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Making a Difference: Identifying Best Practices to Measure the Impact of Patient Engagement



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PFMD.org
Made **WITH** Patients



PFMD Purpose

To improve global health by co-designing the future of healthcare for patients **WITH** patients.




Scaling Patient Engagement Deeper & Wider


Build the Conditions and Enablers of Patient Engagement


Build Patient Engagement in Digital Health & Data



Patient Engagement Management (PEM) Suite is your global hub of practical tools for patient engagement

The PFMD network aggregates existing knowledge and tools, identifying **good practices** and coherently combining them before designing **accessible and useful** avenues for the **various audiences** that will use them.

Start
exploring
now!



What do we mean by patient engagement?

"Patients meaningfully and actively collaborate in the governance, priority setting, and conduct of research, as well as in summarizing, distributing, sharing, and applying its resulting knowledge"

- Canadian Institutes of Health Research

Collaboration

"Patients should be active participants and treated as valued and valuable partners whose input, advice, and guidance is sought and implemented throughout these processes."

- National Health Council

Active, valued &
valuable

"Refers to the active and meaningful involvement of patients and carers"

- PFMD Patient Engagement Quality Guidance

Involving patients
and carers

"Patient engagement refers to the intentional, meaningful interactions with patients that provide opportunities for mutual learning and effective collaborations."

- FDA

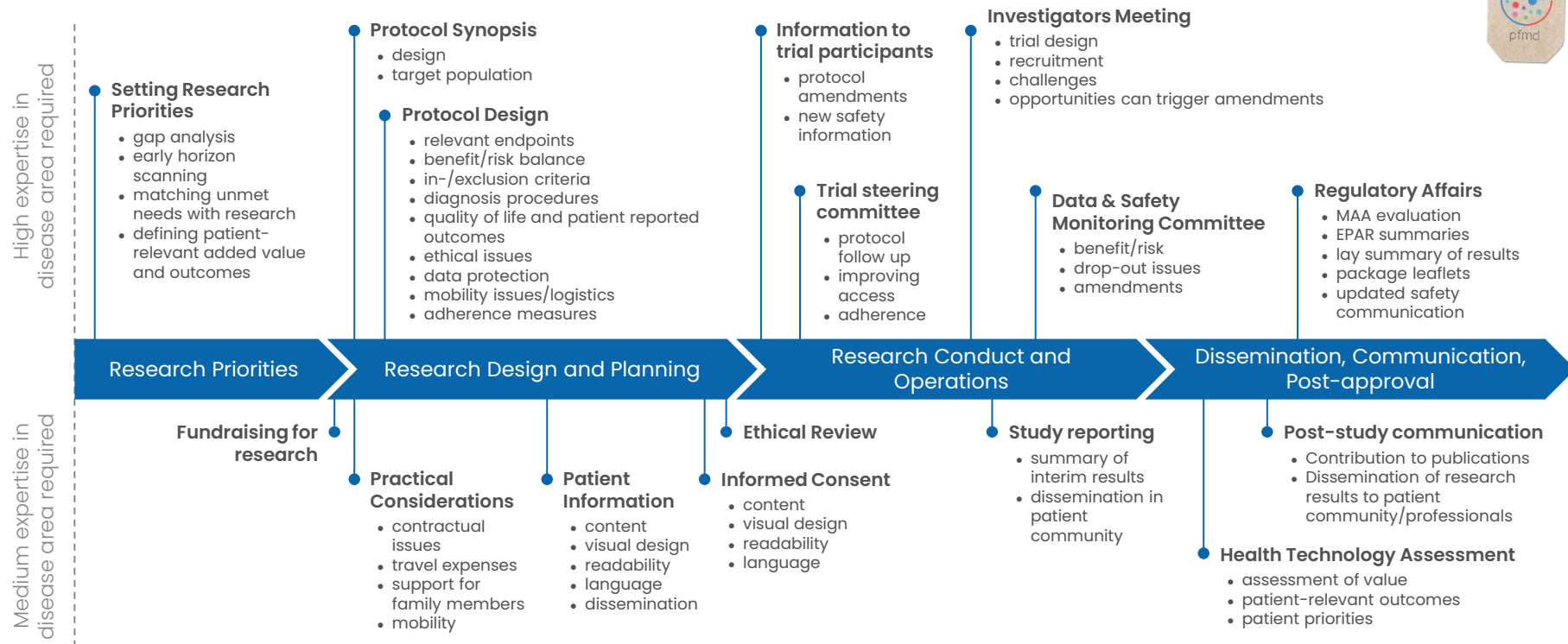
Intentional &
meaningful

"There are many definitions of patient engagement, but all share an underlying theme: the facilitation and strengthening of the role of those using services as co-producers of health, and health care policy and practice."

- World Health Organization

Facilitating &
strengthening

Patient Engagement can support multiple processes in Medicines R&D



What do we mean by patient experience data?

Patient Experience Data (PED) is data that are collected by any persons and are intended to provide information about **patients' experiences with a disease or condition.**

It is information that captures **patients' experiences, perspectives, needs, and priorities.**

Source: 21st Century Cures Act

EVIDENCE ABOUT PATIENTS CAPTURED BY PED



"**The symptoms** of their condition and its natural history"



"**The impact** of the conditions on their functioning and **quality of life**"



"**Their experience** with treatments"



"**Input on which outcomes** are important to them"



"**Patient preferences** for outcomes and treatments"



"**The relative importance** of any issue as defined by patients"



Patient Engagement & Patient Experience

Data: Expectation and demand accelerating in 2022–2023



January 2022

The Added Value of Patient Engagement in Early Dialogue at EMA: Scientific Advice as a Case Study



Japan Agency for Medical Research and Development

2019 (Translated 2022)

AMED – PPI Guidebook



January 2022

360° HTA PATIENT INVOLVEMENT



January 2022

MHRA – Proposals for legislative changes for clinical trials



Health Research Authority

March 2022

NIHR – Shared commitment to public involvement



Canada's Drug and Health Technology Agency

March 2022

CADTH – Impact of Patient Involvement



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

September 2022

Multi-stakeholder workshop: Patient experience data in medicines development and regulatory decision-making



April 2022

Inclusion of patient-reported outcome instruments in US FDA medical device marketing authorizations



May 2023 – Singapore

Process and methods guide for patient involvement



March 2023

Advancing Health Technology Assessment Methods that Support Health Equity



April 2023 – Draft Guidance:

Patient-Focused Drug Development: Incorporating Clinical Outcome Assessments Into Endpoints for Regulatory Decision-Making



2022 – 2025

MHRA Patient Involvement Strategy 2021–2025



Source: [“Patient Engagement and Patient Experience Data in Regulatory Review and Health Technology Assessment: A Global Landscape Review”](#) publication (2023)



**From the Risk of Patient Engagement
to the Risk of not Involving Patients**



The Seven PE Quality Criteria are core values that good PE practice should consider in its processes.



What is it?

A tool that contains seven quality measures to assess projects to involve patients. We call this Patient Engagement Quality Guidance (PEQG). You can also use it to capture the quality of the PE project and the benefit it brings to the stakeholders involved.



How was this tool developed?

It was created by a large community of stakeholders, including patients and others with experience in the medicines-development process, using a development and feedback process.



Who is it for?

Any stakeholder (for example, patient advocate, clinical investigator, researcher, or sponsor) can use it to plan or assess the quality and effect of a PE project.



Why use this tool?

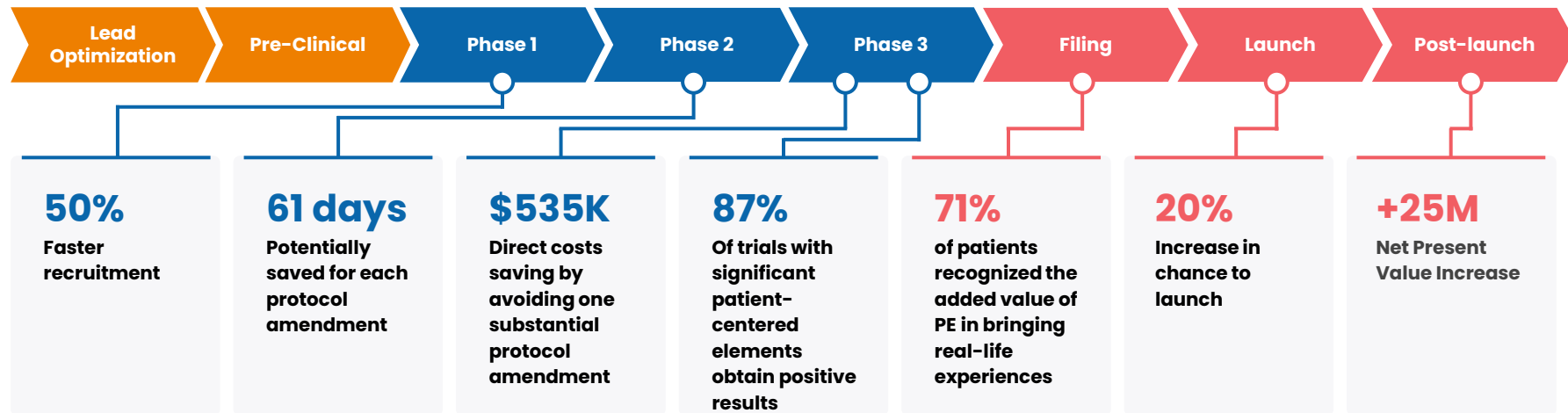
To increase the quality of your (organisation's) PE activities. You can use it as a planning tool before starting a PE project, as an assessment tool at the end of a project, or as a gap-analysis tool to compare projects within an organisation.



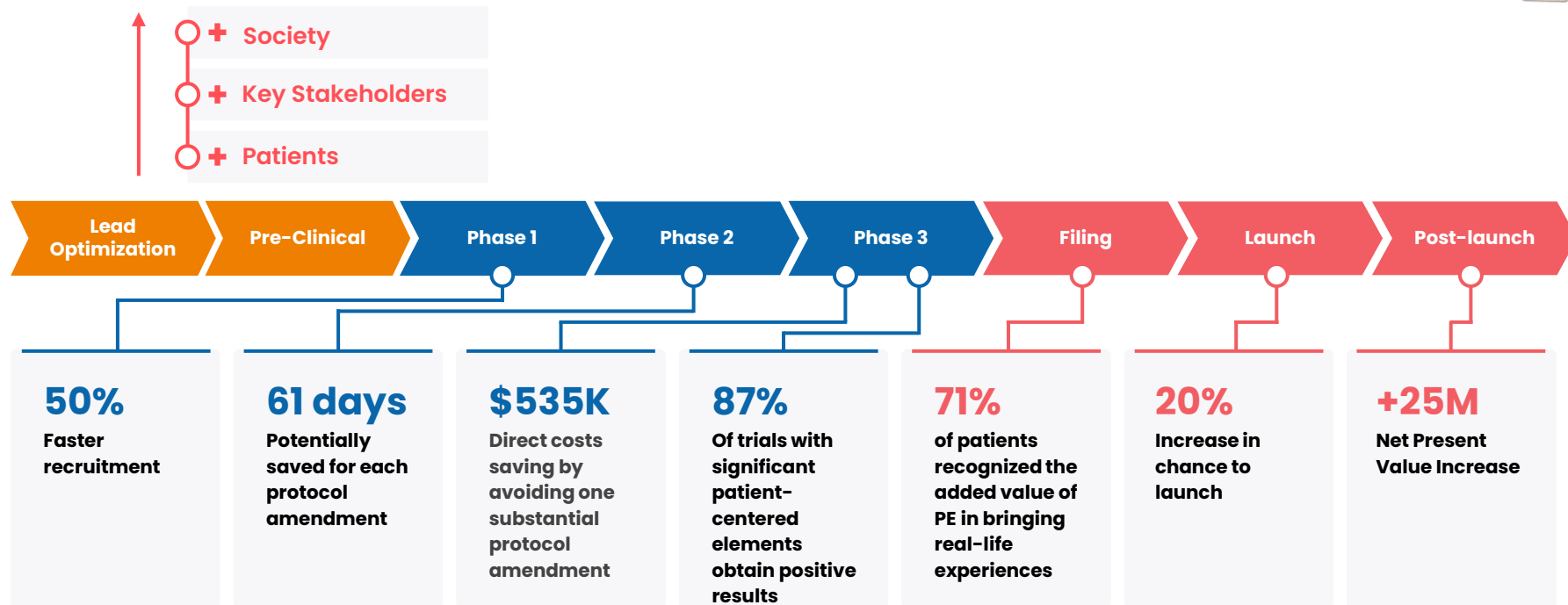
When should it be used?

You can use it for a PE project that takes place at any point along the research and medicines-development continuum, lifecycle of medicines, or care continuum and can be applied to health and social research.

Patient engagement has been shown to benefit industry across the medicine lifecycle



PE projects also generate value for Patients, Society, and Key Stakeholders



The value of PE goes beyond mere quantifiable outcomes



 Healthcare systems	 Patient advocacy	 Patients, caregivers	 Regulators	 Life sciences industry	
Healthcare priorities Performance monitoring Benchmarking Service improvement	Identify patient needs Shape new patient services Inform research Inform health policy argumentation	Inform shared decision-making Contextualize choices Understand experiences of others	Inform regulatory decisions Contextualize clinical evidence Post-marketing data Revise product labelling	Inform priority setting Pipeline and business decisions Value propositions Trial design	
 HTAs organization	 Clinical practice	 Researchers	 Funders	 Payors	 Investors
Inform value assessments Input into scoping and early dialogues Broaden scope of evaluations	Quality improvement Shared decision making Identification of gaps in care and support	Inform priority setting Identification of meaningful outcomes Study design	Informing funding priorities Input into grant assessment criteria Input into research progress assessments	Inform priority setting Budget allocation Reimbursement decision-making	Inform priority setting and business decisions ESG evaluation Value propositions

The Metrics Selector facilitates the monitoring and evaluation processes of patient engagement

The Patient Engagement Metrics Selector

- 87 metrics
- Filters to select relevant metrics for your activity
- Co-created by a community of global stakeholders, including **patients, industry experts, researchers**
- Available on PFMD's [platform Synapse](#)



The Patient Engagement Metrics Selector BETA

Identify the right metrics to capture and monitor the process, outcomes and impact of your patient engagement activities.

[Download metrics](#)



Select a category to show metrics

[Filters description](#)

• Purpose of the evaluation

Rationale for measuring the impact of patient engagement.

- ☐ Accountable (22)
- ☐ Advocacy (23)
- ☐ Adjustment (28)
- ☐ Allocation (28)
- ☐ Analysis (14)

• Type of evaluation

What aspect of the patient engagement initiative are you trying? [More info](#)

- ☐ Process (38)
- ☐ Impact of PE (longer term effect) (45)
- ☐ Outcome (observed effects) (8)

• Medicine life-cycle

Where in the Medicine's Development Life Cycle will this PE activity? [More info](#)

- ☐ All (53)
- ☐ Research Priority Setting (4)
- ☐ Design of Clinical Trials (22)
- ☐ Early Dialogue with HTA®. (3)
- ☐ Post Approval (5)

• Stakeholder group

Results

87 metrics out of 87

Accessibility of language used by other stakeholders during the PE activities

This metric assesses accessibility in terms of language used during patient engagement activities (e.g. plain language, translation). This is a proxy for the opportunity of patients to contribute, and satisfaction with activities, indirectly affecting learnings and chan...

[Read more](#)

Accessibility of preparatory materials

This metric is used to understand the relevance and accessibility of the material given to stakeholders for preparation before a certain patient engagement activity. It is believed that the more they feel prepared, the better they can participate in the activity, and be...

[Read more](#)

Belief of stakeholders in the value of patient engagement

This metric relates to the change in perceptions among stakeholders and the impact on cultural change in the medicine life cycle. It includes the beliefs and attitudes of stakeholders towards patient engagement at its start. If measured quantitatively, it could give an ...

[Read more](#)

Beliefs of stakeholders in the value of patient engagement

This metric relates to the change in perceptions among stakeholders and the impact on cultural change in the medicine life cycle. It includes the beliefs and attitudes of stakeholders towards patient engagement at its start. Greater belief in PE's value to the medicines...

[Read more](#)

Welcome to the Metrics Selector

1. Explore and test this tool for your PE activity
2. Share with us new metrics to be added to the tool!

[Click here to share your suggestions](#)

Related Metrics

Accessibility of language used by other stakeholders during the PE activities

This metric assesses accessibility in terms of language used during patient engagement...

Accessibility of preparatory materials

This metric is used to understand the relevance and accessibility of the material giv...

Belief of stakeholders in the value of patient engagement

This metric relates to the change in perceptions among stakeholders and the impact on...

Beliefs of stakeholders in the value of patient engagement

This metric relates to the change in perceptions among stakeholders and the impact on...

Change in awareness and knowledge about patients' needs

This metric describes the changes in research staff understanding of patients experie...

Balance focus on resources, processes, outcomes and impacts



Resources

Assess whether or not the conditions for meaningful and sustainable patient engagement are in place.

I.e. Needs, beliefs and priorities of stakeholders, accessibility, human and financial resources..

Processes

Show how the implementation of patient engagement is progressing and can elucidate areas for improvement.

I.e. PE facilitation, overall experience, quality of interactions..

Outcome

Show the **short-term, direct results** of patient engagement which give an indication of the progress made towards impacts.

I.e. Insights and recommendations, changes to the research, or to the individual..

Impact

Show the **long-term impacts** for medicines development and stakeholders.

I.e. Relevance of study areas, shifts in decision-making in regulatory bodies or power, diversity and accessibility of studies..

Metrics can illustrate long-term impact of Patient Engagement on patients, business & society



Impacts	 Study ethics and inclusiveness	Metrics that assess the diversity and accessibility of studies.
	 Study quality and efficiency	Metrics that assess the speed of studies and influencing factors such as study participants' experiences in trials
	 Quality of evidence and uptake of products	Metrics that assess the quality and availability information used for decision-making by regulatory bodies and patient communities as well as the accessibility and usability of products
	 Empowerment	Metrics that capture the process of becoming more confident and shifts in decision-making authority or power
	 Reputation and trust	Metrics that capture beliefs and opinions about working relationships, research, a company, organisation and/or community
	 Embedding of patient engagement	Metrics that capture wider consideration of patient engagement in R&D and organisational decision-making

Patient engagement & sustainability plans

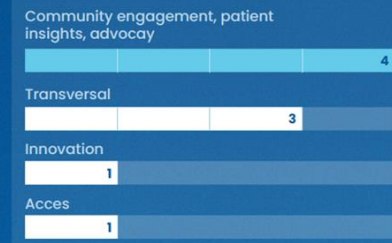
Are pharma companies integrating patient perspectives into sustainability & ESG strategies?



Growing numbers of companies are framing PE in the context of sustainability goals.

Based on analysis of 24 life science organisations, including the top 10 pharma companies.

How do life science companies link patient perspectives and sustainability goals?



Patient insights are seen by some as a feature of communication engagement; for others, it is an overarching commitment or linked to innovation.

Highlights

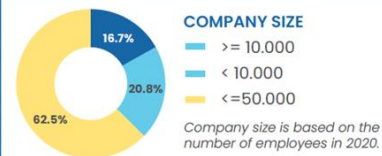
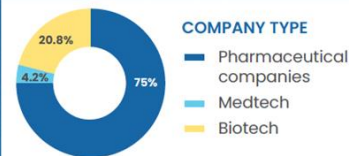
Growing trend to link patient engagement (PE) with sustainability^{1,2}

Strategic value of PE is growing - presenting new opportunities^{3,4}

Variation in how life science leaders frame patient insights

Methodology

The companies analyzed include the **top 10 Pharmaceutical companies**, PFMD full members and associate members, making a total number of **24 companies**.



Company size is based on the number of employees in 2020.

Choosing their words

How do life science companies speak about patients in sustainability strategies?

early partners programs networks studies voice improve advisory perspective
 helps policy best activities ACCESS endpoints innovation communities
 create collaboration help meet healthcare future making health ensure drug
 developed every trial understand embedding clinical solutions patients
 multiple input shows team therapeutic patient needs cancer
 outcomes groups accessible business experience respectively design
 engagement organisations priority across disease commitment perspectives
 research medicines longstanding community effective key new
 incorporate development approach enrolment advocacy address
 trials section lung throughout key real heard insights leads critical see faster respect



