Organisational website
Clinical Trials Ontario 2021 [134]	Yes	Not reported	Not reported	Yes	Yes	Not reported	Organisational website
Cochrane 2022 [141]	Yes	Unclear (Not detailed)	Not reported	Yes	Yes	Not reported	Cochrane website
Duke et al. 2012 [125]	No	Not reported	Not reported	Not reported	No	Not reported	Organisational website

Dunagan et al. 2013 [144]	Yes	Reported	Reported	Yes	No	Reported	Peer-reviewed journal
European Commission 2018 [135]	Yes	Not reported	Not reported	Not reported	Yes	Reported	Regulatory organisation website
European Commission 2021 [136]	Yes	Reported	Not reported	Yes	Yes	Reported	Regulatory organisation website
Fernandez et al. 2003 [126]	Yes	Reported	Not reported	Not reported	No	Reported	Peer-reviewed journal
Fernandez et al. 2012 [132]	Yes	Reported	Not reported	Not reported	No	Reported	Peer-reviewed journal
Health Research Authority, 2021 [127]	Yes	Not reported	Not reported	Not reported	Provides links to further resources and toolkits developed by other agencies	Not reported	Government agency website
Hintz and Dean. 2019 [145]	Yes	Reported	Not reported	Not reported	No	Reported	Peer-reviewed journal

Knowles et al. 2022 [142]	Yes	Unclear (Not detailed)	Not reported	Yes	No	Not reported	Organisational website
MRCT FDA, 2017 [137]	Yes	Not reported	Not reported	Not reported	In the appendix, a toolkit is suggested however it is not finalised	Reported	**Not officially published yet**
MRCT Center 2017 [138]	Yes	Reported	Not reported	Not reported	Yes	Reported	Organisational website
NASEM 2018 [143]	Yes	Reported	Not reported	Yes	No	Not reported	Government agency website
Rosenberg et al. 2021 [128]	Yes	Reported	Not reported	Yes	No	Not reported	Peer-reviewed journal
Solovyeva et al. 2023 [139]	Yes	Reported	Not reported	Yes	Yes	Not reported	Organisational website
Taylor & Francis 2023 [129]	Yes	Not reported	Not reported	Not reported	No	Reported	Taylor & Francis website

TransCelerate BioPharma 2016 [118]	Yes	Not reported	Not reported	Yes	Yes	Not reported	Organisational website
Vanderbilt Institute for Clinical and Translational Research 2022 (a) [131]	Yes	Not reported	Reported	Yes	Yes	Not reported	Organisational website
Vanderbilt Institute for Clinical and Translational Research 2022 (b) [130]	Yes	Reported	Reported	Yes	No	Not reported	Peer-reviewed journal
Zimmerman 2022 [140]	Yes	Reported	Reported	Yes	No	Not reported	Peer-reviewed journal

Appendix 2.4: Suggested content for sharing study results

Report ID	Format of result output	What the content should include:	Template or toolkit given?
Arnstein et al. 2020 [123]	Plain language summary	1. Plain language title 2. Date of summary: indicate how current the summary is 3. Disclaimers: Clarify drug approval status; consider including relevant differences between countries Place study into context as a single piece of evidence in a wider research landscape 4. General information about the study (what did this study looked at) 5. Drug names/technical terms: Include phonetics, generic name, and brand names (usually more familiar to patients; limit use in PLS to keep it non-promotional) 6. Timeline visual: Simple timeline to indicate drug development stage (where is this study in the drug development timeline) 7. Study participants: General information to help readers check how similar they are to the study participants 8. Key results: Keep PLS concise to enhance reading ease 9. Neutral conclusions 10. Shared decision-making prompt: Enhance patient safety and patient-doctor relationship, and involve the reader (key health literacy principle: highlight desirable action) 11. Information about follow-up studies If available 12. Sponsor contact details 13. Thank you to study participants 14. Signpost to further information 15. QR code: Link to digital version of PLS, if applicable 16. Link to original publication: Specify access status 17. Disclosures: Provide transparency around authorship and funding source	Yes
Baba et al. 2023 [133]	Plain language summary	1. Title 2. Thank you! [Language to consider: Thank you for volunteering your time and effort to this clinical trial. (If the study is a long, ongoing study: We appreciate your commitment to this study over X number of years.) We sincerely appreciate your contribution to this trial and in helping to advance medical knowledge.] 3. At a glance.	Yes

		Our goal: [1-2 sentence(s) about the primary aim of the trial.] Participants: [A sentence describing who participated in the trial.] Results: [1-2 sentence(s) about the key findings of the study.] Side effects: [A sentence describing key side effects of the intervention.] Next steps: [A sentence describing what the next steps or follow-up will look like.] 4. Trial information [Include the following information, as applicable: Trial name, investigator name(s), sponsor, funder, study start/completion dates, clinical trial identifier or registration/universal trial number.] For more information: [If relevant, add in link(s) to any publication(s), study website and/or contact information for participants to request the publication if it is not publicly available or to ask questions about the trial, e.g., whether they received a placebo or treatment.] 5. About the trial: What did we do? [1-2 sentence(s) about what the study did to achieve its aim (e.g., we compared two medications and a placebo).] How did we do it? [1-4 sentence(s) about the study's methods.] What did we want to know? [1-2 sentence(s) about the study's hypotheses or research questions.]	

		How did we engage patients/families? [If relevant, add in 1-2 sentence(s) about how the trial engaged patients/families in the planning and conduct of trial, interpretation of results, and/or preparation of this summary.] Study phase: [If relevant, consider including 1-2 sentence(s) to explain what the study's phase means (e.g., Phase 3: This phase focuses on whether the drug works well and how safe it is). Shade in the appropriate phase for your trial. If study phase is not applicable to your trial, consider replacing section with trial type/design.] 6. Participants: [List the main inclusion/exclusion criteria of the trial in bullet point form or provide a brief summary of who could participate in the trial. Consider including link to the full inclusion/exclusion trial for the trial. Number of participants: [Numbers overall and participants per arm. Add in definitions of technical terms (e.g., “randomised”). Differentiate between number of participants who started the trial/were randomised to treatment groups versus those that completed the trial, as appropriate.] 7. Location. [If needed, written description of the location(s) relevant to the trial.] 8. Results: [This section may be broken down into subheadings (e.g., primary and additional secondary outcomes) described in neutral, unbiased language. If applicable, consider identifying patient-reported outcomes. When reporting results in relation to number of participants, include percentages as well as numbers. Differentiate between any short or long-term effects, as appropriate.] [Consider noting that no individual results are provided in this document, and/or including information on the potential impact of the results on the population under study.] 9. Side effects: [Consider including a side effects section here, as applicable. Depending on your trial, consider renaming this section to best fit your purpose (e.g., psychological adverse effects). Include and focus on the most frequent,	

		most serious, and/or unexpected side effects in this section, and provide reasoning behind listing the ones that are on the template.] [A table describing the number and percentage of side effects in each treatment group may be beneficial – feel free to modify the table below as appropriate to fit your specific trial findings. Define or quantify what mild, moderate, and severe means in the context of your trial (e.g., as per GCP guidelines). Consider including a link where individuals can access all side effects experienced during the trial for those who want further details.] 10. Trial limitations: [If applicable, this section may include information on what the trial couldn't show, results for populations that were excluded, etc.] 11. Trial conclusions: [Include details here on conclusions and interpretations drawn from the trial findings and results.] 12. Next steps: [Include details here about what's next for the research (e.g., moving to phase 3 after phase 2, another study, publication, licensing), information or other opportunities to be involved in future phases of the trial if applicable, what the findings of this trial mean for people who live with the condition studied (e.g., clinical care), and whether and when the intervention might be available after the study, etc.] **Discussing this trial with your doctor:** [Consider inserting a summary infographic here. Language to consider for this section: Let your/your child's doctor know the results of the trial that you/your child participated in, experience in participating in the trial (e.g., when the trial started/ended), and whether the trial intervention worked or did not work.]	
Canadian Frailty Network 2017 [124]	Lay summary	Writing a lay summary for research results: • what was the question asked by the researchers, • what did they do to find the answer, • what did they find out, • what do the results mean, and • what should happen next.	Examples given

Clinical Trials Ontario 2021 [134]	Plain language summary	This is a summary document of the results of a clinical trial in which you participated. Trial information: [Trial name, investigator/sponsor, study dates, clinical trial identifier or registration/universal trial number] About the trial: [e.g., disease studied, intervention, goal and hypothesis] Phase of trial Number of participants: [numbers overall and/or participants per arm using graphics/diagram] Location: [may wish to use a map or list if there were local, national, international sites] Results: [related to primary and secondary endpoints (in neutral, unbiased language), side effects, next steps (e.g., another study, publication, licensing, what this means for people who live with the condition studied – e.g., clinical care)] You may wish to note that no individual results are provided in this document, include information on the impact of the results on the population under study, etc. Trial limitations: [this may include populations that were excluded from the study, or other limitations, and how these may be addressed in the future] For more information: [link to publication or study website/contact information to request the publication if it is not open access or to ask questions about the trial, e.g., if participants wish to be unblinded, see if intervention is available after the study] Thank you: [Language to consider: Thank you for volunteering your time and effort to this clinical trial. (If the study is a long, ongoing study, could insert a sentence: It is appreciated that you committed to this study over many years.) We sincerely appreciate your contribution to this trial and to help advance medical knowledge.] How to discuss this trial with your doctor: [insert information – e.g., may wish to share these results with their doctor]	Yes

Cochrane 2022 [141]	Plain language summary	Word limit:400 to 850 words, including the title Template headings • **Plain language summary title** • **Key messages** -The key messages section should include at least two and no more than three bullet points or short paragraphs that summarise: • the most important review findings, including any mention of unwanted or harmful effects. If unwanted effects were not reported, say so. • the main implications of these findings for practice (for example: does the treatment work?) or research (for example: do certain gaps in research need to be addressed in future?). • ***Tailored heading: for example, What is epilepsy?*** • ***Optional tailored heading: for example, How is epilepsy treated?*** • **What did we want to find out?** -The PLS should include a brief explanation of the review topic. You should provide enough information for the reader to understand: • what the review is about. For example, what is the condition of interest? How is it treated? • what the review authors wanted to find out. • **What did we do?** -The Plain language summary should explain the review methods very briefly. For example, that the review authors: • searched for studies with specific characteristics (for example, about a specific population, treatment or comparison); • summarised the evidence across studies; and • evaluated the evidence. • **What did we find?** -This section should report: • the main characteristics of the studies that were included in the review; • the main results of the review (those presented in the summary of findings table(s) and the Abstract). • **Optional heading: Main results** • **What are the limitations of the evidence?**	Yes, a template and examples given

		-The PLS should mention the main reasons for down-GRADEing the certainty of the evidence, using plain language. • **How up to date is this evidence?** -Readers should be able to tell from the Plain language summary how current the included evidence is. Therefore, you should mention the month and year that the review authors searched for studies.	
Duke et al. 2012 [125]	Lay summary	Content The text should provide answers to the essential questions: Who, What, Where, When, Why, How? For example, the reader should easily be able to find answers to questions such as 'By whom was the research funded, and why?' Relevance, application and benefits Aims and objectives should be clearly signalled. For example, the 'point' – the impact – of the work should be clearly understood. Everyday examples Give concrete everyday examples wherever possible. Timescales Timescales, if relevant, should be clearly defined. Risks If it is relevant to the activity, you are summarising, make sure that any risks attached to the activity are clearly identified and described.	No

Dunagan et al. 2013 [144]	When determining which materials and formats to use, teams need to consider the nature of the study data, key messages, the preferences of the study community, and what resources are available. Report-back materials may include graphs, text, pictures, video, DVDs and other media or a combination. Some studies may present opportunities to experiment with new media, such as	**Description** **What did you find?** List of detected chemicals **How much?** Concentration shown in a table or graph **Analysis/Comparison** **Is that high?** Study participant's result shown in relation to • the distribution of others in the study or • a reference group, such as CDC Exposure Report **Is it safe?** Study participant's result shown in relation to • a health-based regulatory guideline • levels associated with health effects in epidemiologic studies **What should I focus on?** Results for tested chemicals shown in relationship to each other **Where did the chemical come from?** List of types of products or processes that commonly contain or emit detected chemicals such as combustion and auto exhaust or specific types of consumer products **Recommendation** **What can/should I do?** Individual and community exposure-reduction strategies, precautionary strategies, research needs	No

	interactive web-based tools; however, these formats may raise additional challenges to protecting confidentiality. Engaging community members or trusted representatives can help teams design materials that are appropriate. Teams can assess participant preferences through focus groups, community meetings, conversations, surveys, or other methods.		

European Commission 2018 [135]	Lay summary	Annex V of the EU CT Regulation sets out ten elements that must be addressed in the lay summaries. 1.Clinical trial identification (including title of the trial, protocol number, EU trial number and other identifiers); 2.Name and contact details of the sponsor; 3.General information about the clinical trial (including where and when the trial was conducted, the main objectives of the trial and an explanation of the reasons for conducting it); 4.Population of subjects (including information on the number of subjects included in the trial in the Member State concerned, in the Union and in third countries; age group breakdown and gender breakdown; inclusion and exclusion criteria); 5.Investigational medicinal products used; 6.Description of adverse reactions and their frequency; 7.Overall results of the clinical trial; 8.Comments on the outcome of the clinical trial; 9.Indication if follow up clinical trials are foreseen; 10.Indication where additional information could be found.	Templates are included in the guidance
European Commission 2021 [136]	Lay summary	Content as Laid Out by the EU CT Expert Group on summary of Clinical Trials results. Although not required by the EU CTR, a short abstract summarising the content of the LS is suggested by the EU Expert Group on Clinical Trials Recommendations. In addition to the content that must be included according to the EU CTR, the GLSP encourages sponsors to thank trial participants for their contribution in the trial within the first paragraphs of the LS. The LS should be dated (e.g., with the date of sponsor's approval), and it should be made clear that information disclosed in the LS is current at that time. It is strongly encouraged that this principle is adopted for all LS versions including any LS based on interim results and all translated versions into local languages. The EU CTR requires the LS to include the main objectives and overall results of the trial. The LS should therefore reflect at a minimum the results of the primary endpoint(s) and potentially patient-relevant secondary endpoints . As no broadly accepted definition for "patient-relevant" endpoints exists and in order to keep the LS short, sponsors may prefer to limit result presentation to the primary endpoint(s). Independent of the sponsor's choice on endpoint presentation, a reference link to the complete list of outcomes in the scientific Summary of the Clinical Trial Results in the EU Database should be included in the LS. Presenting tertiary/exploratory endpoint results in the LS is generally discouraged.	yes

		Safety information: The EU CTR specifies that a “description of adverse reactions and their frequency” must be included in the LS.	
Fernandez et al. 2003 [126]	Internet site/oral report/lay summary with appendix directing to peer-reviewed publications from the study	1. Identify participation of patient in study 2. Identify who gave consent for participation (individual or parent/guardian) 3. Describe consent process and remind participant or parent/guardian of how he or she fits into that process 4. Describe possible harms and benefits of receiving research results 5. Obtain consent to give research results; stop here if consent to provide a summary of research results is not obtained 6. Define in lay language the type of study that the participant took part in (i.e., phase 1, 11, III, epidemiology) 7 State name and objectives of the study (primary and secondary) 8. State the nature of the participant's involvement (i.e., randomised to study arm, biological samples taken, observations made) 9. State overall results of the study including when the results were first available in relation to the participant completing the study 10. State the explicit overall results of the study * Benefits * Harms 11. State anticipated long-term effects and surveillance recommended, if any, for the participant 12. State what has been done with the information obtained from the study 13. State suggested follow-up plans, if any, and arrange for further counselling by appropriate health professional, if needed 14. Provide/offer written copy in lay language of the discussion, if requested. Provide a technical bibliography, if requested. 15. Document: Date of meeting; Who attended meeting; What was said; Follow up plans	No

Fernandez et al. 2012 [132]	Plain language summary	1. Introduction: Thank you for taking part in the research General description of risks and benefits of receiving results Direction of questions to personal health care providers 2. Name of study: Include formal and lay name 3. Brief background reason for the study: List major questions asked in the study 4. Brief summary of what occurred in the study: List major interventions, including elements such as randomisation 5. What are the major findings of study? Include an interpretation as to whether these are positive or negative findings 6. What did researchers learn that will be helpful to children with this condition in the future? Highlight if the experimental or standard arm will likely become the standard of the future 7. What are the next research steps? Include a general statement of how the results from this study will be built upon 8. Are there any steps that you or your child should consider now because of findings of this study? Provide a recommendation if there is clear evidence; provide a suggestion if less clear; qualify that any recommendations listed must be discussed with health care team 9. Are there any steps that you or your child should consider for the future because of study findings? Provide a recommendation if there is clear evidence; provide a suggestion if less clear; qualify that any recommendations listed must be discussed with health care team Provide reference to long-term follow-up guidelines such as http://www.survivorshipguidelines.org/ 10. Whom do I contact to receive additional information? Direct participant to treating institution Provide date of summary Indicate whether and when update may be expected Provide a list of publications with references that were generated from this study. This may be provided separately on the Web site	No

Health Research Authority, 2021 [127]	Plain language summary	PLS should include: Thank you to study participants General information about the research such as: Study title Who carried out the research? (including details of sponsor, funding and any competing interests) What public involvement there was in the study (how many people, what their relevant lived experience was, and what they did) Where and when the study took place Why was the research needed? What were the main questions studied? Who participated in the study? What treatments or interventions did the participants take/receive? What medical problems (adverse reactions) did the participants have? What happened during the study? What were the results of the study? How has this study helped patients and researchers? Details of any further research planned Where can I learn more about this study?	Provides links to further resources and toolkits developed by other agencies
Hintz and Dean. 2019 [145]	Plain language summary	In the summary report, review the study background, aims, findings, and limitations Offer additional ancillary materials with technical findings and directions for accessing the published study or studies If applicable, provide additional sources of support to prevent possible harm resulting from the return of study findings. Elaborated: . When returning findings to participants, regardless of the channel or method used to do so, it is necessary to begin by recapping the type of study the participant participated in, the name and goals of the study, and the nature of the participant's involvement in the study (Fernandez, Kodish, and Weijer, Citation2003). Next, Fernandez, Kodish, and Weijer (Citation2003) further suggest explaining the study findings and defining when the findings became available for disclosure (i.e., when the peer review process was completed). Then, reiterating the potential benefits and harms, if any, to the participant, and offering resources to counteract those potential harms (detailed in the "Additional Resources and Support" section	No

		below) is advised (Partridge et al., Citation2005). Finally, explaining what has been done with the information obtained in the study, and reiterate policies governing the protection of private participant data. If data analyses are ongoing, it is necessary to solicit consent from participants prior to distributing any additional findings (Fernandez, Kodish, and Weijer, Citation2003). The researcher should also explicitly state any follow-up plans for contacting participants and record the date when findings were returned. Participants should be given the opportunity to ask questions about study findings (Fernandez, Kodish, and Weijer, Citation2003).	
Knowles et al. 2022 [142]	Not specified	Content: Better organisation of content is key to helping people navigate reviews and find what they are looking for. Most importantly, outputs for patients shouldn't be presented like a paper! Rather than wanting background, methods, and findings, patients wanted to first know who the info was for, what the key findings were, and then have the option to explore in detail what was done. Process: Probably the most important recommendation from the study is about the need to work on outputs collaboratively. Working out the value of a review for patients themselves, and thinking through how different groups may want to access that information, is something that researchers need to do in partnership with contributors. Working with experts in information design and visual communication is necessary to support researchers who don't have those skill sets. We also encourage researchers to think about the process that patients go through to engage with a review – how do they find it? What do they want to happen afterwards? We need to think about a user journey of a patient seeking and reacting to a review, not just think about reviews as an isolated object.	No
MRCT FDA, 2017 [137]	Plain language summary	The PLS should contain: o Recognition of the contributions of subjects o Study title § A short study title in plain, non-scientific language § The full title (official title) of the study § Include US NCT number (and other identifying information as appropriate, for example the protocol number) o Study purpose § Why the study was conducted o Study information § The FDA-regulated product under study and any comparators (the names for each being the name used in the study registration) § Start and end dates of the study § Countries where the study took place	In the appendix, a toolkit is suggested however it is not finalised

		§ The number of subjects enrolled § The type and phase of the study § The date the PLS was produced with a statement that the PLS is current as of this date Study overview § A high-level description of the study design, treatment(s) and other pertinent information that may be helpful to understanding the results § A picture or diagram as appropriate o Study population § Demographics (e.g., age, gender, and race) § Key inclusion/exclusion criteria o Primary outcome(s) § Describe the results for the primary endpoint(s) for each study arm § Describe the outcome measures in plain, non-technical language § Present the data in simple tables using both absolute numbers and percentages as appropriate § Differences that are not statistically significant should be indicated o Safety: § Provide the incidence of investigator determined “drug-related adverse events” to indicate a potential causal relationship between FDA regulated products under study and an adverse event § The plain language term “side-effects” may be used in this context to indicate “drug related adverse events” § Serious “side effects,” including participant deaths, should be listed as well as non-serious “side effects” using a reasonable and disclosed cut-off for those that are common § Include a link to the reported scientific results for a listing of additional safety information § Additional safety data important to the overall results of the study may be included so long as inclusion is balanced and there is reasonable justification o Comments on outcome of the study § High level statement(s) regarding the study o Additional information § A statement that patients should consult their physicians and/or study doctors with further questions about their individual care and should not make changes in the treatments based on the results of this study § A statement that the summary includes the results of a single study and that multiple studies are used together to assess the risks and benefits of an FDA-regulated product § Where additional information may be found (include a link the scientific summary posted on www.ClinicalTrials.gov)	

		§ Whether further research is anticipated, as appropriate and as available in the public domain. Contact information for and the name of the study sponsor or call centre if applicable.	
MRCT Center 2017 [138]	Plain language summary	Essential Sections for Plain Language Summaries (PLS) A thank you to study participants Includes a simple thank you for the study participant's contribution to the study. This is part of the header in the template, but can also be placed in the body of a letter. Study name Describes the study in plain, simple language for study participants who may not understand medical or scientific terms. The full title is required by U.K. guidelines, with short title added, if desired, as well. State that this summary includes only results from one single study. Other studies may find different results. Newer information since this summary was written may now exist. Who sponsored this study? List all sponsors, including companies, private foundations, public funding, donors, etc. General information about the clinical trial Includes the following § Start and stop dates, with explanation of early stoppage when appropriate (see Early Clinical Trial Closure template in the MRCT Return of Aggregate Results Toolkit) § Countries in which the study was conducted § Why this study is important, purpose of the study, and why the endpoints were chosen. Consider including a brief, simple statement of what is known about the disease/condition and how it is generally treated. What patients/people were included in this study? Includes the following • Characteristics of the study population, number enrolled, number randomised and number completing study. • Clear description of the specific population that was studied (e.g., key eligibility criteria such as age, gender, race/ethnicity, molecular subtype of the disease under study) • A clear statement that the results apply to this population, and not any other population, and under these specific conditions. Explanation that other information may be available later and where such information may be found What medicines [or vaccines] were studied? Explain the phase of this study and the fact that this is only one study in an overall drug development process. Provide a simple explanation and consider picture or diagram that shows the protocol flow, number of arms, treatment per arm, and other pertinent information that is helpful to understanding the results (e.g., study procedures especially if relevant to the understanding of the results). The contextual information should help to ensure comprehension of results. Avoid or minimize the use of unfamiliar acronyms and medical terms. If	Yes

		any medical terms are used, include a simple explanation, followed by the medical term in parentheses. For example: “numbness and pain in hands and feet (peripheral neuropathy).” What were the side effects? Consider using simple terms (e.g., symptoms, side effect81 , warning signs, safety events) instead of “adverse events.” Define the term used in simple language. Additional information to consider in this section: • For each adverse event: how common or rare; how mild or severe? • Any secondary endpoint that statistically measured adverse events • A description of any severe effects (if they occurred), with an explanation of short or long-term consequences, when possible • Additional regulatory requirements - described in clear, simple terms • Plain language should be used, not medical jargon, when describing adverse events (i.e., use “fainting” instead of “syncope”). What were the overall results of the study? Write a concise summary statement with the take-home message (like an abstract to a paper). Results must be communicated in a factual manner and a simple data table presenting the primary endpoint(s) may be helpful. In addition, safety data may be presented that are important to the overall results of the trial. How has this study helped patients and researchers? Include wording such as “This research helps future patients and families by helping us understand more about each medicine today. Include important limitations of the study, the state of result analysis, and how findings from this trial will be used. Are there plans for further studies? Include whether other related trials are ongoing or provide public information about related trials. Where can I find more information about this study? If you have questions, please talk to your [e.g., study doctor, trial designee for study specific questions, or your personal physician about your individual health care] or contact [list appropriate contact information and/or resources available] about the study or your part in it.” List the official numbers (e.g., protocol number, federal number(s), other IDs), followed by the official title of the study, with wording such as “To learn more about this trial, visit the ClinicalTrials.gov website at [provide URL link for this protocol here]. More information may also be available by looking up the official number or title, or by going to [list any websites that may have sponsor information, plain language information, non-scientific articles, etc.].” List additional information that will help explain the study or the disease/condition, such as “You can also find more details about this study at: [List all applicable citations and websites that are not listed in ClinicalTrials.gov. This can include resources as well as articles].” Include date result summary was produced. If there are substantive changes, an addendum will be created. (Occasionally the first communication is updated rather than an addendum created.) Thank them again.	

NASEM 2018 [143]	not specified	Whenever individual research results are communicated to participants, investigators and institutions should facilitate understanding of both the meaning and the limitations of the results by ensuring that there is a clear takeaway message and necessary reference information to convey what is known and not known about both the meaning of the result and potential clinical implications; communicating effectively the level of uncertainty in the result validity; providing mechanisms for participants to obtain additional information and answers to questions when appropriate and feasible; providing guidance for follow-up actions/consultations when appropriate; aligning the communication approaches to the particular needs and preferences of the participants and the context of the study; providing a written summary of the results and other information communicated to participants for future reference by participants and investigators; and leveraging existing and emerging health information technologies to enable tailored, layered, and large-scale communications when appropriate. RESULTS THAT INVESTIGATORS OR LABORATORIES ARE OBLIGATED TO RETURN Urgent, clinically actionable, valid results (ethical obligation under duty to warn/rescue) Results that are in the designated record set of a HIPAA-covered entity if they are requested by the participant (legal obligation under HIPAA, the Health Insurance Portability and Accountability Act of 1996) RESULTS THAT INVESTIGATORS SHOULD BE DISCOURAGED FROM RETURNING Results that cannot be interpreted at the individual level without a risk of misinterpretation Results that have limited value to participants and would entail significant burden (cost or complexity) to return Results without established clinical validity for a life-threatening or sensitive health condition Results for which there are serious questions regarding validity or identity (e.g., those generated in a laboratory with no quality management system and for which a peer-review process has determined that quality assurance processes are insufficient to offer confidence in the results' validity or identity) When results are being offered to participants, the most straightforward way of offering a single, clear takeaway message is to provide a concise statement of why the results are being returned and a clear summary of the meaning of the results based on the research team's current knowledge of the test performed at that point in time. Given that scientific knowledge is constantly evolving, especially in terms of understanding research results, investigators should clarify both the date when the message is being generated by the study team and how likely or unlikely it is that the interpretation of the result might change in the future. In addition, given the evidence discussed above of substantial language and literacy barriers to comprehension, the importance of providing action steps (if appropriate) clearly and in plain language cannot be overstated.	No

Rosenberg et al. 2021 [128]	Plain language summary	these plain language summaries are: Targeted toward a broad, inclusive and non-technical, non-specialist, or time-challenged audience Written in easily understandable, unbiased language that is free of expert or technical jargon and accessible to readers who may have a different first language to that of the summary Text based and concise (of 250 words or fewer) – this allows for indexing in directories such as PubMed and facilitates straightforward translation Explicitly linked to the source publication citation and relevant clinical trial identifiers, with brief reference to the existing evidence Consistent with the same overall key points and conclusions as the scientific publication abstract Developed alongside the main content of the manuscript, in line with the International Committee of Medical Journal Editors' authorship criteria Ideally reviewed by a non-expert during development Fully peer reviewed alongside the main content Made available to read free of charge alongside the scientific publication abstract Tagged with appropriate metadata and keywords to improve discoverability in search engines, directories, and indexes.	No
Solovyeva et al. 2023 [139]	Lay summary	Title/Headline • 1-2 sentences summarising the key findings/main outcome(s) of the trial. • The section should mention the results are from an early phase trial. • Period the study ran for, and date the summary was written should be included. What were the conclusion? • This section could be seen as a "lay abstract", providing high level overview of the study results (beyond the main headline described above) • State the results do not translate into clinical benefit, how the study has helped (who/what?) and briefly outline the implications of these results for the current research landscape (e.g., further trials	yes

		planned or not) • Consider your audience, and what you want them/what they can do with this information. Why was this research needed? • Identify the condition or diagnosis. Provide brief explanation of the rationale for the trial, identifying the state of knowledge before the trial and the key question it was trying to answer. • Include one or two sentences that provide key background information. Who volunteered to take part in the trial? • State the number of participants involved. • State the type and stage of disease. E.g., for cancer, state the type of cancer and the stage of cancer. • Consider the relevance and amount of information provided on trial population. What is important/relevant to provide for this specific question/trial? How did we deliver the trial? • State the type and stage of disease. E.g., for cancer, state the type of cancer and the stage of cancer. • State who the research team are and highlight PPIE involvement in the design or the study delivery. • State where the study took place, and the period of time patients were recruited over (if different from the dates indicated in the headline). How was the trial done? • Describe the intervention in simple pictorial manner (if possible/appropriate) Consider how best to depict the intervention at an individual (patient) level, as well as any group/cohorts (as appropriate). • Focus on what actually happened in the trial, and not what was originally planned (though if important or relevant changes were made during the course of the trial, this should be highlighted and discussed in next sections. • Consider including information on the mechanism of action of the treatment. • Provide information on procedures and frequency of follow-up and safety monitoring (on and off treatment) • Ensure that patient reported outcomes are given equal importance to outcomes related to drug effect. What were the results? • To avoid repetition, summarise this with key statistics from the trial. E.g., X % of participants could tolerate this dose. • This section should be used to report on the trial conduct and results and reflect/assess success/performance against what the trial set out to achieve (consider trial conduct as well as scientific objectives): Ø Trial recruited to target, what safe doses were identified, hypotheses proved. This section	

		should highlight positives from the trial conduct and results. Ø Any issues that necessitated changes to the trial. Ø Any questions that weren't answered or that emerged due to the results. What were the main challenges for patients with the treatment? • Side effects observed. Adverse events/reactions jargon should be avoided. Side effects should ideally not be listed in a table but summarised by relevance and put into context (expectedness, overall tolerability, comparison with other treatments… as appropriate). • Include PROMS and QoL results as appropriate to contextualise tolerability. What happens next? • Any plans/recommendations to answer the remaining questions stated in the section above. • Explain any plans for further studies, already running or planned. Where can I find more information? • Full study name, funder and sponsor • When including link to scientific publication, consider appropriate format (depending on how the summary is disseminated) as well as how accessible the linked publication is (journal subscriptions, etc). Also consider the use of QR codes or any other support to increase accessibility. • If appropriate, include a contact to allow readers to get in touch. Acknowledgments/Statement of thanks: • Use this statement to thanks the study participants and acknowledge their contribution to the study, as well as sites and trial teams and any other relevant contributor.	
Taylor & Francis 2023 [129]	PLSPs can include text and/or graphics, with the optimal format being a mix of graphics and text. Audio and video files are also welcomed. For conciseness	Content ✓ Answer the questions: o Why was the study done? o What did the researchers do and find? o Who took part in the study? o What do the results mean? o What were the main conclusions? o Why are the findings relevant to, and how do they affect, the PLS/PLSP target audience? o What is the objective influence on the wider field? Please note that these questions do not need to be used as headings; they are provided to help authors determine what information to include in PLS/PLSPs. ✓ Keep statements factual and avoid providing opinions or speculation on the study's findings and significance.	No

	and adherence to optimal formatting of graphics and text, the recommended length is 3000 words or less (not including text in graphics). However, please note that this is a guide, not a limit.	✓ Ensure statements accurately reflect the information and data within the original article, and there are no statements that could be considered misleading or misrepresentative.	
TransCelerate BioPharma 2016 [118]	Non-promotional lay summary	Recommendations for Using Non-Promotional Language for Lay Summaries » The overall tone and content should be factual and objective. » Care should be taken that comments on the outcome of the clinical trial are factual in nature and do not make inferences or assessments. The Neutral Language Guidance section of the MRCT Return of Results Toolkit provides examples of recommended language. » Materials should not have a commercial or marketing appearance related to the investigational medicine (e.g., do not use brand colours, brand logos or imagery; however the same concern may not apply to sponsor logos or colours). » Information should be accurate and not misleading in any way. » Materials should be fair and balanced (i.e., include information on the efficacy and the safety data from the trial). Materials should also be fair and balanced in terms of formatting (e.g., appropriate detail and prominence of the safety data). » Care should be taken to ensure that the lay summary is made available in a non-promotional context (e.g., where posted to a sponsor's website, there should not be links from webpages that are promotional). » A statement should be added that further information on the trial can be found on ClinicalTrials.gov and the EU Clinical Trial Register so that additional information is readily available.	No

		» A statement should be included stating that results are from a single trial and new information or different results may be obtained from other studies » A statement should be included that therapeutic changes should not be made based on the results of a single trial without consulting a healthcare professional. » Approval status should not be provided in the lay summary. Specific indications and countries where approved should not be provided as indications may vary in different countries which could lead to a promotional concern if stated too broadly. » If an organisation elects to provide translations, they should be cautious to ensure that the translated text doesn't contain promotional language.	
Vanderbilt Institute for Clinical and Translational Research 2022 (a) [131]	Summary	Critical elements: limit to 2-3 sentences for each element, when possible 1. What is the important question you were answering(background) Why is this important? What is the historical context? What problem does this research address? Who is the target audience? 2. What did you do (methods) What happened? Who was involved? 3. What were the findings (result) How do the findings relate to public health? 4. What does this mean (discussion/implications) How will these findings change things? What are the next steps? 5. Acknowledgement of research participants and community involvement Thank participants in the study Highlight community partnerships and/or extent of community engagement in the study (e.g., community engagement studios, focus groups, community advisory board review) Include additional public dissemination activities 6. Include link to published results	Yes-template

Vanderbilt Institute for Clinical and Translational Research 2022 (b) [130]	Narrative summary/Infographic/Video	CRITICAL ELEMENTS – (limit to 2-3 sentences for each element, when possible): Element 1: Acknowledgement of research participants' involvement Thank you to all participants who contributed to this study. Element 2: What is the question you were answering? (Background) This study investigates [insert research question]. Understanding this is crucial because [explain importance and historical context]. This research aims to address [describe the problem]. Element 3: What did you do? (Methods) We conducted [briefly describe the methods used], involving [mention participants or key collaborators]. Element 4: What were the findings? (Results) Our findings indicate [summarise key results]. These findings are significant for public health because [explain relevance]. Element 5: What does this mean? (Discussion/Implications) These results could lead to improvements in [mention impact on health care, policy, etc.]. Next steps include [describe future plans or implications]. Element 6: Include link to published results. For more detailed information, please refer to our published results [insert link].	Yes-template
Zimmerman 2022 [140]	Lay summary	1. Why was this study needed? 2. What kind of study was this? 3. What happened during the study? 4. What were the study results? 5. What side effects did (infants, children, adolescents, etc.) experience? 6. What happens next? 7. Who conducted the study? 8. Where can I learn more about this clinical trial?	No

Appendix 2.5: Recommendations on how to present study results

Report ID	What are the recommendations on presenting information?
Arnstein et al. 2020 [123]	1. Plain language title: Minimum 16pt font 2. Call-outs: Contrasting colours highlight key content; avoid using white text on a dark background 3. Text hierarchy: Differentiation in text styles help to signpost most important information to the reader; keep font sizes readable 4. 'Funnel' structure: Move from the big picture to the purpose 5. Open question headers: Question format can help to engage readers; numbering is supported by evidence 6. Bullet points: Reduces text density and can help to 'group' related information 7. Respectful language People with (condition), not patients 8. Data visualisation: Simple visuals may enhance reader experience 9. Cultural sensitivity: Use simple icons that can be understood across cultures 10. white space 11. Numeracy principles: e.g., use natural frequencies and percentages; avoid variable frequencies 12. Clear sections: Colour blocks and divider lines ensure clear differentiation between sections
Baba et al. 2023 [133]	Use simple headings and bullet points where possible. Use active voice, non-technical language, and simple sentences. If technical terms must be used, consider adding in a lay definition for the word If sharing electronically, save and share as a PDF, which is a non-editable format and is the most compatible with text-to-speech readers. Keep content to 6 pages or less, or consider developing a summary version and a detailed version. Headings in "At a Glance" are linked to corresponding main sections in the template. [Tip: use graphics to demonstrate number of participants (e.g., people graph, pie charts) for a visual representation.] [Tip: use a map or list sites if it is a multi-site trial.] [Tip: use tables and graphics (e.g., graphs and charts) to explain and show results.] Design considerations: • Add your organisation's logo to suit your style and brand and customise the colour scheme. • Customise the icons to better match your trial using free, open-source icons from healthicons.org. • Avoid using blue font for regular text to avoid confusion with blue text used for links, or change hyperlink colours. • Edit the template as need be for the purposes of your trial. Note that we recommend to follow the template as much • as possible because it reflects the input of parents and youth. • Periods at the end of headers were adapted for compatibility with text-to-speech readers.

	• Accessibility of Ontarians with Disabilities Act (AODA) guidelines were followed in the provided design. • Consider using graphics, visuals, or videos to make summaries more accessible (e.g., video with closed-captions)
Canadian Frailty Network 2017 [124]	• Define any technical terms used • Refrain from using jargon • Refrain from using acronyms, but if necessary, spell out in full when first mentioned in the text • Have someone from outside the field of study read the summary • Read the summary aloud to catch errors or awkward expressions • Provide simple, relevant examples when describing the research • Use people-first language by focusing on the person, not the disability; for example, say “people who are blind” rather than “the blind”, or “older adults living with frailty” rather than “frail older adults”
Clinical Trials Ontario 2021 [134]	Consider using graphics and simple charts to explain and show results. Use your organisation’s letterhead, logo and colours (the template’s generic look is intentional so you can easily use your own style and branding) If icons or graphics are helpful, https://www.slidescarnival.com/ (scientific template) has some that can be used without license or acknowledgement. The icon colours can be changed easily If sending electronically, save and PDF the final document so it cannot be edited Use simple headings and non-technical language without jargon and acronyms. This includes using the active voice, simple sentences, and no adverbs. Use graphics, visuals, or videos to make summaries more accessible (e.g., video with closed-captions). Keep as short as possible (1 to 2 pages) while providing all information or consider a short version of the summary and a more in-depth version for those who may wish to learn more.
Cochrane 2022 [141]	1 Language • Use everyday language. For example, refer to ‘people’ instead of ‘study participants’. • Avoid (or, when this is not possible or desirable, explain): o long words. For example, use ‘blood thinners’ as an alternative to ‘anticoagulants’. o research jargon. Use: ▪ ‘study’ rather than ‘trial’; ▪ ‘people with [condition]’, ‘women’, ‘children’ etc. rather than ‘participants’; ▪ the name of the intervention instead of ‘intervention’ ▪ the name of the control or comparison instead of ‘control’ or ‘comparison’; ▪ the name of the outcome instead of ‘outcome’.

	o words or phrases with dual or nuanced meanings. For example, use ‘medicines’ instead of ‘drugs’. ‘Significant’ means ‘important’ for a lay reader. • Explain o ‘common’ medical words, for example: ▪ ‘acute condition’: a condition or state that develops suddenly and lasts a short time; ▪ ‘chronic condition’: a condition or state that lasts for a long time. o technical medical terms. Plain language does not always mean ‘lay language’. Your reader may know the topic via the technical term – especially if they are a patient or carer, so it might be best to include the technical term and explain it. For example, to explain the action of anticoagulants, you could write: ‘Anticoagulants are medicines that stop harmful blood clots forming. However, these medicines may cause unwanted effects such as bleeding.’ Or you could write the term in plain language followed by the technical term in brackets. For example, ‘blood thinners (anticoagulants)’. Ask one of your readers if you are unsure about using a particular term. • Avoid acronyms and abbreviations. If you cannot avoid them, make sure you define them when you first mention them. o For example, ‘nicotine replacement therapy (NRT)’. o Use phrases like ‘for example’, ‘such as’, ‘in other words’, ‘and so on’ instead of ‘e.g.’, ‘i.e.,’ or ‘etc.’, as they are not always understood if you are writing for a wide audience. • Write for an international audience. Avoid regional words or terms; for example, use ‘hospital emergency care’ instead of ‘Accident & Emergency (A&E)’ (UK) or ‘Emergency Room (ER)’ (USA). Style • Keep paragraphs and sentences short, but vary your sentence length occasionally to keep the readers’ attention. Aim for an average of 20 words in a sentence. Break up longer sentences into shorter ones. For example, instead of ‘Most people who smoke want to stop, however many find it difficult to do so, even though they may use medicines that are designed to help them stop’, you could write ‘Most people who smoke want to stop, but many find it difficult. People who smoke may use medicines to help them stop.’. • Use the active voice. For example, write ‘We compared and summarised the results of the studies’ instead of ‘The results of the studies were compared and summarised’. • Use pronouns. Write in the first-person plural. For example, use ‘we assessed’ instead of ‘the review authors assessed’. Address your reader using the second-person pronoun ‘you’. For example, write ‘A pedometer is a small, portable electronic device that counts the number of steps you take.’. • Use verbs. For example, say ‘the students investigated’ not ‘the students conducted an investigation’, or ‘we analysed the data’ not ‘we carried out an analysis of the data’. • Write numbers as numerals (1, 2, 3…) rather than words. However, avoid starting a sentence with a numeral. If necessary, rewrite the sentence. For example, write ‘The studies included 3260 people’ instead of ‘Three-thousand, two-hundred and sixty people took part in the studies’.

	• Be concise. A Plain language summary can be up to 850 words long, but you do not have to fill the word limit. You should aim to keep it as short as possible while still including the most important information. Replace ‘wordy’ phrases with shorter alternatives: use ‘during’ instead of ‘during the course of’; o use ‘often’, instead of ‘it was often the case that’; o use ‘some’ or ‘many’, instead of ‘a number of’; and o use ‘because’ instead of ‘due to the fact that’ Structure • Use subheadings to guide the reader, break up the text and make it more readable. For example, ‘What is a cataract?’, ‘How are cataracts treated?’, ‘What happens after cataract surgery?’. Whenever possible, we suggest that you phrase subheadings as questions. This gives a more conversational tone to your summary and will help to engage your readers. • Use bullet points to break up lists. Review Manager (RevMan) formatting does not currently support this in Plain language summaries but you can use a dash or hyphen instead. Treatments for boils include: – antibiotics (medicines that fight bacterial infections); – light therapy; and – surgery. • Alternatively, insert a bullet point symbol. o In RevMan Web, choose the bullet point symbol from the dropdown ‘insert symbol’ menu. o In Word, choose Symbol from the Insert menu, make sure Windgings 2 is selected in the Font dropdown and scroll down to select the bullet point, click Insert; o In Windows, hold down Alt and x and type 8226 on the numeric keypad o On a Mac, on the standard keyboard setting hold down the option key and type 8; on the Unicode keyboard hold down the option key and type 2022 (Unicode). Use a numbered list if the rest of the review uses numbered lists but be careful not to start the point with a number, as this can be tricky to read. For example: 1. 86 people died … 2. 34 recovered … • Keep paragraphs short. Start a new paragraph when the theme or topic of a sentence does not directly follow from the sentence immediately before it. • Leave plenty of white space in your summary. Dense text is hard to read. White space separates, and groups, elements of your text, which makes it easier for readers to find their way around.

Duke et al. 2012 [125]	Appropriateness for readership The author should be aware of (and indicate) the intended audience for the text. For example, potential participants in studies OR the general public. Grammar, punctuation and spelling Grammar and punctuation should be accurate, and spelling should follow appropriate conventions. For example, UK spelling should be used if the text is to be published to a UK audience. Level of difficulty of text (words and structure) The text should be written in an easily readable style. The author should use short, clear sentences broken up into paragraphs for readability, and avoid complex grammatical structures where possible. The author should use every day English words in place of complex words. Structure The text should be ordered logically and flow naturally. For example, ideas should be introduced as they are required, and new ideas usually should not be introduced late in the text. Avoid complex or meaningless terms and phrases Many terms used in academic English are either overcomplicated or contain no useful information. Examples include terms such as ‘virtually’ or ‘literally’ or archaic language (e.g., amidst, whilst), as well as verb choices such as ‘purchase’ used in place of the simpler ‘buy’. Expressing ideas in the active voice Text should be written in the active voice ('I... you.') and second person ('you') should be used in place of third person ('he/she'). For example, 'You will have chemotherapy' rather than 'Chemotherapy will be given to you'. Positive phrasing

	Sentences should be phrased positively, rather than negatively. For example, 'You will have repeat appointments at least once a fortnight', rather than 'The usual practice is not to schedule repeat appointments more frequently than once a fortnight'. Adhering to convention The text should have the correct word count and the author should structure it according to relevant guidelines (such as funders' guidelines). Straightforward to read The writer should limit the memory load on readers – don't ask them to remember too much jargon/abstract information. Clear theme A good and relevant title should be provided, and the first sentence should offer a concise introduction to the text.
Dunagan et al. 2013 [144]	-report-back that includes a mixture of information-rich graphs and brief verbal summaries allows for individual differences in the ability and desire to understand report-back information - tables are useful for listing precise results or comparing one result to a health guideline -graphs are preferred for communicating patterns in data -When studies have very large numbers of results to report, graphs may be used to convey the most meaningful or important results, accompanied by tables to make reports comprehensive -include guides that can be used as a roadmap for interpreting graphical presentations of individual exposure data, data from other participants, national averages, and benchmarks -Put results in context with comparisons -Graphs of study-wide results help participants understand the overall findings and put their own results in context Highlight key messages with text -Consider varying levels of literacy and numeracy -Consider community context

European Commission 2018 [135]	1. Communications written for the public should use simple everyday language to ensure ease of reading and understanding. 2. Text should be suitable for people with a low to average level of literacy. 3. Avoid long and complex sentences that include many clauses as these are difficult to understand. 4. Use simple vocabulary familiar to non-medical people: 5. Avoid jargon, technical, medical or scientific language 6. Remove unnecessary or complex words 7. Be consistent in the use of terms/words throughout the document, and define them 8. Ensure that the underlying concepts are clear and easy to understand. Where necessary, explain the underlying concept 9. Avoid ambiguous words and phrases 10. Use active, rather than passive, voice 11. Use the following elements to help improve comprehension: · Headlines and descriptive subheadings to organise information · Presentation of the "big picture" before the detail (inverted pyramid writing style) · Bullet points instead of paragraphs · Numeracy principles to describe data and statistics · Adequate "white space". · 12-point font should be used · The most readable colour combination is black text on a white background. Please avoid using white text on a coloured background as this can be harder to read. Keep in mind how documents will look when online or printed. · Links to additional information, and resources for online summaries and background information. Such links need to be minimal since hyperlinks can become out of date over time. · Limited use of unnecessary imagery that does not enhance understanding (icons, logos, etc.) · Avoidance of text in ALL CAPS and underlining · Use visuals (for example, simple graphs) to convey messages where helpful. Avoid overwhelming the reader with too much information.
European Commission 2021 [136]	Efforts should be made to prepare LS which are understandable for the general public as of the age of 12 years. The GLSP recommends helpful principles to apply, e.g., · Use short words, sentences, and paragraphs · Use active rather than passive voice · Do not use technical or scientific language · Present medical terms in brackets · Use neutral, non-promotional language · Do not use statistical terms · Apply numeracy principles

	· Use words and terms consistently · Be respectful in your language and apply cultural sensitivity · Do not use Latin expressions A list of Practical wording examples are also provided. To maximise the chance for preparation of an accessible LS, the following aspects should be taken into consideration: · Awareness of available guidance and application of practical experience with health numeracy attributes · Consistent non-promotional language · Application of available recommendations on text presentation in LS, e.g., - Use headings and descriptive sub-headings - Use adequate white space and black text on white background - Limit the use of logos and icons but use simple graphs - Use bold text to add emphasis but do not use underlining, italics, fancy fonts, all CAPS -Use of suitable graphics: bar graphs for comparison across groups and pie charts for numerical proportions. Infographics and pictorial representation can also be useful. . In general, bar graphs are recommended for comparison across groups and pie charts for numerical proportions. Infographics or pictorial representation can also be useful. -use left justified text -do not use long lines of text -Place column and page breaks carefully -Use of colour can make a document more attractive but do not overuse -use bullets formatting Detailed explanation and examples of graphics and visuals are provided in the handbook General recommendations for using graphics include: ● Make graphics simple and not overly complex; with one simple message per image. Do not display several relationships, or complex trial design diagrams and flowcharts. ● Use black and white print as a general rule. Colours may be used, however avoid brand colours which may be perceived as promotional. Some colours may be difficult for people with colour-blindness. If colour is used, remember that the LS may be printed in black and white – use of solid colour and hatching may also be helpful to distinguish sections. ● Use clear label captions and axes, along with meaningful scaling and labelling of axes. Do not exaggerate the positive or minimise negative results through the choice of axes. ● If space allows, place the caption inside each bar or pie slice - rather than using colour and a key. This means the reader has to do less work. Also, if possible, write the text describing the vertical axis horizontally – not vertically. This means the reader does not have to turn the LS on its side to read the graph. Labels inside graphical elements need to be able to be translated in the final country-specific LS. If

	using a translation vendor, ensure that the graphics are editable and not read-only, or that the source design-file is available. Health numeracy principles: 1. Use visuals for interpretation of numbers 2. Use whole numbers 3. Keep denominators and units consistent 4. Use percentages carefully 5. Use numerals rather than words for numbers 6. Do not leave calculations to your reader Non-promotional language: 1. The overall tone should be factual and objective 2. No commercial or marketing apparency 3. Superlative and enthusiastic words should be avoided 4. Be careful with high level statements 5. Quantify statements 6. Reinforce that the outcome reflects only one single clinical study 7. Ensure that additional information is readily available
Fernandez et al. 2003 [126]	Not specified.
Fernandez et al. 2012 [132]	The lay summary should be in an accessible level of English and, when locally relevant, translated into additional languages
Health Research Authority, 2021 [127]	1. Be accurate, clear, and concise. 2. Do not assume any prior knowledge. 3. Use words that are appropriate for the reader. 4. Use short sentences (up to 20 words) and short paragraphs (up to 3 sentences). 5. Use neutral language. 6. Consider using infographics with explanatory text. 7. Involve patients, patient representatives, or members of the public in the development and/or review of your summary/feedback plans. 8. Involving professionals with experience of writing in plain language for the public such as medical writers can also help

Hintz and Dean. 2019 [145]	Write an audience-centric summary of findings in plain language Start with the main point, write concisely, and limit the report to one page or less. There are several factors to consider when preparing study findings for return. The researcher must consider how to meaningfully interpret study findings in plain language for participants and how to present findings in written form (if applicable) (DHHS, Citation2015). Literacy levels, and the plain language designed to accommodate them, are one consideration here. Participant populations should be studied to determine literacy levels, and study findings should be written at reading levels consistent with those findings (DHHS, Citation2015). Contrary to popular belief, writing in plain language does not mean "dumbing down" the content of the writing. Regardless of the literacy level of the audience, accessible plain-language writing is always audience-centric, eliminates filler and starts with the main point, and is short and concise (e.g., one page or less with short paragraphs or bullet points) (DHHS, Citation2015). To test the complexity of a selection of text or document, Microsoft Word offers "readability statistics" designed for this purpose.
Knowles et al. 2022 [142]	Visual: The most direct suggestions about how reviews should look – this includes the need for white space, and thinking about visual cues that help orient people, for example logos that help them quickly assess whether the info is trustworthy. 1. Empty space is essential! It can be tempting to pack in text and images but empty space avoids overwhelming the reader. 2. Symbols such as logos Quickly make clear who produced the findings and communicate the trustworthiness of the content. 3. State clearly who the information is for And why they should read it. It is better to produce for a clearly defined audience, as information meant for everyone can be read as being for no one. 4. Think about how the audience goals (These are what your anticipated readers want from this info) and organisational goals (These are your goals in sharing this info) interact with each other. 5. Think of content as conversation What is your audience asking? What are you telling them in return? Being explicit about this can help avoid confusion, for example, if patients expect information that can't be provided (such as health advice). 6. Patient stories Help make sense of the evidence and demonstrate how it is relevant and why it is important.

	7. Don’t use stock photos! Contributors interpret these as ‘fake’ and they distract rather than add value. Use real photos of the team, or bespoke illustrations. 8. Layer your information Start with headlines to orient the reader, and have detail further down. 9. Work with your audience Get feedback on drafts, and check your assumptions. 10. What are your readers' forward paths? Think about where your reader wants to go next – this can mean providing links to further information, opportunities to get involved, or to share feedback. Collaborate with users to tailor your output to meet their specific needs and gain empathy with patients who face challenges in accessing evidence.
MRCT FDA, 2017 [137]	Noting that the summary provides results of a single clinical study and that new information or different results may be obtained from other studies; • Ensuring that the overall tone of the PLS is factual, objective, and accurate; • Avoiding superlative and enthusiastic words; • Avoiding statements that describe the product as being better, more effective, or useful in a broader range of conditions or patients than that study has demonstrated;11 • Avoiding statements that describe the product as being safer, having fewer, or less serious side effects or contraindications than that study has demonstrated;12 • Avoiding statements that represent the product as being safer or more effective than another product other than demonstrated by that study Avoiding using statistical statements in a misleading way, and • Providing a link to the scientific summary for further information

MRCT Center 2017 [138]	Well-organised content presented with familiar vocabulary to non-medical people, and short sentences. · 6-8th grade reading levels. Reading level scales that approximate grade levels are helpful, for health literacy (see Appendix 4 for detailed information). · Elements designed to help improve reader comprehension such as o Headlines to organise information o Presentation of the "big picture" before the details (inverted pyramid writing style) o Descriptive headers and subheadings o Bullet points instead of paragraphs o Numeracy principles to describe statistics (see Appendix 4 for detailed information) o Limited use of tables and charts o Adequate "white space" (e.g., separate paragraphs and topics by one or two lines, a minimum of 12-point font) o Hyperlinks to summary sections, additional information, and resources for online summaries and background information o Where to access additional resources and other online summaries o Limited use of imagery (icons, logos, etc.) o Sufficient contrast between font and background colour o Avoidance of text in "all caps" o Limited use of acronyms, abstract, medical, or multisyllabic words (e.g., "unanticipated," "hematopoietic," etc.). If such words must be used, add clear language to define them. · Avoid complex sentences that include many clauses as these are difficult to comprehend · The use of simpler vocabulary is recommended: o Avoid jargon, technical or scientific language (e.g., "high blood pressure" vs. "hypertension"). Eliminate unnecessarily complex words (e.g., "use" vs. "utilise"). o Be consistent in the use of terms/words throughout the document, and define them. o Ensure that the target audience will understand the underlying idea for words that represent complex concepts (e.g., "risk" vs. "absolute probability"). Where necessary, explain the underlying concept. o Avoid ambiguous words and phrases (e.g., "felt badly"). • Active voice is preferred; use passive voice sparingly. o Active voice: Researchers studied the effect of tamoxifen on breast cancer. o Passive voice: The effect of tamoxifen on breast cancer was studied by researchers. Visuals Well-chosen and clearly designed visual aids can help enhance understanding of text. Where used, visuals should present one message per image and be clearly labelled with captions. Overly complex images, such as graphs demonstrating several relationships, can be easily misinterpreted and should be avoided. Visuals should be placed near the text they attempt to illustrate. For depictions of internal body parts or small objects, use

	realistic images that provide readers with context. Creative solutions to ensure comprehension include videos, cartoons, and you-tube postings. Testing for readability Consider testing the readability of an initial version of the study results summary with a subset of the target population before releasing the summary to the study participants. Use the feedback and suggestions from this type of pilot review to finalise a summary that study participants will understand. Detailed guidance on numerical information is presented in the appendix 4 of the guidance.
NASEM 2018 [143]	Refer to research volunteers as participants, not subjects in all regulations relevant to human research This may entail: creating materials in users' primary languages and considering language-based sources of misunderstanding to address language barriers, creating materials that reflect participants' preferences regarding terminology, using plain language to overcome low literacy (CDC, 2016; IOM, 2014), and using evidence-based formats that facilitate understanding of quantitative information by those with low numeracy and graphical literacy (IOM, 2014). 'Good design practices can significantly improve people's ability to overcome communication barriers'..... 'These include the use of materials translated into the recipient's primary language, use of plain language with minimal jargon, use of good visual design principles, and use of evidence-based visual displays of data' The appropriate use of visualisations can help achieve the communication goal for the return of research results.
Rosenberg et al. 2021 [128]	Plain language data presentation best practices have been detailed in other resources and initiatives,[1, 6] and were therefore also considered outside the scope of the recommendations.
Solovyeva et al. 2023 [139]	Keep the language consistent throughout, for example when using the terms study/trial – keep to the same term. - Tables/ statistical information should be avoided. Simple graphics and statements should be used instead. - Keep it brief – preferably up to 2-3 pages Further advice and resources are available at: https://www.nihr.ac.uk/documents/plain-english-summaries/27363 Evidence-Based graphics resources are available at: http://www.vizhealth.org/

Taylor & Francis 2023 [129]	Composition ✓ Use short, clear sentences and phrase sentences in neutral language, remaining as objective as possible. ✓ Use the active voice rather than the passive voice (for example, “Dr Smith’s team report several improvements” rather than “Several improvements were reported by Dr Smith’s team”). ✓ Use language that aligns with preferences of the patient community. For example, use person centered language rather than focusing on the condition/illness or disability; however, alternative preferences may exist. ✓ Avoid jargon, complex grammatical structures, and abbreviations. If you need to use a technical term or abbreviation, explain it the first time you use it.
TransCelerate BioPharma 2016 [118]	1. use neutral language 2. » Superlative and enthusiastic words should be avoided (e.g., the most, the best, extraordinary, unsurpassed) as they could lead to a determination that a communication is promotional.
Vanderbilt Institute for Clinical and Translational Research 2022 (a) [131]	Reading Level Aim to write the summary at a 6th grade reading level. Keep in mind that including certain scientific terms may be unavoidable and will raise the reading level. In these cases, be sure to define these terms in plain language and/or use a simplified figure or picture to illustrate your point. Ways to lower reading level: Use short sentences (15 words or under) to improve the readability of the abstract. Whenever possible, use words that are no longer than two syllables Tip! Use tools in Microsoft Word to quickly and easily check readability statistics. Understandability: The public summary should be clear and understandable to a diverse audience of varying levels of educational attainment and understanding of scientific findings. Avoid using medical or research jargon. (Example: use "high blood pressure" instead of "hypertension"). Communicate the real-world application of the results - describe what the results mean in a larger context (for the population, for science, etc.). Use simple figures and pictures to enhance understanding. Include research participants Ask your research participants to review your public summary and offer feedback on ways to improve it. Include Research Participants Tip! Plan to integrate this step into your research protocol and prioritise doing this after data are collected. Make Use of Readability Resources: For additional tips about improving readability and clarity of documents, please refer to the following:

	CDC Plain Language Materials and Resources MRCT Center Health Literacy in Clinical Research website PRISM Readability Toolkit MHP Salud Reading Assessment Tool
Vanderbilt Institute for Clinical and Translational Research 2022 (b) [130]	Reading Level Aim to write the summary at a 6th grade reading level. Keep in mind that including certain scientific terms may be unavoidable and will raise the reading level. In these cases, be sure to define these terms in plain language and/or use a simplified figure or picture to illustrate your point. Ways to lower reading level: Use short sentences (15 words or under) to improve the readability of the summary. Whenever possible, use words that are no longer than two syllables. Tip! Use tools in Microsoft Word to quickly and easily check readability statistics! Understandability The Narrative Summary should be clear and understandable to a diverse audience of varying levels of educational attainment and understanding of scientific findings. Avoid using medical or research jargon. (Example: use "high blood pressure" instead of "hypertension"). Communicate real-world application of the results – describe what the results mean in a larger context (for the population, for science, etc.). Use simple figures and pictures to enhance understanding. Audience: Direct the Narrative Summary to research study participants by using appropriate language (i.e., "you" and "your"). Make Use of Readability Resources: For additional tips about improving readability and clarity of documents, please refer to the following: CDC Plain Language Materials and Resources MRCT Center Health Literacy in Clinical Research website

	PRISM Readability Toolkit MHP Salud Reading Assessment Tool
Zimmerman 2022 [140]	PTN lay summaries should be written at an eighth-grade reading level with the following characteristics: (1) descriptive headers; (2) bullet lists; (3) graphics to illustrate concepts and aid in comprehension; (4) a link to additional information on the study; and (5) answers to 8 questions (listed in Appendix 2.5)

Appendix 2.6: Timeline and dissemination

Report ID	How to share results	when to share results	Guidance for planning resources	Target audience of the result report
Arnstein et al. 2020 [123]	Not specified	Not specified	Not specified	Both
Baba et al. 2023 [133]	Ensure the document and your distribution plan is reviewed by your REB. Ensure that a trial results dissemination plan is included in your REB application. Give trial participants the option to opt in/out of receiving trial results when discussing the trial with them. Ensure content is permissible to share with participants. If the results are from an industry-sponsored trial, ensure sponsor has approved wording. Consider how web-based platforms such as ClinicalTrials.gov might be appropriate for sharing the summary. If you would like the CommuniKIDS team to post your completed template on the Clinical Trials Ontario website to serve as an example on how the template can be used, consider sharing your template with us.	Advices: Consult your Research Ethics Board (REB) and patient partners/advisors on your research team, as appropriate, for advice on when to send out the results.	Not specified	Participants

Canadian Frailty Network 2017 [124]	Not mentioned	Not specified	Not mentioned	General Public
Clinical Trials Ontario 2021 [134]	Ensure that content is in the public domain (i.e., has been published) and can be shared with participants. If the results are from an industry-sponsored trial, ensure the wording has been approved by the sponsor. Ensure the plain language summary is approved by a Research Ethics Board prior to sending it to participants. See if or how web-based platforms such as ClinicalTrials.gov or similar trial listing sites might be appropriate for sharing the summary See if or how other methods of sharing the results, in addition to with participants, are appropriate (e.g., social media, institutional or patient newsletters)	Not specified	not specified	Participants
Cochrane 2022 [141]	Not specified. Cochrane Plain language summaries are freely available on cochrane.org and in the Cochrane Library in a range of languages. The aim is that anyone looking for information about the key points of a Cochrane Review can read and understand them.	Not specified	Not mentioned	General Public
Duke et al. 2012 [125]	not applicable as guideline is not for result	not applicable as guideline is not for result	not applicable as guideline is not for result	General Public

Dunagan et al. 2013 [144]	Options for disseminating results include mail, telephone, drop-off, face-to-face, internet, or a combination of approaches. Consulting with community members will help teams determine a suitable process. In our experience combining communication materials with in-person home visits works well; however, this is not always feasible. Regardless of which strategy a team chooses, we expect a researcher would still need to be accessible by phone to respond to questions. Based on our experience, the research team can expect a small number of participant queries. In addition, researchers may want to phone participants with unusually high measurements. Researchers may find that some communities, especially tribal ones with their own IRBs and similar bodies, have express criteria for "community-first" report-back.	Reporting individual results should be part of a strategy for reporting aggregate results to the study community, the broader scientific community, and the news media (See Box on community report-back). The sequence of these events depends on weighing a number of factors: participant and community wishes, time required for data analysis, scientific journal publication practices, and media coverage of results presented at scientific conferences. Study teams have a responsibility to return results promptly; however, reporting results too soon could mean the interpretation doesn't benefit from the peer review process. Also, peer-reviewed publication is a signal of credibility to the news media, which affects the coverage and impact of the results. However teams decide to	Plan for report-back when you plan your study. Budget time and money to get it done. Don't forget to allocate time for interpreting data, developing and disseminating materials, answering participants' questions, and maintaining regular communications with the study community. Some studies need funds for translating materials into multiple languages. Build these costs into the research budget when possible. If a large sample size is important, or even mandated, computerised approaches to report-back may be useful.	Participants

		proceed, they should communicate with participants up front about expected timing and update them if the schedule changes.		
European Commission 2018 [135]	The summaries would be published on an EU database. Although not required by regulation, sponsors may provide trial results to investigators or third parties to feedback to patients who have taken part in their trials, along with an acknowledgement of their contribution and an expression of appreciation	Both clinical trials results and layperson summary should be submitted to the European Union (EU) database within one year from the end of a clinical trials in all member states (MS)	Not mentioned	General Public
European Commission 2021 [136]	The EU Portal will accept LS to be uploaded in a PDF file format. This entails materials suitable for print which include text and figures as well as cartoons but excludes videos and animations at the current stage of the technical system. Sponsors must upload the LS to the EU Database via the EU Portal as required by EU CTR. The EU Expert Group on Clinical Trials' preferred additional option to the EU Portal is direct dissemination to trial participants. In the interest of transparency, sponsors may wish to disseminate the LS further. Delivery of the LS outside of the EU mandate needs to be done in compliance with local laws, restrictions, and standards. The sponsor's LS dissemination strategy can consist of a direct approach that for example involves sharing of printed LS with trial participants by the investigator and/or an indirect, approach through	The LS must be submitted to the CTIS via the EU Portal no later than 12 months from the protocol-defined end of the clinical trial, 6 months for paediatric studies, and up to 30 months for nontherapeutic Phase 1 trials. If the lay summary cannot be reported within these timelines for scientific reasons, it shall be submitted as soon as possible. In that case the protocol shall specify when the results are going to be submitted. Trial participants must be informed about the LS availability and, to the extent	Generally, but especially for resource-limited sponsors from academia, charities, or Small Medium-sized Enterprises (SME), planning of the process and resources required for production and dissemination of a LS should begin with budgeting at the time when a research proposal for a clinical trial is submitted to a funding source. Budget implications such as patient involvement in the LS process, costs of standard or special patient population communication tools, and for translations and/or dissemination beyond the CTIS need to be factored in at the proposal stage. The major costs will account for staff or contractors for the production and translation of the lay	Both

	unrestricted, open communication channels such as publicly available websites. To be readable by people with visual impairment, electronic copies of the LS in PDF format are the most accessible; however, it should be ensured that any security settings of the PDF file do not interfere with the screen reader's ability to convert the on-screen text to speech or Braille. HTML or XML formats may also be used and should be accessible to this population as well. Partially sighted readers benefit from larger fonts and enhanced contrasts. Charts or graphs are not always legible with screen readers and LS should encompass colour-blind peoples' needs. Therefore, a short summary of charts or graphs might be provided. According to EU CTR Article 29.6 the trial participant must be informed that a LS will be made available in the EU Database and, to the extent planned, when the LS will become available, potentially also through other distribution channels. Examples of technical distribution methods: o Email o Sponsor's investigator trial portal o Investigator site/clinic's portal containing a patient portal o Sponsor website o Third-party website for trial participant LS registration and notification o Patient organisation website o Global open access portals providing support in	possible, its timing within the Informed Consent process.	summary. Sponsors who decide to provide LS beyond dissemination through the EU Database will need to plan for additional translation and/or dissemination costs. Additionally, remuneration for the functions involved in LS generation, including patient advisors and reviewers should be taken into account during planning. If appropriate, representative patient involvement in relation to the development of the LS may require additional funding. It should be noted that most funding bodies do not foresee budget allocation for LS preparation. Moreover, most funding bodies require eligible costs to have been incurred during the funding period. As the LS may only be due after the end of the project and thus the funding period, it may be impossible to secure funds for LS simultaneously with the main part of the trial. It may be prudent to check the policy of the funding body in advance.	

	various languages Examples of non-technical distribution methods: o Print/postal service o Printed and handed to the trial participant o Face-to-face meeting between the trial participant and the investigator Two common dissemination methods employed: 1. Indirect (unrestricted) dissemination: to trial participants and/or the public by providing the information on an open, publicly available website. 2. Direct (restricted) dissemination: to trial participants and investigators through a targeted, restricted delivery system			
Fernandez et al. 2003 [126]	If there are significant consequences anticipated, disclosure should always occur orally, and preferably face-to-face. Following that initial discussion of substantive clinical results, an Internet site can provide ongoing updates of results in a lay form. Some results, such as summary findings from studies of the biology of disease, can be provided without personal interaction, but even in this situation research participants should have the opportunity to pose questions. Investigators should disclose results in lay terms and provide a written copy of the research summary and its discussion, along with an appendix directing participants to peer-reviewed publications from the study. The research summary is best prepared by the principal investigator or his/her delegate.	the original consent form should indicate how and when research results might be disclosed, and make clear who is responsible for maintaining contact and how this should be undertaken	There are financial costs associated with programs for sharing results that should be considered in building research budgets. These costs may extend to follow-up medical and psychological care	Participants

Fernandez et al. 2012 [132]	Results should be provided via a publicly accessible Web site. Participants (and the general public) should be able to register for e-mail notification of a lay summary posting related to the study. It is the responsibility of the interested participant to register for automatic e-mail notification of study results or to check periodically to determine if secondary analyses or biobank results have been posted. Participants should be informed of the intent to offer results within the informed consent document.	Results should be posted within one year of completing data collection for the prespecified primary outcomes of the study. If an abstract is to be presented at a meeting before this 1-year deadline, then a lay summary should be released as soon as is acceptable by the meeting's organisers and no later than the scientific presentation or publication of results. For secondary analysis, provision of the lay summary should occur with acceptance of the manuscript for publication	Not mentioned	Both
Health Research Authority, 2021 [127]	Does not specifically mention about disseminating to participants. Sponsors need to include the PLS in their final report and HRA will publish it on their Research Summaries website which is publicly available. https://www.hra.nhs.uk/planning-and-improving-research/application-summaries/research-summaries/	Not specified	Not mentioned	General Public

Hintz and Dean. 2019 [145]	The researcher or a trained delegate should return findings If applicable, the delegate should have been present at the original consent, have an ongoing relationship with the participant, and be knowledgeable enough to contextualise findings and answer questions. Rich communicative channels are optimal for returning findings Matching the channel used to return findings to the channel used to recruit participants is an advisable second-best option	Return findings to participants after data and interpretations have been peer-reviewed	The mode through which findings are returned will depend on the financial and personnel-related resources available to the researcher (Fernandez, Kodish, and Weijer, Citation2003). To account for the financial cost of returning findings, this amount should be estimated and included within any grant or funding applications as well as within the research protocol (NASEM, Citation2018).	Participants
Knowles et al. 2022 [142]	Not mentioned	Not specified	Not mentioned	Both
MRCT FDA, 2017 [137]	Examples of potentially acceptable methods of delivering PLS are: • One-way communication methods to general public: web-enabled communications; 20 such as posting of the PLS to a publicly available internet site or web-based portal; • One-way communication methods to subjects: (e.g., video summary, printed materials) that respects the confidentiality of the recipient. For example, if a letter is sent to the research subject, the outside envelope should not mention the topic of the study or describe the contents of the envelope; 21 • Two-way interactive methods (e.g., face-to-face meeting(s), telephone call(s), online meeting(s), dynamic email exchange), Of note, industry sponsors of clinical trials typically do not have access to personal participant information; in	As a general matter FDA suggests that provision of a PLS occur within one year of study end (which is last subject last visit, unless otherwise defined in the protocol together with appropriate scientific rationale).19 Public release of the PLS should be aligned with release of the study's scientific summary to enable cross referencing. For some studies, sponsors may be interested in communicating results after the primary	Not mentioned	Both

	this method of communication, therefore, arrangements with the investigators or healthcare providers may need to be made. FDA realises that it is difficult to control the content of these communications and recommends that a written PLS be provided as a guide.	endpoint has been reached but while the study remains open for the completion of the secondary endpoints. Sponsors should consider whether provision of a PLS while a study is ongoing may introduce bias and compromise the integrity of the research data. PLS should be postponed until study completion if communication of interim results could compromise study integrity.		
MRCT Center 2017 [138]	organisations should determine the most appropriate method(s) of delivery as well as the infrastructure and resources, including cost and time, as returning results to participants can be a resource-intensive activity. Importantly, the method for delivery should be consistent with the characteristics, cultural needs and expectations coupled with an understanding of the study population. Consideration should be given to any cultural differences as well as to the need to return results in a timely manner. As a general rule, however, we recommend that any communications be targeted for a non-technical audience, using simple language and health literacy principles to the greatest extent possible. Some participants may not have access to the Internet or may require special resources to understand the content. On a practical level, the options for PLS delivery vary	Regulated trials (typically industry sponsored, industry-initiated interventional studies, and academic trials [investigator initiated trials] regulated by the European Medical Agency (EMA) and other relevant regulatory bodies) Within one year of Last Subject Last Visit (LSLV) for adult trials53 unless otherwise specified in protocol Informed consent form (ICF) and study protocol, clinical study report (CSR) and/or ICHE3 synopsis (CSR synopsis	Planning for PLS prior to study start can help the organisation implement a smooth process. The primary pre-study activities include: · Updating organisational policies, processes and procedures as needed. · Updating investigator and site policies, processes and procedures as needed. · Establishing the level/timing/delivery method of the planned PLS. · Budgeting for PLS activities. · Developing and incorporating the PLS information into appropriate study documents including the informed consent document, the program	Participants

	based on cost, resource requirements, technology, and degree of support for the participant (i.e., the opportunity for participants to ask questions). . Greater flexibility and comprehension may be achieved using a variety of simultaneous delivery methods although these differing methods will differ in cost and practicality. The following questions may be helpful in planning for the method(s) of delivery: • Does the method depend upon a face-to-face meeting at the study site, access to a telephone, or access to the Internet? Does the study population have access to a telephone or the Internet? Consider whether the method places a burden on the study site and how that may impact both the capacity of the site and potentially the participant's care decisions after the trial. • What is the likelihood that the implications of the study results will elicit follow-on complex questions? If the likelihood is great, a face-to-face meeting at the site may be preferable to a written communication that requires participant follow-up. In this approach, there are practical implications and additional resources that may be necessary to field questions (discussed later). • Is it likely that the study physician/investigator will have a continuing care responsibility for the participant once the trial is over? If not, who will have that responsibility and how will the caregiver or additional healthcare provider be alerted? It is important to outline the investigator and site responsibilities, to set expectations, and to ensure alignment of activities. In this section, various PLS delivery options are	Academic and trials not regulated by the EMA or other relevant bodies (including most investigator initiated industry sponsored trials) Within one year of the study close by the IRB, or final data analysis, or concurrent with the release of the first study publication	communication and publication plan and possibly the study protocol and investigator contract (see discussion above). · As appropriate, developing an information sheet for participants57 · As appropriate, building staff capacity (e.g., conduct training) with appropriate expertise. e. Increasingly complicated study designs require accurate budget forecasting and should include PLS budgetary needs (for PLS planning, data analysis and compilation, and execution). Additionally, this is an ideal time to identify and schedule the following items: · The sponsor should notify, discuss, and agree internally upon the resources responsible for PLS execution (i.e., internal departments, external vendors, investigators, and/or study sites) If PLS will be disseminated while the study is ongoing (e.g., longitudinal studies) and provided individually to the participants, the investigator should dialogue with their IRB/REC to determine whether and what IRB/REC review is necessary. If PLS is	

	categorised as (1) Internet-based; (2) interactive; and (3) one-way communication. 1. Internet-based methods. Participant and public communication can be provided through an Internet web-based portal. Security considerations should be considered; no personal information (e.g., adverse event reports with protected health information) should be posted. Unlike the interactive methods that rely heavily on the research study site for PLS delivery, a study sponsor can offer and support an online portal and a highly consistent experience for the user. The quality of the user interaction will depend on the quality of the system design and testing. § An Internet portal provides significant flexibility for the sponsor (whether industry, not-for-profit, or individual investigator). The sponsor is able to create a landing page or site for each clinical trial, giving each participant the web address. Importantly, the site—and the path to it—should be so constructed that it is not promotional.45 The participant is then empowered to control whether to log onto the site for information and whether to give the information to a third-party designee. In fact, the sponsor can create the site (and, if password protection is desired, the password may be created before the study begins), and provide the information at the time of enrollment46—potentially even in the informed consent document or through an information sheet—and again at end-of-study visit. Sponsors should consider the need for a third-party vendor to develop and manage a password-protected website since		envisioned by posting to a public site and not returned individually to participants, IRB/REC review is not required. If the study has ended, the investigator may inform the IRB(s) of record of PLS and even provide an PLS copy to the IRB (see Role and Involvement of the IRB/REC above). In some cases, institutions may have separate review boards for PLS, especially when genetic research results are involved and can be provided.	

	sponsors cannot have individual patient identifying information. Empowering the participant to exercise choice as to whether to review results respects the fact that any individual may change their mind between the time of informed consent at the beginning of the trial and study end. § In any Internet-based method, information on the web site should be kept current (including interim messages such as “enrolment is continuing for this study. Results are not available at this time,” or “all necessary information (data) has been collected and the results are currently being analysed. We anticipate results to be available in about six months.)” § The security of the system should be addressed. Some sponsors may wish the site to be accessible to the public. Some may wish the site to be password-protected. Not all participants have access to a computer or the Internet, although many have access through mobile devices. Not all participants are computer-literate or can read; and many have literacy issues. Provisions should be made utilising alternative methods in such cases.47 All communication should use health literacy principles, no matter what level of education is assumed (see Appendix 3 and Appendix 4). • The EU Clinical Trials Regulation 536/2014 (Article 37) requires PLS for studies conducted in the EU to be submitted to the EU database once it becomes available. 2. Interactive methods. Interactive methods (e.g., face-to-face meeting(s), telephone call(s), two-way online meeting(s), dynamic email exchange, etc.) provide participants support and the opportunity to ask questions. However, these			

	methods place a greater burden on the site and the investigator or their team. The consistency and quality of the interaction is difficult to monitor and is often dependent upon a staff member to facilitate the discussion. In this situation, industry sponsors will need to provide training and support materials and consider and address key issues such as staff turnover. Investigator-initiated trials may be able to standardise the communication more effectively, particularly if only a single site is involved in the study. Interactive methods can also be used in conjunction with some centralised information (e.g., Internet-based methods) to ensure participant questions can be answered and follow-up arranged, as discussed below. § If a biopharmaceutical company sponsors the trial and an interactive method is chosen, the sponsor should consider whether PLS is included as a requirement of study conduct in the negotiated contract with the site. 3. One-way communication methods. One-way communication methods (e.g., video summary, automated phone message(s)48, printed materials) do not allow participants to ask questions or engage in conversation. Because these delivery methods are not interactive and can be uniform, they tend to have more consistent quality. These delivery methods tend to consume fewer research study site/sponsor resources since the site may simply notify, forward, and/or coordinate PLS delivery. Any one-way communication should be careful to avoid any information that may breach privacy (e.g., a return address on an envelope reading “Hepatitis C Study Partners”). Different			

	situations may require one or a combination of methods. The consistency of the message is optimised in one-way personal or web-enabled communications, but comprehension and follow-up questions may require interactive methods.			
NASEM 2018 [143]	: Research results can be returned through a variety of communication methods that are matched to participants' needs and the context of the research results.	Not specified	Research institutions and funding agencies should develop and provide access to the resources and infrastructure needed to ensure that investigators conducting testing on human biospecimens can meet the necessary standards for quality so that research test results can be returned to participants obtaining stakeholder input during the study design phase to understand participant preferences and plan for disclosure. The resources needed to return individual research results include funding, time, expertise, personnel, and infrastructure, and finding such resources is an inevitable challenge for researchers who wish to return results. suggests that institutions could assist research teams by developing infrastructure for the return of results and integrating research communication cores into institutional development grants. Finally, it recommends expanding the empirical evidence base through funding support from sponsors and funding	Participants

			agencies, with an emphasis on understanding participant needs, preferences, and values, as well as developing best practices and guidance for the return of individual research results.	
Rosenberg et al. 2021 [128]	Not specified	Not specified	Not specified	General Public
Solovyeva et al. 2023 [139]	guidance is not explicitly given. It is stated: ''Consider where and how this will be disseminated (to relevant charities/advocacy groups/patients organisations etc.) as well as linking to main results, and how this might impact the summary content as well as layout/graphic design etc. of the document (e.g., use of QR codes instead of links on printed documents)''	Not specified	Not mentioned	Both
Taylor & Francis 2023 [129]	PLSPs should be published as open access(OA) articles.	The PLSP should be submitted within 2 years of the original article's online publication date	Not mentioned	Both
TransCelerate BioPharma 2016 [118]	States the following: "A lay summary....may be posted to public websites and/or provided to trial participants after the trial has concluded. The European Medicines Agency (EMA) intends to post these summaries to the European Union (EU) database according to the EU Clinical Trial Regulation (EU Regulation) where the public may view the summaries. At this time, there are no regulatory requirements	Not specified	Not mentioned	Both

	for lay summaries to be posted outside of the EU nor are there regulatory requirements world-wide for disseminating lay summaries more directly to clinical trial participants. However, sponsors may decide at their discretion to provide them to clinical trial participants.			
Vanderbilt Institute for Clinical and Translational Research 2022 (a) [131]	They provide a list of publicly available Dissemination Toolkits that are free to download and use. These toolkits contain guidelines, strategies, checklists, worksheets, templates, examples, and case studies for developing dissemination plans and products.	Not specified	Not mentioned	General Public
Vanderbilt Institute for Clinical and Translational Research 2022 (b) [130]	Not mentioned	Not specified	Not mentioned	Participants
Zimmerman 2022 [140]	The guidance did not indicate any specific methods and said: Each method of lay summary delivery has potential benefits and drawbacks for use within the context of PTN and other innovative or pragmatic trials.	Not specified	Planning for distribution of results must clearly be done in the early stages of trial design and budgeting, and will likely require additional resources in terms of finances and personnel.	Participants

Appendix 3.1: Standards for Reporting Qualitative Research (SRQR)

	Page/line no(s).
Title and abstract	
Title - Concise description of the nature and topic of the study Identifying the study as qualitative or indicating the approach (e.g., ethnography, grounded theory) or data collection methods (e.g., interview, focus group) is recommended	71
Abstract - Summary of key elements of the study using the abstract format of the intended publication; typically includes background, purpose, methods, results, and conclusions	N/A
Introduction	
Problem formulation - Description and significance of the problem/phenomenon studied; review of relevant theory and empirical work; problem statement	71-72
Purpose or research question - Purpose of the study and specific objectives or questions	73
Methods	
Qualitative approach and research paradigm - Qualitative approach (e.g., ethnography, grounded theory, case study, phenomenology, narrative research) and guiding theory if appropriate; identifying the research paradigm (e.g., postpositivist, constructivist/ interpretivist) is also recommended; rationale**	74
Researcher characteristics and reflexivity - Researchers' characteristics that may influence the research, including personal attributes, qualifications/experience, relationship with participants, assumptions, and/or presuppositions; potential or actual interaction between researchers' characteristics and the research questions, approach, methods, results, and/or transferability	85-87
Context - Setting/site and salient contextual factors; rationale**	71-72
Sampling strategy - How and why research participants, documents, or events were selected; criteria for deciding when no further sampling was necessary (e.g., sampling saturation); rationale**	75-77
Ethical issues pertaining to human subjects - Documentation of approval by an appropriate ethics review board and participant consent, or explanation for lack thereof; other confidentiality and data security issues	74
Data collection methods - Types of data collected; details of data collection procedures including (as appropriate) start and stop dates of data collection and analysis, iterative process, triangulation of sources/methods, and modification of procedures in response to evolving study findings; rationale**	79-81
Data collection instruments and technologies - Description of instruments (e.g., interview guides, questionnaires) and devices (e.g., audio recorders) used for data collection; if/how the instrument(s) changed over the course of the study	79-81
Units of study - Number and relevant characteristics of participants, documents, or events included in the study; level of participation (could be reported in results)	88-91

Data processing - Methods for processing data prior to and during analysis, including transcription, data entry, data management and security, verification of data integrity, data coding, and anonymization/de-identification of excerpts	82-85
Data analysis - Process by which inferences, themes, etc., were identified and developed, including the researchers involved in data analysis; usually references a specific paradigm or approach; rationale**	82-85
Techniques to enhance trustworthiness - Techniques to enhance trustworthiness and credibility of data analysis (e.g., member checking, audit trail, triangulation); rationale**	85-87

Results/findings

Synthesis and interpretation - Main findings (e.g., interpretations, inferences, and themes); might include development of a theory or model, or integration with prior research or theory	93-116
Links to empirical data - Evidence (e.g., quotes, field notes, text excerpts, photographs) to substantiate analytic findings	93-116

Discussion

Integration with prior work, implications, transferability, and contribution(s) to the field - Short summary of main findings; explanation of how findings and conclusions connect to, support, elaborate on, or challenge conclusions of earlier scholarship; discussion of scope of application/generalizability; identification of unique contribution(s) to scholarship in a discipline or field	117-120
Limitations - Trustworthiness and limitations of findings	121

Other

Conflicts of interest - Potential sources of influence or perceived influence on study conduct and conclusions; how these were managed	N/A
Funding - Sources of funding and other support; role of funders in data collection, interpretation, and reporting	N/A

*The authors created the SRQR by searching the literature to identify guidelines, reporting standards, and critical appraisal criteria for qualitative research; reviewing the reference lists of retrieved sources; and contacting experts to gain feedback. The SRQR aims to improve the transparency of all aspects of qualitative research by providing clear standards for reporting qualitative research.

**The rationale should briefly discuss the justification for choosing that theory, approach, method, or technique rather than other options available, the assumptions and limitations implicit in those choices, and how those choices influence study conclusions and transferability. As appropriate, the rationale for several items might be discussed together.

Appendix 3.2: Interview topic guide

Group 1 topic guide:

Consent:
Q: Have you had sufficient time to read and understand the information that was sent to you?
Prompts:
1. Before we start, do you have any questions about this research?
2. is there something you do not understand?
[Start recording]
Q. Do you agree/consent that you understand what the study involves, are happy to participate and are happy for this interview to be audio recorded?
Your study ID number is: XX
Involvement in trials:
Q. Any current or previous experiences or involvement in clinical trials?
Prompt
a. What was/is your role?
b. How many years have you been involved in a trial?
Q. Are you sharing or planning to share results with patients and the public at the end of your trial? / Have you previously shared results…?
A. If yes:
A1. Please could you tell me why you are sharing the trial results?
A2. What does sharing results with patients and the public mean to you in context of your trial?
A3. How are you sharing the results with them?
Prompt
a. When did you plan to share results of your trial? Did you plan it from the beginning?
b. Talk me through the process.
A4. What does your end product look like?
Prompt:
a. What are the contents of your report?
b. What are the mandatory/optional items?
c. How long is your report? (word count etc.)
d. Who prepared the report from your team? In your opinion, who is primarily responsible for preparing the result report?
e. Is this the only way you shared the results? Would you plan to include any interactive elements in the report (e.g., Q&A sessions, forums)?
f. What is your planned timeline for sharing the results?
A5. How did you decide what to write? How and why did you decide on those strategies?
Prompt
a. Are you following any guidance?
b. Did you receive any plain language training
A6. How will the participants receive the report?
Prompt
a. What are some of the formats and channels you have used or are planning to use to share results with patients and the public? And why?
b. For example, will you be using written reports or infographics or videos or podcasts or telephone calls (audio format)?
c. Did the participants opt to receive the results?

A7. What were your priorities when presenting the information in the report?
Prompt
a. How would you make sure that patients and the public will understand the information?
A8. What do you think about involving patients and the public in the process of sharing results?
Prompt
a. Can you share some ways your trial involved patients and the public in the process of sharing results at the end of the trial?
A9. What is your opinion on the resources needed to complete this process?
Prompt
a. Would you plan a budget for this process?
A10. Have you faced or are you anticipating any challenges in facilitating the sharing results process?
A11. What do you think would be the impact on patients and the public upon receiving the result?
Prompt
a. emotional consequence/ improved understanding of the trial
B. If no,
B1. What is your opinion on sharing trial results to patients and the public at the end of a trial?
B2. Can you share why your trial is not planning to share trial results?
B3. Hypothetically, if you were sharing the results with patients and the public, how would you structure your report?
Prompt:
a. What mandatory/optional items would you consider to be included in a report of trial results for patients and the public?
b. Would you include visuals?
c. How long do you think the report should be?
d. Would you want to include any interactive elements in the report (e.g., Q&A sessions, forums)?
e. When do you think it is appropriate to release trial results reports to the public?
f. In your opinion, who should be preparing the result report?
B4. How will you decide on those strategies? What are your priorities?
Prompt
c. Will you follow any guidance that you know of on sharing results with patients and the public?
B5. How will the participants receive the report?
Prompt
a. What format or channel would you think to use for dissemination?
b. For example, will you use written reports, infographics, videos, or summary text?
g. What is your planned timeline for sharing the results?
B6. What will be your priorities when presenting any information in the report?
Prompt
b. How would you make sure that patients and the public understand the information presented?
B7. Do you anticipate any potential challenges in facilitating this process?
B8. What do you think would be the impact on patients and the public upon receiving the result?
Prompt

a. emotional consequence/ improved understanding of the trial
B9. Would you engage patients and the public in preparing the result report?
B10. What is your opinion on the resources needed to complete this process?
Prompt
a. Would you plan a budget for this process?
Focus group:
We would also do a focus group discussion with interested participants on this topic. In a focus group discussion, members discuss a given topic in depth, sharing their opinions over a course of interaction with others. This process is conducted by a moderator.
Q. Would you be interested in joining this focus group discussion?
If yes, can I contact you to arrange the interview? Would you prefer to do the meeting online or face-to-face?
Closing:
We are at the end of the interview now.
Q. Would you like to share any additional thoughts or considerations that I have not covered?
Demographic Information:
I would now like to collect some brief demographic information from you.
Q. How would you describe your ethnicity?
Q. Are you ok with sharing your age? If not, could you give me an age range?
18-25, 26-35, 36-45, 46-55, 56-65, >65
Q. How would you describe your gender?
a. Male, Female, Prefer to identify as_____, Prefer not to say
Q. What is your Current job title?
Q. What is your current residing city? Would you be ok with sharing your postcode?
Q. Would you like to receive a summary of the findings of this study when it is finished? [If so, would it be OK if I sent that to you via email?]
Q. Would you be happy for us to keep your contact details for any future research associated with this DPhil, for example to contribute towards a focus group to feedback on any guidance that is developed?
Thank you again for your time today.
[stop recording]

Group 2 topic guide:

Consent:
Q: Have you had enough time to read and understand the information that was sent to you?
Prompts:
1. Before we start, do you have any questions about this research?
2. is there something you do not understand?
[Start recording]
Q. Do you agree/consent that you understand what the study involves and are happy to take part?
Q, Are you happy for me to record this interview?
Your study ID number is: XX
[Participant to give verbal consent. If not, do not proceed]

Transition to interview questions
Have you ever been or are you currently involved in a trial as a participant/patient/PPI?
A. If yes, were results shared with you or is there a plan to share results with you?
A1. Could you talk me through the process of how you received the results?
A2. When did you receive the results?
A3. What was the format?
A4. What did you like about the report?
A5. What was difficult to understand?
A6. Did you opt to receive the results?
A7. Was there a follow-up session/resources provided to help with understanding the results?
A8. What would you have liked to be different?
B. If no, Imagine, you were a participant in a trial.
B1. Do you think researchers should share the final trial results with you and the other people who took part in the trial and with the public?
Prompt
a. Could you share some of the reasons why you think it is important/unimportant for researchers to share results with patients and the public?
b. Do you think study participants and the public would benefit from receiving the results?
B2. What items would you like to see in the trial results report? And why?
Prompt
a. What results or other information would be the most meaningful to include? Why?
b. What other things could the researchers include?
c. How long should the report be?
B3. How would you like to receive the report?
a. (e.g., email, postal mail, online platforms)? Why?
b. When would you like to receive it?
c. Would you like supporting material to help with your understanding?
d. Would you like an interactive element in the result sharing process such as Q&A session with the researchers?
B4. How would you like the researcher to present the information? And why is that?
Prompt
a. What would help with understanding and usability, e.g., using written reports?
b. Should the report include audio visuals? Such as pictures/graphs/, infographics /videos
c. Would you prefer an audio format? Such as a telephone call or a podcast
B5. Do you have any previous experience with receiving such reports?
B6. What sort of impact do you think hearing the results will have on those who took part and their families?
(e.g., Emotional consequences), Impact future participation in trials
B7. If your native language is not English, would you like to receive a translated version of the results report in addition with the main report?
B8. What other recommendations do you have for researchers who may be planning to share results that we have not already discussed?
Focus group:
We would also do one focus group discussion with interested participants on this topic. In a focus group discussion, instead of individual interviews, members get a chance to have an open discussion with each other and voice their opinions over a course of interaction with others. This will take about an hour of your time.

Q. Would you be interested in joining this focus group discussion?
If yes, can I contact you to arrange the interview? Would you prefer to do the meeting online or face-to-face?
Closing:
We are at the end of the interview now.
Q. Would you like to share any additional thoughts or considerations that I have not covered?
Demographic Information:
We want this study to be inclusive and recruit participants from diverse backgrounds. I would now like to learn a little bit about you, it is fine to say, 'I'd rather not answer that' to any of the questions.
Q. How would you describe your ethnicity?
Q. Are you ok with sharing your age? If not, please could you give me an age range:
a. 18-25, 26-35, 36-45, 46-55, 56-65, >65
Q. How would you describe your gender?
a. Male, Female, Prefer to identify as_____, Prefer not to say
Q. What is your native language?
Q. Any current or previous experiences or involvement in clinical trials?
Q. Which city (? Or county) do you live in? Would you be ok with sharing your postcode?
Q. Please could you tell me about your family.
Q. Would you like to receive a summary of the findings of this study when it is finished? [If so, would it be OK if I sent that to you via email?]
Q. Would you be happy for us to keep your contact details for any future research associated with this DPhil, for example to contribute towards a focus group to feedback on any guidance that is developed?
Thank you again for your time today.
[stop recording]

Focus group topic guide

Introduction

Thank you for attending the meeting today. This will be a focus group discussion, which means we will discuss our topic of trial result reports by interacting with each other. I will be the moderator conducting this process.

The discussion should last no longer than one hour.

All information collected will be confidential and participants names will not be disclosed in the final report. Data will be de-identified and stored confidentially in line with the General Data Protection Regulation (GDPR) and Data Protection Act 2018.

Topic:

1. Preliminary results from the interviews

2. Invite comments on the results
3. What does sharing trial results with patients and the public mean to you?
4. How can we improve the result sharing practice?
5. Would you like to add something?
6. How should the report include visuals/audio (podcasts)?
7. Mention unusual items recorded during in-depth interviews and ask for opinions.
8. Would you like a follow-up Q&A session for the report?
9. Is there anything else you would like to share?
10. Does anyone want to share their experience of receiving such results?

Appendix 3.3: Participant information sheet

A qualitative research study to investigate approaches for sharing trial results with adult patients and the public

PARTICIPANT INFORMATION SHEET

Central University Research Ethics Committee Approval Reference: [R93417/RE001]

Version Date: v1.0 21st May 2024

We would like to invite you to take part in this research study conducted by the University of Oxford. Before making a decision, please take your time to read through the following information to understand the purpose of the research and what it will involve. If anything is unclear or if you have additional questions, please feel free to reach out to us directly, or discuss it with others if you wish.

What is the purpose of the research?

It is vitally important that results of a trial are reported to patients and the public to ensure transparency, accountability and integrity of a given trial. We are in the process of developing a standard reporting guideline for reporting trial results to patients and the public. For this purpose, we aim to explore the perspectives of the relevant stakeholders on their preferences and opinions on the content and structure of the report.

We will interview 2 groups of participants:

1. Researchers who are involved in a trial (the writers of the report)
2. Members of the public and patient representatives (the intended target audiences of the report).

Why have I been invited to take part?

You have been invited to take part because you are a potential participant meeting the following eligibility criteria.

The eligibility criteria are:

- You are aged 18 years and older
- You are willing and able to give verbal informed consent
- You are either:
    - A researcher involved/previously involved in a trial setting or
    - A member of the public or patient representative

Do I have to take part?

No. It is up to you to decide if you want to take part in this research. If at any point, you choose to withdraw from the study, you can do so without giving any reason. If you do decide to withdraw, we kindly request you to inform the researchers of this decision. This would not affect your legal rights.

What does the research involve?

If you agree to take part in the study, we will contact you via email or phone to arrange an interview at a suitable time and location for you. At this time, we will explain the study activities and ask you a few questions to confirm your eligibility. If you choose to do a virtual interview, we will send a Microsoft Teams invitation at an agreed time that is suitable for you. You will be sent a web URL that will take you to the virtual interview. You will not need Microsoft teams to access the interview.
We will also provide the option of a face-to-face interview, (particularly if you are based in the Oxford area) or a telephone interview. Again, we will arrange a suitable time and location after discussing with you.
On the day of the interview, we will explain the study activities and the purpose and will give you the chance to ask any questions you might have. The interview will involve answering questions about your opinions on the contents of a trial result report. The interview will take approximately 45 minutes.
If you are still happy to take part, you will then be asked to give verbal consent. This will be recorded at the start of the interview for purpose of an audio recording.

All participants will also be invited to express their interest in attending a focus group discussion with fellow participants. In a focus group discussion, members discuss a given topic in depth, sharing their opinions over a course of interaction with others. **This is completely optional, and you can say no**. Those interested will be contacted later to arrange the meeting. The focus group session will last around an hour.

We will also ask you if we can retain your contact details for future studies or to share the results of the study with you. This is again optional, and you can say no.

Are there any risks in taking part?

This is an interview-based study, and the risk of harm is unlikely. There is a risk of inconveniencing you with the burden and time associated with participating in an interview. To minimise this burden, we aim to keep all interviews to approximately 45 minutes in duration.

Your data will be de-identified and stored securely on the University of Oxford server. Any research outputs will not be traceable back to you.

Are there any benefits in taking part?

There will be no immediate personal benefit to you from taking part in this research. However, this research will add to ongoing research efforts to develop a standard reporting guideline for reporting results to patients and the public which will improve the reliability and transparency of trials. Your contribution will be invaluable to this research efforts.

Will my time/travel costs be reimbursed?

Given that this is a student project, funding is limited and participants will not receive any reimbursements. Your participation in this study is voluntary and your contribution is greatly appreciated for the academic and research purposes of the project.

What happens to the data provided?

The information you provide as part of the study is the **research data**. Any research data from which you can be identified (e.g. your name, job title, institution, and any affiliations), is known as **personal data**. For the purpose of the research, we will de-identify research data and give them unique ID which will not be traceable back to you (making it anonymous data). We will minimise our use of personal data in the study as much as possible.

All **research data** (including anonymous audio recordings and transcripts) will be stored on a secure University of Oxford server. **Personal data** and the linkage record will be saved in a password protected file on a secure university of Oxford server. The research team will have access to the research data, but only the primary researcher will have access to personal data. The personal data will be destroyed once the study is complete. We will ask for your consent to be contacted for future studies and also for sharing the results of this study with you. If you agree, we will retain your contact details.

All research data and records will be securely stored on the University of Oxford server for 5 years.

We would like your permission to use fully anonymised direct quotes in any research publications.

What will happen if I don't want to carry on with the study?

You have the freedom to withdraw from the study at any time without giving any reason and without your legal rights being affected. If you decide to withdraw from the study during the interview, the interview audio recording will be promptly deleted, and you will be withdrawn fully from the study. In the event you decide to withdraw after the interview, please note that interview data will still be included in the final analysis due to the complexities associated with withdrawing data that has already been audio recorded, anonymised, transcribed, and analysed. However, no direct quotes from you will be included in any research outputs in this case.

Who will know that I am taking part in this research?

All information collected about you will be kept strictly confidential. All such data are kept on firewall and password-protected computers. Designated individuals of the University of Oxford may be given access to data for monitoring and/or audit of the study to ensure we are complying with guidelines.

What will happen to the results of the research?

The research may be published in a peer review journal and/or presented at national or international conferences either as a stand-alone study or as part of the broader research agenda. The research will also be written up as a thesis chapter of the primary researchers DPhil. A copy of the completed thesis will be deposited as open access both in print and online in the Oxford University Research archives, to facilitate its use in future research.

Who has reviewed this study?

This study has been reviewed by, and received ethics approval through, the University of Oxford Central University Research Ethics Committee Reference: R93417/RE001.

Who is organising and funding the research?

Sanjana Choudhury is a DPhil candidate (DPhil in Clinical Epidemiology and Medical Statistics) at the University of Oxford. The Principal Investigator for this research is her primary supervisor Professor Sally Hopewell. This research is funded through a DPhil studentship awarded to Sanjana Choudhury. (Clarendon Scholarship and Medical Sciences Graduate School Studentship.)

What if something goes wrong?

If you have a concern about any aspect of this study, please speak to the relevant researcher Sanjana Choudhury (+44 7574279163) or supervisor Professor Sally Hopewell (Phone: +44 (0)1865 223458; email: sally.hopewell@csm.ox.ac.uk), who will do their best to answer your query.

The researcher should acknowledge your concern within ten working days and give you an indication of how they intend to deal with it. If you remain unhappy or wish to make a formal complaint, please contact the University of Oxford Research Governance, Ethics and Assurance (RGEA) team at rgea.complaints@admin.ox.ac.uk or on 01865 616480.

Data Protection

The University of Oxford is the data controller with respect to your personal data and, as such, will determine how your personal data is used in the study. The University will process your personal data for the purpose of the research outlined above. Research is a task that we perform in the public interest.

Further information about your rights with respect to your personal data is available http://www.admin.ox.ac.uk/councilsec/compliance/gdpr/individualrights/.

Contact Details

If you would like to discuss the research with someone beforehand (or if you have questions afterwards), please contact:

Ms Sanjana Choudhury

Centre for Statistics in Medicine

Nuffield Department of Orthopaedics, Rheumatology and Musculoskeletal Sciences

University of Oxford

Botnar Research Centre

Old Road, Oxford, OX3 7LD

Tel: +44 7574279163

Email: sanjana.choudhury@wolfson.ox.ac.uk

Appendix 3.4: A priori codes and thematic framework

Deductive codes are shaded in blue while inductive codes are shaded in green.

Parent node	Upper-level child nodes
Accessibility	Academic writing; Comfort level with accent and clarity; Don't compromise integrity; Media involvement; Learning differences; Engaging and accessible
Areas for improvement	Developing a standard template; Access to fund; Dissemination plan; Institutional support; Trial team planning and budgeting; Public sharing; Regulatory support
Barriers	Lack of guidance and inconsistency; Legal and regulatory barriers; Practical and logistical barriers; Cultural and institutional barriers; Communication and engagement barriers; Timing and continuity barriers
Benefits of sharing	Informed health choices; Raising awareness; Transparency; Family and friends
Communication	Balance detail and clarity; Don't underestimate lay people; Text overload; Formal versus informal
Consent	—
Current guidelines awareness	Not aware; EU Clinical Trials Regulation; Good Lay Summary Practice; General PPI guidance; New area of research; Country-specific regulations
Demography	—
Diversity and inclusion	In trial design and staffing; Targeted recruitment strategies; Trust and distrust in research; Feeling safe; Harder-to-reach people
Emotional impact	Feeling of contribution; Sense of closure; Undue expectations; Frustration; Varied reactions
Ethical obligation	—
Experience with result sharing	—
Follow-up interactive session	Interactive; Credibility; Direct communication; Opportunity cost; Confidentiality issues; Accessibility; Anxiety; Lack of funding and resources
Formats	Audio; Video; Social media; Digital media; Telephone; Webinars and podcasts; Infographic; Written reports
How to present information	Short summaries; Sensitive; Appropriate tone; Framework approach; Snappy headlines; Meaningful; Visual formats; Signposting

Identifying the audience	Affected people; Carers; Charities; Paediatric trials; Sensitive trials; Healthcare professionals; PPI input
Involvement in clinical trials	—
Jargon free	Avoid acronyms; Clear terminology; Glossary
Length of report	Brevity for public engagement; Variable; Meaningful content; Focus on language; Audience-specific
Motivation	Altruism; Interest in research
No one-size-fits-all	Core commonality; Different preferences; "mix and match" approach; Tailor to different people
Patient participation	—
Respect and recognition	Committed time to research; No participants, no trials; Deserve to know; Voice being heard; Showing gratitude
Right to opt in or out	Compulsory
Sharing negative results	Acceptance of outcome; Be mindful; Transparency; Prevent research waste; Value in learning from failure
Simplicity is key	Casual everyday language; Less is more
Structure of the report	Break the text with images; Broken in small paragraphs; Clear index; Needs to reflect PIS; PPI input
Timeline of sharing results	Sign of respect; Journal embargo; Peer review provides credibility; Simultaneous sharing
Translation of results	Audio as well as written translation; Cost-effectiveness vs worthwhileness; Logistical issue; AI tools
What to report	Results; Clinical implications; Demographic information; Future directions; Aim and background; Accessibility
Why share results	Autonomy and ownership of data; Moral and democratic imperative; Effect on health and lifestyle; Feeling insulted if results are not shared; Regulatory and funder requirements

Appendix 4.1: Recruitment pathways for the Delphi survey

Table: Recruitment pathways

Recruitment pathway	Details
Group 1: Trial professionals	
Trial networks	- UK Trial Manager's Network (UKTMN) - UK Clinical Research Collaboration (UKCRC) Registered Clinical Trials Unit - MRC-NIHR Trials Methodology Research Partnership (TMRP) groups - NIHR Oxford Biomedical Research Centre (BRC) - NIHR Centre for Engagement and Dissemination -NIHR coordinating Centre (Southampton: Beth Giddins -Cancer Research UK Clinical Trials Unit (CRCTU), Birmingham -Oxford University Research Services - RISN (Research and Innovation Support Network) Engagement and Impact CoP Teams channel, and the RISN Noticeboard Teams channel. -Society for Clinical Trials Conference 2025
Local trial units	- Oxford Clinical Trials Research Unit (OCTRU) - National Perinatal Epidemiology Unit (NPEU) - Diabetes Trials Unit (DTU) - Clinical Trial Service Unit (CTSU) - Surgical Intervention Trials Unit (SITU) - Nottingham Biomedical Research Centre PPI network -ICNARC CTU - Edinburgh Clinical Trials Unit -CRN east of England -Leeds CTRU -Southampton SCTU -- Cambridge Clinical Trials Unit
Medical writer's networks	-Syneos Health: Shaun Villa -European Medical Writers Association https://www.emwa.org/ -UNICEF, Bangladesh Coxs bazar branch, Irfath Sharmin -Open Pharma: Adaline Rosenberg -eLife: features@elifesciences.org. -Medcomms networking -Council of science editors -Society for Health communication
Journal editors	-Taylor and Francis: Kelly Soldavin -Health Expectations-Professor Carolyn Chew-Graham -BMJ Open: Adrian Aldcroft - Epidemiology: Timothy L. Lash -SAGE Publishing: Hamish McDougal -SAGE journal editorial board: https://journals.sagepub.com/editorial-board/taw AGU journal: https://www.agu.org/plan-for-a-meeting/agumeetings -BMJ: Timothy Feeney -JAMA: Professor Bibbins-Domingo -Journal of Clinical Epidemiology: Richard Hooper, Dr Jessie McGowan, Prof Dawid Pieper

Statistician/ Methodologists	-NDM Centre for Global Health Research-Forhad Choudhury -Irish HRB-TMRN: Marci Livingston - Researcher and supervisor's personal networks
Charity and funding institutions	-Kidney Research UK -Alzheimer's Research UK -AgeUK - UK research and innovation network: Biotechnology and Biological Sciences Research Council (BBSRC) members: https://www.ukri.org/who-we-are/how-we-are-governed/council-members/ -UKRI Medical Research Council (MRC) members: https://www.ukri.org/who-we-are/how-we-are-governed/council-members/ -Shaping policy and health conversation: Thana Asaad
International networks	-Chinese Equator Network - Indian Council of Medical Research Headquarters, New Delhi, India -MORU Bangkok-CTSG -Rising Scholars -Society for Clinical Trials -North East Medical College, Bangladesh: Nazia Choudhury -Dhaka Medical College Hospital, Bangladesh -SPIRIT-CONSORT update executive group -Australian Clinical Trials Alliance -Paediatric Trials Network (PTN), USA -Clinical research Ontario, Canada -People's health movement -Vanderbilt Institute for Clinical and Translational Research, USA -Hintz and Dean, University of South Florida -Canada PPI: Strategy for patient-oriented research -WHO regional offices media contacts: https://www.who.int/news-room/media-contacts -The Global Health network, https://tghn.org/ - Université Paris Cité and INSERM- Centre of Research in Epidemiology and Statistics (CRESS)
Group 2: Patient representatives and member of the public	
Diversity networks website advertisement	- Oxford BRC, Diversity in Research Group - People in Research Group -NIHR Cambridge BRC weekly roundup -Oxford CTU PPI group -NIHR Patient Research Champion -Cambridge BRC PPI weekly bulletin -International PPI network
Social media	- #OxfordPPI Twitter - Researcher's personal Twitter accounts
Religious and community groups	- Oxford Islamic Society Community of Women

Patient and public involvement (PPI) networks	- Local PPI Groups -Open Arms -Oxford PPI group: Polly Kerr - NDORMS Open Arms PPI group - Be Part of Research-NIHR -Lived Experience Advisor/EBE, NHS NATP - Neurodivergent Trainer: Amy Wizard Ponter - Andrew Ashley, PCER
Snowball sampling	- Personal contacts -Researcher and supervisor networks

Appendix 4.2: Participant information sheet

A Delphi survey to identify a core set of items for sharing the results of randomised trials with patients and the public

PARTICIPANT INFORMATION SHEET

Central University Research Ethics Committee Approval Reference: MS IDREC 1149364

Version Date: 1.0 23rd April 2025

We would like to invite you to take part in this research study conducted by the University of Oxford. Before making a decision, please take your time to read through the following information to understand the purpose of the research and what it will involve. If anything is unclear or if you have additional questions, please feel free to reach out to us directly, or discuss it with others if you wish.

1. What is the purpose of the research?

It is important that the results of a trial are shared with patients and the public to ensure transparency, accountability and integrity of a given trial. We are in the process of developing a standard reporting guideline for what information to include when sharing the results of a randomised trial with patients and the public.

2. General Information

We are inviting you to take part in a study that aims to improve how the results of randomised trials are shared with patients and the public. Randomised trials are used to test how well treatments and healthcare interventions work, and it's important that their findings are shared in a way that is clear and useful to everyone.

In this study, we are creating a reporting guideline to help researchers share trial results in ways that meet the needs of patients and the public. This guideline is not for sharing results with the scientific community.

We are conducting an online survey (using a Delphi method). To do this, we need your input. Your participation will involve taking part in this online survey where you'll share your opinions about what

information is important to include when trial results are shared with patients and the public. Your insights will play a key role in helping us develop this guideline.

3. Delphi Survey

We appreciate your interest in participating in this online Delphi survey. You have been invited to participate as you have knowledge and/or previous experience/interest of randomised trials. Or you are a valued member of the public or patient representative whose perspective and preferences are crucial for developing this guideline.

Please read through this information before agreeing to participate (if you wish to) by ticking the 'yes' box on the last page. You may ask any questions before deciding to take part by contacting the researcher (details below).

The lead researcher is Sanjana Choudhury, who is a DPhil (PhD) student at the Nuffield Department of Orthopaedics, Rheumatology and Musculoskeletal Sciences at the University of Oxford, the principal supervisor is Prof Sally Hopewell, who is attached to the Oxford Clinical Trials Research Unit / Centre for Statistics in Medicine in the same department.

4. What does participation involve?

You will be invited to take part in two to three rounds of an online survey. Each round will take about 15–20 minutes to complete, and you don't need any special background knowledge to take part.

In the survey, we'll ask for your opinion on what information is most important to share with patients and the public. After each round, we'll summarise everyone's responses (without names) and share them with the group. You'll then have the chance to review the results and give your thoughts again in the next round.

Proposed Key Dates:

Delphi Survey Round 1: April-May 2025

Delphi Survey Round 2: June-July 2025

Delphi Survey Round 3 (if needed): August-September 2025

Please note these dates may change subject to the progress of the study.

5. Do I have to take part?

No. Please note that participation is voluntary. If you do decide to take part, you may withdraw at any point for any reason before submitting your answers by closing the browser. If you withdraw, we will no longer collect any new information about you or from you, but we will keep any data that have already been collected and stored in previous survey rounds. This information may have already been used in some analyses and may still be used in the final study analyses. All questions are optional.

6. Will my time/travel costs be reimbursed?

Given that this is a student project, funding is limited, and participants will not receive any reimbursements. Your participation in this study is voluntary and your contribution is greatly appreciated for the academic and research purposes of the project.

7. Are there any risks in taking part?

This is an online survey study, and the risk of harm is unlikely. There is a risk of inconveniencing you with the burden and time associated with participating in an interview. To minimise this burden, we are hoping that each round will take no longer than 20 minutes to complete.

8. Are there any benefits in taking part?

There will be no immediate personal benefit to you from taking part in this research. However, this research will add to ongoing research efforts to develop a standard reporting guideline for sharing results of randomised trials with patients and the public which will improve the reliability and transparency of trials. Your contribution will be invaluable to these research efforts.

9. How will my data be used?

The data we will collect that could identify you will be your name, email address, gender, how you identify yourself professionally, and area of residence.

Your IP address will not be stored. We will take all reasonable measures to ensure that data remain confidential.

After each Delphi round, the votes and comments will be summarised and sent back to all participants anonymously as rates. Participants' personal information will be used for managing distribution of later survey rounds and for statistical analysis of the data only. Only the lead researcher will have access to the final database of individual responses.

The responses you provide will be stored in a password-protected electronic file on University of Oxford secure servers and may be used in academic publications, conference presentations and websites. We will maintain anonymity of all respondents in all research outputs. Research data will be stored for five years after publication or public release of the work of the research.

10. Who will have access to my data?

The University of Oxford is the data controller with respect to your personal data and, as such, will determine how your personal data is used in the study. The University will process your personal data for the purpose of the research outlined above. Research is a task that we perform in the public interest. Further information about your rights with respect to your personal data is available from https://compliance.admin.ox.ac.uk/individual-rights.

Once the study has finished, a summary of the data from the survey will be shared openly so that other researchers can view the results. Nobody will be able to identify you from this information. We will not share your original individual responses with anybody outside the research team.

11. What will happen to the results of the research?

The research may be published in a peer review journal and/or presented at national or international conferences either as a stand-alone study or as part of the broader research agenda. The research will also be written up as a thesis chapter of the lead researcher's DPhil. A copy of the completed thesis will be deposited as open access both in print and online in the Oxford University Research archives, to facilitate its use in future research.

12. Who has reviewed this study?

This project has been reviewed by, and received ethics clearance through, a subcommittee of the University of Oxford Central University Research Ethics Committee MS IDREC 1149364.

13. Who do I contact if I have a concern or I wish to complain?

If you have a concern about any aspect of this study, please speak to the lead researcher Sanjana Choudhury (Sanjana.choudhury@wolfson.ox.ac.uk) or the DPhil supervisor Prof Sally Hopewell (sally.hopewell@csm.ox.ac.uk, Tel: +44 1865 223458), and we will do our best to answer your query. We will acknowledge your concern within ten working days and give you an indication of how it will be dealt with. If you remain unhappy or wish to make a formal complaint, please contact the Chair of the Research Ethics Committee at the University of Oxford who will seek to resolve the matter as soon as possible:

Medical Sciences Interdivisional Research Ethics Committee; Email: ethics@medsci.ox.ac.uk; Address: Research Services, University of Oxford, Boundary Brook House, Churchill Drive, Headington, Oxford OX3 7GB.

Please note that you may only participate in this survey if you are 18 years of age or over.

☐ I certify that I am 18 years of age or over

If you have read the information above and agree to participate with the understanding that the data (including any personal data) you submit will be processed accordingly, please tick the box below to start.

☐ Yes, I agree to take part

Would you be happy to be re-approached for participation in any future studies related to this project? (If yes, then we will retain your contact details (email address) in order to re-approach you)

☐ Yes, I agree, and I am happy for you to retain my contact details

Appendix 4.3: Delphi participants who consented to acknowledgement

I thank all Delphi participants for their contribution to the reporting guideline development. The following participants consented to being acknowledged by name:

Abi Dennington-Price, Adele Horobin, Adeline Rosenberg, Alan Smith, Alice Guazzelli, Amena Fardous, Amy Ponter, Angela Flynn, Angela Watt, Ann Muir, Anthony Muchai Manyara, Ashleigh, Begum Zeybek Saglam, Beth Giddins, Carolyn Newbert, Catherine Barry, Ceri Steele, Charlotte Bevan, Charlotte Munro, Claire Ayling, Conrad Fernandez, Daniel Morgenstern, David Moher, David Phillips, Dawn Richards, Dominic Stringer, Donna, Eileen Morrow, Eric Frison, Farzana Firuz Samantha, George Tattersall, Grace Young, Gulnaz Iqbal, Harriet Horsham, Ian Hudson, Iffat Noshin Juthi, Immanuel Tang, Jade Jordan, James Piercy, Jeremy Dearling, Jim Determeijer, Jodi Gallant, Joletta Belton, Joshua Savage, Julie Camsooksai, Kamil Sterniczuk, Karen Keates, Karen Ma, Karen Morecroft, Karen Williams, Katharine Wilson, Kathryn Hubbard, Katie Gillies, Kayleigh Stanbury, Kelly Loffler, Kelly Tunley, Kenneth F Schulz, Kim Madden, Kimberly Mitchell, Laura Farrelly, Laura Gray, Lesley Sutton, Marci Kay Livingston, Martin Cox, Maureen Smith, Md. Hasan Alam, Mehran Sakib Choudhury, Michael Berkson, Michael D Lapenna, Michael Gregg, Mohammad Sayeem, Murray Walz, Nadia Frowd, Neil Adams, Nicola Harman, Pamela Shahbakhti, Patricia Logullo, Patrick McGuire, Paul Bateman, Peter Bates, Peter Clark, Priota Islam, Rabiul Alam Md Erfan Uddin, Ramesh Poluru, Rhys Denton, Richards, Ruth Tunn, Sarah Alderson, Sarah Markham, Shahria Raquib Liza, Shailesh, Sharon Windsor Harker, Shaun Villa, Shirley Samuels, Simona, Sophie Staniszewska, Sophie Whiteley, Stephanie Stinton, Stuart Nicholls, Sue Duncombe, Sumoni Mukherjee, Terry Hawrysh, Thana Asaad, Therese Lane, Ummi Rukaiya Munni, Xuan Yu, and Yanfang Ma.

Appendix 5.1: Consensus meeting participants

Name	Key role/Area of expertise / Location
Participant 1	Methodologist, PPI expert, guideline, policy, UK
Participant 2	Methodologist, trial, guideline, France
Participant 3	Trial, PPI, UK
Participant 4	Clinician, Trials, Epidemiology, Zimbabwe (Did not attend)
Participant 5	Methodologist, trial, Cochrane, Denmark
Participant 6	Trial, CI, UK
Participant 7	Trial, UK
Participant 8	Trial, Australia
Participant 9	Journal editor, epidemiologist, UK
Participant 10	Reporting guideline, UK
Participant 11	PPI expert, trial, Nigeria and USA
Participant 12	PPI expert, policy, UK
Participant 13	PPI expert, medical communications, USA
Participant 14	Trial manager, UK
Participant 15	PPI expert, lived experience, UK (partial attendance)
Participant 16	PPI expert, ethics, Systematic reviewer, UK
Participant 17	Member of the public, UK
Participant 18	Member of the public, UK
Participant 19	Member of the public, UK

Appendix 5.2: Pre-reading materials

Pre-reading for the consensus meeting

Developing a reporting guideline for sharing results of randomised trials with patients and the public

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Why are we here?

When a trial finishes, the results are usually written up for scientific journals. But patients who took part and the wider public often never see these results.

- Most patients say they would like to know what was found.
- Sharing results can build trust, show respect, and encourage more people to take part in research.
- Sharing trial results with participants will become a legal requirement in the UK from April 2026.
- At the moment, there is no standard reporting guideline for *what* information should be shared, or *how*.

This project is about developing a **reporting guideline**: a clear list of the essential things that should always be included when results of randomised trials are shared with patients and the public.

Who are we?

This project is carried out by Sanjana Choudhury as part of her DPhil (PhD) project at the Nuffield Department of Orthopaedics, Rheumatology and Musculoskeletal Sciences at University of Oxford. The project is supervised by Professor Sally Hopewell, Professor Gary Collins, Associate professor Charlotte Albury and Dr Jennifer de Beyer.

What has been done so far?

Figure 1 shows the flow of the projects to develop this reporting guideline. We will share more details from each project and how it informed the development of the reporting guideline during the consensus meeting.

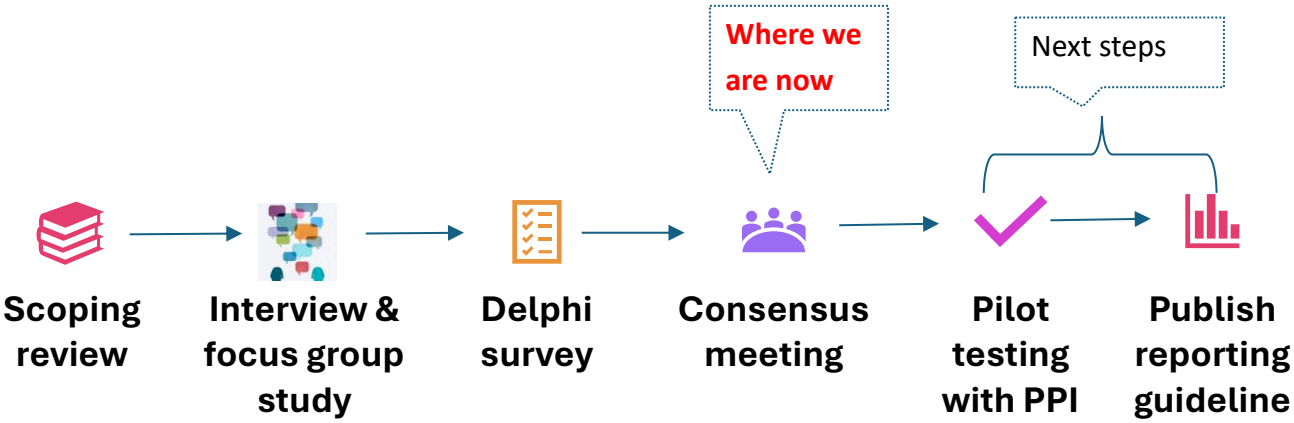


Figure 1: An overview of the projects to develop a reporting guideline on sharing results of randomised trials with patients and the public.

1. **Scoping review**

We first checked if any guidelines already exist on sharing trial or research results with patients and the public. We summarised what is out there and where the gaps are.

2. **Interviews and focus groups**

We then talked to researchers, patients, and members of the public. This helped us understand what information people want to see in trial results and how it should be shared.

3. **Delphi survey (3 rounds)**

Next, we performed a Delphi survey which is a way to build agreement among a group of people. We asked three groups to rate the items to include when trial results are shared:

- Research/trial professionals
- Patient representatives

    - Members of the public

To ensure all voices were heard, we did separate analysis in these three groups and gave equal weight to each of them.

- An item counted as reaching consensus if at least 80% of all three groups thought it was important or very important to include.
- This gave us a **shortlist of items** to help develop the reporting guideline checklist
- A **reporting guideline checklist** is a simple tool that lists the key pieces of information researchers should include when they share their study results. It helps make sure studies are reported in a clear, complete, and consistent way.
- For our project, the checklist will be built from the items identified through the Delphi process and refined during the consensus meeting.

What is a consensus meeting?

- A structured discussion where expert stakeholders come together to decide on an agreed set of items
- Stakeholders can be research/trial professionals, methodologists, statisticians, clinicians, patient representatives, and members of the public

---

Focus of the consensus meeting

We want to agree on the content of the reporting guideline checklist:

- Agree on the **minimum essential items** that must always be included when results of randomised trials are shared with patients and the public
- Agree on **additional items** that may be useful but are not always required

The decision process is visualised in Figure 2.

Decision process

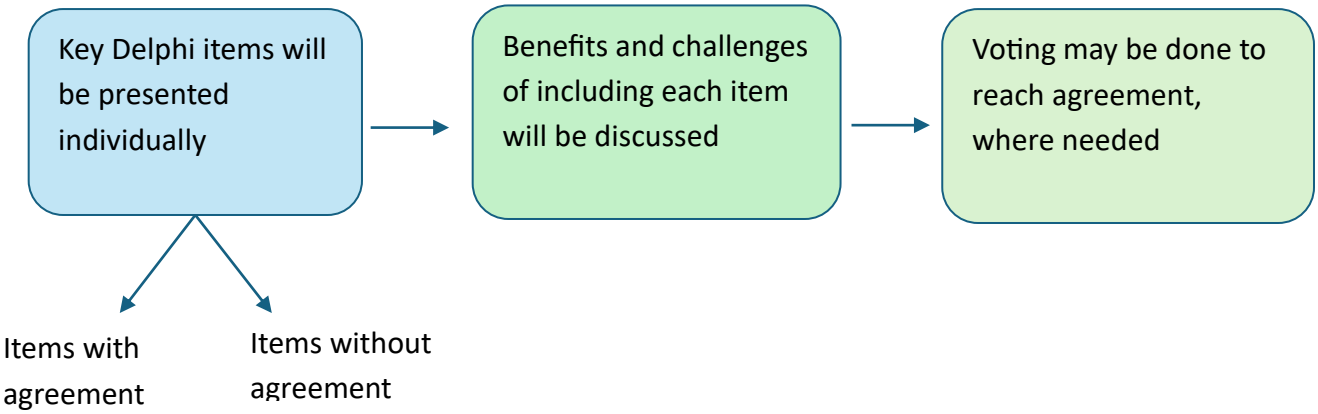


Figure 2: A flowchart showing how agreement will be reached during the consensus meeting

Items that reached consensus

14 items reached consensus(agreement) in the Delphi (at least 80% of the participant groups thought it was important or very important to include.)

Since our meeting time is limited, **we will spend less time on these**.

Please review them in advance and bring forward any major concerns or comments you may have to allow time for any discussion.

Our main focus during the meeting will be on items that **did not reach consensus.**

Consensus items that reached agreement in the Delphi:

Theme	Item
Thank you	1. Trial participants: Thank the participants for taking part in the trial
Background	2. Objective: Objective(purpose) of the trial
	3. Health condition: Description of the health condition being studied
Methods	4. Intervention(s): Intervention(s) for each group and what they were compared with
Results	5. Main findings: A summary of the primary outcome results
	6. Significance of main results: Explanation of the statistical significance of the primary outcome results

	7. Side effects: Main adverse events experienced by the trial participants during the trial
	8. Follow-up plan: Suggested follow-up plans (if applicable)
Conclusion	9. Interpretation: General interpretation of the trial results
	10. Generalisability: How applicable are the trial results to the broader general population beyond the specific context of the trial
	11. Clinical practice: How the intervention(s) may improve the health condition and the effectiveness of the intervention(s)
	12. Healthcare policy: Whether and when the intervention(s) might be available after the trial
	13. Comparison: How the trial results compare with current treatment options and existing research
Discussing the trial results with healthcare providers	14. Direction of questions: Advise the trial participants to consult healthcare providers before making any changes in their treatment plan based on the trial results

Items that did not reach consensus

34 items did not reach consensus(agreement) in the Delphi. Since our time is limited, **we will focus on discussing 13 high-priority items**. These 13 items were selected from:

- 11 items that had moderate agreement across the three participant groups and were close to reaching consensus
- 2 items that raised significant comments in Delphi rounds

If time permits, rest of the items may be discussed at the meeting. A list of these items are presented in Appendix 1.

Here is a list of these 13 items:

Theme	Item
Background	1. Benefits/risks of receiving results: Potential benefits and risks for the trial participants of receiving the trial results
Methods	2. Trial journey: Any notable events or issues that happened during the trial (if applicable)
	3. Eligibility criteria: Inclusion and exclusion criteria for the trial participants
	4. Number of participants: Number of participants included in the trial
	5. Demographics: Age, sex, and/or gender of the trial participants
	6. Demographics: Diversity of the trial participants (e.g., ethnicity, religion, language, income, location, health conditions)
	7. Patient and public Involvement and engagement: Whether and how patients and/or the public helped in the design and delivery of the trial
Conclusion	8. Strengths and limitations: Strengths and limitations of the trial results
	9. Next steps: Next steps for the trial (e.g., licensing of the medication, publication)
Additional information	10. Accessibility: How the trial participants can get more information
	11. Drug approval status: Current approval status of the treatment or intervention(s) studied in the trial
	12. Data protection policy: How the data of the trial participants will be protected
	13. Frequently Asked Questions: A section providing answers to common questions patients and/or the public may have about the trial, its results, or the next steps

What happens next?

The items we agree on will form the basis of a draft reporting guideline.

- This guideline will then be **tested (piloted)** on completed/soon to complete trials and reviewed by both researchers and patient/public groups.

- The aim is to make sure it is practical, meaningful, and easy to use.

What to keep in mind

- There are no right or wrong answers --- we want your honest views.
- Everyone's perspective matters equally, the aim is to reach common ground.
- Think about what is **useful, meaningful, and realistic** to share.
- We want a core set to include in our checklist, not an exhaustive list.
- **Including too many items can make result reports difficult to understand, harder to read and less interesting.**
- Remember the two main audiences:
    - **Patients who took part in the trial**
    - **Members of the public interested in the results**

Appendix 1: Low-priority items

Across the three rounds of the Delphi survey, these 21 items consistently received low importance ratings from participants. These items are:

Items

- Item. Trial team: Thank trial sites, trial teams, and other contributors for their role in the trial
- Item. Rationale: Rationale (the reason) behind choosing a randomised trial design
- Item. Title or Trial name: Identification as a randomised trial
- Item. Trial duration: Trial start and completion dates
- Item. Settings and location: Where the trial participants were recruited from
- Item. Randomisation: How the participants were allocated to the intervention(s) in the trial
- Item. Blinding: whether the trial participants, care givers, or trial team knew which intervention(s) the participants received
- Item. Analysis: Statistical methods used to analyse the trial data

- Item. All findings: All other outcomes assessed in the trial
- Item. Significance of all results: Explanation of the statistical significance of all outcome results
- Item. Economic implications: Cost-effectiveness of the intervention(s) tested
- Item. Media coverage: Significance of the trial's impact on public interest and media attention
- Item. Uncertainty: Any unanswered questions or emerging questions from the trial results
- Item. Future studies: Opportunities for involvement in future studies
- Item. Direction of questions: How the trial participants can discuss the trial results with health care providers to make informed health choices
- Item. Publication details: Where and when the trial report will be published
- Item. Funding: Who funded the trial
- Item. Ethics approval: Details about the ethical approval of the trial and the ethics committee
- Item. Trial registry record: Details about the trial registration (new item added after Round 1)
- Item. Post-trial contact information: Contact information for the trial team after the trial has ended (new item added after Round 1)
- Item. Conflicts of interest: Disclosing any conflicts of interest related to the trial (If applicable) (new item added after Round 1)

Appendix 6.1: Versions of the checklist: Concise version (Before piloting)

Essential items

These essential items represent the minimum reporting requirements and should be included in all summaries of trial results, regardless of audience or format, to support transparency, completeness, and clear communication. The items are not prioritised or ranked; they are presented in a logical sequence to guide reporting.

Theme/item	No	Checklist item description	Reported (Y/N)
Background			
Objective	1	Main objective of the trial	_____
Health condition or area of focus	2	Description of the health condition or broader area addressed by the trial	_____
Methods			
Interventions	3	Interventions for each group and what they were compared with	_____
Summary of eligibility criteria	4	Key inclusion and exclusion criteria for participation in the trial	_____
Results			
Number of participants	5	Number of participants included in the trial	_____
Demographics	6	Key participant demographics (e.g., age, ethnicity, sex, and/or gender)	_____
Main findings	7	Summary of the primary outcome results of the trial	_____
Side effects	8	Any important adverse (or unexpected) events experienced by trial participants	_____
Conclusion			
Interpretation	9	Interpretation of the trial results, noting potential clinical implications	_____
Strengths and limitations	10	Strengths and limitations of the trial, including factors that may influence the interpretation or generalisability of the results	_____

Additional items (where applicable)

The additional items should be included where relevant and feasible, considering the needs of the intended audience and any constraints such as word limits. While these items are strongly recommended for participant-facing materials, they add valuable context to other public summaries, such as journal plain language summaries, website content, or reports for regulatory organisations) where word limits and format allow.

Some items apply only in certain situations (for example, when long-term follow-up is planned), so authors should consider including each item wherever it is relevant and feasible, while recognising that not all items will be appropriate or possible in every format. For journal publications, inclusion may be constrained by word limits, so authors should prioritise the items that are most relevant to their intended audience while maintaining transparency.

Theme/item	No	Checklist item description	Applicability (Who/where this may be relevant)	Reported (Y/N)
Thank you				
Trial participants	11	Thank participants for taking part in the trial	Trial participants, Trial/sponsor websites	_____
Methods				
Patient and public involvement and engagement	12	Whether and how patients and/or the public helped in the design and delivery of the trial	Trial participants, Members of the public, Journal Plain Language Summary (PLS), Trial/sponsor website	_____
Results				
Follow-up plan	13	Any plans for long-term follow-up of trial participants after the trial has ended	Trial participants, Trial/sponsor website	_____
Conclusion				
Existing research	14	How the trial results compare with existing evidence (e.g., systematic reviews and other trials)	Trial participants, Members of the public, Journal PLS, Trial/sponsor website, Trial registry, Regulatory agency report	_____
Next steps	15	Next steps for the trial (e.g., publication, licensing of the medicine or treatment, or integration into healthcare policy)	Trial participants, Members of the public, Journal PLS, Trial/sponsor website, Trial registry, Regulatory agency report	

Discussing the trial results with healthcare providers				
Advisory statement	16	Statement advising the reader to consult their healthcare provider before making any changes to their treatment based on the trial results	Trial participants, Members of the public, Trial/sponsor website	_____
Additional information				
Further information	17	Where more information about the trial results or related resources can be found	Trial participants, Members of the public, Trial/sponsor website	_____

Appendix 6.2: Versions of the checklist: Expanded version (Before piloting)

Essential items

These items form the core checklist and represent the minimum reporting requirement. They should be included in all summaries of trial results, regardless of audience or format. The items are not prioritised or ranked; they are presented in a logical sequence to guide reporting.

Instruction for use:

If word limit is not an issue, consider presenting the results in a **question-and-answer format**, using the **lay headers** as section titles or guiding questions. While this is optional, it can help make the summary more engaging and easier to follow for patients and the public, while ensuring all key information is clearly addressed.

Theme/item	No	Checklist item description	Lay item description	Reported (Y/N)
Background				
Objective	1	Main objective of the trial	**Lay header:** *What did we want to find out?* • State, in plain language, the main question the trial aimed to answer.	_____
Health condition or area of focus	2	Description of the health condition or broader area addressed by the trial	**Lay header:** *What did we study*? • Provide a brief description of the condition, disease, or health issue addressed by the trial, including why it is important to patients or the public.	_____
Methods				
Interventions	3	Interventions for each group and what they were compared with	**Lay header:** *What did we do?* • Describe what treatments, tests, or actions participants received in each group and what these were compared against. • Focus on the essential features that distinguish the experimental intervention from the comparison.	

Summary of eligibility criteria	4	Key inclusion and exclusion criteria for participation in the trial	**Lay header:** *Who could take part in the trial?* • Summarise who could and could not take part, highlighting the main criteria e.g., age range, clinical diagnosis, or key health factors. • You do not need to list every inclusion or exclusion criterion. Include only those most relevant for understanding who the trial results apply to.	_____
Results				
Number of participants	5	Number of participants included in the trial	**Lay header:** *How many people took part?* • Report the number of participants included in the trial or analysis, and, where relevant, how many were in each group.	_____
Demographics	6	Key participant demographics (e.g., age, ethnicity, sex, and/or gender)	**Lay header:** *Who were the participants?* • At minimum, age, ethnicity, sex, and/or gender should be reported where collected. • If additional diversity data were collected (e.g., income, socio-economic status, language, or other relevant factors), report those as well.	_____
Main findings	7	Summary of the primary outcome results of the trial	**Lay header:** *What did we find out?* • Summarise the main results for the primary outcome of the trial. • Focus on what the results mean for patients (e.g., whether the new treatment worked better, the same, or worse than the comparison). • Avoid technical or statistical terms and use clear comparisons.	_____
Side effects	8	Any important adverse (or	**Lay header:** *Were there any side effects?*	_____

		unexpected) events experienced by trial participants	• Summarise the main or frequent adverse events and refer readers to further guidance if applicable. • Clarify how common or serious they were using language understandable to non-specialists. • If no adverse events were identified, this should be stated.	
Conclusion				
Interpretation	9	Interpretation of the trial results, noting potential clinical implications	**Lay header:** *What do the results mean?* • Briefly explain what the results mean in real-world terms. • Provide a balanced interpretation of the findings, relating them to possible clinical relevance without exaggeration.	_____
Strengths and limitations	10	Strengths and limitations of the trial, including factors that may influence the interpretation or generalisability of the results	**Lay header:** *How confident can we be in these results?* • Acknowledge key strengths (e.g., large sample size or diverse participants) and limitations (e.g., short duration or small numbers) to help readers interpret the findings appropriately. • Explain how relevant the findings are to the broader patient population or real-world settings. • Avoid overstating the generalisability of the findings to prevent misleading conclusions.	_____

Additional items (where applicable)

The additional items should be included where relevant and feasible, considering the needs of the intended audience and any constraints such as word limits. They are strongly recommended to include in communications directed to trial participants and are also useful additions to other public-facing summaries (for example, journal plain language summaries, website content, or reports for regulatory organisations) where word limits and format allow.

Some items apply only in certain situations (for example, when long-term follow-up is planned), so authors should consider including each item wherever it is relevant and feasible, while recognising that not all items will be appropriate or possible in every format. For journal publications, inclusion may be constrained by word limits, so authors should prioritise the items that are most relevant to their intended audience while maintaining transparency.

Instruction for use:

If word limit is not an issue, consider presenting the results in a **question-and-answer format**, using the **lay headers** as section titles or guiding questions. While this is optional, it can help make the summary more engaging and easier to follow for patients and the public, while ensuring all key information is clearly addressed.

Theme/item	No	Checklist item description	Applicability (Who/where this may be relevant)	Lay item description	Reported (Y/N)
Thank you					
Trial participants	11	Thank participants for taking part in the trial	Trial participants, Trial/sponsor websites	**Lay header:** *Thank you!* • Acknowledge and thank the trial participants for their time and contribution.	_____
Methods					
Patient and public involvement and engagement	12	Whether and how patients and/or the public	Trial participants, Members of the public, Journal Plain	**Lay header:** *What patient and public involvement was there in the trial?* • Briefly report whether patients and / or the public were	_____

		helped in the design and delivery of the trial	language summary (PLS), Trial/sponsor websites	involved in the design or conduct of the trial, and describe their role (e.g., reviewing trial materials or advising on recruitment).	
Results					
Follow-up plan	13	Any plans for long-term follow-up of trial participants after the trial has ended	Trial participants, Trial/sponsor website	**Lay header:** *Will there be any follow-up?* • Explain whether participants will be followed up after the trial, for how long, and what this means for them.	_____
Conclusion					
Existing research	14	How the trial results compare with existing evidence (e.g., systematic reviews and other trials)	Trial participants, Members of the public, Journal PLS, Trial/sponsor website, Trial registry, Regulatory agency report	**Lay header:** *How do these results compare with other research?* • Summarise how the trial findings relate to previous studies or what is already known about the topic. • Highlight whether the results support, contradict, or add new insights compared with existing evidence, without going into exhaustive detail.	_____
Next steps	15	Next steps for the trial (e.g., publication, licensing of the medicine or	Trial participants, Members of the public, Journal PLS, Trial/sponsor website,	**Lay header:** *What happens next?* • Briefly describe any activities following the trial, if planned or known. • This could include publication of results, further research, regulatory review, or potential	_____

		treatment, or integration into healthcare policy)	Trial registry, Regulatory agency report	changes in healthcare practice or policy.	
Discussing the trial results with healthcare providers					
Advisory statement	16	Statement advising the reader to consult their healthcare provider before making any changes to their treatment based on the trial results	Trial participants, Members of the public, Trial/sponsor website	**Lay header:** *Discussing the trial results with your doctor* • Include a short statement advising readers not to alter their treatment plan based on the trial results without consulting their healthcare provider first. • If possible, provide guidance on questions they may wish to discuss with their doctor.	_____
Additional information					
Further information	17	Where more information about the trial results or related resources can be found	Trial participants, Members of the public, Trial/sponsor website	**Lay header:** *Where can you find more information?* • Provide clear directions on where readers can learn more (e.g., links to websites, trial registries, or contact details for investigators).	_____

Appendix 6.3: Versions of the checklist: Merged version (Before piloting)

Essential items

These items form the core checklist and represent the minimum reporting requirement. They should be included in all summaries of trial results, regardless of audience or format. The items are not prioritised or ranked; they are presented in a logical sequence to guide reporting.

Instruction for use:

If word limit is not an issue, consider presenting the results in a **question-and-answer format**, using the **lay headers** as section titles or guiding questions. While this is optional, it can help make the summary more engaging and easier to follow for patients and the public, while ensuring all key information is clearly addressed.

Theme/item	No	Checklist item description	Reported (Y/N)
Background			
Objective	1	Main objective of the trial **Lay header:** *What did we want to find out?* • State, in plain language, the main question the trial aimed to answer.	
Health condition or area of focus	2	Description of the health condition or broader area addressed by the trial **Lay header:** *What did we study*? • Provide a brief description of the condition, disease, or health issue addressed by the trial, including why it is important to patients or the public.	
Methods			
Interventions	3	Interventions for each group and what they were compared with **Lay header:** *What did we do?* • Describe what treatments, tests, or actions participants received in each group and what these were compared against. • Focus on the essential features that distinguish the experimental intervention from the comparison.	

Summary of eligibility criteria	4	Key inclusion and exclusion criteria for participation in the trial **Lay header:** *Who could take part in the trial?* • Summarise who could and could not take part, highlighting the main criteria e.g., age range, clinical diagnosis, or key health factors. • You do not need to list every inclusion or exclusion criterion. Include only those most relevant for understanding who the trial results apply to.	
Results			
Number of participants	5	Number of participants included in the trial **Lay header:** *How many people took part?* • Report the number of participants included in the trial or analysis, and, where relevant, how many were in each group.	
Demographics	6	Key participant demographics (e.g., age, ethnicity, sex, and/or gender) **Lay header:** *Who were the participants?* • At minimum, age, ethnicity, sex, and/or gender should be reported where collected. • If additional diversity data were collected (e.g., income, socio-economic status, language, or other relevant factors), report those as well.	
Main findings	7	Summary of the primary outcome results of the trial **Lay header:** *What did we find out?* • Summarise the main results for the primary outcome of the trial. • Focus on what the results mean for patients (e.g., whether the new treatment worked better, the same, or worse than the comparison). • Avoid technical or statistical terms and use clear comparisons.	
Side effects	8	Any important adverse (or unexpected) events experienced by trial participants	

		Lay header: *Were there any side effects?* • Summarise the main or frequent adverse events and refer readers to further guidance if applicable. • Clarify how common or serious they were using language understandable to non-specialists. • If no adverse events were identified, this should be stated.	
Conclusion			
Interpretation	9	Interpretation of the trial results, noting potential clinical implications **Lay header:** *What do the results mean?* • Briefly explain what the results mean in real-world terms. • Provide a balanced interpretation of the findings, relating them to possible clinical relevance without exaggeration.	
Strengths and limitations	10	Strengths and limitations of the trial, including factors that may influence the interpretation or generalisability of the results **Lay header:** *How confident can we be in these results?* • Acknowledge key strengths (e.g., large sample size or diverse participants) and limitations (e.g., short duration or small numbers) to help readers interpret the findings appropriately. • Explain how relevant the findings are to the broader patient population or real-world settings. • Avoid overstating the generalisability of the findings to prevent misleading conclusions.	

Additional items (where applicable)

The additional items should be included where relevant and feasible, considering the needs of the intended audience and any constraints such as word limits. They are strongly recommended to include in communications directed to trial participants and are also useful additions to other public-facing summaries (for example, journal plain language summaries, website content, or reports for regulatory organisations) where word limits and format allow.

Some items apply only in certain situations (for example, when long-term follow-up is planned), so authors should consider including each item wherever it is relevant and feasible, while recognising that not all items will be appropriate or possible in every format. For journal publications, inclusion may be constrained by word limits, so authors should prioritise the items that are most relevant to their intended audience while maintaining transparency.

Instruction for use:

If word limit is not an issue, consider presenting the results in a **question-and-answer format**, using the **lay headers** as section titles or guiding questions. While this is optional, it can help make the summary more engaging and easier to follow for patients and the public, while ensuring all key information is clearly addressed.

Theme/item	No	Checklist item description	Applicability (Who/where this may be relevant)	Reported (Y/N)
Thank you				
Trial participants	11	Thank participants for taking part in the trial **Lay header:** *Thank you!* • Acknowledge and thank the trial participants for their time and contribution.	Trial participants, Trial/sponsor websites	
Methods				
Patient and public involvement and	12	Whether and how patients and/or the public helped in the design and delivery of the trial	Trial participants, Members of the public,	

engagement		**Lay header:** What patient and public involvement was there in the trial? • Briefly report whether patients and / or the public were involved in the design or conduct of the trial, and describe their role (e.g., reviewing trial materials or advising on recruitment).	Journal Plain language summary (PLS), Trial/sponsor websites	
Results				
Follow-up plan	13	Any plans for long-term follow-up of trial participants after the trial has ended **Lay header:** *Will there be any follow-up?* • Explain whether participants will be followed up after the trial, for how long, and what this means for them.	Trial participants, Trial/sponsor website	
Conclusion				
Existing research	14	How the trial results compare with existing evidence (e.g., systematic reviews and other trials) **Lay header:** *How do these results compare with other research?* • Summarise how the trial findings relate to previous studies or what is already known about the topic. • Highlight whether the results support, contradict, or add new insights compared with existing evidence, without going into exhaustive detail.	Trial participants, Members of the public, Journal PLS, Trial/sponsor website, Trial registry, Regulatory agency report	
Next steps	15	Next steps for the trial (e.g., publication, licensing of medicine or treatment, or integration into healthcare policy) **Lay header:** *What happens next?*	Trial participants, Members of the public, Journal PLS, Trial/sponsor	

		• Briefly describe any activities following the trial, if planned or known. • This could include publication of results, further research, regulatory review, or potential changes in healthcare practice or policy.	website, Trial registry, Regulatory agency report	
Discussing the trial results with healthcare providers				
Advisory statement	16	Statement advising the reader to consult their healthcare provider before making any changes to their treatment based on the trial results **Lay header:** *Discussing the trial results with your doctor* • Include a short statement advising readers not to alter their treatment plan based on the trial results without consulting their healthcare provider first. • If possible, provide guidance on questions they may wish to discuss with their doctor.	Trial participants, Members of the public, Trial/sponsor website	
Additional information				
Further information	17	Where more information about the trial results or related resources can be found **Lay header:** *Where can you find more information?* • Provide clear directions on where readers can learn more (e.g., links to websites, trial registries, or contact details for investigators).	Trial participants, Members of the public, Trial/sponsor website	

Appendix 6.4: List of recruitment networks where pilot testing was advertised

- OCTRU (Oxford Clinical Trials Research Unit)
- SITU, NDS (Surgical Intervention Trials Unit, Nuffield Department of Surgical Sciences)
- SITU, NDORMS (Surgical Intervention Trials Unit, Nuffield Department of Orthopaedics, Rheumatology and Musculoskeletal Sciences)
- NPEU (National Perinatal Epidemiology Unit)
- Primary Care Research Networks
- Nottingham Clinical Trials Unit (NCTU)
- EMR (Experimental Medicine Research groups)
- Trauma trials (Trauma and orthopaedic clinical trials groups)
- Leeds Institute of Clinical Trials Research (LICTR)
- ICNARC (Intensive Care National Audit and Research Centre)
- CTRU Leeds (Clinical Trials Research Unit, University of Leeds)
- CRN East of England (Clinical Research Network East of England)
- Edinburgh Clinical Trials Unit (ECTU)
- Warwick Clinical Trials Unit (WCTU)
- Centre for Trials Research, Cardiff University
- College of Biomedical and Life Sciences, Cardiff University
- The Hospital for Sick Children (SickKids), Toronto
- University of Toronto

Appendix 6.5: List of trial reports used during Phase 2

ID	Trial given	Trial source	Trial publication
1	A multicentre, randomized, double-blind, parallel and controlled with placebo pilot study to evaluate the efficacy and safety of a single dose of botulinum toxin Type A (Dysport®) associated with rehabilitation treatment, in patients with primary myofascial syndrome of cervical and dorsal localization.	https://www.clinicaltrialsregister.eu/ctr-search/trial/2004-001443-29/results	-
2	Levocarnitine in treating fatigue in cancer patients	https://clinicaltrials.gov/study/NCT00091169?tab=results	-
3	Ketamine as an adjunctive therapy for Major Depression - a randomised controlled pilot trial: the KARMA-Dep trial	https://pubmed.ncbi.nlm.nih.gov/35036831/	https://www.clinicaltrialsregister.eu/ctr-search/trial/2016-004764-18/results#moreInformationSection
4	The Hypertension in the Very Elderly Trial (HYVET)	https://clinicaltrials.gov/study/NCT00122811	https://pubmed.ncbi.nlm.nih.gov/18378519/
5	A randomised, double-blind, placebo-controlled Phase IIb trial to test FLU-v vaccine	https://clinicaltrials.gov/study/NCT02962908?intr=randomised%20controlled%20trial&aggFilters=results:with,studyType:int&rank=10&tab=results#study-record-dates	https://pubmed.ncbi.nlm.nih.gov/32150750/
6	Piroxicam and levonorgestrel co-treatment for emergency contraception	https://clinicaltrials.gov/study/NCT03614494?intr=randomised%20controlled%20trial&aggFilters=results:with,studyType:int&page=3&rank=23&tab=results#results-overview	https://pubmed.ncbi.nlm.nih.gov/37597523/

7	Tenofovir-lamivudine-dolutegravir combination as second-line ART: a randomised controlled trial (ARTIST)	https://clinicaltrials.gov/study/NCT03991013?intr=randomised%20controlled%20trial&aggFilters=results:with,studyType:int&rank=5&tab=results	https://pubmed.ncbi.nlm.nih.gov/36645792/
8	A randomised controlled clinical trial in type 2 diabetes comparing Semaglutide to placebo and liraglutide	https://clinicaltrials.gov/study/NCT00696657?intr=randomised%20controlled%20trial&aggFilters=results:with,studyType:int&rank=6&tab=results	https://pubmed.ncbi.nlm.nih.gov/26358288/
9	A randomised clinical trial in a population of health care workers with hand eczema (het)	https://clinicaltrials.gov/study/NCT01012453?intr=randomised%20controlled%20trial&rank=2	https://www.bmj.com/content/345/bmj.e7822.long
10	Community based interventions to improve HIV outcomes in youth: a cluster randomised trial in Zimbabwe (CHIEDZA)	https://clinicaltrials.gov/study/NCT03719521?intr=randomised%20controlled%20trial&rank=6	https://www.researchsquare.com/article/rs-5594349/v1
11	The effect of breath exercise and reiki application (Reiki app)	https://clinicaltrials.gov/study/NCT06902259?intr=randomised%20controlled%20trial&rank=1	file:///C:/Users/SChoudhury/Downloads/the_effect_of_distant_reiki_sessions_on_holistic.131.pdf
12	Text message-based cessation intervention for people who smoked or used smokeless tobacco in India: a feasibility randomized controlled trial	-	https://pubmed.ncbi.nlm.nih.gov/38468498/
13	Third-generation cognitive behavioural therapy versus treatment-as-usual for attention deficit and hyperactivity disorder: a multicentre randomized controlled trial	https://doi.org/10.1186/s13063-021-05983-2.	-

Appendix 6.6: Pilot testing feedback form

Reviewer demographics

Variable	**Response Format**
Participant Name/Initials	Text
Role/experience	☐ Trial manager ☐ Medical Writer ☐ Researcher☐ Trial coordinator☐ Chief investigator ☐ PPI representative ☐ Other (free text box)
Research field / trial type	Text
Years of experience in trials/health research	Numeric field
Prior experience writing or reviewing trial summaries	☐ None ☐ writing☐ reviewing
Prior experience with reporting guideline (e.g., CONSORT, EQUATOR)	☐ Yes ☐ No
Checklist testing completed?	☐ Yes ☐ No
Date completed	Dd/mm/yyyy

General Feedback Form Template (All Phases)

Section	Question	Response Format
A. Ratings	1. How clear was it to understand when and for whom this checklist should be used (e.g., when sharing randomised trial results with patients and the public)?	1 = Not clear at all → 5 = Very clear
	2. How easy was it to use the checklist item to write a summary?	1 = Very difficult → 5 = Very easy
	3. How useful was the checklist for deciding what to include?	1 = Not useful → 5 = Very useful
	4. Did the checklist cover everything you needed to report the trial results?	1 = Incomplete → 5 = Very complete
	5. How likely are you to use this checklist in future summaries?	1 = Unlikely → 5 = Very likely
B. Open-text feedback	Did you find any items unclear or confusing? If yes, please name the item number(s) and briefly explain why.	Free text
	Were any item(s) unnecessary, repetitive, or overlapping with other items? If yes, which item number(s)?	Free text
	How much time did it take to use the checklist and write a summary?	Numeric / text
	Were there any checklist items you could not include in your summary? If yes, please list the item number(s) and the reason (e.g., word limit, not reported in the trial, Checklist wording unclear)	Free text
	Did you expect any topics to be included that are not covered by the checklist? If yes, what was missing?	Free text
	Any other comments or suggestions to improve the checklist (e.g., wording, order, format, examples)?	Free text

Phase 2: User Testing: Cognitive Interviews

Observation Focus	Notes
Points of hesitation or confusion	Open-text comment
Alternative interpretations of terms	Open-text comment
Suggestions for rewording	Open-text comment
Missing items identified	Open-text comment
Short thematic summary	With example quotes

PPI demographics

Variable	Response Format
Participant Name/initials	Text
Age range	☐ 18–25 ☐ 26–35 ☐ 36–45 ☐ 46–55☐ 56–65 ☐ 65+
Sex	☐ Female ☐ Male ☐ Other / Prefer not to say
Lived experience/expertise/special interest	Text
Prior experience with plain language summaries	☐ Yes ☐ No
Pilot testing completed on	Date

Phase 3: PPI Testing (Readability)

Area	Example	Response Format
Ratings	How clear was the summary?	1–5 Likert
	Did the summary cover everything you needed to understand the trial results?	1–5 Likert
	Did the information feel relevant to you as a reader?	1–5 Likert
Open comments	Did you find any parts unclear or confusing?	Free text
	Did you expect any topics to be included that are not covered by the checklist? If yes, what was missing?	Free text

	Any other comments or suggestions to improve the checklist (e.g., wording, order, format, examples)?	Free text

Appendix 6.7: Phase 1 detailed results

Phase 1a detailed results: Application of the draft checklist to ten completed randomised trials

This table presents detailed results from Phase 1a, including trial titles, data sources, and the checklist items reported when summaries were produced under word-restricted and non-word-restricted conditions. The table illustrates how word limits affect the inclusion of additional checklist items across different trial types.

Test No.	Summary name	Result source	Result link	Items that could be reported	
				Essential	Additional
1	Improving cardiac rehabilitation session attendance: a randomised controlled trial	Trial registry	ClinicalTrials.gov ID NCT00956657	All	11, 16,17 in 300-words summary 11, 14-17 in long version
2	Eating two larger meals a day (breakfast and lunch) is more effective than six smaller meals in a reduced-energy regimen for patients with type 2 diabetes: a randomised crossover study	Journal article	https://pmc.ncbi.nlm.nih.gov/articles/PMC4079942/	All	11, 14, 16 in 300-words summary, 11, 14-17 in longer version
3	Effect of patient education on adherence to drug treatment for rheumatoid arthritis: a randomised controlled trial	Journal article	https://pubmed.ncbi.nlm.nih.gov/11502614/	All	None in 300 words summary 11, 14-17 in longer version
4	A multicenter, double-blind, randomized study to evaluate the safety and efficacy of the addition of mk-0431 compared with sulfonylurea therapy in	Trial registry + Journal article	https://trialsearch.who.int/Trial2.aspx?TrialID=EUCTR2004-002159-16-DK https://www.sciencedirect.com/science/article/pii/S0168822711001252?via%3Dihub	All	11, 15,16 in 300-words summary,

	patients with type 2 diabetes with inadequate glycaemic control on metformin monotherapy - active-controlled combination study				11, 14-17 in long version
5	A prospective, randomised, controlled study examining binaural beat audio and pre-operative anxiety in patients undergoing general anaesthesia for day case surgery	Trial registry + Journal article	https://pubmed.ncbi.nlm.nih.gov/16115248/ ISRCTN	All except 6 (demographic info not collected)	11, 14, 16 in 300-words summary, 11, 14-17 in long version
6	A randomized controlled trial of laser treatment among hirsute women with polycystic ovary syndrome	Trial registry + Journal article	https://pubmed.ncbi.nlm.nih.gov/15888157/	All	None in 300-words summary, 11, 13-17 in longer version
7	Randomised, controlled trial of an individual deprescribing intervention for nursing homes residents (OLD-NH-IDeI)	Trial registry	https://clinicaltrials.gov/study/NCT03655405?intr=randomised%20controlled%20trial&aggFilters=results:with,status:com,studyType:int&rank=3&tab=results	All	None in 300-words summary 11, 14-17 in longer version
8	Prevention of falls in the elderly trial (PROFET): a randomised controlled trial	Trial registry + Journal article	https://pubmed.ncbi.nlm.nih.gov/10023893/	All	None in 300-words summary 11, 14-17 in longer version
9	Effects of aromatase inhibition versus testosterone in older men with low testosterone: randomized-controlled trial.	Trial registry+ journal article	https://pmc.ncbi.nlm.nih.gov/articles/PMC4880169/	All	14-16 in 300-words summary 11, 14-17 in

					longer version
10	A Phase III randomized, placebo-controlled study of sorafenib in patients with advanced hepatocellular carcinoma	Trial registry+ journal article	https://www.nejm.org/doi/10.1056/NEJMoa0708857?url_ver=Z39.88-2003&rfr_id=ori:rid:crossref.org&rfr_dat=cr_pub%20%200www.ncbi.nlm.nih.gov	All	11, 14, 15 in 300-words summary 11, 14-17 in longer version

B. Phase 1b detailed results: Mapping of published plain-language summaries to checklist items

This table shows item-by-item mapping of six published plain-language summaries against the draft checklist. Each checklist item is coded as present (Y), partly present (partly), not present (N), or not applicable (N/A), highlighting common reporting practices and frequent omissions in current summaries.

Test no.	Summary name	Summary type	Summary source	Health condition or area of focus	Objective	Interventions	Summary of eligibility criteria	Number of participants	Demographics	Main findings	Side effects	Interpretation	Strengths and limitations	Thank you	Patient and public involvement and	Follow-up plan	Existing research	Next steps	Advisory statement	Further information
1	A study of the safety, efficacy, and biomarker response of BMS-986165 in participants with moderate	Sponsor website-plain language summary	https://www.bms.com/assets/bms/shared/plain-language-summary/im011-127/im011-127-pls-en-final-approved.pdf	Y	Y	Y	Y	Y	Y	Y	Y	Y	Partly	Y	N	N/A	Partly	N	Y	Y

	to severe ulcerative colitis																			
2	Effectiveness and safety of tofacitinib in children and adolescents with systemic juvenile idiopathic arthritis (sJIA) that affects the whole body	Sponsor website-plain language summary	https://www.pfizer.com/sites/default/files/plsr-studies/A3921165%20Plain%20Language%20Study%20Results%20Summary%20%28PLSRS%29%20Phase%202-4_0.pdf	Y	Y	Y	Y	Y	Y	Y	Y	Y	N	Y	N	N/A	N	N	N	Y
3	Ibrutinib plus venetoclax in subjects with treatment	Sponsor website-Plain language summary	https://www.abbvieclinicaltrials.com/study/?id=PCYC-1142-CA	Y	Y	Y	Partly	Y	Y	Y	Y	Partly	N	Y	N	N/A	Partly	Y	N	Y

	-naive chronic lymphocytic leukaemia /small lymphocytic lymphoma (CLL/SLL)																			
4	Community-based football in men with prostate cancer: 1-year follow-up on a pragmatic, multicentre randomised	Journal-author summary	https://journals.plos.org/plosmedicine/article?id=10.1371/journal.pmed.1002936	Y	Y	Y	Partly	Y	N	Y	N	Y	Y	N	N	N/A	Y	Partly	N	N/A

	controlled trial																			
5	Plain language summary of the SHAMAL study in patients with severe eosinophilic asthma treated with benralizumab	Plain language summary of publication	https://pubmed.ncbi.nlm.nih.gov/39780731/	Y	Y	Y	Y	Y	Y	Y	Y	Y	N	Y	N	N/A	Y	N	N	Y
6	Safety and tolerability of the Japanese encephalitis vaccine IC51. Double	ClinicalTrials.gov Protocol and Results Registration System	https://www.clinicaltrialsregister.eu/ctr-search/trial/2005-000100-14/results	Y	Y	Y	Y	Y	Y	Y	Y	Y	N	N	N	N	N	N	N	N

	blind, randomized, placebo controlled phase 3 study	(PRS) Receipt																		
7	A study to provide additional treatment of levodopa-carbidopa intestinal gel to patients with advanced Parkinson's disease	Sponsor website-Plain language summary	https://connect.trialscope.com/rails/active_storage/blobs/redirect/eyJfcmFpbHMiOnsiZGF0YSI6MTU4OSwicHVyIjoiYmxvYl9pZCJ9fQ==--d37f58a9dd2bc0a1fe8d788d39d2c270dd904a18/Clinical%20Study_S187.3.005_English.pdf	Y	Y	Y	Y	Y	Y	Y	Y	Y	Partly	Y	Y	N/A	N	Y	N	Y
8	A study of the long-term safety and efficacy of adalimum	Sponsor website-Plain language summary	https://www.abbvieclinicaltrials.com/study/?id=M11-327	Y	Y	Y	Y	Y	Y	Y	Y	Y	Partly	Y	Y	Y	Y	Y	Y	Y

	ab in subjects with intermediate-, posterior-, or pan-uveitis																		