Patient Technology Implementation Framework

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What is Patient Technology?

Patient Technology (PT) includes any digital technology with which patients interact (actively or passively) to engage in clinical trial activities. This includes technologies and use cases that:

- Collect clinical data (e.g., an ePRO or wearable device)
- Collect non-clinical data (e.g., a patient engagement app)
- Do not collect data, but facilitate patient participation in a trial (e.g., a telehealth platform)

What is the Patient Technology Implementation Framework?

The Patient Technology Implementation Framework outlines a possible approach to Patient Technology implementation developed by TransCelerate to help a sponsor develop a holistic approach to PT within its own organization with the company’s long-term goals in mind. The Framework outlines a practical approach to developing a PT implementation plan and encourages a mindset of strategic thinking, rapid learning, and patient-centric design.

The Framework is divided into three primary stages and four sub-stages. Each stage contains a Definition which summarizes the purpose of that stage and a Suggested Approach that details many of the major steps and considerations that sponsors likely would want to address during that stage. Additional Tools & Resources that may help teams progress through the stages are available.
How was the Framework developed?
The Framework was developed by TransCelerate Biopharma's Patient Technology Workstream, a team tasked with enabling, facilitating, and accelerating the adoption of patient technologies in clinical trials.

To understand the opportunities and barriers to adopting patient technologies as clinical research tools, the team conducted an extensive series of interviews and surveys with almost 600 sponsor company representatives, site staff, and patients. An analysis of these barriers and recommendations for overcoming them has recently been published. This Framework was developed as a practical guide for developing a plan for implementing Patient Technology and is the first in a series of tools designed by the Patient Technology Workstream to help sponsors overcome common challenges and pitfalls associated with Patient Technology implementation.

For more information on the findings of our surveys and interviews, see “Accelerating Adoption of Patient-Facing Technologies in Clinical Trials: A Pharmaceutical Industry Perspective on Opportunities and Challenges.”

How can the Framework bring value to my team?
The framework provides potential approaches for:

- Getting started or moving forward with PT implementation
- Enabling PT programs to build toward a company’s unique strategic vision through internal goals and metrics
- Identifying important considerations early in the program design process
- Mitigating common risks associated with PT implementation
- Incorporating an iterative, rapid-learning approach to identifying fit-for-use PT and progressing from PT identification to implementation
- Considering patient and site perspectives during program design
- Utilizing additional resources that may offer insights or support during PT program design

The Framework is intended to help teams identify potential opportunities, risks, and unknowns associated with PT implementation early in the program development process, such that they can be addressed proactively. The steps outlined in the Framework can help teams implement PT more efficiently and effectively, while laying the groundwork and value proposition that will drive the adoption of PT at scale.

Who should use the Framework?
Potential users of the Framework include, but are not limited to:

- Study teams who want to start or continue working with PT
- Innovation teams who help other groups implement PT
- Technology teams who strive to establish processes and value with PT programs
- Leadership and decision-makers who are developing PT strategy
- Those that wish to foster PT-enabling practices and mindsets in their organizations
Do I have to start at “Strategy Development” and work through each stage of the Framework?
No. The Framework was designed to allow teams to start working in any stage of implementation. Teams can “enter” the Framework at the stage most relevant to their PT development, revisit stages if adjustments need to be made, or skip stages that may not be applicable to their PT (e.g. A technology that has already been evaluated and used in a clinical setting may not need to go through the Proof of Concept stage). Use the Stage Selection Guide to determine how and when to progress to each stage.

I already work with Patient Technology. Can I still use the Framework?
Yes! The Framework can be used to support both new and ongoing programs. Even if you have already run trials or pilots with Patient Technology, the Framework can help ensure that you are using best practices and approaching the work with a strategic mindset. You could use the Framework:

- As a guide for becoming more strategic in the way Patient Technology is implemented
- As a method for incorporating more patient and other stakeholder perspectives into program design
- As a model for incorporating a mindset that allows iteration and rapid learning into PT program development
- To communicate PT program design principles and activities to those who are new to PT

I want to work with multiple patient-facing technologies in my studies. Can the Framework still help me?
Yes! If you are working with multiple technologies in a single study or program, most (if not all) of the Framework still applies! When multiple technologies are used, appropriate planning and testing are even more critical, as seamless integration of multiple technologies into a single experience is highly complex. In this case, teams should consider expanding proof of concept testing to include integrations or interactions between technologies, as well as patients’ perceptions of managing multiple technologies during the study.

If I follow each step of the Framework, will it capture everything I need to consider when implementing PT?
No. This Framework outlines a high-level approach to PT, and detailed considerations are often technology, program, or sponsor-specific. This Framework can help teams identify considerations that are often overlooked during study design, but it is up to the individuals or teams using the Framework to ensure that all considerations have been identified and addressed.

For more information, visit www.TransCelerateBioPharmaInc.com/patient-technology-assets/.