Patient Protocol Engagement Toolkit and the Study Participant Feedback Questionnaire

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Disclaimer

The views and opinions expressed in this presentation are those of the individual presenter and do not necessarily reflect the views of the Clinical Trials Transformation Initiative (CTTI) or the U.S. Food & Drug Administration (FDA).
Our Shared Vision:
To improve the health of people around the world by accelerating and simplifying the research and development of innovative new therapies.

A Not-for-Profit Entity Created to Foster Collaboration
TransCelerate’s Initiatives deliver practical solutions to overcome inefficiencies in research & development

OUR MISSION:
Collaborate across the global biopharmaceutical R&D community to identify, prioritize, design and facilitate implementation of solutions designed to drive the efficient, effective and high-quality delivery of new medicines.

HARMONIZE PROCESS AND SHARE INFORMATION
- Clinical Data Standards
- Common Protocol Template
- Common Statistical Analysis Plan Template
- Comparator Network
- DataCelerate™
- eSource
- Digital Data Flow
- Placebo Standard of Care
- Toxicology Data Sharing
- Common Clinical SAE*
  - Modernization of Statistical Analysis*

IMPROVE THE PATIENT AND SITE EXPERIENCE
- Clinical Research Access and Information Exchange
  - Common Registry Data Packet
- Clinical Research Awareness
- eConsent
- eLabels
- Investigator Registry
  - Patient Experience
- Patient Technology
- Site Qualification and Training
- Shared Investigator Platform

ENHANCE SPONSOR EFFICIENCIES & DRUG SAFETY
- Advancing Safety Analytics
- Clinical Data Transparency
- Data Monitoring Committee
- Intelligent Automation Opportunities in Pharmacovigilance
- Interpretation of Guidance and Regulations*
- Protocol Deviations
- Quality Management System
- Risk-Based Monitoring
- Value of Safety Information Data Sources

* New Work approved by TransCelerate Board for 2019
Patient Experience Initiative Roadmap

2016
- Assess literature & conduct Patient interviews

2017
- Development of toolkits (P-PET & SPFQ)

Q1 – Q2 2018
- Obtain patient advisor and member company stakeholder feedback and continue toolkit development

Q3 – Q4 2018
- Finalize toolkits and start Member Company pilot testing

Q3 2019
- Update toolkits based on learnings from the pilot and release for public use
TransCelerate Patient Experience Initiative

- This initiative seeks to develop patient engagement tools will contribute to an improved partnership between sponsors and patients in clinical studies.

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**Patient Protocol Engagement Toolkit**

- P-PET
  - Target Product Profile
  - Clinical Development Plan
  - Protocol Concept
  - Protocol Optimization

**Study Participant Feedback Questionnaire Toolkit**

- SPFQ
  - Protocol Execution
  - Data Analysis
  - Data Dissemination
  - Post Study

Design clinical studies with patient input

Gather patient feedback during clinical studies
How TransCelerate is Developing the Patient Experience Toolkits

**Research Phase**

- **SECONDARY RESEARCH**
  - Search, summarize, analyze, & categorize 110+ related publications, articles, and conferences

- **PRIMARY RESEARCH**
  - Interview 40 SMEs from 12 sponsor companies
  - Conduct Patient Advisory Board for initial feedback
  - Patient focus groups to understand universal study elements from patient perspective

- **THE TOOL KITS**
  - Conduct Patient Advisory Board for P-PET input
  - Conduct site focus group for patient clinical study experience-specific input
  - Conduct 1:1 concept elicitation interviews with patients

- **BUILDING the TOOL KITS**
  - Prioritize study elements by leveraging the Common Protocol Template (CPT) and develop questions, visual aids, guidance for sponsors

- **TESTING the TOOL KITS**
  - Test P-PET questions with patient advisors
  - Test P-PET with mock study team (proof of concept)
  - Conduct ex-US concept confirmation / cognitive debrief interviews
  - Run pilot programs with Member Companies
  - Engage with external organizations

**Launch Phase**

- Launch P-PET Version 1 for public use
- Toolkit maintenance activities

**In Progress**
Patient Protocol Engagement Toolkit (P-PET)

- **User Guide**
- **Resource Guide**
- **Templates**
- **Satisfaction Survey**
Study Participant Feedback Questionnaire (SPFQ) Toolkit

Socialization Deck

Implementation User Guide

- Patient Experience (PE) Initiative
- Study Participant Feedback Questionnaire (SPFQ) Toolkit
- Implementation User Guide for Wave 1 Pilot Testing

Table of Contents:
1. SPFQ Toolkit Implementation User Guide: Wave 1 Pilot - testing the implementation materials
2. Introduction
3. User Guide
4. SPFQ Sponsor considerations for implementation
5. Protocol: IS, Privacy, and Regulatory Considerations
6. Mode of Administration Considerations
7. Data Management & Analysis
8. Communication, Awareness, and Training Material Considerations
9. SPFQ Results Sharing

SPFQ (Beginning, Middle, End)

Section A: Your experience before you started the study (to be completed within 1 month of study enrolment)

Thank you for your participation. Your experiences in this trial are important to us and we would like to hear about them. Your answers will help us improve future trials. There are no right or wrong answers, and it will take approximately 15 minutes to complete. Your answers will be kept anonymous and will not impact your participation in the trial.

Please select one response for each item.

- Agree
- Strongly Agree
- Disagree
- Strongly Disagree

A. I understand the treatment process in this trial (for example: when and how I take the treatment):
B. I felt informed about the care for my study:
C. I felt the clinical trial staff were approachable:

Section B: Your experience during the trial (to be completed during trial progress)

Thank you for your participation. Your experiences in this trial are important to us and we would like to hear about them. Your answers will help us improve future trials. There are no right or wrong answers, and it will take approximately 15 minutes to complete. Your answers will be kept anonymous and will not impact your participation in the trial.

Please select one response for each item.

- Agree
- Strongly Agree
- Disagree
- Strongly Disagree

A. I felt included in my treatment:
B. My care was uncomplicated by side effects:
C. I received a complete and accurate summary of my care:

Section C: Your experience at the end of the trial (to be completed at last trial visit)

Thank you for your participation. Your experiences in this trial are important to us and we would like to hear about them. Your answers will help us improve future trials. There are no right or wrong answers, and it will take approximately 15 minutes to complete. Your answers will be kept anonymous and will not impact your participation in the trial.

Please select one response for each item.

- Agree
- Strongly Agree
- Disagree
- Strongly Disagree

A. I received a complete and accurate summary of my care:
B. I have followed up with my healthcare provider:
C. I understand the treatment process in this trial:

CTTI
Thank You For Your Input!
For more information on the TransCelerate Patient Technology Initiative, visit us: https://www.transceleratebiopharmainc.com/initiatives/patient-experience/

For more information about TransCelerate, visit us: www.TransCelerateBioPharmaInc.com

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