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

## 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

## Clinical Development

### Research & Discovery
- Experience on current treatments
- Unmet medical need
- Disease familiarization

### Preclinical Development
- Treatment burden
- Patient input on protocol designs
- Clinical trial burden
- Disease burden
- Natural history study
- Identification of clinical outcome assessments

### Phase I
- 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

### Phase 2
- Patient risk tolerance
- Clinical outcome assessments

### Phase 3
- Patient outcome in clinical practice
- Clinical outcome assessments
- Development of patient support applications

## Relevant Decisions made During this Phase of the Product Lifecycle

### 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