

## Nuffield Department of Surgical Sciences

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## **PARTICIPANT INFORMATION SHEET**

### **Delphi round 1 and 2**

Version 1 – 15.12.20

**Developmental and Exploratory Clinical Investigation of DEcision support systems driven by Artificial Intelligence (DECIDE-AI): development of new reporting guidelines through a Delphi process.**

CUREC Approval Reference: R73712/RE002

We'd like to invite you to take part in our research study. Before you decide, it is important that you understand why the research is being done and what it would involve for you. Please take time to read this information, and discuss it with others if you wish. If there is anything that is not clear, or if you would like more information, please don't hesitate to contact us.

### **What is the purpose of the study?**

This study aims to develop new reporting guidelines to make the early clinical evaluation of AI driven algorithms more consistent, comprehensive and reproducible. A robust evaluation at this stage where algorithms are first used by clinicians is indispensable to bridge algorithm development to large-scale clinical trials. To this end, DECIDE-AI ambition is to improve the evaluation reporting along four main axes: i) the algorithm performance when first used with humans in small-scale, representative clinical conditions, ii) the safety profile of the algorithm prior to its wider-scale utilisation, iii) the human factors (ergonomic) evaluation of the algorithm, and iv) the preparatory steps towards large-scale clinical trials.

A more detailed description of the project can be found in the document "DECIDE-AI project presentation".

### **Why have I been invited?**

You have been invited on account of your expertise and experience in the field of artificial intelligence and/or evaluation of clinical intervention. We believe that your expert opinion will contribute to develop comprehensive and well-informed reporting standards.

## **Do I have to take part?**

No. Please note that participation is voluntary. If you do decide to take part, you may withdraw consent at any point for any reason, and without any adverse consequences or penalty. You can exit the survey at any time before submitting your answers by closing the browser. If you need to interrupt your session but wish to continue participating, you can choose the option to save your progress and return later. If you do not wish to answer a question, you can simply fill the answer field with “NA” or choose the “I don’t know” option.

## **What will happen to me if I decide to take part?**

The research project is based on the published Delphi methodology. The main goal of a Delphi process is to reach consensus between experts through several rounds of feedback. The results of each round are presented during the following round to inform participants’ decision and guide them toward consensus. The present Delphi adaptation will include two general rounds, followed by a consensus meeting (for a subset of participants). The present invitation and information sheet refer to the two general rounds only. Consent will be asked before each round through an online form.

Round 1 (online survey): you will be asked to answer open-ended questions about what you think should be reported when evaluating an artificial intelligence based algorithm for the first time in clinical settings. You will then be asked to rank, on a 0-9 Likert scale and according to their importance, a list of provisory items developed by the research team and reviewed by the DECIDE-AI steering group. You will also have the opportunity to add comments, propose new items and recommend additional experts to take part in the Delphi. This round should take you between 45 and 60 minutes, depending on the extent of your free text inputs. You can interrupt your session at any time and resume later.

Round 2 (online survey): you will be asked to rank, on a 0-9 Likert scale and according to their importance, a modified list of reporting items, updated based on the first-round results and feedback. You will again have the opportunity to provide open comments. This round should take you between 30 and 45 minutes, depending on the extent of your free text inputs. You can interrupt your session at any time and resume later.

## **Are there any possible risks from taking part?**

This study is considered to be at very low risk of physical or psychological harm. Issues related to data breaches or loss of confidentiality cannot be totally excluded. However, the research team took this aspect very seriously and designed a data handling strategy to minimize this risk.

## **How will my data be used?**

The data we will collect that could identify you will be: your name, your affiliation, your main professional geographical location, your stakeholder group, your experience with AI/clinical evaluation and your professional email address. Your answers will be dissociated from these data using the REDCap software and data analysed in a de-identified manner. We will take all reasonable measures to ensure that your answers remain confidential.

Your personal data and answers will be retained in the REDCap DECIDE-AI project database. REDCap is a secure web application, developed by a multi-institutional consortium initiated at Vanderbilt University. Access to the REDCap DECIDE-AI project database is password

protected and for authorized users only. Additionally, your personal data and de-identified questionnaires' answers will be stored on a password-protected university network drive. Any linkage between your personal data and questionnaires' answers as well as your professional email addresses will be deleted one month after the publication of the study results. De-identified questionnaires' answers and consent records will be stored for at least three years on a password-protected university network drive. Your name, affiliation, main professional geographical location, stakeholder group and experience with AI/clinical evaluation will remain part of the study outputs (see below).

### **Who will have access to my data?**

The University of Oxford and REDCap are 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>. The data you provide will be de-identified before it is shared outside the research team. As required by the Delphi methodology, anonymous (and often aggregated) answers will be presented to the other participants during the second round, to members of the steering group and to members of the consensus group. Anonymous quotes and anonymous aggregated answers may be used in academic publications.

### **Will my taking part in the study be kept confidential?**

In your capacity as invited expert, and for the transparency of the process, your name and affiliation will be disclosed in the final publication. However, your answers will be kept confidential and no linkage between your personal information and answers will be shared outside the research team.

### **Will I receive compensation for taking part?**

There will be no financial or in-kind compensation for taking part.

### **What will happen if I don't want to carry on with the study?**

You may withdraw consent at any point for any reason, and without any adverse consequences or penalty. If you withdraw your consent up to ten working days after the end of a Delphi round, all data collected during this round will be deleted. Otherwise, your personal information will be deleted but the rest of your answers will remain part of the analysis. To withdraw consent after completing one or both of the surveys, please contact the primary researcher or Principal Investigator (details below).

### **What will happen to the results of this study?**

The results of this study will be published in a peer-reviewed journal and advertised through social media platforms. Participants will have full access to the results on request to the research team.

This project will be written up for a DPhil degree.

## **Who is organising and funding the study?**

The Principal Researcher is Baptiste Vasey and the Principal Investigator is Prof Peter McCulloch, who are affiliated to the Nuffield Department of Surgical Sciences at the University of Oxford. The project is carried out in collaboration with the DECIDE-AI Steering Group. No specific funding was acquired for the project. Funding is available if required from the IDEAL Collaboration research group general funds. BV is supported by a Berrow Foundation Lord Florey scholarship.

## **Who has reviewed this study?**

This project has been reviewed by, and received ethics clearance through, the University of Oxford Central University Research Ethics Committee (R73712/RE002).

## **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 Baptiste Vasey ([baptiste.vasey@nds.ox.ac.uk](mailto:baptiste.vasey@nds.ox.ac.uk)) or their supervisor Prof Peter McCulloch ([peter.mcculloch@nds.ox.ac.uk](mailto:peter.mcculloch@nds.ox.ac.uk)/+44 (0)1865 740870), and we will do our best to answer your query. We will acknowledge your concern within 10 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](mailto:ethics@medsci.ox.ac.uk);

Address: Research Services, University of Oxford, Wellington Square, Oxford OX1 2JD