

Co-design and its consequences: developing a shared patient engagement framework in the IMI-PARADIGM project

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Abstract

Whilst patient engagement (PE) activities have become increasingly prevalent in development of medicines, collaborating actors have different perspectives on the goals of PE and its added value. In the production of PE standards and frameworks, the significance of these differences tends to be minimised. Boundary objects have been shown to mediate knowledge exchange between multiple social worlds, thereby playing an important role in participatory technology governance processes. In this article, we draw on boundary objects to learn from the process of co-designing a PE monitoring and evaluation (M&E) framework within the Innovative Medicines Initiative–Patients Active in Research and Dialogues for an Improved Generation of Medicines (IMI-PARADIGM) consortium (2018–20). As facilitators of PARADIGM's co-design process, we report on the challenges encountered in developing a practicable M&E framework that serves a variety of needs and interests. We argue these challenges of co-design reflect a negotiation of different frames throughout, thereby providing insight into how such work may contribute to addressing the challenge of knowledge integration in institutional medicines development settings.

Key words: medicines development; patient engagement; patient and public involvement; clinical trials; health technology governance; boundary objects.

1. Organising the diverse field of patient engagement in medicines development

Medicines development tends to be criticised for its supply-driven dynamics: generally, researchers, industry and governance actors prioritise and decide which products are developed and how (Abma et al. 2015; Broerse and Grin 2017). Following earlier successes of patient activism in breaking through ‘expertise barriers’ in the health research domain (see Parthasarathy 2010), the participation of patients or medicines users has been advanced as a means of legitimising health research processes and outputs (Geissler et al. 2017). Proponents of ‘patient engagement’ (PE) in health-related research define PE as ‘the active, meaningful, and collaborative interaction between patients and researchers across all stages of the research process, where research decision making is guided by patients’ contributions as partners, recognising their specific experiences, values, and expertise’ (Harrington et al. 2020). PE has been proposed to benefit medicines development processes¹ by contributing to, for instance, improving the relevance of medical products and their assessment with respect to patients’ needs, constructing more appropriate, inclusive, and sensitive research design and communication, improving the efficiency of clinical studies, and higher and wider uptake of clinical evidence (Vat et al. 2019).

The growing recognition of the importance of collaboration with patients in research decision-making is reflected in the institutionalisation of a PE discourse and practice in medicines development. This includes the activities of pharmaceutical companies, research institutes, health technology assessment (HTA) and regulatory bodies, and regional, national, and international patient organisations (Cavaller-Bellaubi et al. 2021; European Medicines Agency 2014; EURORDIS 2020; Food and Drug Administration 2020; Forsythe et al. 2016).

Collaborating actors have different goals and expectations of PE. Common objectives are complicated by other commitments: industry actors place emphasis on the prevention of business failure and enhanced transparency, trust, and cultural change in their organisations; patient actors favour the output of the medicines development process, prioritising broadened access to drugs and improved quality of life; and regulators value a robust and more comprehensive drug approval process (Boudes et al. 2018; Hansen et al. 2019; Parsons et al. 2016). These groups tend to agree that patients should be more structurally involved in all stages of development, but simultaneously highlight the persistence of basic questions about who to engage, when, and how (Boudes et al. 2018; Hansen et al. 2019). A lack of alignment contributes to a messy and ‘fragmented PE ecosystem’, a problematique shared by different

actor groups (Cavaller-Bellaubi et al. 2021). Fragmentation of efforts manifests in the evaluation of PE initiatives. Various commentaries call upon the field to strengthen PE evaluation, but views on what constitutes ‘good’ evaluation vary substantially (Brett et al. 2014; Faulkner et al. 2021; Russell et al. 2020).

Several international initiatives have been set up to create more consistency and cohesion in the PE landscape. Where some of these try to incorporate an amalgamation of different stakeholder views, for instance regarding how PE’s ‘impact’ on the medicines development process can be evaluated (Dukhanin et al. 2018; Stergiopoulos et al. 2019), they tend to downplay the substantive differences between different actor perspectives. In contrast, it may be central to the success of PE that ways are found to allow (some of) the relevant differences to persist (Knaapen and Lehoux 2016). The question of how PE resources mediate cooperation between different actors — who inhabit different social contexts, hold different problem definitions, and draw upon different epistemologies (Pols 2014) — is thus one where the challenge of fostering connections between substantially different actor positions, whilst equally allowing such differences to be preserved, becomes central. How can patient, industry, and governance stakeholders cooperate in PE practices productively, whilst acknowledging their different commitments to medicines development?

A tradition of analyses in science and technology studies (STS) has focused on how certain ‘objects’ can enable collaboration between actors from different social worlds with varying commitments, allowing for ‘cooperation without consensus’ (Clarke and Star 2008: 113). Such objects do not necessarily refer to material structures but include conceptual models and their related notions which can traverse the boundaries of different meanings afforded to them by different groups. To avoid naïve understandings of what happens when patients are engaged in dominant practices of medicines development, turning to this study of boundary objects may thus be of value.

2. Boundary objects and collaboration across differences within PE

The notion of boundary objects was originally introduced by Star and Griesemer (1989) to address how different actors involved in scientific work could cooperate in the face of heterogeneous practices and perspectives.

Boundary objects facilitate articulation of collective meanings between actor groups operating within some shared space or across boundaries (Star and Griesemer 1989). The materiality of a boundary object ‘derives from action, not from a sense of prefabricated stuff or “thing”-ness’ (Star 2010: 603). Living simultaneously in the different worlds of various social groups, boundary objects ‘have different meanings in different social worlds but their structure is common enough to more than one world to make them recognizable, a means of translation’ (Star 2010: 393). Boundary objects thus essentially transform between different settings; a more loosely structured object, commonly used by different groups, assumes more granularity and concreteness when it becomes examined and used by one specific group perspective. Boundary objects are related closely to the idea of standards but generally allow for heterogeneity of practices whilst generating a

sense of coherence, rather than the harmonisation of practices which is more conventionally attributed to standards (Star 2010).

The boundary object notion has been used to explore the role of information and resources in health-care practices, such as how care pathways function as tools that enable translation between specialist care and home-care services (Håland et al. 2015). Here, the room for local adaptation of a standard (the care pathway) to different local purposes or contexts enabled care practitioners to use and develop their professional competencies (see also Allen 2009). Analyses have also focused on how the ‘blurred meanings’ of an object contribute to the coordination of different actors’ activities. Examining the development of the rare disease category, Huyard (2009) shows that different ‘local uses’ of the definition, in combination with a much simpler common understanding, had a purpose of re-establishing collaborative relationships between patient groups, regulatory authorities, and the pharmaceutical industry — a range of actors who strived for a new regulatory framework to foster collective action. In the context of innovation management and product development, Carlile (2002: 451) adds that boundary objects establish shared syntax and languages and can be used as interfaces for knowledge integration that can be ‘shared across different problem-solving contexts’.

These dynamics of boundary objects — particularly those related to the movement between generic and tailored forms — have proven fruitful in organising and analysing multi-stakeholder governance processes. For instance, sustainability indicator development has been shown to comprise a social process that enables the exchange of views and negotiation of different perspectives (Turnhout 2009).

Given the coordinating potential of boundary objects, analyses have turned to the question whether and how boundary objects cannot simply be readymade but may also be ‘purpose-built’ to suit specific needs linked to multi-stakeholder cooperation. Bowker and Star were wary of the ability of ‘engineered boundary objects’ to fulfil the same functions as their ‘organic’ namesakes. They note that attempts tend to fail often due to a lack of the same level of ambiguity possessed by organic boundary objects (Bowker and Star 1999: 306). In this context the following dynamic is interesting: by definition, boundary objects foster cooperation by *not* translating different knowledge types; leaving different social worlds intact, apart. And yet now boundary objects are becoming more readily connected to collaborative processes that bring different stakeholder groups closer together. In the case that follows, we describe the co-design process of a monitoring and evaluation (M&E) framework for PE that served as an object for fostering cooperation between medicines development stakeholders. We utilise the concept of boundary objects to learn from the exercise in dealing with precisely this dynamic, that of facilitating cooperation between different stakeholder groups, without flattening out their differences.

2.1 Initiating coherence in PE: IMI-PARADIGM

The case is our involvement in the IMI–Patients Active in Research and Dialogues for an Improved Generation of Medicines (PARADIGM) project (March 2018–November 2020). This consortium focused on the development of tools, resources, and frameworks by a multi-stakeholder group representing medicines development actors working on PE. In

doing so, the project sought to strengthen the embedding of meaningful and sustainable PE practices across the medicines development landscape. The consortium was funded by a 50–50 contribution of the European Federation of Pharmaceutical Industries and Associations and the EU Commission's Horizon 2020 research and innovation programme. Partners involved in the consortium (from Europe and North America) represented the following stakeholder groups: biopharmaceutical industry organisations, international patient organisations and networks, regulatory/HTA agencies and organisations, payer organisations, and academia. The consortium website specifies that the project, and the toolbox and resources it developed, aims to support the institutionalisation of PE in medicines development (PARADIGM 2021). The project specified three 'key decision-making points' in the product development life cycle — research priority setting, design of clinical trials, and early dialogues with HTA and regulatory bodies — where interactions between the aforementioned stakeholder groups regularly take place under the guise of PE.

We co-led one workstream aimed at strengthening the M&E of PE. Specifically, the work package was tasked with developing ways of monitoring and evaluating the outcomes and impacts of PE — notions that have persisted as notoriously challenging to PE, and the public and patient involvement field more broadly (Greenhalgh et al. 2019). Challenges relate to the diversity of engagement activities conducted at different stages of medicines development, and, with little formal obligation to engage patient actors in specific ways, the regulation of accountability in PE is generally unclear. The working group thus included representatives from the aforementioned key stakeholder groups with experience working on PE initiatives in their organisations. The working group sought to co-design a framework for monitoring and evaluating PE that was relevant to all stakeholder perspectives. The framework's design would include how it could be operationalised as a practical, usable tool to support medicines development organisations (represented by the partner organisations in the consortium) in conducting PE.

At this point, it is important to note that the project and its products sought to align explicitly with existing PE platforms.² The consortium website specifies that PARADIGM would build 'A set of comprehensive tools, that built upon, and will align with, amongst others, existing EUPATI and PFMD platforms, in order to *support mainstreaming the integration of patient perspectives and experiences* while enhancing mutual trust among the different stakeholders in the patient engagement process' (emphasis added) (PARADIGM 2021).

The co-design process therefore provided an opportunity to explore how a common framework could be designed to play the role of a boundary object, thereby taking account of the diversity of PE stakeholders, whilst being practicable for all stakeholders and capable of eventually being embedded within existing institutional platforms and frameworks.

In this article, we report on the M&E framework's co-design and the challenges this process encountered in attempting to meet these different requirements. Doing so will provide insight into understanding how co-designing boundary objects may contribute to addressing the challenge of knowledge integration in institutional settings of technology governance.

3. Methods: the transdisciplinary work of designing a boundary object for PE

We applied a form of reflexive monitoring in action (van Mierlo et al. 2010), a transdisciplinary methodology aimed at fostering co-learning and reflection within multi-stakeholder projects mainly in innovation governance settings to guide the co-design of an M&E tool during the PARADIGM consortium.

Throughout the co-design process, we, the research team, recorded the various forms of interactions and engagements related to the co-creation of the PARADIGM framework. Recordings of these exchanges as well as our observations from them formed the empirical dataset analysed in this article. Before providing an overview of the dataset and our analytical approach, we briefly outline the activities that elicited the data set, namely facilitating the framework co-design process using the reflexive monitoring approach.

Within the M&E workstream of PARADIGM, the activities undertaken to develop an M&E framework for PE were as follows: after an initial mapping of reported impacts of PE in the literature, a *testing* phase (September 2018–October 2019) then developed a draft framework by analysing existing PE initiatives within the medicines development and evaluation lifecycle. The development of the framework by using practical examples, or *case studies*, aimed to examine its relevance to and usability amongst different PE stakeholders, whilst the monitoring cycle provided useful lessons for the organisers of the ongoing PE initiatives (van Mierlo et al. 2010: 18; see also Guba and Lincoln 1989). These case studies would form the basis of the M&E framework as a practice-based tool. Here, the research team interacted with twenty-four preselected cases of PE (purposely selected, based on the availability of information through partner organisations) through documentary analysis, interviews, and reflection meetings with organisers and participants of the PE activities.

In total, the twenty-four separate case studies elicited forty-seven interviews and twenty-three reflection meetings. We also directly observed eight PE activities across five different cases (of varying length, ranging from 1 h to a 2-day meeting). Insights from the cases were used to build case-specific evaluation models whilst feeding into an overall analysis led by the research team. Cross-case interpretations were performed during weekly team meetings during 2018–19, and during two specific one-day analysis sessions (in 2019 and 2020), which fed into the design of the overall M&E framework. At the end of the case study phase, draft case reports were sent to partners for feedback and validation, resulting in the final case reports detailing key learnings and how these were integrated into the design of the overall framework.

Furthermore, a one-day multi-stakeholder workshop (with thirty-six participants) took place in March 2019 that focused on co-designing 'test' M&E frameworks for five specific PE cases provided by different partner organisations. In doing so, the group gathered insights on both the content and applicability of a preliminary M&E framework against specific examples, from the perspective of relevant stakeholder groups as prospective users of the framework tool. A questionnaire administered in July 2019 gathered further information from partners about a provisional framework's applicability to potential users (seventeen responses).

Insights related to the M&E of PE in medicines development from individual and cross-case analyses, as well as learnings regarding a co-designed M&E tool's applicability to current practices, were then integrated into a *consensus and alignment* phase (October 2019–August 2020) towards the development of a common M&E framework, which became part of the final PARADIGM toolbox for supporting PE practices.

Another one-day multi-stakeholder workshop was held in April 2020 to focus on reaching consensus between different stakeholder groups on the final contents of the M&E framework. Insights from stakeholders on the usability of the final framework were gathered in May 2020 via another questionnaire (eleven responses).

Regular monthly workstream teleconference calls (twenty-one calls, chaired by the research team) were undertaken to ensure congruence between different stakeholder groups throughout different stages of the framework's development.

The activities and procedures involved in the workstream are also described by [Vat et al. \(2021\)](#), who detail the contents of the final framework.³ Participation in wider project activities also contributed to the framework's development and thus the analysis we present in this article. These include four 'PE Open Forums'—two- and three-day events organised by PARADIGM and key partners during the project (2018, 2019, and 2020) and after its completion (2021). We facilitated an interactive workshop (with over fifty participants) on the M&E tool at the 2019 open forum; the structure and functionality of the framework was discussed by different stakeholder groups representing prospective users.

We analyse the framework's co-design process here as a case study ([Yin 2018](#)). Data were collected from several sources by the research team during the mixed-methods research process we conducted, as well as from our participation in the wider PARADIGM project activities (March 2018–November 2020) and the period immediately after the project's completion. Stemming from this corpus of data and ongoing reflection, members of the research team also developed observational accounts of our active involvement in the project ([O'Reilly 2012](#)) where we assumed the role of reflexive monitors ([van Mierlo et al. 2010: 18](#); see also [Guba and Lincoln 1989](#)).

Sources of qualitative data thus include case study interview and reflection meeting transcripts; recorded workstream workshop transcripts; observational findings from case studies, work package, and wider consortium meetings/workshops; official summary reports of case studies, teleconference calls, and workshops and other consortium meetings; partner responses to two questionnaires; internal project documentation (grant proposal submitted to IMI [2017] and the project mid-term evaluation report [2019]).

3.1 Analysis

Researcher observations from case studies, workstreams, and wider project workshops and meetings were recorded as field notes and uploaded to a secure shared portal. All meeting recordings, transcripts, summaries, and other project-related documentation were placed in the shared, protected portal.

Initially, a content analysis was performed on the textual data sources (internal project reports, questionnaire responses, draft case study reports, and summary reports of conference calls, workshops, and conferences). Separately, materials from the interactions we facilitated with

stakeholders during the project (interview and workshop transcripts and observational notes) were analysed together using an open coding approach and a thematic analysis.

These initial rounds of analysis were used to make sense of the overall process of co-design and to identify general categories related to the M&E framework design process as a form of intervention, including our intentions as facilitating researchers and the responses of the participating stakeholder groups.

Analysis of the triangulated data sources then drew upon boundary object theories (e.g. [Star and Griesemer 1989](#); [Star 2010](#)) in examining the challenge of designing the framework to play the role of a boundary object whilst serving the practical needs of different stakeholders involved in PE. Initially, a phase of open coding by the first and second authors explored the perceived applicability and usability of an M&E tool among different groups and anticipations of the framework's ability to enable cooperation between different stakeholder perspectives. Preliminary themes were actively discussed and developed by the research team following the project's completion. The themes presented next, related to the challenges and consequences of co-designing the M&E framework in the PARADIGM working group, were abductively refined ([Le Gall and Langley 2015](#)) via ongoing interactions of the data with concepts and theories ([O'Reilly 2012](#)). Credibility was established through the use of thick description (complemented by researcher reflexivity) to contextualise inferences of project interactions, enriched through our prolonged engagement in the field as consortium partners ([Creswell and Miller 2000](#)). Draft versions of the overall narrative were checked with key project partners to further ensure trustworthiness ([Creswell and Miller 2000](#)).

3.2 Ethics statement

All direct quotations of recorded interactions have been anonymised. Direct quotations of individuals have been omitted in line with the relevant participants' request and consent, with paraphrasing being employed where necessary. An assessment from the Faculty of Science Research ethics review committee (BETHCIE) at Vrije Universiteit Amsterdam concluded that this project did not require ethics clearance due to the lack of vulnerability of participants and confidentiality of recorded responses. All data were stored securely through an ISO-certified cloud-based server used by Vrije Universiteit Amsterdam with access restricted to authorised personnel only.

4. Speaking to different worlds: co-designing a common framework structure

The differences in positions of actors involved in this PE project, as well as the heterogeneity of activities and contexts within different phases of medicines development and evaluation, were to be overcome in the production of common resources in the PARADIGM toolbox, including the M&E framework. To be usable in supporting organisations across medicines development with PE, the M&E framework had to be designed according to different stakeholder perspectives on PE; these included institutional contexts, preferred forms, and acceptable approaches, which likely reflected varying commitments to medicines development.

4.1 Different groups, overlapping commitments

Consortium leaders advocated the co-production approach by emphasising the overlapping interests of all PE actors in medicines development. The excerpt below describes a statement made by an active working group partner representing an industry organisation in preparation for the consensus-building workshop in 2020:

[Industry representative] introduces the consensus workshop by framing patient engagement in relation to the shared interests of medicines development stakeholders. The industry representative states a company who makes a medicine which is 'scientifically very interesting' but doesn't meet the particular need/interest of patients will start to struggle fiscally. On the other hand, a company 'will thrive' if they produce therapies that meet the needs of patients (field notes, TC #14).

4.2 Coordinating M&E: impact metrics

Evaluation metrics were considered by consortium leaders as the way to organise and coordinate PE M&E.

In the project grant proposal, metrics to be developed by the workstream were prescribed as "return on engagement" metrics [...] formulated as Key Performance Indicators to be used to *objectively measure* the impact of patient engagement [...] so as to meet the needs and expectations of each stakeholder group' (PARADIGM Consortium 2017: 25, emphasis added). Whilst acknowledging that PE stakeholders might define impact differently, this formulation implies that constructing accountability measures of shared value stipulates the need for methodologically sound and impartial systems of measurement.

Metric formulations reflecting impactful PE were well defined at the very start of the project. During the first PE Open Forum event in early 2018, breakout groups defined several efficiency-related metrics that feature in the final framework. Mainly relating to the organisation of clinical trials, these included: 'Lower recruitment time' (of participants to a clinical trial), 'more diversity (of trial participants) in recruitment', 'retention (of trial participants) rate', and 'fewer trial protocol amendments'.

The interest in formulating impact metrics and the specific formulations identified at the very start of the framework's co-design process are both interesting for two reasons. First, an efficiency framing was dominant from the start — to some extent, this was to be expected in a consortium comprising a majority of biopharmaceutical industry partners. This informs the second, that the task of co-designing the M&E framework would be about balance, to ensure that different perspectives could be given sufficient weight for consideration despite not being the dominant view. To play the role of boundary object, the framework would somehow have to work for the information needs of efficiency-driven framings *as well as* those of other framings.

Learnings from the case study examples of PE and their eventual synthesis in the workstream meetings and workshops contributed to the framework's development over the period of March 2018–July 2020. The final framework comprised a collection of metrics for tracking PE, organised into inputs, activities, outcomes (learnings and changes), and impacts—these categories were adopted from the theory of change

structure for organising programme evaluation (Davidoff et al. 2015).

Based on partner feedback about the need for a certain level of user guidance, the framework was stratified into 'sets of metrics' that organised metrics around specific objectives or rationales for conducting PE in medicines development. The sets were agreed as a reference for measuring different metrics together to elicit an effective way of monitoring and evaluating PE in medicines development. The sets' structure risked the exposure of users to different perspectives, since users could simply select their objective of interest. However, in response to that risk, each set contained metrics from a multitude of stakeholder perspectives (more explicitly) as well as framings of PE (more implicitly); all sets sought to reflect plurality in that sense.

The example shown (see Table 1) is an efficiency-focused 'set'; whilst many metrics here stem from an efficiency framing of PE (e.g. the impact of 'number of protocol amendments'), even this set is inflected with other perspectives (or, more implicitly, other framings of PE) such as 'belief of stakeholders in the value of PE' as an input and 'trust between stakeholders' as an impact. The sets also explicitly connected 'impacts' to processes and contexts of engagement, which represented a means of challenging an instrumentalised conception of PE.

4.3 Different framings or logics of 'valuable' PE

Four sets based on distinct objectives were agreed by the working group. These were improved alignment of product development with (unmet) patient need, improved efficiency of the medicines development process, improved quality of evidence generation, and improved transparency, trust, and relationships. However, the working group was also keen to ensure that the framework could guide users even more explicitly. A summary of the 2020 consensus workshop stated that:

A handful of the selected metrics here may also be included within a pre-defined global, generic set of metrics which all evaluations of PE should probably include in some way. This set could be described as a 'must have' set.

A 'must have', universal set of metrics suggests a more standard approach to the M&E of PE. This is telling of the key challenge co-designing the framework's grappled with inscribing a balance between structure and flexibility in the framework.

4.4 Balancing structure and flexibility in co-design: between generic and tailored frameworks

The key tension of the framework's co-design was how it could be a common resource that all stakeholders understand and value whilst reflecting the different needs of different groups, per stakeholder group, type of organisation, or in different PE contexts.

The final, general M&E framework comprises a large number ($n=87$) of metrics. Users are asked to select the metrics most meaningful to them based on their own engagement contexts; the metric sets based on the objectives of engagement projects provide a starting point for selecting metrics that align with particular aims or intentions of

Table 1. Example of a ‘set of metrics’ developed by the working group.

Set objective	Input	Activities/processes	Learnings and changes	Impacts
Set 2: improved efficiency of the medicines development process	Feeling of preparedness	Satisfaction with support from activity organisers	Number and type of actions/recommendations implemented	Study participant experience in trial/perceived burden
	Expectations of PE	Timing of engagement with stages of the R&D cycle	Learnings from engagement activities	Percentage of studies with patient-reported outcomes
	Diversity of staff/department representatives	Number type and frequency of engagement activities	Dissemination of learning in stakeholders’ organisations	Number and type of avoidable study protocol amendments
	Diversity of patient representatives	Clarity of the goals of engagement activities		Number of clinical trials including a previously-excluded patient (sub)population
	Money spent	Usefulness of engagement activities		Trial completion rate
	Time spent	Feelings of trust, transparency, respect, shared learning, and/or a give-and-take relationship		Dropout rate/retention rate
	Beliefs of stakeholders of the value of PE			Trust between stakeholders Willingness to continue the collaboration between stakeholders Feeling of being valued/heard

conducting PE. By inviting users to develop specific evaluation strategies, we positioned the M&E framework as having two distinct forms: a more general list of metrics (as in Table 1), and varied, tailored collections that are assembled according to the local information needs of different PE settings.

Many partners found the full framework too complicated to work with as a starting point for M&E. The interests of several partners in making evaluations ‘simpler’ throughout the co-design process reflected concerns of ‘survey fatigue’ in professional bureaucracy. For example, during a session at the 2019 Open Forum, where we presented a preliminary M&E framework, one participant suggested making the exercise ‘less complex’ by utilising a ‘net promoter score’: a single survey question with which engagement participants could rate an initiative they were involved in, allowing for simple comparisons of different organisations’ PE performance.

The movement between general and tailored frameworks became a site of friction between more concrete and more flexible ways of defining the metrics. At the final consensus-building workshop, groups of partners (with representatives from each stakeholder group in each working group) worked on co-defining the most relevant metrics for the final framework, organised into different sets based on different objectives of engagement. The extract below is from the group that worked on a set related to ‘improving trust and relationships’ as an overarching objective. The discussion here is concerned with how the metrics can be defined and operationalised in practice.

Patient organisation #1: I don’t think that we would need that one [specific metric], but maybe it’s needed for the stakeholders.

Academic: I think for all of these [metrics], we have to be in a whole other phase of work about how we actually operationalise them. That’s a different problem.

Patient organisation #1: The definition is yes or no. The metrics way is yes or no, black or white.

[...]

Patient organisation #2: Some of these metrics are very specific activity focussed in the wording, and for the purpose of measuring trust and relationships, which are the result of multiple engagements or activities, it is hard to use them as a measure.

Academic (facilitator): So, we need to work on precise wording, the actionability, and the operationalising ability of the metrics.

Industry: This is definitely a time when less is more.

This passage shows the challenge at the very core of the co-design process. The representative from Patient organisation #1 argues that metrics, by definition, are *unambiguous*. The industry partner seems to support this by suggesting that the metrics should be basic, yet precise, which would make them more actionable and operable in themselves—requiring *less work* to implement, since they would readily plug into different PE M&E contexts. Meanwhile, the representative from Patient organisation #2 points to the limits that highly precise metrics would have when it comes to less efficiency-focused framings. They are warning that the framing of trust and relationships, i.e. network and organisational learning dimensions of PE, could result in it being overlooked or misrepresented in a more concrete metric measuring system.

Here, we observe some resistance to designing the framework to take the form of a boundary object that would let users, operating from different sorts of frames, work on tailoring to specific local contexts. As mentioned earlier, the key

challenge of the framework development process was balancing different (possibly competing) perspectives on how best to organise PE M&E.

Managing the trade-off between structure and flexibility can be seen as a choice between two basic routes: metrics are standardised so all groups know exactly what and how to measure or the metrics provide a reference point from which different M&E actions can be taken to match the specific needs and requirements of those doing (M&E of) PE. As co-leaders, we aimed to keep partners mindful of performing context-sensitive PE evaluations through the act of tailoring the framework.

Furthermore, we can examine how certain stakeholders' anticipations of the framework's implementation in institutional settings added to the challenge of the co-design process. Here too, some partners viewed a standard approach beneficially, since it would provide clear rules for the accountability of organisations conducting PE in medicines development.

This [framework] looks comprehensive. Making it actionable would be a **MUST** for sections Learnings and Changes and Impact. How to ensure stakeholders are completing these by capturing the fundamentals? These metrics need to become universal: everybody recognise them when working in PE and apply them. (Industry representative, emphasis in original)

Meanwhile, this example is taken from the project's mid-term evaluation, written at the end of 2019.

EU policy context has been recently very supportive to facilitate patient engagement [...] However, this positive trend may not continue with the same scale in the future, and it may be implemented unequally in different countries. Time will tell us how project deliverables could be translated to policy actions in EU Member States. The PARADIGM project can be considered successful only if PE tools and metrics will be routinely applied in the three key decision-making points in medicines development.

Especially in respect of shifting policy support — even before the effects of the Covid-19 pandemic would become known — this passage implies that routine application of agreed metrics will benefit potentially disparate PE contexts. Reflecting the views of those steering the consortium, this language does raise questions about the potential malleability of the framework in institutional practice. Indeed, another challenge noted by partners was the disparity in organisational readiness or capacity to adapt the M&E framework to local settings.

We attempted to design the PARADIGM M&E framework to function as a boundary object that could be used differently across varying contexts to suit the needs of different PE initiatives and actors. The main challenge of co-design is aligning with dominant perspectives of medicines development (to facilitate buy-in) whilst seeking to retain the diversities of different frames which PE can amass. Whilst aligning with dominant perspectives obviously risks any intervention being subsumed by them, the potential for generative outcomes of such co-design work was noted throughout.

4.5 Designing movement between different framework forms and its consequences

The act of making a local framework was intended to invoke the boundary object properties of the framework: meaning different groups, either different stakeholder organisations or groups working in different contextual settings, have a shared reference point, the framework of metrics, from which to do different things. Since PE is by definition a multi-stakeholder process, the act of converting the full M&E framework — the selection of meaningful collections of metrics into something relevant to different PE initiatives in different settings — was intended to foster mutual learning and reflection amongst those involved in any PE initiative.

As facilitators, we advocated that the process of developing tailored sets of metrics would hold intrinsic value: discussions were organised to interrogate how and why certain metrics would be relevant to specific initiatives and how feasible each metric would be to measure in practice. This approach was executed during the case study phase, with the research team taking the role of asking these sorts of questions in facilitating each of the cases to build a tailored framework of metrics. The selection of different metrics in each subsection of the framework mapped a theory of change for an organisation's PE initiative.

In several cases, this elicited more reflective dialogues between those involved in the initiative, enabling a more acute confrontation of the different values and frames at play in constructing M&E strategies for determining 'meaningful' engagement. This included acknowledgement of both how the conventional arrangements of medicines development practices hindered the potential for PE activities to generate 'impact' on the terms of efficiency-driven frames of PE, as well as the extreme difficulties of producing an objectively sound way of measuring such effects. Furthermore, negotiating how to tailor the framework into a theory of change model between the different groups involved in PE helped some cases in the collaborative planning of PE initiatives.

Unsurprisingly, the role of facilitation was considered crucial for achieving meaningful processes of reflection in PE settings (Metze and Van Zuydam 2018). Developing a locally relevant framework, in theory, provided an opportunity to integrate perspectives of the different stakeholder groups involved in PE initiatives into the co-creation of an M&E strategy. Whilst partners recognised the value of developing locally specific sets of metrics using more co-constructive approaches with different (inter- and intra-organisational) groups, many felt restrained by organisational structures and demands, including, for example, a lack of time to dedicate to complicated M&E processes where other immediate organisational priorities were more pressing. During the framework testing phase, when considering how partners might tailor their own sets of metrics together with patient (and other) stakeholders, feedback from one organisation noted that:

the group discussion version would be preferable but impossible to envision using due to time pressures.

A co-creative approach was considered ideal, but impracticable. Summarising feedback from the framework testing phase, we noted that 'most common issues were that [the framework] needed simplifying to suit the time pressures of regular organisational work'. Moreover, using the framework

to reflect meaningfully on the importance of PE contexts for M&E proved persistently challenging across many cases—whilst the relevance of context was widely acknowledged, how context could ‘fit into’ a framework of metrics remained ambiguous throughout.

The framework co-design process was a way to reflect on the plurality of stakeholder values and frames in PE and medicines development more broadly. The practical issues analysed above show that in no way were generative, frame-reflective engagements guaranteed through stakeholders’ interaction with the framework. In general, however, the framework exercise in PARADIGM (the general process of attempting to co-design a framework) was able to interrogate the pre-eminence of an efficiency-driven framing of PE amongst leading stakeholder groups. This includes a general shift away from a sole focus on the performance measure model for monitoring and evaluating PE, and a shift in prominent discourse was notable throughout the project (observational notes, TC #16). For instance, at the 2021 PE Open Forum, where we presented the final framework in an online panel and workshop session, the audience was asked a more fundamental question on the need for and purpose of PE evaluation. The responses reflected that the participants considered ‘proving’ the effects of engagement on medicines development as highly intertwined with evaluating for learning and continuous improvements. These two streams of evaluation were seen as two sides of the same coin. Summarising the responses, the session chair commented:

We have moved away from the proving. We have moved away from having to justify the benefits of engagement in order to embed it.

This can be seen as an ‘effect’ of the co-design process organised in PARADIGM’s timeline — both in the specific activities related to converting the full framework to a local metrics set by certain PE initiatives and in the challenges thrown up by the task of co-designing the M&E framework between different stakeholders.

4.6 Summary of findings

The challenge we faced involved producing an M&E framework to be flexible and reflective of plurality in PE; how could we achieve that with an agreed impact metrics framework structure which implies standardisation? The approach came in the combination of different framework components, where there are three aspects of tailoring related to specific requirements; first, by concentrating on representing the different perspectives of different stakeholders in the framework (valuable for all those involved) in a sense of *balancing* between viewpoints or frames, second, by having the sets as a means of *organising* amongst different frames and contexts and, third, by emphasising the need to tailor metrics from the full framework into locally meaningful collections for *coordinating* and *negotiating* between different frames. Whilst the consequences of tailoring were varied across different case studies, the overall work of co-design throughout PARADIGM, featuring these different aspects, contributed to a shift in dominant framings of PE.

5. Discussion

This article has analysed the challenge of co-designing a shared resource, the M&E tool, to act as a boundary object whilst serving the practical needs of different stakeholders involved in PE in medicines development.

The framework’s co-design reflected the various interests of different actors with different commitments to medicines development, working on different sorts of engagement initiatives. Co-designing a shared resource with different medicines development stakeholders meant grappling with producing a framework that is representative of different values, and, more implicitly, *different frames* of PE. The co-design process highlighted much of this challenge in the struggle to develop an agreed structure and function for the framework, including how it may be implemented as a practical M&E tool.

The PARADIGM consortium sought to develop tools and resources, including the M&E framework, to facilitate greater consistency of PE across the medicines development landscape. Stakeholders have different commitments but work together under the premise of a shared enterprise in the development of valuable treatments and therapies. For that reason, the development of a commonly-agreed M&E framework intended to serve the different actors involved in medicines development whilst *balancing* between different stakeholder positions in PE (as well as diversity between initiatives); this required both a generic framework of metrics to enable shared understandings (Allen 2009) and a locally specific and usable toolkit for different users in different contexts.

5.1 Engineering boundary objects with a consequence

Boundary objects are being more frequently deployed and analysed in attempts to support cross- and transdisciplinary collaborations (Berker and Kvellheim 2018; Hoffmann et al. 2017). In particular, proponents elaborate how boundary objects act as a ‘shared reference that is meaningful’ for collaborators from different backgrounds (Fominykh et al. 2016: 86), facilitating dialogue between the variant frames of different stakeholder groups (Cuppen et al. 2021; Metze and Van Zuydam 2018). As such, these analyses are more prominently emphasising the role of boundary objects as successful ‘leverage points’ for transformative initiatives in the context of transdisciplinary technology governance (Cuppen et al. 2021). For instance, Pülzl and Rametsteiner (2009) emphasise sustainability indicator development as a boundary-spanning social process that enables the exchange of and negotiation between perspectives. Franco-Torres et al. (2020) show that actor collectives can employ boundary objects to bridge ‘conflicting worldviews’ in the face of an expanding range of inputs to the formation of institutional logics. The consequence is that diversities—political, epistemic, ideological, and so on—can be maintained rather than flattened out in the production of a collective institutional logic through the use of boundary objects.

Boundary objects have been considered to induce frame-reflective discussions between various actors (Metze and Van Zuydam 2018). Metze and Van Zuydam (2018: 678) argue that ‘boundary concepts create new discursive horizons. Their ambiguity enables coordination and cooperation between otherwise agonistic interpretations of actors.’ Theorising the

transformative potential of boundary objects, these authors conclude that boundary objects can enable frame-reflective processes between different knowledge types if supported by facilitation.

Whilst engineered or purpose-built boundary objects' limitations have been pointed out by Bowker and Star (1999) and others, the PARADIGM project, with its partners representing dominant players but with an interest in the integration of different perspectives through PE activities, invited us (as facilitators) to explore it as a site for experimentation. To achieve buy-in from more powerful actors, the framework co-design exercise needed to partially align with their dominant perspectives (Grin 2020). That led to a basic structure centred around impact metrics that suited the needs of established medicines development actors. As many readers might assume, *organising* between different perspectives in such a manner indeed risked the essential ambiguity needed to traverse between different contexts and groups (Bowker and Star 1999). We tried to balance the dual risks of this process; on one hand that of bringing different 'worlds' too close together through the object — where diversity would be engulfed by prevailing and powerful frames in the creation of unitary engagement measures — and on the other, leaving different worlds too far apart — which would undermine critical acknowledgement of different stakeholder perspectives and frames.

Overall, we cannot be sure whether the direct stakeholder engagements during the framework's co-design have led to productive boundary working in PE. But what we can say is that the co-design process certainly contributed to processes of frame reflection during the timeline of the PARADIGM project. The dominance of a purely efficiency-driven framing of monitoring and evaluating PE was questioned and calls grew for a more combined approach, where co-learning and reflection were part of the story of M&E. This reflects a kind of reframing of PE that occurred in response to the fray of co-design — where dominant perspectives become challenged through *negotiation* with other types of framings (see Stilgöe and Cohen 2021). This supports findings from earlier studies in innovation management that suggest boundary objects can trigger reflexivity in collaborating groups (see Caccamo et al. 2022).

What might this all mean for (the study of) engineered boundary objects? The work of attempting to co-design a boundary object contributed to a specific shift or transformation, in this case the framing of PE by dominant medicines development actors. Despite the risks of 'shared resources' like the M&E framework, becoming mainly useful for dominant stakeholders, inviting and triggering frame-reflective processes as a consequence of the co-design process — appears a promising way forward for fostering more generative and transformative forms of stakeholder engagement in institutional technology governance settings.

After their creation, the management of boundary objects is crucial to 'developing and maintaining coherence across intersecting social worlds' (Star and Griesemer 1989: 393). We found that anticipations of the framework's use contributed to the quandaries of the co-design process. Here again, the risk of creating close attachments to dominant practices, for instance in embedding into existing (knowledge) infrastructures, is that the shared resource becomes something that lacks the ambiguity needed to traverse between different

worlds, evolving into a resource more suited only for dominant perspectives to enact participatory practices in more instrumental ways (Chilvers and Kearnes 2020).

How the framework's use will contribute to challenging dominant perspectives in practice remains to be seen. Following the PARADIGM project's completion, several organisations have attempted to 'implement' the framework in ongoing collaborations. Despite enthusiasm for the M&E framework, partners and organisations struggled to make sense of tailoring the metrics sets into locally meaningful collections. These challenges likely reflect the frictions of generating coherence in epistemologically plural settings (see Knaapen 2013). Other concerns were raised about the limits of the framework's relevance to larger-scale programmes of PE, such as patient organisations' long-term involvement in EU projects — a potential myopia that points towards the co-design process reflecting an overly 'event-focused' framing of PE (Chilvers and Kearnes 2020) and thus its outcomes on medicines development practices. This likely reflects an initial 'embeddedness' in the existing infrastructure (Star 2010) of medicines development.

For further efforts in engineering boundary objects, there are some avenues to explore more deeply than we have done in this article. We have analysed how co-designing the common framework had to work with dominant perspectives, but only really in terms of efficiency-driven versus other framings — which is generally reflective of industry versus other stakeholder viewpoints — and not at a deeper level of knowledge production and epistemology. Moreover, we tried to be balanced in giving attention across different cases, but we focused naturally on cases with more interaction, for instance in cases with direct observations of PE, where clearer depictions of the PE initiative, and the framework's application to it, were easier to develop. Probably unsurprisingly, too, the cases that had greater interaction with facilitators were also those where more productive frame reflection took place. This points towards the need for skilled facilitation, the resource intensity of transdisciplinary experiments, and the influence of wider organisational and network relations on more generative outcomes (Hoffmann et al. 2022).

In the context of medicines development and governance, the articulation of diverse knowledge types appears more pertinent than their instrumental 'integration'. In the PARADIGM case, we attempted to produce a framework for PE that would be serviceable to all organisations in medicines development. The challenges encountered throughout represent a negotiation of different frames, which ultimately contributed to challenging the dominant instrumental motivations for PE in medicines development. Whilst the adoption of the PARADIGM products may yet not yield significant changes to engagement practices, these findings encourage further experimenting and conceptualising in co-design work as a means of institutionalising more reflexive forms of PE in medicines development.

Data availability

Data available on request, subject to third party restrictions.

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Notes

1. Cavaller-Bellaubi et al. (2021: 936) define medicines development as including the following activities: ‘research prioritization, clinical programme and clinical trial design, early dialogues with regulators, HTA bodies and competent authorities on pricing and reimbursement (“payers”), regulatory approval and post-approval phases including HTA evaluation and payer decision-making’.
2. The PARADIGM International Liaison Group connected the consortium’s efforts to a range of similar frameworks and initiatives. See <https://imi-paradigm.eu/paradigm-international-liaison-group/> (accessed 26 May 2023).
3. For the M&E framework as part of the PARADIGM toolbox, see also <http://imi-paradigm.eu/petoolbox/monitoring-evaluation/> (accessed 26 May 2023).

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