

Engaging Patients in the Design, Generation, and Use of Patient Experience Data, including Real World Data

GetReal Institute Summit



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PFMD Purpose:

PFMD's goal is 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**

46 Active Partners

**Global
Multi-stakeholder Reach**



Patient Engagement & Patient Experience Data Project



Clarifying, integrating and streamlining the design, generation, analysis and decision-making about patient experience data (PED) through, and with, patient engagement (PE)

Objectives				
 1. Provide clarity, structure and alignment of PED	 2. Create a common understanding and language	 3. Ensure relevance and accessibility for all stakeholders in healthcare decision-making	 4. Integrates PE through co-creation , as POs and patient experts contribute to development	 5. Emphasizes the need to prioritize what is most important and meaningful for patients

Patient engagement needs to be active and meaningful



Regulator's Definition of Patient Experience Data (PED)



Data collected by any individual or organization

Captures patients' experiences, perspectives, needs, and priorities related to (but not limited to):



“**Input on which outcomes** are important to them”



“**Patient preferences** for outcomes and treatments”



“**The relative importance** of any issue as defined by patients”



“**The symptoms** of their condition and its natural history”



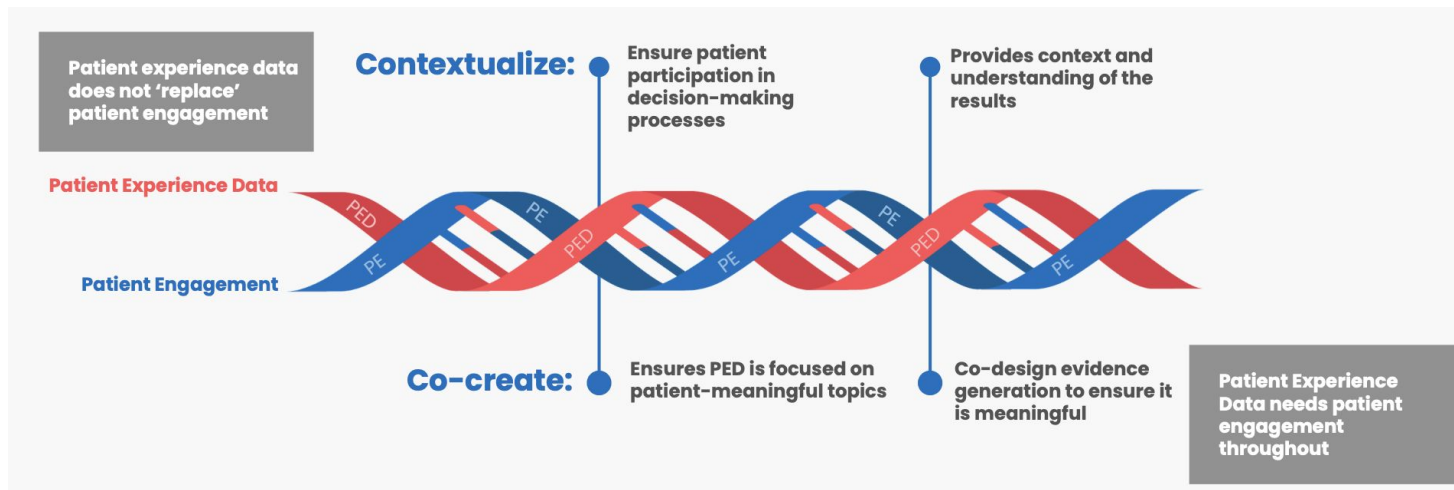
“**The impact** of the conditions on their functioning and **quality of life**”



“**Their experience** with treatments”

Source: Section 569C of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360bbb-8c).

All must understand that patient experience data does not replace patient engagement



“ PE can support PED to ensure patient-centricity of measurement, contextualization of data, increased understanding of the evidence generated, and the co-creation of the design, generation, collection and analysis of PED.

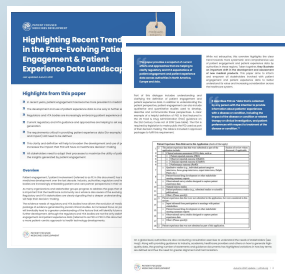
Co-creation with 300+ individuals, from 45+ organizations, with 600+ insights



2021–2022, PE & PED resources and tools increased awareness and provoked change



Landscape Paper v.1



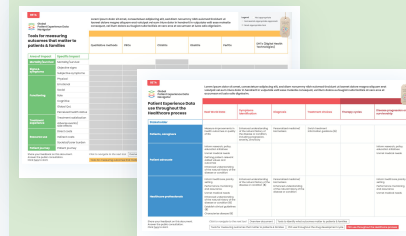
Collective Value Publication



Landscape Paper v.2



Global PED Navigator



Global PED Navigator responds to 5 key questions resulting in 2 comprehensive and integrated templates



1. WHAT:

Highlight the needs that are most important to patients

2. HOW:

Review the approaches and methodologies available (and identify gaps) to measure these patient experiences

3. WHEN:

Consider when stakeholders are using this data and 4. WHY

5. WHO:

Identify the stakeholders that are using PED

BETA

Global Patient Experience Data Navigator

The current matrix can help you identify the methods or tools for measuring outcomes that matter to patients & families. In grey you can see what methods are the most appropriate for a specific area of impact.

Legend:
 Not appropriate
 Somewhat appropriate approach
 Most appropriate approach

Tools for measuring outcomes that matter to patients & families

Show your feedback on this document. Answer the public consultation. Click here to start.

Area of Impact*	Specific Impact	Qualitative methods	PROs	ClinROs	ObsROs	PerfROs	DHRs (Digital Health Technologies)
Mortality/survival	Mortality/survival						
Signs & symptoms	Objective signs						
	Subjective						
Functioning	Physical						
	Emotional						
	Social						
	Role						
Treatment experience	Cognitive						
	Global QoL						
Resource use	Perceived						
	Treatment						
Patient journey	Adverse or side effect						
	Direct cost						
	Indirect cost						
	Societal cost						
	Patient job						

* The areas of impact / specific impact were also elaborated with an ongoing online survey (see Global Patient Experience Data Navigator for details).

BETA

Global Patient Experience Data Navigator

The Stakeholder matrix helps you understand how Patient Experience Data is used in the drug development process and the healthcare process. The matrix gives you the opportunity to see the collective value behind PED use. This view would support stakeholders' alignment to avoid duplication and inefficiencies.

Stakeholder	Real World Data	Symptoms identification	Diagnosis	Treatment choices	Therapy cycles	Disease progression or survivorship
Patients, caregivers	Measure improvements in health outcomes or quality of life	Enhanced understanding of the natural history of the disease or condition, including progression, severity, chronicity	Personalised medicine/ biomarkers	Enrich treatment information guidance (8)		
Patient advocate	Inform research, policy, education initiatives	Unmet medical needs				Inform research, policy, education initiatives
	Delivering patient-relevant added values and outcomes	Enhanced understanding of the natural history of the disease or condition				Unmet medical needs
Healthcare professionals	Inform healthcare priority setting	Enhanced understanding of the natural history of the disease or condition (8)	Personalised medicine/ biomarkers	Enhanced understanding of the natural history of the disease or condition		Inform healthcare priority setting
	Performance monitoring and reassurance	Enhanced understanding of the natural history of the disease or condition (8)				Performance monitoring and reassurance
	Unmet medical needs	Establish clinical guidelines (8)				Unmet medical needs
	Characterise disease (8)					

Share your feedback on this document. Answer the public consultation. Click here to start.

Click to navigate to the next tool | Overview document | Tools to identify what outcomes matter to patients & families

Tools for measuring outcomes that matter to patients & families | PED use throughout the drug development cycle | PED use throughout the healthcare process

Patient experience data relevant for many stakeholders



Healthcare systems <ul style="list-style-type: none">Healthcare prioritiesPerformance monitoringBenchmarkingService improvement	Patient advocacy <ul style="list-style-type: none">Identify patient needsShape new patient servicesInform researchInform health policy argumentation	Patients, caregivers <ul style="list-style-type: none">Inform shared decision-makingContextualize choicesUnderstand experiences of others	Regulators <ul style="list-style-type: none">Inform regulatory decisionsContextualize clinical evidencePost-marketing dataRevise product labelling	Life sciences industry <ul style="list-style-type: none">Inform priority settingPipeline and business decisionsValue propositionsTrial design
HTAs organization <ul style="list-style-type: none">Inform value assessmentsInput into scoping and early dialoguesBroaden scope of evaluations	Clinical practice <ul style="list-style-type: none">Quality improvementShared decision makingIdentification of gaps in care and support	Researchers <ul style="list-style-type: none">Inform priority settingIdentification of meaningful outcomesStudy design	Funders <ul style="list-style-type: none">Informing funding prioritiesInput into grant assessment criteriaInput into research progress assessments	Payors <ul style="list-style-type: none">Inform priority settingBudget allocationReimbursement decision-making

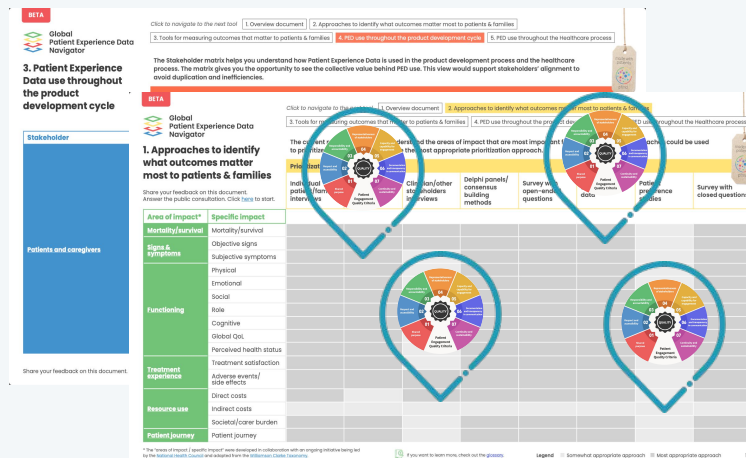
2023 – Co-creating first version of multi-stakeholder Global PE & PED Navigator



Patient Engagement Quality Criteria



PE & PED Navigator (Phase II)



2023 – Exploring opportunities to consider Real World Data in relation to Patient Experience Data



Real-world data

1. Provide guidance on the “how and when” of PE for the generation and use of RWD
2. Capacity building tools/resources for patient organizations to collect RWD
3. Develop tools to increase awareness of importance of contributing data amongst HCPs and patients
4. Provide recommendations on the inclusion of patient experience data in the collection of RWD

PE and Patient Experience Data Questions? Want to chat?

Please provide your email address

bit.ly/3h8gkAm

