METHODICAL study results.

The table below shows the PPI research topics in order of priority. The priority was agreed at a face to face meeting of 12 lay and 13 non-lay people involved in PPI following the online Delphi survey. Grey shaded rows show topics that were thought to be of critical importance by over 70% of the people at the meeting.

Ranking	Topic Title	Help Text	Percentage of people who thought the topic was critically important
1	Developing strong and productive working relationships between researchers and PPI contributors	Research on what defines and enables a good working relationship between researchers on a trial team, trial committee (e.g. trial steering committee or ethics committee) or funding panels and PPI contributors? Exploring the impact of role descriptions, selection criteria, clear expectations, language, communication and handling conflict.	96%
1	A systematic review of PPI activity in improving the accessibility and usefulness of trial leaflets and information sheets for clinical trial participants	Patient/public contributors often help trial teams to design and produce information sheets. An assessment of existing research to evidence how PPI impacts patients understanding and acceptability of PIS within trials? How do PPI contributors write or review Patient Information Sheets? How often are they given guidance for this? Do trial teams listen to the advice of PPI contributors, how often are their changes adopted?	96%
1	PPI practices in selecting trial outcomes of importance to patients	A review of PPI practices that influence the primary outcomes within clinical trials e.g. seizure control at 6 months, time to healing. How often are these outcomes that are important to patients, and what role did PPI play in the decision making process?	96%
4	Adapting PPI to the particular needs of individual clinical trials	Research on how to tailor PPI plans to take into account key design features or specific patient groups e.g. critically ill patients or children, including how the needs of clinical trials for PPI might change over the life of a trial, For example would a specific type of trial benefit from the use of patient panels rather than having one or two lay members on the trial steering committee?	92%
4	PPI practices to address the challenges of recruiting and retaining participants (e.g. patients) in clinical trials	Exploring the effectiveness of PPI practices to improve recruitment of patient participants (i.e. the people taking part as ‘subjects’ in clinical trials), or help keep patients within a trial.	92%

4	The resources needed for PPI activity including time and money.	What are the resource implications for undertaking PPI? Do resource limitations impact upon PPI activity? What is spent on PPI activity for grant applications? How much budget is allocated within trials, what does it actually cost and is it possible to quantify the benefits in monetary terms? Evaluating current payment systems upon Involvement of PPI contributors at all stages of a trial.	92%
7	PPI practices in selecting how to measure trial outcomes	A review of how PPI is used to decide on how outcomes are measured. For example how does PPI contribute to deciding whether a trial should collect data from patients using a weekly diary or a monthly questionnaire?	88%
8	How is PPI involved in the dissemination of results and assessment of effectiveness?	A review of how PPI contributors are involved in writing lay reports for patient organisations or trial participants and presenting findings at conferences. Does involving PPI contributors impact on the effectiveness of dissemination? How often are funds available for this PPI work?	84%
9	How do PPI contributors achieve and maintain an authentic patient perspective?	How does personal experience along with social demographics shape the perspective and input of a PPI contributor? Do PPI contributors become “professionalised” (i.e. more like researchers) over time? What helps to avoid this and keep them “in touch” with the authentic patient perspective? Do PPI contributors collect feedback from members of the public/ other patients to help them in their role? If so what methods do they use and are they effective?	84%
10	Effectiveness of different methods to capture wider patient or public perspectives on clinical trial designs e.g. surveys, social media	PPI traditionally involves one person or small numbers of patients or public representatives seeking to share a ‘lay perspective’ on trials. This research would look at ways to involve larger numbers of people in PPI within clinical trials.	80%
10	What is the impact of PPI activity on the experience of patients who participate in a clinical trial?	Assessing the impact of PPI activity on a patients experience of trial participation, including their experience of consent, treatment, follow up and communication of the results.	80%
12	Developing critical appraisal guidelines for funding boards to assess PPI activity within funding application forms	Clinical trialists are increasingly required to describe their PPI plans within funding applications, but how do funding boards assess this information? How feasible is the funding organisation’s PPI policy? Is research needed to develop guidelines for funding boards to help them assess the quality of PPI within clinical trial proposals?	79%
13	Exploring the role of PPI in the early stages of testing of new treatments (e.g. Phase 1 and Phase 2 trials)	Understanding current PPI practices in Phase 1 trials (where new treatments are tested in a small number of patients) and in Phase 2 trials (where new treatments are tested in a larger group of patients with the same health condition). Identifying how PPI can be developed in early phase trials. This topic does not include Phase 1 trials that test interventions in healthy volunteers	79%
14	Reviewing PPI and the involvement of patients in	A review of how PPI and patients are involved in choosing what research is undertaken within clinical trials.	76%

	setting research priorities for different health conditions		
15	Core outcomes for assessing PPI impact	Development of a minimum set of outcomes for assessing PPI impact and agreement about how these should be measured. A set of core outcomes for PPI would allow comparison across trials, however it is unclear what is most important to assess. For example PPI impact could be measured on recruitment rates, retention rates, levels of missing data, or need for funding extension.	76%
16	Assessment of different methods (e.g. social media, incentives) to increase the diversity of PPI contributors (age, ethnicity, socioeconomic status, disability)	Research on how diverse PPI contributors are within trials? Is there good inclusion of people of different ages, ethnicities, socioeconomic, educational backgrounds? What groups are not currently involved and what methods can ensure people from a wider range of different backgrounds and walks of life get involved?	72%
17	Ongoing support and development for PPI contributors	How are PPI contributors supported throughout their roles? Do PPI contributors with physical difficulties (e.g. hearing loss or mobility limitations) receive appropriate support to assist engagement? Do PPI contributors want opportunities for feedback and development within their roles?	68%
18	Ways to negotiate with PPI contributors about their role within a trial (induction practices)	Exploring the content and format of effective ways to help PPI contributors learn about their roles in trials and refine or negotiate their roles. How are training needs assessed at induction?	64%
19	The inclusion of PPI activity within existing trial guidelines e.g. SPIRIT, CONSORT	Guidelines inform the practices and processes within Clinical Trials. For example SPIRIT offers a framework for writing trial protocols and CONSORT for publishing trial results. Do existing guidelines include recommendations around PPI, and what should be included?	64%
20	Assessing the impact of PPI activity on trial staff	What makes for a positive vs. negative experience of PPI? What is the impact on trial staff time, productivity, skills, confidence, motivation, perceived power, career etc?	63%
21	Developing common values, principles and standards for PPI specifically for clinical trials	Existing guidance from INVOLVE covers values, principles and standards for PPI across all types of health research. This work would develop a framework specifically for clinical trials, describing how PPI should be conducted within them. For example setting goals and objectives for PPI in a trial.	60%
22	Review of PPI practices in trials that stopped early	Are there any lessons that can be learnt about PPI from trials that stopped early for problems associated with trial design and conduct e.g. poor recruitment or retention? For example, reviewing the reasons for stopping the trial early, trial context and PPI activity? This does not include trials that stopped early due to treatment effect (e.g. confirmed benefit or suspected harm)	60%

23	Guidance for reporting PPI activity and impact in trial publications	How frequently is PPI activity included within journal articles and newspaper reports of clinical trials? What type of information is communicated and is it more frequently reported in certain journals or for certain types of trials? How should PPI activity be reported given the restrictive word counts within journals? When should PPI be reported in main trial publications and when should a separate PPI focused paper or hybrid approach be used? What terms would be useful for tagging PPI research within databases of journal articles (e.g. MESh terms) to allow researchers to identify and use data across trials?	54%
24	Funding application timescales and the impact on PPI quality in designing clinical trials	What is the impact of timescales for preparing and submitting funding applications impact on the plans and does this affect the quality of PPI in the early stages of a trial? What is the best application of PPI within the possible timeframes?	52%
25	Understanding how Research Ethics Committees review PPI plans and activity in trials	How are PPI plans and activity in the design process of a trial taken into account during the ethics review process? Does PPI affect the ethical decision making process? Do different ethics committees take similar approaches to reviewing PPI?	48%
26	Training needs assessment for researchers, trial managers and PPI contributors	Do PPI contributors, chief investigators, trial managers and other trial staff want or need training on PPI in clinical trials? What training is currently available and what needs developing?	44%
27	Review of factors influencing the attendance of PPI contributors at Trial steering committee and Trial Management group meetings	Exploration of the attendance levels by PPI contributors, along with any effective approaches which could maximise attendance? For example does the approach to organising meetings limit PPI contributors attendance? What options are available for maintaining the involvement of people with poor health status?	44%
28	Selection methods for PPI contributors	Research on what criteria (e.g. PPI person specifications) and processes (interviews) are used to select PPI contributors? Do trial teams tend to select people who share their views, or are already known to them and if so how does this influence the effectiveness of PPI?	44%
29	Learning lessons from other academic sectors, public services, third sector and business to inform PPI models for clinical trials	Exploring PPI models from other sectors and types of health research to inform clinical trials.	40%
30	Assessing the impact of PPI activity on PPI contributors.	What makes for a positive vs. negative experience of involvement? What is the impact on PPI contributors' skills, knowledge, self-esteem, time, emotional burden, career opportunities, etc.?	38%
31	Reasons for involvement and refusing involvement by potential PPI contributors	Research on why patients and members of the public become involved within trials and why might they decline invitations? Why might people feel they have nothing to contribute?	36%

32	Sources for identifying and approaching PPI contributors e.g. social media, charities, community organisation.	Research on how are PPI contributors are identified and approached to become involved in the design and conduct of clinical trials? What are the most effective sources/ways to do this and what are the challenges?	24%
33	Exploring why PPI contributors may want or need to stop their involvement early.	Clinical trials can run for many years, making it difficult for people to be involved throughout the lifetime of a trial. This research would explore the reasons why PPI contributors may need or want to stop their involvement, along with the benefits of PPI contributor continuity and practices that help facilitate longer term involvement.	24%
34	Do journals review PPI activity during the editorial process	When considering a trial report for publication, do journal editors consider or assess PPI involvement? Do they give any feedback about PPI reporting?	17%
35	To what extent are lay members involved in reviewing manuscripts for journals and what is the impact of this?	How are patients and members of the public involved in reviewing articles for publication within journals? What influence do they have within the editorial process? How does this work alongside or as part of the peer (professional) review process?	16%
36	Comparing the effectiveness of patient/public panels versus individual patients/members of the public in clinical trials	Research on which is more effective – involving panels (groups) of patients/public contributors within a trial, and/or one or two patient/public contributors? Is there an optimal number of PPI people for various activities?	16%
37	Defining the boundaries between PPI and qualitative research	Research on understanding what is PPI and what is qualitative research? Does there need to be a clear distinction to assist research teams and funding reviewers?	13%
38	10. Assessing involvement of the wider trial team (e.g. statisticians, health economists) in planning and delivering PPI activity	Is PPI activity currently managed by Chief Investigators and trial managers/ trials co-ordinators? To what extent do other trial team members such as statisticians, data managers, qualitative methodologists and health economists help plan and implement PPI? Does who manages PPI activity impact upon trial design and conduct?	12%
39	Exploring the definition of PPI and people's understanding of it	What is PPI? What do different groups of people consider as PPI? What are the boundaries between involvement, engagement and participation in trials? (Whilst INVOLVE have written a definition of PPI, we have included this due to the number of people who took part in round 1 of this Delphi who suggested it as a new topic)	12%
40	Mapping PPI activity and practices within UK Clinical Research Collaboration CTUs	Involvement of one of the 47 registered clinical trials units is often recommended to use their knowledge and expertise to ensure trials are well run and minimise resource waste. Research into how PPI conducted within this network, and what approaches are used to monitor and develop PPI activity.	8%