This user guide is intended to support a sponsor company’s customization and unique implementation of the PTSFQ. The user guide is structured by category of considerations. It is proposed that the user guide be read in full and adapted to the sponsor’s timelines and processes.
Patient Technology Site Feedback Questionnaire (PTSFQ) Sponsor Implementation User Guides

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# 1 PTSFQ 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 sites regarding specific challenges faced during deployment of patient-facing technologies in clinical studies. With this vision in mind, the Patient Technology Site Feedback Questionnaire (PTSFQ) was developed.

The three-part questionnaire and its contents were developed using key concepts and challenges identified during interviews with site and sponsor company representatives. Each part of the PTSFQ is designed to capture site’s experiences of patient-facing technology as well as site’s impressions of the patient experience using technology. Additionally, the PTSFQ is designed to capture structured feedback in a more actionable way. This is to:

1) help mitigate potential issues as the study progresses and
2) inform future study design and 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., a telehealth platform)

The PTSFQ is composed of three sections (A, B, C), each of which are intended to be completed at a different point in time during study conduct. **It is proposed that the PTSFQ be completed by the lead study coordinator on the study and one form should be used for each device used in the study.**

<table>
<thead>
<tr>
<th>SECTION</th>
<th>PROPOSED TIMELINE FOR COMPLETION</th>
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<tbody>
<tr>
<td>Section A: Initial Feedback</td>
<td>Within 1 month of enrolment of the first Patient</td>
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<tr>
<td>Section B: In-Study Feedback</td>
<td>While the study is in progress</td>
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<tr>
<td>Section C: End of Study Feedback</td>
<td>At the conclusion of the study</td>
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The questionnaire’s three sections each have a particular focus (i.e., training, technical, and overall satisfaction with the use of the patient-facing technology) that closely corresponds to the type of activity occurring during that point in time of study conduct. Each section of the PTSFQ provides an opportunity for sites to provide comments via Likert Scale as well as free text format.

Please note that use of the PTSFQ can be initiated by sites (to provide unsolicited feedback) or as part of a process initiated by the Sponsor to collect solicited feedback. Feedback can be provided for any or all of the patient-facing technologies used in a study at the discretion of the initiating party.

Sponsors should consider the line of communication between sites and Sponsor for all studies including those run by CROs. Special consideration should be given when this feedback is unsolicited (i.e., the PTSFQ was not provided as part of the study, but sites provided feedback spontaneously using a paper or other version of the questionnaire).

**Benefits:** The PTSFQ provides a medium to create dialog between sponsors and sites to gain feedback on the use of patient-facing technology in studies. Using near real-time surveys to understand the impact of patient-facing technology may provide sponsors with the opportunity to mitigate dissatisfaction, and gain insight into the actual needs of participants. Use of the PTSFQ may contribute to patient-centric clinical studies, with the long-term potential to:

- Support patient recruitment into clinical studies
- Identify opportunities to respond to an area of site and participant dissatisfaction during a study
- Improve patient adherence in use of technology in clinical studies
- Enhance data quality/reduce missing data due to missed assessments
- Reduce number of amendments

Use of the information collected in the PTSFQ is up to the discretion of the particular sponsor and participating sites. Collected information should not be shared back with TransCelerate in any form.
2 Sponsor Planning (and decision to use the PTSFQ)

Sponsor teams responsible for the design, planning and conduct of a clinical study/clinical program should decide as early as possible, (ideally in the beginning or prior to the design phase of a clinical study protocol/clinical program) if a PTSFQ should be utilized, what purpose/objective the PTSFQ will have, and how site’s feedback can best be implemented:

i. In the clinical study protocol/program planning phase
ii. In an amendment for a currently ongoing/recruiting clinical study
iii. In future clinical study/clinical programs (same, similar or different therapeutic area)

The Sponsor team should also identify early on who will be involved in the PTSFQ process (Owner, Lead, SME, etc.). Throughout this document this group is referred to as the “PTSFQ Team”. This team should be advised on the business case for utilizing the PTSFQ to support buy-in and ownership of the project.

An assessment of internal support and available resources should also be conducted at this time; the sponsor team may wish to ensure that key functions/stakeholders are consulted, and decisions are logged for future reference.
3 PTSFQ Sponsor Considerations for Implementation

There are several implications for using the PTSFQ in a clinical study program:

- Consider holding an exploratory kick off discussion (as necessary) between the study team and the company’s internal PTSFQ team* about:
  - PTSFQ implementation logistics
  - Timing of administration and perceived impact of obtaining feedback during the clinical study. The study team should evaluate benefit/risk.
  - Whether there are available internal resources capable of managing the PTSFQ administration in a clinical study or if an outside vendor will be retained.

- If external vendors and CROs are used, PTSFQ team should consider holding kick-off meeting with vendor(s) to discuss/review study-specific PTSFQ implementation. Vendor kick-off meetings might address:
  - Alignment with study team on questionnaire administration schedule, question selection, and key communications during kick-off meeting
  - Responsibility for communication process with study team and others, e.g., country leads, CRO
  - Key project milestones, including proactive collaboration with sponsor to identify potential challenges, and mitigation plan
  - Site selection criteria and contact information
  - Producing and managing PTSFQ-related site facing materials
  - If utilizing a CRO for study management activities, consider how the CRO may be involved in this process:
    a. Would the CRO manage the PTSFQ vendor (if used)?
    b. Would the CRO implement training at the study sites/investigator meeting?
    c. Will the study team need to support the CRO in executing the surveys?
      - Consider how responses from any unsolicited PTSFQ completion will be added to other PTSFQ data obtained for future pooling and learning.
      - Consider whether PTSFQ is appropriate for all regions where the study is being conducted.
      - Consider whether implementation in certain countries or regions requires additional planning, instruction and support due to cultural and regulatory practices.

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* Some sponsors may not have a separate internal PTSFQ team, leaving the role to be incorporated into the study team. Regardless of “PTSFQ team” format, the exploratory discussion should be held with all key team functions.
4 Mode of Administration Considerations

The mode of administration for any other questionnaires/assessments in the study should be considered when choosing the mode of administration of the PTSFQ. Timing of PTSFQ administrations, number of PTSFQ administrations, etc. should not interfere with other study endpoint assessments and will not impact the burden to the patient.

If a patient satisfaction survey is being utilized, the Sponsor could consider using the same vendor / mode of administration for the PTSFQ.

All modes of administration carry specific resourcing, handling, and tracking implications. It is critical to involve key functions in choosing the mode of PTSFQ administration. Data management responsible roles must be included in the initial planning to ensure that data handling and appropriate data fields are defined and tested early in the implementation process. It’s very important that data handling and data fields are consistent during all uses of the PTSFQ. Also consider consulting legal, data privacy and/or regulatory representatives regarding the impact of data privacy requirements on collecting these data (e.g., GDPR).

Considerations for web-based administration of the PTSFQ

- Sites could answer the questions online utilizing a secure web address (URL)

A specification document outlining the acceptable parameters for the PTSFQ administration via a web-based application may be provided for vetting of potential vendor capabilities.

If sites are located in areas with poor internet support, it may be necessary to include additional methods for providing survey responses.

Consider whether a timeframe for responding to the survey should be included (e.g., “The Study Team requests your response within x days of the first randomized patient.”; “This survey will close within 7 days after the last patient completed all study visits.”; “You may provide your responses any time after x days.”).

Considerations for paper-based administration of the PTSFQ

- Paper format administration, while alleviating the need for special equipment, may still require site and data resources. Some key factors in selecting paper administration are:
  - How will paper PTSFQ forms be produced and distributed to sites?
  - Who will enter the data at the sponsor?

Data on PTSFQ is not considered as clinical data.
5 Data Management & Analyses

The Sponsor study team should determine how the PTSFQ data will be used, where it will be stored, what analyses will be conducted, and if processes need to be put in place to handle changes to study design (as a result of real-time data access).

What analyses will be conducted; who will conduct the analyses and how will findings be shared between sponsor and the responding site(s) while the study is still on-going? Consider steps to maintain confidentiality.

• The sponsor’s PTSFQ database should consider all responses collected electronically or via paper.
• Determine how and where the PTSFQ data will be transferred.
• Allow time for creating data fields or use available data field format.
• Test transfers early in the process.

The Sponsor study team should align on the following topics when choosing the database:

• Who owns the data/who owns and maintains the sponsor database?
• Does the team want access to real-time data, if feasible?
• How will access permissions be provided and monitored?
6 Communication Considerations

Sponsors should provide a brief overview of the purpose of the PTSFQ and how it intends to use the results, including any potential sharing of results at the end of the study with the participating sites.

It is expected that there will be minimal impact on site operations as the PTSFQ is only completed three times per study, however, there are some considerations. For example:

- What materials/support will be necessary to facilitate appropriate administration of the PTSFQ?
- Will sites be given the choice to opt out of participation? Who will communicate with sites when a CRO is involved and vice versa?
- How will patient and/or site privacy be protected (where necessary)?
- What will be required to submit responses, i.e., log-in credentials (for electronic) or return process for paper?
- What additional contact information may need to be provided?
7  PTSFQ Results Sharing

A sponsor should determine how best to use the results from the PTSFQ for its own internal purposes, including how to analyze/interpret these data. For example, results can be used to modify/enhance future clinical study designs or study conduct process (future or current).

Sponsors should also determine the process and format for distribution of anonymized or aggregated PTSFQ results. For example:

- Internal communication processes (e.g., reviewers, approvers, timelines)
- External communication processes (e.g., feedback to participating sites)
- Frequency of analysis and reporting to internal and external stakeholders
- Format and content of reports (e.g., descriptive tables, narratives, recommendations for next steps)
- Maintenance, storage and access to reports in internal systems/libraries
- Cross study analysis and pooling of data to identify potential trends.

*Note: Consider steps to maintain confidentiality of results as necessary.*