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Global Patient Experience Data Navigator

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1. Overview document | 2. Approaches to identify what outcomes matter most to patients & families | 3. Tools for measuring outcomes that matter to patients & families | 4. PED use throughout the product development cycle | 5. PED use throughout the Healthcare process

3. Patient Experience Data use throughout the product development cycle

The Stakeholder matrix helps you understand how Patient Experience Data is used in the product 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	Research	Pre-Clinical	Clinical	Regulatory review	HTA Review Process	Post-approval
Patients, caregivers	Understanding of the natural history of the disease or condition Inform initial development or refinement of a clinical outcome assessment (1) (6) (7)		Reported changes in symptoms or functioning (1) Participant treatment expectations (1) Anticipated and unanticipated symptoms and side effects (1) Viability of proposed dosing regimen (1) Patients' experience with clinical trial participation (1) Benefit-risk perspective(s) from the patient/caregiver (1) (4) (7)		Horizon scanning (2) (3) Priority setting or selection of technologies for assessment (2) (3) Conduction of the HTA (2) (3) Review of the evaluation results and generation of recommendations (2) (3) Implementation of the funding recommendations (2) (3) Dissemination of the decisions (2) (3)	
Patient advocate	Unmet medical needs Defining patient-relevant added values and outcomes (6)					Inform research, policy, education initiatives Unmet medical needs Defining patient-relevant added values and outcomes Understanding of the natural history of the disease or condition

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Stakeholder	Research	Pre-Clinical	Clinical	Regulatory review	HTA Review Process	Post-approval
Healthcare professionals		Inform patients about clinical trials and ensure they are making an informed choice (**6**) Talk with patients about interest/ eligibility for clinical trials (**6**) Support patients throughout the trial and give regular feedback (**6**)				
Regulators				Inform regulatory decisions (**5**) Revise product labelling (**4**) Risk assessment and tolerance (**4**) Sub- group preference identification (**4**) Label/indication expansion (**4**)		Monitor post-marketing safety (**7**) Quality of care/adherence (i.e., label clarification, physician counseling)
Life sciences industry	Inform priority setting, value propositions, pipeline and business decisions	Trial design (**4**) Product design (**4**) (**7**)	Treatment arm selection (**4**) (**7**) Subpopulation identification (**4**) (**7**) Risk mitigation (**4**) Benefit-risk assessment (**4**) (**7**) Clinical outcome Assessment Identification (**4**)	Generate evidence for submission to Regulatory and HTA		Inform priority setting, value propositions, pipeline and business decisions Assessment of current treatments Pharmacovigilance, continued monitoring, PSPs (**7**)

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Stakeholder	Research	Pre-Clinical	Clinical	Regulatory review	HTA Review Process	Post-approval
Life sciences industry			Clinical trial design (**4**) (**7**) Personalized medicine/ biomarker (**4**) To inform the development of product development tools (**4**) Eligibility for expedited programs (**4**) Product design validation (**7**)			
HTAs organization					Inform value assessments Broaden scope of evaluations Reimbursement decision making Cost- effectiveness evaluation (**7**) Labelling optimization (**4**) Clinical effectiveness Quality of Life estimation (**7**) Patient trade-offs Structured benefit-risk assessment (**4**) Subpopulation identification (**4**) Discussion at Advisory Committee meetings	Monitor post-marketing safety (**7**)
Clinical practice						

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Stakeholder	Research	Pre-Clinical	Clinical	Regulatory review	HTA Review Process	Post-approval
Researchers	Assessment of current treatments(4) Unmet medical needs (4) Defining patient-relevant added values and outcomes (4) Enhanced understanding of the natural history of the disease or condition, including progression, severity,chronicity	Subpopulation identification In-/exclusion criteria (4) Adherence measures Mobility issues/logistics Ethical issues Data protection Establish design changes Product design (i.e., type of device, how to take the medicine, etc.) (4) (7) Protocol design (i.e. meaningful endpoints) (4) Risk mitigation Eligibility for expedited programs				Augment real-world evidence Assessment of current treatments Unmet medical needs Defining patient-relevant added values and outcomes
Funders	Requirement as a decision of funding Input in grant protocol Joint research priority partnership (6)				Propose patient-oriented labeling (6)	
Payors	Joint research priority partnership (6)				Inform priority setting Reimbursement decision-making Propose patient-oriented labeling (6)	

Resources

(1) Patient-Focused Drug Development: Methods to Identify What Is Important to Patients Guidance for Industry, Food and Drug Administration Staff, and Other Stakeholders

(2) Scott AM, Wale JL. Patient advocate perspectives on involvement in HTA: An international snapshot. Res Involv Engagem. 2017;3(1):1–17.

(3) Level of Patient Involvement in Health Technology Assessment (HTA) Agencies: A Systematic Literature Review by Alira Health

(4) Framework for the Use of Patient Experience Data Throughout the Product Lifecycle

(5) COLLECTING PATIENT EXPERIENCE DATA: HOW YOU CAN BEST HELP FDA?

(6) Patient involvement in the development, regulation and safe use of medicines CIOMS Working Group report Draft, 24 February 2022

(7) Patient Preferences throughout the Medical Product Lifecycle

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