THE PARADIGM DELPHI Process

Expectations for effective and meaningful patient engagement in three phases of the medicines development lifecycle

PARADIGM
Patients Active in Research and Dialogues for an Improved Generation of Medicines

What is PARADIGM project?

PARADIGM is a public-private partnership that brings together 34 partners with the mission of developing a framework that enables structured, effective, meaningful, ethical, innovative, and sustainable patient engagement (PE) and demonstrates the 'return on the engagement' for all players. For more information, click here.

WHY DID WE DO THIS WORK?

Patient engagement in the medicines research and development has increased over the past few years, though, despite such development, patients continue to be a largely underutilised resource. The overarching mission of PARADIGM is to develop a framework that allows structured, meaningful, sustainable and ethical patient engagement throughout three key decision-making points of the development of medicinal products. The results of this piece of work serve as the base from which the framework and tools will be developed to be delivered in 2020.

OUR OBJECTIVE

The objective of this work was to identify and define stakeholders' preferences, needs and expectations in patient engagement through an online survey and focus group consultations, and co-create a set of minimum criteria for assessing effective and meaningful patient engagement based on those needs and expectations.

Three expert panel groups were created for each decision-making point - due to the varied expertise needed in each - to prioritise the identified needs and expectations using a modified Delphi methodology.

These needs and expectations were prioritised and turned into the final set of criteria for assessing patient engagement practices and processes.

PARADIGM focuses on three time points:

- Research and priority setting
- Design of clinical trials
- Early dialogues with regulators and HTA bodies

RESULTS AND OUTCOMES

The result of this work helps to identify the expectations for effective and meaningful patient engagement practices the three time points. Although the prioritised criteria differ slightly in each, there are overall similarities that include the importance of defining aims and objectives, defining and targeting the right patients, supporting the patient community in capacity building to ensure more meaningful involvement in specific activities and the impact of patient engagement.

The criteria in each time point are prioritised in the order of importance, with weights allocated to each. The weights help create an overall score to determine the level of patient engagement in the activity or project being assessed[1].

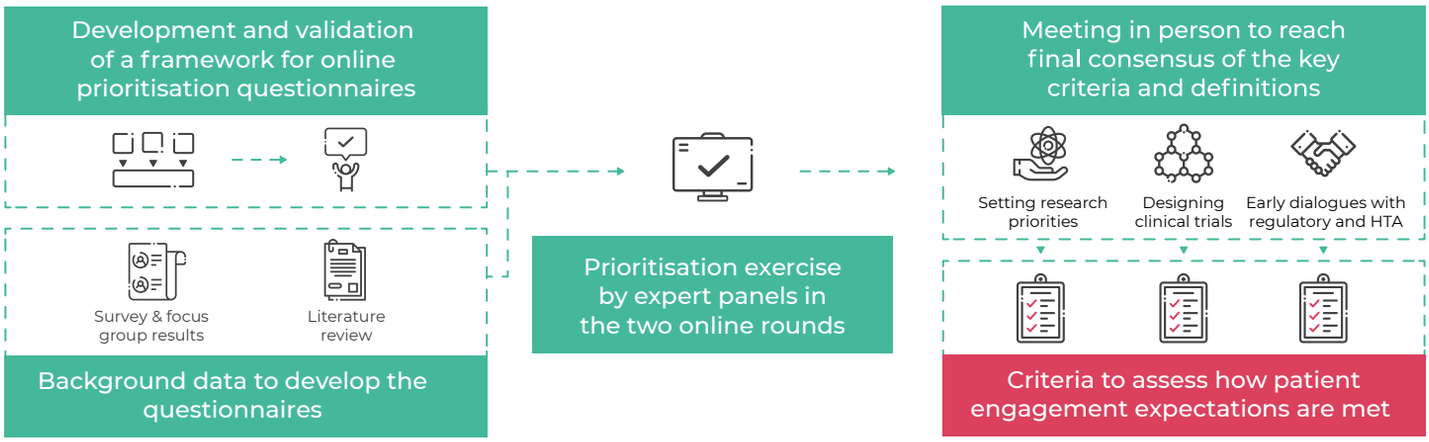
Setting Research Priorities		Designing Clinical Trials		Early Dialogues with Regulators and HTA	
CRITERIA	WEIGHT	CRITERIA	WEIGHT	CRITERIA	WEIGHT
Key Elements of Practice Design	19.5	Aim and objectives	14	Aim and objectives	17.9
Resources	16	Patient engagement impact	14	Target participants involved in patient engagement	15.3
Evaluation of the PE Practice in Setting Research Priority	12	Target patients involved	12	Involvement and participation	14.7
Capacity Building	12	Legal and ethical consideration	11	Code of conduct	11.3
Patient Engagement Impact	11.5	Involvement and participation	11	Capacity Building	11.1
Involvement and Participation	11	Resources	10	Resources	10.9
Code of Conduct	10	Capacity building	10	Patient engagement Impact	10
Sustainability	8	Evaluation of the PE practice in the Design of Clinical Trials	10	Evaluation	8.8
		Sustainability	8		
TOTAL	100	TOTAL	100	TOTAL	100

Table: Final set of criteria for each time point for assessing good patient engagement practices and processes.

[1] More information on how to use the criteria can be found in the original report.

THE DELPHI METHODOLOGY TO REACH CONSENSUS

The Delphi technique uses two online surveying rounds to elicit responses from the expert panelists in a systematic manner, and a subsequent meeting in person that allows expert panelists to interact, discuss, debate and justify their viewpoints.



THREE EXPERT PANELS

Experts were chosen to join the Delphi panel groups for their perspectives and expertise and due to their potential to provide relevant and rich information on patient engagement in each of the time points.

	Stakeholder	Individuals working on or with experience in:
Delphi 1 Research Priorities	Research Funders (public and/or private)	*Responsibility in management and/or design of Public funding schemes for research (government agencies, public organizations, funding programs at universities, etc.). *Responsibility in management and/or design of Private funding schemes for research (research and development departments in companies, scientific societies, charities and other private organizations, etc).
	Regulators	Health authority at national or regional level (end user of evidence to inform its decision making)
	HTA Bodies	Health Teachnology Assesment
	Academics, researchers	Conducting and/or managing research
	Healthcare Professionals	Healthcare providers (healthcare managers (primary care and hospital), clinicinas/health professionals associations).
	Patients/Patient organisations	Participating (in the role of patient) in research priorities setting, research projects, research design, etc.
Delphi 2 Clinical Trials	Clinical trials promoter (pharma companies or else)	Designing, preparing and conducting clinical trials
	Academisc, researchers	Designing, preparing and conducting clinical trials
	Healthcare professionals	Designing, preparing and conducting clinical trials
	Regulators	Clinical trials regulation
	Patients/Patient organisations	Participating (in the role of patient) in designing, preparing and conducting clinical trials.
Delphi 3 Early Dialogues	HTA Bodies	Participating in Early Dialogues
	Pharma companies, Industry	Participating in Early Dialogues
	Regulators	Health authority ar national or regional level (reimbursement decision maker) participating in early dialogues
	Patients/Patient organisations	Participatnig (in the role of patient) in early dialogues

Special attention was paid to the representativeness of various stakeholders in all phases of the process:

Participants in the Delphi expert groups

Participants	Initially	Round 1	Round 2	Round 3 F2F	Profiles in the F2F meeting
DELPHI					
Setting research priorities	24	20	16	10	Research funders (public and/or private), Regulator, Academic, Healthcare professionals, Patients, Pharma company
Design of clinical trials	31	29	26	18	Researcher funder, Healthcare professionals, HTA, Regulators, Patients, Pharma company, Academic /Researcher
Early Dialogues with HTA and Regulators	26	20	18	12	Research funders (public and/or private), Regulator, Academic, Healthcare professionals, Patients, Pharma company
TOTAL	81				

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
imi-paradigm.eu/resources/

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