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1. **Introduction**

To complement the TransCelerate vision of simplifying and accelerating the research and development of innovative new therapies, the Patient Experience initiative seeks to contribute by shifting the paradigm in the healthcare ecosystem by incorporating patient insights into study design.

The value of the SPFQ (Study Participant Feedback Questionnaire) is that it provides a way to measure patient satisfaction with their experience as participants in clinical studies. Using real-time questionnaires to understand clinical study experience may provide sponsors with the opportunity to mitigate dissatisfaction, improve the patient experience, and gain insight into the actual needs of participants. Furthermore, using participant feedback to improve study design and execution can motivate participants and their health care providers to view clinical studies in a more collaborative nature and potentially encourage participation in ongoing and future clinical studies. Therefore, use of the SPFQ may contribute to patient-centric clinical studies, with the long-term potential to:

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

The SPFQ is a set of three brief, validated patient questionnaires designed to capture patient trial experience at the start, mid-point, and end of each study, independent of disease and treatment. The general questions are about both protocol-specific and site-specific components including study burden and interaction with site staff. The SPFQ does not contain open text fields due to the difficulty of correctly interrupting unstructured feedback and risk of capturing anonymous incomplete adverse event information. Feedback is anonymous and not shared directly with sites. It can be reviewed by the Study Sponsor on study-level, site-level, country-level and per region. As a patient feedback tool, ethics committees have to date been supportive around using tools similar to the SPFQ, however it is important to note that it should not be considered a patient reported outcome tool for submission purposes.

This user guide is intended to support each sponsor company’s customization and unique implementation of the SPFQ. The user guide is structured by category of considerations. It is recommended that the user guide is read in full and adapted to the sponsor’s timelines and processes.
2. **Sponsor Planning**

   a) Sponsor Teams responsible for the design, planning, and conduct of a clinical study/clinical program will decide as early as possible, ideally in the beginning or prior to the design phase of a clinical study protocol/clinical program, if a SPFQ should be conducted, which purpose/objective the SPFQ would have, and how patients’ feedback can be implemented best

   a. In the clinical study protocol/program planning phase

   b. In an amendment for a currently ongoing/recruiting clinical study

   c. In future clinical study/clinical programs (same, similar or different therapeutic area)

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

   c) An assessment of internal support and available resources should also be conducted at this time; the sponsor team may wish to incorporate any RACI tools/templates into this process to ensure that key functions/stakeholders are consulted, and decisions are logged for future reference. Support and resources might include patient engagement functional teams and study budget allocations assigned early in the planning process.
3. **SPFQ Sponsor Considerations For Implementation**

There are several implications for using the SPFQ in a clinical study program.

a) Methodological and scientific considerations
   a. Consider engaging an internal Clinical Outcomes Assessment (COA) or Outcomes Research (OR) subject matter expert in the decision to use the SPFQ in a clinical study.
      i. If adaptations/modifications to the SPFQ are requested, how will the team ensure that methodological and conceptual integrity are maintained?
      ii. In the case of adaptations/modifications to the SPFQ, including trial specific questions in the SPFQ may not work well.

b. What is the risk that use of the SPFQ may inadvertently influence study participants’ responses on other questionnaires included to measure study endpoints?

c. Consider mitigating the risk that feedback may be linked to an individual participant if obtained at a site level and site enrolls only a few or one participant(s).

b) Consider holding an exploratory kick off discussion between Study team and the company’s internal SPFQ team* about:
   a. SPFQ implementation logistics
   b. Timing of administration and perceived impact of obtaining feedback during the clinical study. The study team should evaluate benefit/risk.
      i. Consider the “time to complete” for each questionnaire is an estimated 5 minutes but actual time to completion will vary and could be shorter or longer.
      ii. Consider whether the administration of the first SPFQ occurs during or after the screening visit
      iii. Consider timing of the SPFQ administration in relation to the protocol type and patient burden
      iv. Consider the benefit/risk of optional multiple administrations of the second SPFQ.

c. Are there available internal resources to manage the SPFQ administration in a clinical study or will an outside vendor be retained?

d. The Sponsor Team will determine if the SPFQ is part of the protocol, data handling methods and implications (see Section 5 – Mode of Administration Considerations).

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1 Some sponsors may not have a separate internal SPFQ team, leaving the role to be incorporated into the study team. Regardless of the “SPFQ team” format, the exploratory discussion should be held with all key team functions.
e. The Sponsor Team will determine whether the SPFQ will be managed in-house or out-sourced to a vendor or CRO and what budget implications there might be for each choice.

c) If external vendors and CROs are used, the SPFQ team should consider holding a kick-off meeting with the SPFQ Vendor to discuss/review study-specific SPFQ implementation

a. Vendor management scope could include:
   i. Alignment with study team on questionnaire administration schedule, question selection, and key communications during kick-off meeting
   ii. Responsibility for communication process with study team and others, e.g., country leads, CRO
   iii. Key project milestones, including proactive collaboration with sponsor to identify potential challenges, and mitigation plan
   iv. Site selection criteria and contact information
   v. Producing and managing the SPFQ-related site and patient facing materials (see Section 7 - Communication, Awareness and Training Material Considerations)
   vi. If utilizing a CRO for study management activities, consider how the CRO may be involved in this process:
      1. Would the CRO manage the SPFQ vendor (if used)?
      2. Would the CRO implement training at the study sites/investigator meeting?
      3. Will the study team need to support the CRO in executing the questionnaires?

d) Consider whether the SPFQ is appropriate for all regions where the study is being conducted.

   a. Consider whether implementation in certain countries or regions requires additional planning, instruction and support due to cultural and regulatory practices.
   
   b. Consider translations. Do translations exist? If not, the SPFQ will need to be translated, using appropriate translation methodology
      i. Consider impact of new translations on cost and timeline for study start-up
      ii. Translate the SPFQ into the relevant languages needed for the study, if readily available translations of the SPFQ do not exist in relevant language(s).
4. **Protocol, ICF, Privacy and Regulatory Considerations**

a) Local and regional regulatory or legal considerations regarding data privacy (including process to obtain consent, to manage withdraw of consent, data transfer, analysis and storage) should be understood and used to guide the implementation process.

b) Consider how to integrate the SPFQ submission within your existing procedures and processes.

c) Whether or not to use a SPFQ should ideally be decided during the drafting of the protocol. If the decision is made to use the SPFQ, determine whether the SPFQ-related protocol content should be added to existing sections of the protocol, or a new section will need to be added.

d) Incorporate language about the SPFQ into the study protocol including how the data will be used as desired by the sponsor.

   i. Consider adding a statement that completion of the SPFQ is not mandatory and therefore does not constitute missing data if it is not a part of the trial database.

   ii. If it is not possible to include the SPFQ in the study protocol, ethics bodies may provide expedited approval for this type of questionnaire as a separate submission.

   iii. While including the SPFQ in the study protocol may not be required from a regulatory perspective, this approach allows for a more seamless implementation.

e) The SPFQ is offered as voluntary for patients, so consider any protocol or ICF language to allow for this option to prevent protocol deviations or similar risks.

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**Sample protocol text:**

This trial will include an option for patients to complete an anonymized questionnaire, ‘Study Participant Feedback Questionnaire’ for subjects to provide feedback on their clinical trial experience. Individual subject level responses will not be reviewed by investigators. Responses would be used by the sponsor to understand where improvements can be made in the clinical trial process. This questionnaire does not collect data about the subject’s disease, symptoms, treatment effect or adverse events and therefore would not be trial data. Should any spontaneous information be collected about AEs, this would be reported and transferred to the safety database.
f) Informed Consent
   a. Consider whether the use and timing of the SPFQ administrations, can be included in the clinical study informed consent or a separate ICF is needed. Caution that if the SPFQ is included in the ICF, a separate signature line could create significant administrative burden for sites and study staff.
   b. Review ICF language to ensure that references to the SPFQ are consistent with other sections of the ICF and/or protocol, as appropriate
   c. Seeking input from country/region submission managers prior to completing ethics committee submission packages may be helpful

g) Consider patient privacy regulations and how they may impact the implementation of the SPFQ for your study

h) Consider conferring with global and regional experts on privacy regulations (e.g. GDPR) that may impact the implementation plan for the SPFQ

i) Generally, RA/IRB-approval processes must follow local legal and regulatory requirements but commonly will include at least:
   a. Validated questionnaire translation in local language
   b. Screenshots from the device on which patients will access the electronic SPFQ if available per country requirements
   c. If using postcards to distribute the SPFQ URL for data collection, submit samples of the postcards
   d. If parts of a clinical study protocol are embedded into the SPFQ, it might need to undergo regulatory (Health Authority) approval in addition to EC/IRB approval, depending on local requirements. Consider any resource or timeline implications that this additional item within the submission may require.
   e. The SPFQs are patient-facing materials associated with trial participation and need to undergo EC/IRB approval.
      i. To facilitate EC/IRB approval process, the SPFQ should ideally be part of the general initial submission package for the clinical trial. If the SPFQ is implemented during the study, consider including it with an amendment submission and consider whether the beginning and middle SPFQs are applicable for some study volunteers by that time.
      ii. Consider that an EC/IRB may have interest in the method of administration for a SPFQ including data privacy and other risk mitigations
5. **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 SPFQ. Timing of the SPFQ administrations, number of SPFQ administrations, etc. should not interfere with other study endpoint assessments and should not significantly increase the burden to the patient.

All modes of administration should consider privacy to ensure that honest feedback is received. All modes of administration also carry specific resourcing, handling, and tracking implications. It is critical to involve key functions in choosing the mode of the SPFQ administration. Sponsors may consider involving a patient advisory board and/or site in mode(s) of administration. Data management responsible roles must be included in the planning to ensure that appropriate data fields and handling are defined and tested early in the implementation process (see Section 6 - Data Management & Analyses). Also consider consulting legal, data privacy and/or regulatory representatives regarding the impact of data privacy requirements on collecting and sharing these data (e.g., GDPR).

a) **Considerations for electronic administration of the SPFQ**

   *There are many choices for electronic administration of the SPFQ (e.g., web-based, provisioned devices, bring your own device (BYOD), site-based tablets). Regardless of specific devices, all likely will require outside vendor services. The study team will need to provide clear direction to the vendor, in addition to reviewing and approving “specification documents,” as they may not have experience in these types of patient experience instruments. Consider additional requirements such as system validation and/or plans for UAT (user acceptance testing), if necessary.*

   **When choosing a device for electronic administration of the SPFQ where ePRO and other electronic assessment tools are being used, consider whether consolidation of devices is preferred and/or possible (e.g., Can the SPFQ be included on the ePRO device?)**

b) **Considerations for Web Based administration**

   a. Study participant could answer the questions online either during their site visit or off site utilizing a secure web address (URL)

   b. A specification document outlining the acceptable parameters for the SPFQ administration via a web-based application may be provided for vendor vetting

   c. If study participants are located in areas with poor internet support, it may be necessary to include optional methods for providing questionnaire responses.

   d. Consider whether a timeframe for responding to the questionnaire should be included (e.g., “The Study Team requests your response within 24 hours of your visit to the study site.”; “This questionnaire will close within 72 hours of your visit to the study site.”; “You may respond at any time after your visit to the study site.”) and what impact that may have on the participant’s willingness to
respond (i.e., if timeframe is too short) and the ability to include the responses (i.e., if no timeframe or if too long).

c) Considerations for ePRO Handheld Device administration
   a. Study participant would be assigned a handheld device (smartphone or tablet) or apply a BYOD (bring your own device) approach that is pre-loaded with the questions and administration days/times.
   b. A specification document outlining the acceptable parameters for the SPFQ administration via a handheld device may be provided for vendor vetting.

d) Considerations for paper administration
   a. Paper format administration, while alleviating the need for special equipment, may require more site and data resources. Some key factors in selecting paper administration are:
      i. How will paper SPFQ forms/booklets be produced and distributed to sites?
         1. If paper SPFQ forms/booklets are administered at site visits, who will enter the data?
         2. If paper SPFQs forms/booklets are sent home with or mailed to study participants, how will the site ensure that they are returned?
      ii. Determine whether the SPFQs are considered source documentation; if “yes” then original, completed questionnaires will need to be treated accordingly.
      iii. Would a paper format be better suited to the target patient population?
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6. **Data Management and Analyses**

a) The sponsor’s SPFQ database will vary depending on whether paper or electronic format are used.
   a. Determine how and where the SPFQ data will be transferred/stored
   b. Allow time for creating data fields or use available data field format
   c. Test transfers early in the process
   d. Consult with appropriate functions (e.g., BioStats) to confirm timeline rules for the SPFQ data (e.g., database lock?), regardless of where data will be housed.

b) The Sponsor Team is responsible for the design, planning and conduct of a clinical trial/clinical program; the team should align on the following topics when choosing the database:
   a. Who owns the data/who owns and maintains the sponsor database?
   b. Process to handle data in case the patient withdraws consent
   c. Will the SPFQ data reside in the same database as the safety & efficacy data? Using a separate database might offer more flexibility during data base lock.
   d. Does the team want access to real-time data?
   e. Is access to real time data feasible?
   f. How will access permissions be provided and monitored?
   g. What analyses will be conducted; who will conduct the analyses and how will findings be shared while the study is still on-going?

C) The Sponsor study team should prospectively determine how the SPFQ data will be used, where it will be stored, what analyses will be conducted (including e.g. if a separate Statistical analysis plan is required) and in case real-time data access is available, the process to handle potential changes to the study design. See Section 7 for Communication Plan considerations.
7. **Communication, Awareness and Training Material Considerations**

Training materials are recommended to facilitate ease of administration. Effective training materials may reduce site burden, support willingness to participate, and minimize missing data. The study team should determine when and where to conduct the SPFQ training, and any criteria for retraining.

Training materials could be printed, video, presentation format for meeting audiences, etc. Consider making training materials available on a website platform with other study management materials for new and refresher site staff review.

Audience and type of training materials to consider

a) CRO training materials are critical and may include information on
   a. Specific CRO responsibilities
   b. Monitoring plan (if any)
   c. “Train the trainer” instructions for sites
   d. Operations and vendor communication process

b) Investigator and Site training materials
   a. Communication and contact information for the SPFQ manager (vendor or sponsor)
   b. “Train the trainer” instructions to train subjects
   c. Subject-facing materials (instructions, FAQs)
   d. Overview of the purpose and how you will use the SPFQ results

c) Study participant materials
   a. Advanced notice of the SPFQ and timing of the SPFQ administrations
   b. Information & overview of the SPFQ (including why collecting this information is valuable) and how data will be used
   c. Statement on how privacy will be protected
   d. Instructions for completion
   e. Log-in credentials (for electronic) or return process for paper
   f. FAQ sheet or online page
   g. Help instructions/contact information
   h. Participant thank you

SITE CONSIDERATIONS
Clinical study sites may not be familiar with the concept of an SPFQ. Consider how site operations and study visits may be impacted by the SPFQ

a) How will sites be involved in administering the SPFQ?

b) What materials/support will be necessary to facilitate appropriate administration of the SPFQ (e.g., reminders on timing of administration, etc.)?
c) Will sites be given the choice to opt out of participation? How would this impact data integrity and interpretation?

d) Who will communicate with sites when a CRO is involved?

8. **SPFQ Results Sharing**

a) Internal use of the SPFQ data: each sponsor will determine how to use the SPFQ data for internal purposes, and how to analyze/interpret these data. Some high-level examples are:
   a. Key performance indicators
   b. Information to modify future clinical study protocols or study conduct process

b) Presentation of the SPFQ data: each sponsor will determine the process and format of the SPFQ results. Some considerations are:
   a. Following internal communication processes (e.g., reviewers, approvers, timelines)
   b. Format and content of reports (e.g., descriptive tables, narratives, recommendations for next steps)
   c. Maintenance, storage and access to reports in internal systems/libraries