PATIENT TECHNOLOGY VENDOR AND SPONSOR ENGAGEMENT CONSIDERATIONS
Introduction

To complement TransCelerate’s vision of simplifying and accelerating the research and development of innovative new therapies, the Patient Technology initiative seeks to foster open dialog between sponsors and vendors. Specifically, as it relates to successes and challenges faced during deployment of patient-facing technologies (PT) in clinical studies. With this vision in mind, the Patient Technology Vendor and Sponsor Engagement Considerations were developed. The PT Vendor and Sponsor Engagement Considerations are intended for 1) sponsor employees managing supplier relations or leading technology implementation with a vendor and 2) vendors who are looking to review or debrief a technology implementation with a sponsor. It’s also intended for anyone who needs to run and/or collect feedback from a third-party interaction deploying patient technology.

This document and its contents were developed using key concepts and challenges identified as part of surveys and interviews with vendor company representatives. The considerations are designed to assist teams with reviewing and debriefing the setup and execution of PT use, including the identification of future improvements. Additionally, the considerations are designed to enable better communication of two-way feedback. This is to:

1) Improve the partnership between sponsor companies and vendors
2) Accelerate adoption of the same or similar patient-facing technology(ies).

**Patient Technology (PT)** includes any digital technology with which patients interact (actively or passively) to engage in clinical study activities. This includes technologies 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 study (e.g., telehealth platform)

**Why:** The Patient Technology Vendor and Sponsor Engagement Considerations were developed to assist the facilitation of more routine two-way feedback discussions between sponsors and vendors on the deployment of PT in clinical studies. The document is designed to help enable open discussion environments between parties where learnings can be shared, documented and leveraged for future studies. Our research shows that dialog between parties too often occurs only after an issue is found. Engaging only for this purpose misses valuable opportunities for capturing feedback throughout the periods of PT implementation and use. The need to improve the partnership between sponsor companies and vendors is further supported by TransCelerate primary research that shows that over 90% of PT deployed in clinical trials is externalized and/or co-developed with vendors.

**Benefits:** The considerations propose various ways to improve the effectiveness of sponsor and vendor meetings. Using the considerations to understand the impact of PT may provide sponsors with an opportunity to mitigate dissatisfaction and gain insight into the actual needs of participants. Use of the considerations may also contribute to patient-centric clinical studies, with the long-term potential to:

- Improve the partnership between sponsor companies and vendors enabling opportunities for greater success in the rollout of PT in studies
- Improve patient experience using technology in clinical studies
- Accelerate adoption of patient facing technology(ies)
- Increase the effectiveness and outcomes of sponsor meetings with vendors

**Timing:** This document and its associated considerations are most effective and meant to be used at a point in time after a vendor is selected, contracted, and performs services.

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1 Collected information should not be shared back with TransCelerate in any form
Section A: Tips for Running a Successful Session

The following guidelines can be considered during the planning and execution of any feedback conversations between vendor and sponsor on the deployment of PT in clinical trials.

<table>
<thead>
<tr>
<th>ACTIVITY</th>
<th>DESCRIPTION</th>
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<tbody>
<tr>
<td>Meeting Preparation</td>
<td>What inputs, information or data points are required for a successful meeting? How much lead time is needed to prepare? Consider whether patient or site feedback on the PT is valuable for the meeting’s purpose.</td>
</tr>
<tr>
<td>Define the “Why”</td>
<td>Ensure that the meeting purpose and objectives are established in advance and agreed by key meeting stakeholders. Develop an agenda with clear outcomes. Example meeting objectives may include determination of what worked well, what didn’t work, what can be improved, and how feedback will be shared.</td>
</tr>
<tr>
<td>Identify Facilitator(s)</td>
<td>Confirm a meeting lead or set of leads to facilitate the group through the pre-established agenda. Consider whether this person is someone from the sponsor team, vendor team or a neutral party.</td>
</tr>
<tr>
<td>Identify Stakeholders</td>
<td>Who should be involved in the meeting from the sponsor’s side and from the vendor’s side? Consider the role that each attendee has based on the meeting’s purpose. Try to avoid overloading the meeting with attendees who do not have a necessary role.</td>
</tr>
<tr>
<td>Meeting Location</td>
<td>Consider organizing the location and meeting type based on necessary stakeholders (e.g. Virtually, Face to Face). Consider any budgetary needs relating to the meeting site.</td>
</tr>
<tr>
<td>Meeting Timing</td>
<td>Take into account the duration of the clinical study/project and whether it makes sense to meet at different milestones. For example, major milestones may include study launch, at the midway point and lastly at the conclusion.</td>
</tr>
<tr>
<td>Define “Next Steps”</td>
<td>Clearly outline next steps and actions for all attending stakeholders. Define timelines for pending urgent actions (quick changes vs long term solutions). Determine what outputs should be shared and with who. Also consider whether an action plan should be created for embedding any lessons learned or best practices into common ways of working.</td>
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Section B: Engagement Considerations for Discussion

The following section proposes discussion topics and questions that can be used during any session. Please note that these should be used as a general guide and actual topics and questions should be dictated by your specific situation. Each consideration is followed by a descriptive rationale.

- **Budget & Resourcing**
  - o Could contracting and onboarding of the vendor have been more efficient and/or accelerated? Were there clear sponsor processes for onboarding the vendor (as applicable)?
    - ▪ **Rationale**: Vendor qualification and selection can be a very long process involving various stakeholders (e.g. Procurement, Quality, etc.). It’s important to set expectations with both sponsors and vendors about the requirements for successful completion.
  - o Were sufficient (e.g. specialist) resources available throughout the project or was a resource bottleneck identified on either side?
    - ▪ **Rationale**: Outlining and agreeing sponsor and vendor required resources early in the program can increase your likelihood of success and reduce the chance of bottlenecks.

- **Feasibility & Quality**
  - o Was the vendor engaged early enough for the objectives of the program? Was the engagement prior to protocol finalization? If not, did this have an adverse impact?
    - ▪ **Rationale**: Vendor interviews told us the number one item that could have been improved is earlier engagement with vendors on projects. This early engagement allows the vendor to bring the best possible options to the table. Involvement of vendors early may help sponsors better think about ‘where we’re going’ and not always ‘how we’ve done it before’. The PT landscape changes quickly.
    - ▪ **Rationale**: If early engagement didn’t happen, consider how you can find opportunities to start the discussion earlier in future studies or engagements. Earlier collaboration may allow vendors to better anticipate the study needs and propose appropriate and innovative solutions.
  - o Were the appropriate stakeholders involved in the development of project strategy? If not, how did that affect any outcomes?
    - ▪ **Rationale**: Ensure key stakeholders have visibility to project plans early and often. A key stakeholder without early input may not be able to fulfill expectations later on, or they could request changes late into study execution.
  - o Were unexpected impacts or other outcomes identified? What can be learned from the experience and how can this be avoided in the future?
    - ▪ **Rationale**: Having a formal risk mitigation process and sharing the outcomes with everyone involved can improve outcomes and avoid unexpected challenges during future deployment of PT.
Were there sufficient Key Performance Indicators (KPI) established to monitor performance of activities and quality of deliverables? We’re KPIs established during project launch to manage activities & quality of deliverables?

- **Rationale**: Both sponsor companies and vendors tend to perform better when clear deliverables and targets are established early in a program.

Was site and patient usability of the PT as expected, or were an unexpected amount of questions/support requests raised? Was technology usability research conducted?

- **Rationale**: Proper training methods along with proper training materials, written and delivered in a medium that the audience will use, can help to reduce unexpected questions or additional support requests. Fewer support requests can result in reduced burden on sponsor and vendor.

### Legal & Regulatory

- Were any data privacy issues identified throughout the project? Were they sufficiently mitigated? If not, what learnings can be applied to future studies?

  - **Rationale**: As you plan the project, ensure requirements like HIPAA and GDPR are understood and accounted for by both sides.

- Was GxP validation readily achievable?

  - **Rationale**: Ensure early communication between vendor and sponsor quality departments to allow for alignment in validation and documentation requirements.

- Were any regional legal or regulatory limitations identified during the project, such as import regulations prohibiting deployment?

  - **Rationale**: If so, what were they and how were they mitigated?
    - Regional/local may be more stringent than HIPAA and GDPR that only apply to US and EU respectively.

### Process & Strategy

- Does your company have an overarching PT strategy?

  - **Rationale**: If not consider using the PT framework and discussion guide to help develop and implement an overall PT strategy to accelerate future programs.

- Were responsibilities of involved parties clearly understood or was work duplicated and/or missed?

  - **Rationale**: In many cases there are multiple people working in the same scope. Without clear remits and responsibilities, you can get people working on the same issues without sharing information. Setup sharing sessions or roles & responsibilities documents to avoid duplication.
• **Scalability & Support**
  
  o Was the support provided by sponsors and vendors adequate for the project in all planned geographies?
    
    • Rationale: Support models can vary drastically depending on complexity of PT utilized, geography, and patient population. It’s important that proper support is provided throughout the duration of the study.
    
    • Rationale: Ensure vendor support teams are appropriately trained, especially when directly contacting patients. Clearly map out when to re-direct them to site staff in case of any questions related to protocol, adverse events, etc.
  
  o Was the project scale successfully supported or were any bottlenecks identified (e.g. device supply)?
  
  o Were support hours and languages offered sufficient for the project?

• **Site Impact**
  
  o Was feedback collected from sites on their implementation and support of the PT?
    
    ▪ Rationale: If not, consider using the Patient Technology Site Feedback Questionnaire to gather both site and patient feedback regarding the use of a PT.
  
  o Was site feedback with regards to site burden positive or negative? Has negative feedback been accounted for?
    
    ▪ Rationale: Make sure to highlight, continue and share positive experiences and then look to understand root causes for negative experiences.
  
  o Was there appropriate training for the site before study start up? Was there appropriate training for the patient?
    
    ▪ Rationale: It’s important to provide sites with appropriate training and training materials. Not all sites and individuals will have experience using the technology in question. Sites should be sufficiently educated to handle basic patient questions about the PT. Sponsors and vendors should be providing regular updates, feedback and tips on the recurrent issues and mistakes associated with the PT.

• **Technology & Infrastructure**
  
  o Was system integration successful or were unforeseen obstacles identified?
    
    ▪ Rationale: It’s important to understand the end to end experience of the users and how the data flows between systems.
  
  o Was the device model (e.g. sponsor supplied vs bring our own device) suitable and viable?
    
    ▪ Rationale: Gathering feedback on devices can help understand the user experience and inform the selection of future devices.
• **Patient Impact**
  
  o Was patient feedback gathered? Was this positive or negative? Has negative feedback been accounted for and/or addressed?
    ▪ **Rationale:** If it’s not clear on how the feedback was or will be used, it is unlikely you will receive future feedback.
  
  o Did patients understand what was asked of them? Did patients understand how to use the PT?
    ▪ **Rationale:** To maximize patient compliance, ensure that the objective of the PT is fully understood by the patient population.
  
  o Was patient compliance with the PT an acceptable level? If not, are you able to identify cause(s) for low compliance?
    ▪ **Rationale:** Patient compliance is one possible measure for understanding whether patients have been appropriately trained on the use of PT and have access to training documentation at any time during the study.
  
  o Did you assess the practical impacts of implementing PT into a clinical trial from the perspective of patient burden?
    ▪ **Rationale:** Gathering patients’ insights on PT provides insights which the project team may not have considered.

• **Communication**
  
  o Were the right stakeholders on both sides involved in the relevant forums and given the necessary details to achieve the desired outcome?
    ▪ **Rationale:** If the right decision makers and subject matter experts aren’t identified in the relationship, it will be hard to close and/or resolve issues.
  
  o Was there regular communication between sponsor and vendor? Were response times acceptable?
    ▪ **Rationale:** Communication is fundamental to establishing the right environment for collecting and acting on feedback.
Section C: Closing an Engagement or Debrief Session and Next Steps

After documenting and agreeing on the outcomes from the session, consider the following activities:

- Share the learnings and any best practices across relevant internal stakeholder groups. This might include the immediate study team, extended study team members, subject matter experts, procurement, or quality for example. Also consider what can be shared internally with any non-participating vendor stakeholders. Potentially look to adopt any major learnings into interactions with other vendors.

- Agree on clear actions and ensure proper owners including timelines for delivery.
  - Align on who and how any additional data will be collected, or open questions answered.
  - If you don’t have some formal governance mechanism considering developing one.

- Collect feedback on how the meeting went and setup the next meeting including any possible topics you would like to discuss further. Re-evaluate stakeholders to ensure the right group is always present for discussion.

Insights from these sessions are one piece of the overall relationship status. Be sure to consider other factors established in your procurement and/or outsourcing guidance/SOPs. Any action and/or decision should be made in accordance with your companies’ procurement and contracting practice.