

*March 18<sup>th</sup>, 2019*

# Patient Protocol Engagement Toolkit and the Study Participant Feedback Questionnaire

Mary Elmer, TransCelerate BioPharma Patient Experience 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.



# 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



\* 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.*

## Patient Protocol Engagement Toolkit

### P-PET

Target  
Product  
Profile

Clinical  
Develop-  
ment  
Plan

Protocol  
Concept

Protocol  
Optimi-  
zation

## Study Participant Feedback Questionnaire Toolkit

### SPFQ

Protocol  
Exec-  
ution

Data  
Analysis

Data  
Dissem-  
ination

Post  
Study

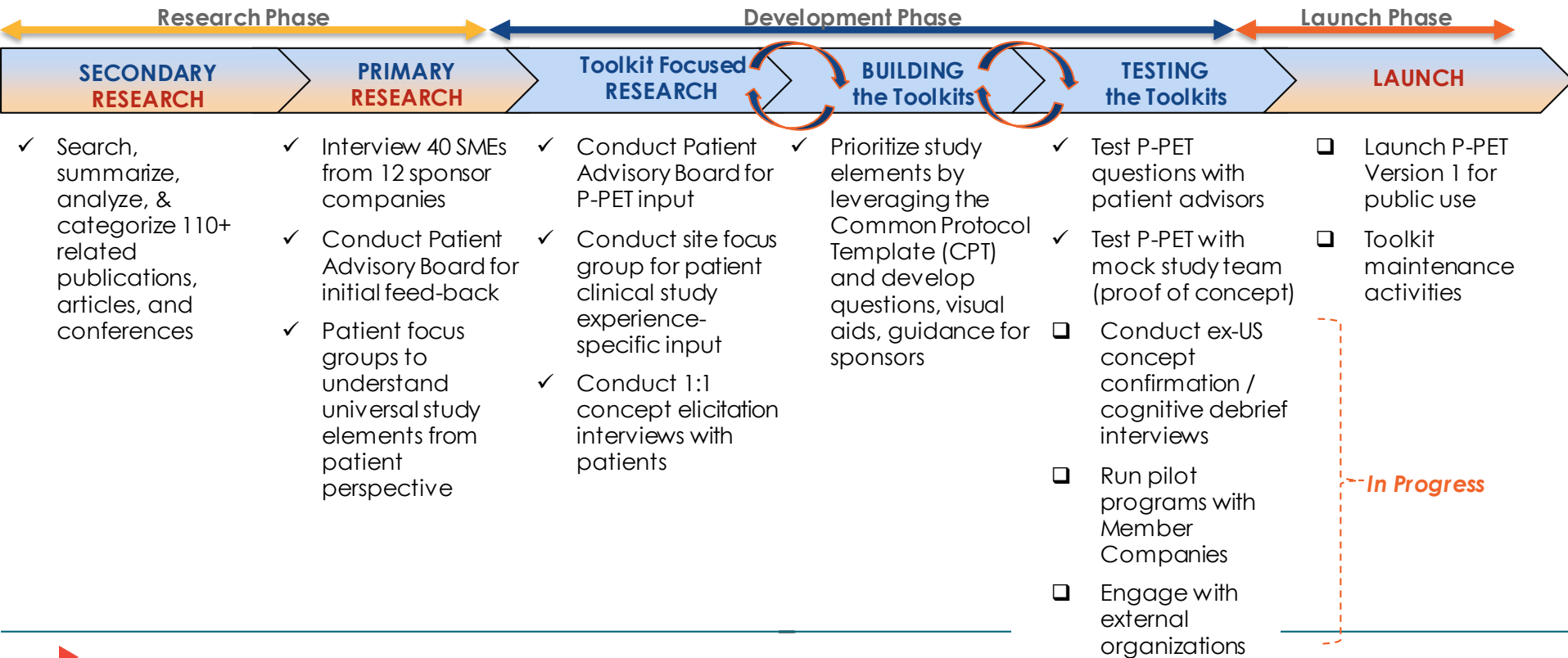


*Design clinical studies with patient input*



*Gather patient feedback during clinical studies*

# How TransCelerate is Developing the Patient Experience Toolkits

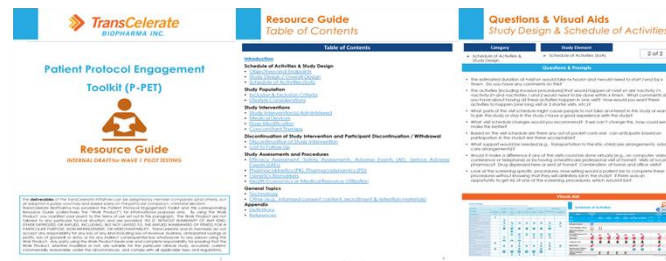


# Patient Protocol Engagement Toolkit (P-PET)

## ➤ User Guide



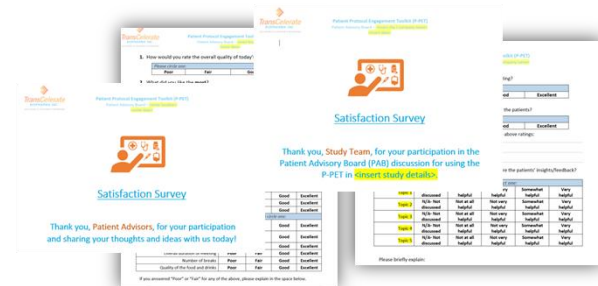
## ➤ Resource Guide



## ➤ Templates



## ➤ Satisfaction Survey





# Study Participant Feedback Questionnaire (SPFQ) Toolkit

## Socialization Deck



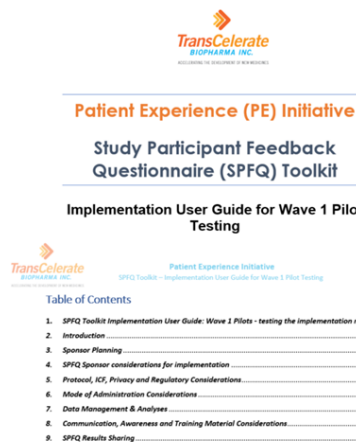
The Socialization Deck includes the following slides:

- TransCelerate BioPharma Inc.**
- AGENDA/CONTENTS**
  - Introduction to TransCelerate & Patient Experience Initiative overview
  - SPFQ Elevator Pitch
  - SPFQ ToolKit Overview
  - SPFQ ToolKit Values Proposition
  - SPFQ ToolKit Implementation Overview
  - SPFQ ToolKit Action Support
- SPFQ Elevator Pitch**

The SPFQ is a questionnaire given to patients at the beginning, middle and end of a clinical study so sponsors can improve studies by learning from patients
- Developing the SPFQ**

A flowchart showing the process of developing the SPFQ, from initial planning to final results sharing.

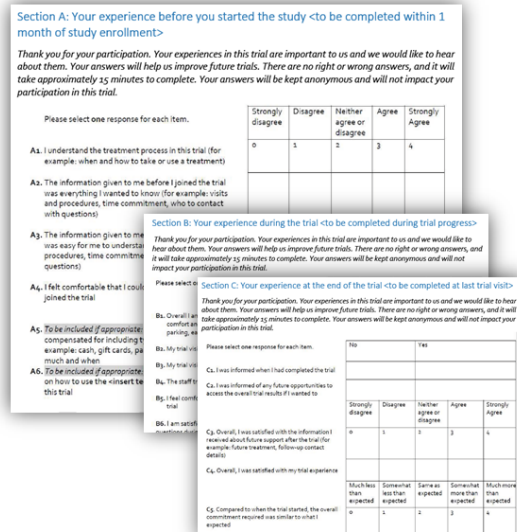
## Implementation User Guide



The Implementation User Guide for Wave 1 Pilot Testing includes the following sections:

- TransCelerate BioPharma Inc.**
- Patient Experience (PE) Initiative**
- Study Participant Feedback Questionnaire (SPFQ) Toolkit**
- Implementation User Guide for Wave 1 Pilot Testing**
- Table of Contents**
  - SPFQ Toolkit Implementation User Guide: Wave 1 Pilots - testing the implementation materials - 2
  - Introduction - 4
  - Sponsor Planning - 5
  - SPFQ Sponsor considerations for implementation - 6
  - Protocol, ICF, Privacy and Regulatory Considerations - 8
  - Mode of Administration Considerations - 10
  - Data Management & Analysis - 12
  - Communication, Awareness and Training Material Considerations - 13
  - SPFQ Results Sharing - 14

## SPFQ (Beginning, Middle, End)



The SPFQ questionnaire includes the following sections:

- Section A: Your experience before you started the study <to be completed within 1 month of study enrollment>**

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 this trial.

Please select one response for each item.

Strongly disagree	Disagree	Neither agree or disagree	Agree	Strongly Agree
0	1	2	3	4

A1. Understand the treatment process in this trial (for example: when and how to take or use a treatment)

A2. The information given to me before I joined the trial was everything I wanted to know (for example: visits and procedures, time commitment, who to contact with questions)
- 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 this trial.

Please select one response for each item.

Strongly disagree	Disagree	Neither agree or disagree	Agree	Strongly Agree
0	1	2	3	4

B1. Overall, I am comfortable participating.

B2. My trial was as easy for me to understand as I expected.

B3. My trial was as easy for me to follow as I expected.

B4. I was informed when I had completed the trial.

B5. I was informed of any future opportunities to access the overall trial results I wanted to see.

B6. I am satisfied with the overall experience.
- 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 this trial.

Please select one response for each item.

Strongly disagree	Disagree	Neither agree or disagree	Agree	Strongly Agree
0	1	2	3	4

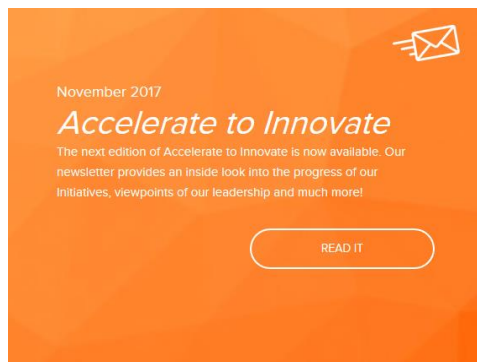
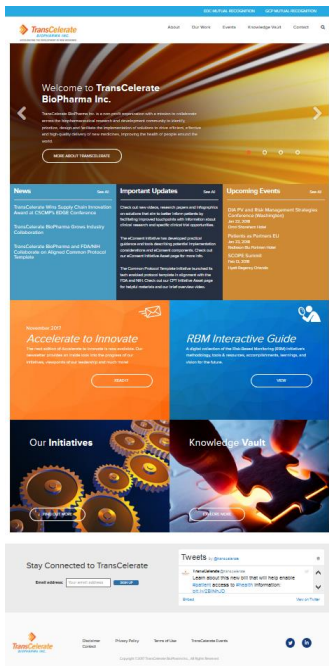
C1. Overall, I was satisfied with the information I received about future support after the trial (for example: follow-up treatment, follow-up contact details).

C2. Overall, I was satisfied with my trial experience.

C3. Compared to when the trial started, the overall experience required was similar to what I expected.

# 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](http://www.TransCelerateBioPharmaInc.com)

**Watch our “[About Us](#)” Video**

**Sign up for our Newsletter, *Accelerate to Innovate***



@TransCelerate



TransCelerate  
BioPharma Inc.