

THE PARADIGM GAP ANALYSIS

Identifying how existing gaps in patient engagement (PE) can inform the development of appropriate tools and resources for improved and sustainable PE.



What is the PARADIGM project?

PARADIGM is a European project funded by the Innovative Medicines Initiative from 2018-2020. The project brings together 34 partners (including public and private organisations). Its mission is to develop a framework that enables structured, effective, meaningful, ethical, innovative, and sustainable patient engagement (PE). The project is also looking at the value and impact of PE for the different organisations and individuals involved. For more information, [click here](#).

WHAT DOES THE TERM “GAP ANALYSIS” MEAN?

A gap analysis is a method used by researchers to identify the differences between current practice and how things should ideally be done (e.g. desired best practice). The analysis provides an opportunity to address those differences or gaps.

WHY DID WE DO A “GAP ANALYSIS” IN PARADIGM?

- The involvement of patients in medicines research and development has increased over the past few years. It is often described as “patient engagement” (PE).
- However, patients could still be better involved. PARADIGM aims to develop tools and resources which could help organisations to improve the way they involve patients in the process of developing medicines.
- In achieving its aim PARADIGM has already developed a set of agreed criteria based on the needs, expectations and preferences for PE of the different people and organisations involved in medicines development. These criteria have been developed using a well-established consensus approach (a technique called Delphi) and involved a diverse group of experts.
- The gap analysis was an important part of continuing this work. It assessed the extent to which those needs, expectations and preferences for effective PE were being met in reality. This work is a key link in ensuring that any new tools and resources developed by PARADIGM address a relevant gap and are fit for purpose.

WHAT DID WE WANT TO ACHIEVE?

The objective of this work was to identify and collect examples of relevant PE initiatives (i.e. practices and processes) and to compare them against the criteria for effective PE developed by the project.

Thanks to this work, we were able to consolidate a number of known gaps and reveal many lesser known gaps. These outcomes are being incorporated into the development of tools and resources to address some of these gaps.

PARADIGM focuses on three points in the process of developing medicines:



Research and priority setting



Design of clinical trials



Early dialogues with regulators and HTA bodies

HOW DID WE APPROACH IT?

- In total, we collected seventy PE initiatives. The initiatives were identified from existing international databases. We used information about the PE initiatives which was in the public domain. When relevant, we also contacted the organisation responsible for the PE initiative and asked them to provide further details.

Read more about the work in the executive summary, accessible here:

<https://imi-paradigm.eu/wp-content/uploads/2020/02/D2.2-Inventory-of-gaps-in-existing-practices-and-processes.pdf>

- Using a gap tool in the form of an online survey, we assessed each of these PE initiatives against the PARADIGM criteria for effective PE. The initiatives which we looked at covered a variety of patient populations, disease areas and methods of engagement.
- There were forty-four PARADIGM criteria grouped in fourteen overarching themes related to the PARADIGM criteria for PE.
- The assessment was conducted by members of PARADIGM (e.g. patient organisations, pharmaceutical companies, universities, HTA bodies).

WHAT DID WE FIND OUT?

The main results of the gap analysis include:

- Several criteria assessed contained two elements – a process element (i.e. training for their roles and responsibilities) and a context element (i.e. training material is accessible to all participants). We often found that the process element was adhered to but the context element was often missing entirely or poorly adhered to.
- In addition, we found two other, more general gaps namely: (i) lack of or incomplete reporting and dissemination of PE activity outcomes and (ii) lack of or incomplete interpretation of the criteria or principles defined in existing frameworks and guidance into actual practice.

HOW ARE THE IDENTIFIED GAPS BEING USED TO CREATE TOOLS?

Amongst the gaps identified (sixteen specific gaps across nine of the fourteen overarching themes), a number of those are being incorporated into topics that are being addressed through the creation of new tools and guidance by the PARADIGM consortium (Table 1).

General findings are also helping with the development of other practical tools that PARADIGM are already creating. These include; **updating EUPATI guidance for industry**, and developing a **monitoring and evaluation framework for PE**.

Topic covered	Gap addressed
Code of conduct	Code of conduct which clearly states the ethical principles, governance requirements, rules and procedure of participation for all stakeholders involved
Conflict of interest	Management of potential conflicts of interest, disclosure, transparency and accountability
Community Advisory Boards	Ensure the formation and maintenance of a partnership between all stakeholders
Identification of the right match, for the right activity	Clear description of the criteria followed to identify patient representatives
Lay language of legal terms	Legal agreements written in a clear and accessible way and adapted to the target population
Reporting, dissemination and communication plans	Dissemination and communication plan sharing the process and the outcomes of PE

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WHAT HAVE WE LEARNT?

The gaps identified represent areas of action that PARADIGM could address collaboratively to help improve and advance PE. We developed the recommendations below to guide this and future work:

- The content of any new tool that addresses one or more of these gaps should not be created in isolation.
- Content and tools should be co-created and tested with representatives of all the types of organisations that intend to use it.
- Tools should be developed in a way that makes them easy to adapt and to update in the future if necessary (e.g. as experience and evidence accumulates).
- There should be clear links between any gaps/criteria addressed within a guidance or framework and the practical implementation of that criteria in day-to-day practice.
- Some of the gaps identified are already being covered in part by other initiatives and multi-stakeholder consortia. This presents new opportunities to address some of the identified gaps in a collaborative and synergistic way.

WHAT'S NEXT?

- The final outputs of the PARADIGM initiative will include the development of tools and resources that help facilitate more effective PE. This work will be based on the more relevant gaps identified in the gap analysis.
- We plan to publish and disseminate a full report on the methodology and findings from the PARADIGM gap analysis. We hope this knowledge and resource sharing helps the collective PE community to advance continuous improvement efforts and get the most value for all involved in PE around medicines research and development.

Read more about the work in the full report, accessible here:

imi-paradigm.eu/Paradigm-documents/D1.2Criteria-for-assessing-how-PE-expectations-are-met-practices.pdf

  <https://imiperadigm.eu>