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Patient Protocol Engagement Toolkit and the Study Participant Feedback Questionnaire

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CLINICAL TRIALS **TRANSFORMATION** INITIATIVE

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).

TransCelerate

A Not-for-Profit Entity Created to Foster Collaboration

Our Shared Vision:

To improve the health of people around the world by accelerating and simplifying the research and development of innovative new therapies.

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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***
  - Advancing Safety Analytics
  - Clinical Data Transparency
  - Data Monitoring Committee
  - Intelligent Automation Opportunities in Pharmacovigilance

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

- **Interpretation of Guidance and Regulations***
- Protocol Deviations
- Quality Management System
- Risk-Based Monitoring
- Value of Safety Information Data Sources

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*** New Work approved by TransCelerate Board for 2019**

Patient Experience Initiative Roadmap

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.***

Patient Protocol Engagement Toolkit

P-PET

Target Product Profile → Clinical Develop-ment Plan → Protocol Concept → Protocol Optimi-zation

Design clinical studies with patient input

Study Participant Feedback Questionnaire Toolkit

SPFQ

Protocol Exec-ution → Data Analysis → Data Dissem-ination → Post Study

Gather patient feedback during clinical studies

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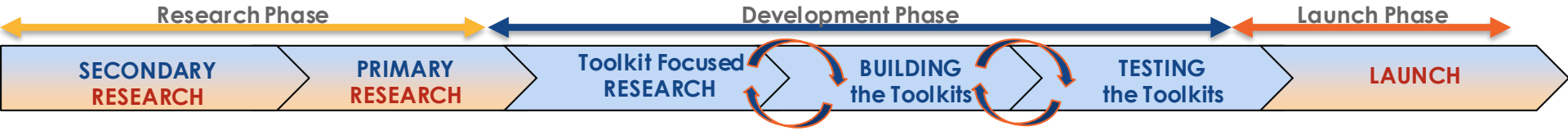
How TransCelerate is Developing the Patient Experience Toolkits



- ✓ Search, summarize, analyze, & categorize 110+ related publications, articles, and conferences

- ✓ Interview 40 SMEs from 12 sponsor companies
- ✓ Conduct Patient Advisory Board for initial feed-back
- ✓ Patient focus groups to understand universal study elements from patient perspective

- ✓ 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

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

- ✓ 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 P-PET Version 1 for public use
- ❑ Toolkit maintenance activities

In Progress

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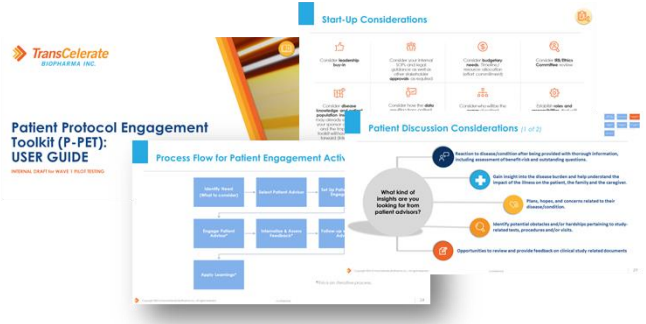
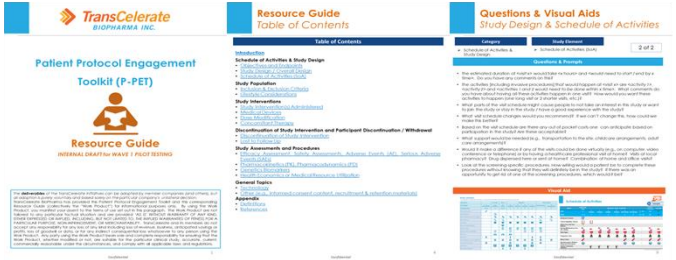
Patient Protocol Engagement Toolkit (P-PET)

User Guide



Resource Guide



Templates

Satisfaction Survey

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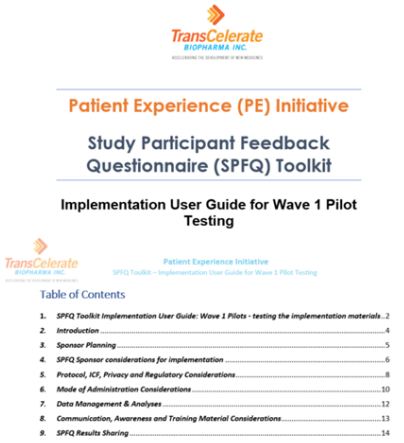
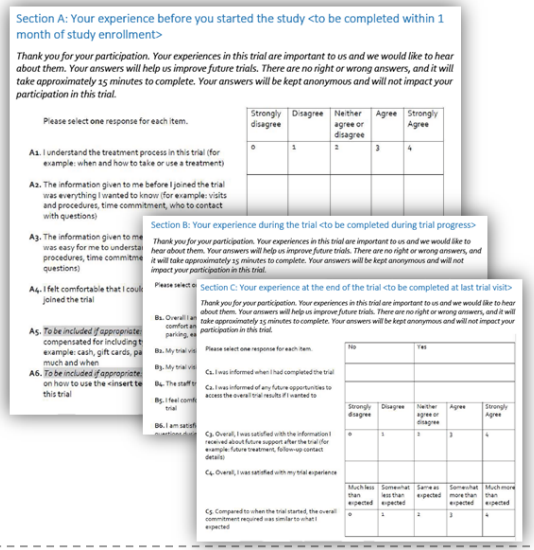
Study Participant Feedback Questionnaire (SPFQ) Toolkit

Socialization Deck

Implementation User Guide



SPFQ *(Beginning, Middle, End)*



Thank You For Your Input!

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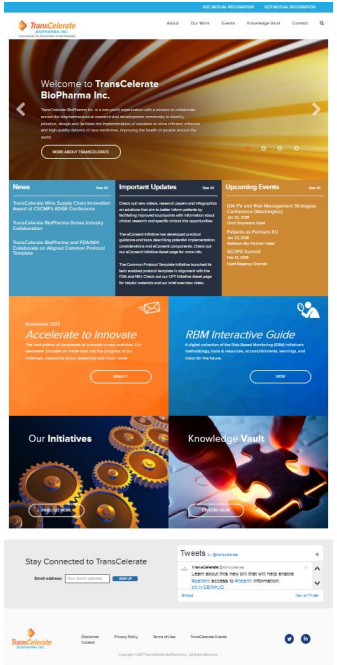

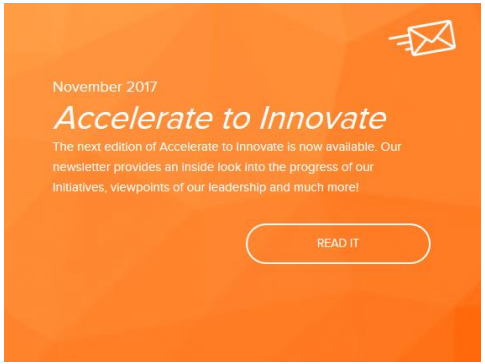

For more information on the TransCelerate Patient Technology Initiative, visit us:
https://www.transceleratebiopharmainc.com/initiatives/patient-experience/

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