

Patients and public Involvement in the study

Please ensure that the below questions are properly addressed in your study proposal submission package (if needed a separate document could be uploaded as annex).

During the study design:

In this document we will use the term 'patient' for simplicity and clarity sake however please be aware that by this we mean any individual with lived experience either directly or indirectly and that some of these individuals may be carers or members of the public who are not patients at that time (studies on pregnant women or studies on subjects e.g. of vaccines). Other terms can also be used e.g. patient representatives, patient advocates, patient experts.

1. How have you involved patients in the study set-up and how will you ensure their input is meaningful such as:
 - a. Did you create a patient advisory group through your own research team or speak informally with patients
 - b. Which patient organisation(s) have you contacted to get patient input for your study proposal or how have you done this?
 - c. What input have patients had in the selection of the clinical question (how can you demonstrate that this is a high priority question for patients)?
 - d. What input have patients had in the selection of the outcomes and the possibility to comment on the minimal important difference (relevance)?
 - e. What input have patients had in the evaluation of the equipoise between the study arms/treatments?
 - f. Did patients assess the burden of the study procedures and visit schedule?
 - g. Did you involve the general public in any way not mentioned above, informal care givers etc.

During the study set-up

2. How will patients be involved in the study set-up and how will you ensure their input is meaningful such as:
 - a. Reviewing Informed consent forms, reviewing questionnaires to assess the burden to patients, reviewing patient diary questions/timepoints, reviewing study website if patient facing, reviewing recruitment tools and how best to publicise the study (also through patient organisations), etc.
 - b. Involving patients in the feasibility assessment and check if there are specific questions they have on the acceptability of the study for patients which should be asked to sites
 - c. Participation in Trial Steering Committee meetings (with discussion/support beforehand to ensure it is clear what input is expected and participation can be meaningful)

During the study conduct

3. How will patients continue to be involved in the project during study conduct and how will you ensure their input is meaningful?
 - a. Participation in the Trial Steering Committee (with discussion/support beforehand to ensure it is clear what input is expected and participation can be meaningful)

- b. Review of protocol amendments, review of changes to informed consent documents, assessment of the burden on the participants if assessments changes, if new information becomes available reassess the equipoise
- c. Input in the plan to boost recruitment, if applicable
- d. Etc.

During the analysis and report

- 4. How will you involve patients in the analysis of the study results and the writing of the clinical study report?
 - a. Help with interpretation of questionnaire results or PROs
 - b. Review the clinical study report or comment via the Trial Steering Committee (and they should be acknowledged for their input)

Communication during the study and communication of the study results

- 5. How will you involve patients in communication during the study and in the communication of the study results to the study subjects and to the general public?
 - a. Help plan how best to thank the participants (letter, info on website etc.)
 - b. Ability to give a patient view on the results via many communication media
 - c. Review communication material and if appropriate material to communicate to GP
 - d. Communication to specific patient group(s) or via patient managed channels
 - e. Help publicise results activities to patients and patient groups

Definitions:

GP: general practitioner

Feasibility assessment: The Chief Investigator should assess the feasibility of the study from a site and patient perspective. Therefore specific questionnaires for potential participating sites are prepared. KCE in collaboration with a Contract Research Organisation (service provider) and the study team, will visit participating sites to check accrual commitments and predictions.

PRO: Patient Reported Outcomes e.g. quality of life, symptoms diary.

Trial Steering Committee: The role of the Trial Steering Committee (TSC) is to provide the overall supervision of the trial. The TSC should monitor trial progress, conduct and advise on scientific credibility. The TSC will consider and act, as appropriate, and ultimately carries the responsibility for deciding whether a trial needs to be stopped on grounds of safety or efficacy. The TSC is composed of the CI, the trial statistician, the trial Project Manager, an independent expert, a representative of other participating centres or groups, up to 2 patients or members of the public, 1 representative of the sponsor, 1 representative of the funder, adapt/complete as applicable.