

Guidance For Planning Your Patient Engagement In Research

Early involvement of patient partners, based on co-design principles allows a better formulation of relevant research questions, more credibility of the knowledge produced, improved identification of and possible solutions to challenges faced during the trial, and better application of outcomes to specific contexts.

Here is a checklist to help you plan patient engagement and complete our Patient Engagement Plan Table that will be required as part of your Letter Of Intent. It encompasses points that should be considered for the application phase, during project implementation, and beyond.

Please note – guidance and steps listed below are aspirational. Efforts to increase patient-centricity can take time and practice; and while developing tools, protocols and best practices will take time and ideally will evolve over time. Patient-centric research begins by recognizing patients as the ultimate stakeholder.

Before the project starts

- Patient engagement is planned across the entire project lifecycle;
- The most appropriate patient engagement model is selected;
- The appropriate patient partners are involved early in formulating the concept, hypothesis; and
- Appropriate budget for patient engagement activities and compensation of patient partners is reflected in the Patient Engagement Plan and the overall grant budget request.

During the project

- Assessment of needs of trial participants by patient partners is included within regulatory and/or confidentiality confines;
- Adaptation of trial and procedures where necessary to meet trial participants' needs; and
- Assessment of the impact of patient engagement in your project at mid-term and at the end of the project is considered.

Beyond the project

- Communication and dissemination of study outcomes with patient / public partners is planned after project end; and
- Collaboration with patient community on trial outcomes is planned.

For more information, please refer to: <http://synapse.pfmd.org/resources/considerations-guide-to-implementing-patient-centric-initiatives-in-health-care-product-development/download>

Choice Of Model Of Patient Engagement In Research Projects

Research teams should think carefully about the activities across the whole project lifecycle that the patient partners could undertake. Short term activities are easy to define upfront, but it is more challenging to think about sustained involvement across the entire project.

Therefore, depending on the research project, it is important to think about the most applicable role of a patient partner for contributing in a clinical research project:

Patient role	Examples	Engagement level
Consultant role	<ul style="list-style-type: none"> • Patients provide input based on their lived experiences and continuous consultation on outcomes of importance, study design, etc. • Patients are paid investigators or consultants • Patients have a governance role – “a seat at the table” 	High
Advisor role	<ul style="list-style-type: none"> • Patients serve as advisory committee members, provide input based on their lived experiences, or consultation on outcomes of importance and study design, but have no leadership role or governance authority 	Moderate
Reactor role	<ul style="list-style-type: none"> • Patient input is collected distally through surveys, focus groups or interviews, but patients are not consulted directly on such things as study design and outcomes of importance • Patients are asked to react to what has been put before them rather than being the origin of the concepts of interest 	Low

Patient Engagement Plan

We require you to submit a "Patient Engagement Plan" as part of your LOI and Full Application. The plan should describe patient engagement processes during the generation of the application as well as during the implementation of your project. It describes engagement e.g., how you engaged with the patient community when your research question was defined, while the proposal is written, when it is being submitted and resubmitted, and which patient engagement model you chose for the implementation of your project.

When developing your project budget, please make sure that adequate and realistic resources for patient engagement are reflected in the Patient Engagement Plan and the overall grant budget request. This could include e.g. appropriate budget for work time (staff or contractors in patient organizations) as well as project-related pass-through costs (e.g. travel expenses and meeting venue costs).

Different phases of research will need different activities to ensure patient engagement is implemented in the way defined in this document, *for example Phase I first in human studies may require a different approach than other studies.*

We accept different formats of patient engagement plan, as long as:

- Activities proposed are listed and properly described;
- Activities proposed are designed for patients and with patients; and
- The results of these activities are implementable in the clinical trial design or execution to ensure patient needs are met

Be very clear at the outset about what you expect to achieve and what metrics – both quantitative and qualitative – you will use to measure progress against and achievement of both overall research goals and specific patient-centricity goals.