Framework for the Use of Patient Experience Data Throughout the Product Lifecycle

Biotechnology Innovation Organization

Clinical Development

Current Meeting Opportunities	Critical Path Innovation Meetings	Pre-IND Meetings Other Type A , B, or C Meetings Critical Path Innovation Meetings INTERACT Meetings (CBER)	EoP1 Meetings Other Type A, B, or C Meetings	EoP2 Meetings Other Type A, B, or C Meetings	Pre-NDA/BLA Meetings Other Type A, B or C Meetings	Mid-cycle Communication Late Cycle Meetings Advisory Committee Meetings	Other Type B or C Meetings
Product Stage	Research & Discovery	Preclinical Development	Phase I	Phase 2	Phase 3	Health Authority Review and Marketing Authorization	Postmarketing
Examples of Patient Experience Data Applicable to the Product Lifecycle	• Experience on current treatments • Unmet medical need • Disease familiarization	• Treatment burden • Patient input on protocol designs • Clinical trial burden • Disease burden • Natural history study • Identification of clinical outcome assessments	• Patient preference for treatment • Patient benefit-risk acceptability • Treatment burden • Patient input on protocol designs • Clinical trial burden • Disease burden • Natural history study • Validating clinical outcome assessments • Patient reported outcomes • Quality of life			• Patient risk tolerance • Clinical outcome assessments	• Patient outcome in clinical practice • Clinical outcome assessments • Development of patient support applications
Relevant Decisions made During this Phase of the Product Lifecycle	• Product design adaptation	• Product design (i.e., type of device, how to take the medicine, etc.) • Protocol design (i.e. meaningful endpoints) • Clinical trial participation • Understanding the feasibility of trial participation	• Treatment arm selection • Subpopulation identification • Risk mitigation • Benefit-risk assessment • Clinical outcome Assessment Identification • Clinical trial design • Personalized medicine/biomarker • To inform the development of drug development tools • Eligibility for expedited programs			• Structured benefit-risk assessment • Subpopulation identification • Labeling optimization • Discussion at Advisory Committee meetings • Labeling	• Label/indication expansion • Shared decision making • Personalized medicine/ biomarkers • Quality of care/adherence (i.e., label clarification, physician counseling) • Risk management • Value frameworks