

Guidance for Developing A Patient Engagement Plan

Applicants for the RTFCCR-MRA Special Opportunity must submit a "Patient Engagement Plan" as part of both the LOI and Full Application. The plan should describe the patient engagement processes during the generation of the application, as well as in the design of the trial and during the trial. It describes engagement e.g., how the applicants engaged with the patient community when the research question was defined, while the proposal was written, and which patient engagement model the applicants chose for the implementation of the project.

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

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

We encourage you to use the template in the Upload Attachments section of the application in Proposal Central, but will also accept different formats of the 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 implemented in the clinical trial design and/or execution to ensure patient needs are met.

We define patient engagement as meaningful engagement of patients in the development of therapeutic, detection, or prevention approaches. It encompasses the active, meaningful, and collaborative interaction between patients and researchers across all stages of the research process, where research decision making is guided by patients' contributions as partners, recognizing their specific experiences, values, and expertise.

For this Special Opportunity, we are adopting Patient-Centered Outcomes Research Institute's (PCORI) definition of **Patient Partners**: it includes patients (those with lived experience), family members, caregivers, and the organizations that are representative of the population of interest in a particular study.

It is important that Patient Partners are not confused with trial participants. Patient Partners are members of the research team and involved in the planning, conducting, and dissemination of the research, whereas trial participants are those individuals actually enrolled into the study.

The strategy, modalities, and budgets, related deliverables, and expected outcomes for patient engagement must be clearly described in the application.

Guidance for Planning 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, identifying, and solving potential challenges faced during the trial, and better application of outcomes to specific contexts.

Here is a checklist to help applicants plan patient engagement and complete a Patient Engagement Plan that is required as part of both the Letter of Intent and Full Application. It encompasses points that should be considered before the trial starts, during the trial, and beyond.

Before the trial 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 and 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 trial

- Assessment of needs of trial participants by Patient Partners is included;
- Adaptation of trial and procedures where necessary to meet trial participants' needs; and
- Assessment of the impact of patient engagement in the trial at mid-term and at the end of the trial is considered.

Beyond the trial

- Communication and dissemination of study outcomes with patient/public partners is planned after trial 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 trial:

Patient role	Examples	Engagement level
Consultant role	<ul style="list-style-type: none">• Patients provide a priori 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 or provide a priori 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 or a priori 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