Opportunities for patient and public involvement (PPI) in trial design

The involvement of patients in trial design has recognised benefits. Research shows that patients have better outcomes in research-active centres and that patients who are involved in research know more about their condition. Patients and carers have unique experience and expertise which they can bring to trial design. This enables them to be part of the solution to the problems faced by researchers when designing a trial.

The guidance here suggests opportunities for lay involvement for both patients and researchers to consider when designing a trial. It is not an exhaustive list, nor is it anticipated that patients would involve themselves in all of these opportunities; just the ones that are relevant and appropriate.

Ideas generation

- Deciding and articulating the question
- Articulating the difference that lies within the question
- Prioritising the question

Project design

- Feasibility of randomisation
- Content of control arm
- Recruitment strategy
- Consent methodology
- Consent approach
- Staging posts for data collection
- Location points of data collection
- Burden and fatigue issues
- Identification of PPI as co-applicant
- Outcome measures: survival, progression-free survival (PFS), overall survival (OS), local control, metastatic free survival, toxicity – acute / chronic, quality of life
- Lay summary
- User testing
- Align patient-related outcome measures (PROMs) used to measure effectiveness
- Contributing to writing protocol document

Funding application

- Content of outline guide for focus groups
- PPI as co applicant
- Involvement at submission
- Articulate how the research proposal has benefitted from PPI

Study preparation

- Comment on participant information and consent form
- Input into ethics application
- Input into ethics committee
- Patient preparation of protocols

Study execution

- Membership of reference/steering group
- Be a voice for the consumer during the study execution

Dissemination of results

- Write lay summary of findings
- Dissemination to lay people and appropriate organisations, including clinical community
- Content for focus groups/data collection tools
- Be a voice for the researcher and for the consumer community
- Writing the final paper for dissemination

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You can download this document here: http://www.ncri.org.uk/ctrad/res/ppi_in_trial/