PCSIG

PCSIG Patient Acceptability Survey

Instructions for Researchers

Table of Contents

Purpose of the PCSIG Patient Acceptability Survey

It is essential that new remote patient sampling processes are fit for purpose and meet accepted professional and regulatory standards. Although we can define analysis, logistical, clinical, and other requirements, there is no standard way of gathering information and understanding what recipients of the sample kits may need to successfully complete the tasks they are being asked to perform. This survey has been produced to address this gap in understanding. It has been reviewed by the PCSIG community and also patient representatives to ensure that it is relevant, meaningful, helpful, understandable and considered (by patients) to be easily achievable for patients.

Once piloted, the aim for this survey is to become a standard tool to be used by a trial sponsor for capturing patient-centric sample collection approaches during the early stages of new clinical trial design or for healthcare patient-centric sample collection approaches.

The survey should be tailored to fit the needs of individual projects and contexts, where required in descriptions and permitted in the responses (described below). This consistency is important for the community to gather data and build up a repository of information that moves the field forwards.

This instruction manual should be read alongside the survey so that researchers know the rationale behind each question and what can/cannot be changed.

Survey Delivery Approaches

This survey is available in both paper and online formats. It is recommended that the online survey is used wherever possible because:

1. online is easier to distribute,
2. online is responsive and helps focus the user on the question at-hand and is therefore quicker for respondents because it only shows questions that are relevant based on their answers,
3. the dataset is automatically gathered thus minimizing potential transcription errors.

A paper version is available because it is acknowledged that in some populations and contexts, a paper version will be better received and improve response rates. Format selection will be at the discretion of the researchers.

Where there are privacy and data protection concerns, a company may want to work with third party researchers for distribution of the survey so that any reimbursement results or personal information in free-text boxes can be removed from the returned dataset.

Structure of the Survey

The survey has been built using modules. Each module has a defined purpose and, by grouping similar questions together, helps researchers remove or reposition whole sections as needed. When patient's themselves reviewed the survey they recommended that no sections are missed out. Their opinion is that it is easy to complete and all sections are needed to be able to gain the understanding that is relevant to their experiences.

The overall structure of the survey can be seen in the table below.

Module 1	Introduction
Module 2	AE Reporting (called 'Disclosure' based on patient feedback that AE reporting language was too complex and long and would put people off completing the survey). Only use this section if it is needed to meet pharmacovigilance compliance requirements.
Module 3	Demographics: Including care role, age category, sex, gender, location, race, ethnicity, socioeconomic characterisation, and physical state of health
Module 4	Current standard approaches: Including what is most helpful, and what is most frustrating with current methods. What kinds of communication people like, how much effort they would like to put into sampling, and whether they have had previous bad experiences.
Module 5	Novel approaches: Including the type of experience people have with this and comparison between these and standard methods.
Module 6	Requirements for the new process: a prioritisation and ranking of the practical elements patients feel they need in order to have a good blood sampling experience.
Module 7	Anything else we've forgotten? A chance for respondents to tell us what is important to them and whether we've missed anything that is relevant when asking the survey questions.
Module 8	Reimbursement details. This module will have to be included / amended / excluded depending on your project's privacy agreements around personally identifiable information, who is delivering the survey, and where the survey is being delivered.

Important: Survey respondents do not see the module numbers or titles so are guided through a simpler set of Sections.

Module and Section numbers are not the same.

Use of the Results

The aim is for survey results to have two primary purposes:

1. To help you design the best process possible and meet prioritised requirements from all stakeholders.
2. For the PCSIG to collate de-identified data across multiple communities and share general learnings and requirements that help move the whole field forwards.

All data shared with the PCSIG must be de-identified. The method of sharing results will depend upon your survey data collection approach – excel spreadsheet exports and survey engine exports are accepted. If a paper version of the survey is used, then an excel template will be provided to ensure that results are compatible with the structure of online data collection.

If it is the researchers intention to gather large amounts of information using free-text boxes, it is advised to work with a qualitative researcher who is trained in identifying, coding, and reporting key themes emerging from the data.

If conflicting responses are collected, a sample of those respondents should be followed up with qualitative discussion to understand why this is occurring in more detail. Conflicting responses are highly unlikely to occur throughout the survey, with the exception Module 4, which contains options for respondents to prioritise. For example, the category ‘Convenience’ could be selected for both most helpful and most frustrating points of current sampling approaches. This could simply be reporting that different aspects are helpful and hindering (e.g., arranging the appointment may be easy, but getting to appointments problematic).

Step by step instructions and rationale for each module and question

A description of the rationale behind each module is included below. Question numbers are also included throughout this survey structure to help researchers navigate and link instructions to the corresponding sections. They are not visible to respondents.

Sections of text that researchers need to modify to fit their requirements are identified by [ ].

Module 1. Introduction

Ensures that respondents understand the purpose of the research project, expectations about the survey itself, use of the data, and where to go for help. Please amend this as required based on the order and inclusion of modules as well as any cultural or linguistic amendments to make the text more understandable and appropriate.

- Any third party company and their role in survey distribution, participant support, and data collection, should be introduced either at this stage of the survey, and/or in associated communication.
- If respondents are being reimbursed for their time, please state the amount, how this will be done, and when this is likely to be done.

Module 2. Adverse Event (AE) Reporting

Based on feedback from patients, this section is called ‘Disclosure’ and seamlessly integrates into the introduction from an end user perspective. AE Reporting is a pharmacovigilance requirement that your company may need to meet. If this survey is being completed by, or on behalf of any company that needs to comply with AE reporting, then this module (or other company approved AE reporting statement) must be included and free-text boxes are retained for maximum understanding and knowledge gathering.

The online version of the survey has been built with embedded logic, so that if a respondent doesn’t agree to AE reporting requirements, they will not be able to proceed with the rest of the survey. The paper version includes written text to the same response. Please replace contents of square brackets to accurately reflect the situation.

There are two circumstances in which this module (and the corresponding question in Module 8. AE reporting and reimbursement details) can be deleted:

1. If the legal entity commissioning the survey work does not need to comply with AE reporting (e.g. they have no products)
2. If free-text boxes are removed from the survey so that there is no opportunity for respondents to mention AEs, making the statement void.

Module 3. About you (Demographics)

This module is also called Section 1 for respondents.

	Notes
Section title	Used to help the respondent navigate through the survey
Role	Understanding who is answering the questions – the patient, or someone on behalf of the patient.
Age category	Depending on your population you may want to narrow the list of these age categories (e.g. if your population is elderly, you don't need the paediatric options). **If reducing the number of options, please keep the category definitions the same so that anonymised data sets can be merged.**
Sex assigned at birth	This is likely to be most biologically relevant for comparing with your epidemiology data and planning.
Gender	This is likely to be at least equally important when trying to characterise people's experience of blood sampling within their healthcare system and how to support certain groups that may have traditionally been under-represented within research.
Healthcare worker specialism	To identify the context within which a healthcare worker may complete the survey. Their experience may differ for example between a general practicioner and someone at a specialist centre for rare disease.
Location	This question asks where the respondent is currently living to gather an idea of the general kinds of health systems that they are currently interacting with at the point of answering the survey. It is not possible for a standard survey to produce a working solution that is optimised for all. Therefore it's recommended that you focus the options on those most relevant for the situation you are trying to address. If you focus the survey and make these options country-specific. Please also provide a 'mapping' to PCSIG along with de-identified results so that we know how to link your categories into these central ones.
Race	There is no defined standard for global data collection about race and ethnicity. In 2003 the UN Statistics Division considered creating a standard and concluded that due to the high levels of heterogeneity and complexity no international criteria can be recommended. Instead: "countries should determine their own informational needs and select the criteria according to those needs". Please be aware that some countries do not permit focussed gathering of race and ethnicity data and so local law should be consulted. That said, we need a workable solution. Current gold-standard guidance exists for the USA, UK, and has been produced by a civil rights group. They all have particular focuses on defined countries.

	To produce our question format we have copied the approach used by the civil rights group (which was based on FDA guidance) because this was the simplest for respondents to use. This asks for broad race self-classifications, then provides the most likely options for ethnicity for each, as well as an open-text box for where suitable options are not provided. Selection of multiple answers is allowed so that people of mixed race/ethnicity can feel represented.
Ethnicity	Most likely ethnicity options for each race category. Options are only shown if the corresponding race category is selected in Question 9. Ethnicity categories have been chosen as follows: • Merged the US, British, and Civil Rights guidance • Tweaked according to country population size If collecting data from a targeted/limited population, the race x ethnicity categories selected for your survey should be adapted based upon the defined countries in the survey distribution list. In the best case scenario, researchers should refer to the government census and at least one other reliable race x ethnicity database for that country to garner an understanding of the countries' 'main' ethnicity groups. If this is done, please send a ‘mapping’ to PCSIG along with de-identified results so that we know how to map your categories into these central ones.
Highest qualification	Introductory question for socioeconomic status. This approach mimics the simplified approach used by the UK civil service and then has been tailored by the community and patients to make it more relevant within this setting.
Other qualifications	Education levels and types to support socioeconomic analysis.
Employment status	The impacts of attending clinic and blood sample are likely to be different depending on the employment/education situation people are in.
Physical state of health	Assessment of current state of health. This may influence the attitude and experience that the respondent has when completing the survey and may be useful for analysis.
Chronic conditions	Question requested by patients because those undergoing long term monitoring requirements will have a very different perspective.

Module 4. Current Standard Approaches

This module is also called Section 2 for respondents. This module includes questions 17 to 20. All respondents see all questions in this module.

Question	Notes
What is most helpful	This is a high-level question because introducing subcategories quickly became very complex for the respondent and the aim of the survey is to help researchers identify what matters most and needs to be looked into in greater detail during design stages.
What is most frustrating	High-level question with rationale as described above. Please see analysis note in 'Use of the Results'.
Communication methods	Patients mention that communication is very important within processes and that the method used should align with the preferred approach for that population if full engagement is desired.
How much effort should patients/ care givers put in	The aim is to understand how much personal responsibility the respondent believes patients should have in the process. This will help with understanding their responses, when combined with other responses it will help designing an approach that provides support needed.
History of problems	This question was initially in the 'About you' (Demographics) Module. The aim of the question is to understand the perspective of the respondent when answering the survey as our expectations and requirements are shaped by our learned and emotional responses. However, it may also flag underlying issues that may need to be addressed if the dataset flags a multitude of pre-existing issues. The question was moved into this module because it sat more naturally for respondents here.

Module 5. Current Novel Approaches

This module is also called Section 3 for respondents. This module includes questions 21 to 24.

	Notes
Experience	This question aims to separate respondents who have experience of patient-centric sampling methods from those who do not. Those who didn't, initially skipped this module, but patients requested that it be kept for all because people are likely to have very relevant perceptions and expectations in either case that this module will help characterise.
Frequency of experience	Frequency of experience (only for those who have experience). Used to understand the level of knowledge behind answers.
How blood collected	To understand the previous experience as this may affect people's responses.
Prioritisation for good experience	Based on their experience what are the key components for success.
Comparison	Understanding where the different approaches differ in terms of 4 essential categories that were identified by the PCSIG community and patients. Note: This is in a matrix format which is difficult for a text-to-audio reader to navigate. If your population is likely to be visually impaired, it is recommended that you keep the options the same but reformat.
Preference	This direct question was included at the recommendation of patients, as it will help assess people's preferences and enable researchers to understand whether these differ between those who have previous experience and those who do not.

Module 6. What is needed (requirements for the new process)

This module is also called Section 4 for respondents. This module gathers detailed practical requirements for the new process and asks for the level of importance of each. The options provided were gathered through previous feedback. An 'other' category used to capture anything researchers may have missed.

Module 7. Anything we've forgotten?

This module is also called Section 5 for respondents.

Free text boxes are provided to:

- Give people the chance to share their thoughts about requirements in their own words and express anything that researchers may not have heard before (and therefore have not created a category).
- Give people an opportunity to flag anything else that may be important that they think researchers have missed in the survey.

During pilot phases, the survey may be iteratively updated, based upon this feedback until there is a consistent and tested relevant approach.

Module 8. Reimbursement details

This module is also called Section 6 for respondents. Remove the module or sections of the module as required.

Only include questions for AE reporting if the corresponding 'Module 2. Adverse Event (AE) Reporting' is included.

There are many different requirements for reimbursement as defined by local regulations and patient preference. Update this section of the survey to allow patients choice wherever possible and provide only the approved approaches for your situation. Examples of requirements include:

- Bank details differ between countries and whether cross-border payments are required.
- Reimbursement by gift card to people's email addresses is also a viable option in some countries.
- Donation to a charitable organisation is viable in some countries. If this is the standard approach then include somewhere for someone enter their email address if they want confirmation when this donation was made.

Important: Module 8 is where most personally-identifiable information is likely to be collected. Do not send this to PCSIG. Agree before starting on who can see this and how this information is going to be handled and reflect this accurately in Module 1 (Introduction).

Thanks at the end of the survey.

A standard thanking statement has been included in the survey template. Edit this as needed to clearly state whether respondents can request a report/overview of the survey results, and/or a summary of what happened because of these survey results (note: it is okay if not everything was acted on, transparency and feedback is key).

If you can’t send anything back, tell people this politely and let them know how the information is going to be used. Respondents need to know that their effort mattered and can make a difference, and generic wording won’t be enough.

This has been requested by patients themselves, is very much appreciated, and is likely to be essential if you want to begin to partner with patients during the study to help with other aspects such as recruitment.