

QUESTIONS TO CONSIDER WHEN PLANNING CONSUMER INVOLVEMENT FOR A CLINICAL TRIAL

If you have not considered consumer and community involvement in the past, these questions may provide insights into some of the areas across a study's life cycle where involvement may help ensure your study is patient centred. Further information on these areas can be found in the Toolkit.

RESEARCH AIMS

- Is the research question important to patients/carers or the health service?
- Does a core outcome set exist for this condition? (e.g. through the COMET Initiative¹)? If not, are the outcomes chosen for this study the most important to potential patients?

RESEARCH DESIGN

- Is the magnitude of the difference being measured relevant to patient care?
- Are there potential ethical issues with the study design?
- Will the planned process for seeking informed consent be acceptable to potential participants; both the approach and the timing of that approach?
- Does the Participant Information and Consent Form (PICF) have the right amount of information to allow a potential participant to decide whether or not to take part?
- Is the PICF written in plain language with as few non-technical terms as possible?

RECRUITMENT AND RETENTION

- Will the additional burden of study participation be acceptable or is it likely to impact on potential participants' willingness to take part?
- What concerns may potential participants have about the planned intervention and its associated risks when compared with normal care for the condition?
- Is the study taking the right approach to recruitment? Is there any way it could be improved?
- What is the best way to raise awareness about the study with appropriate consumer groups or with the community to maximise recruitment?
- What is the best way to maintain participant interest in the study over time?
- If recruitment challenges arise, what would be the best way to address these?
- What information might potential participants like to receive through the study website/newsletters?

¹ [The COMET Initiative](#)

ANALYSIS, DISSEMINATION & IMPLEMENTATION

- Could consumers have a different interpretation of the study results/sub study results to the researchers?
- How readable and understandable is the Plain English/Language Summary for the study results?
- How readable and understandable is the lay Summary providing participants with information on the study outcome?
- How readable and understandable are the communication materials about the study results for the community (e.g. written information, presentations to consumer groups)?
- How might participants wish to be provided with access to study results, will they all want to receive the information?
- What are the best ways of disseminating study results to the wider community?
- Are there any gaps in the dissemination plans and are the right people/organisations involved?
- How could consumers provide support for implementation (e.g. develop training materials)?
- How should local implementation of the study results in the community be managed?