

PIRRIST: A patient and public involvement (PPI) intervention to enhance recruitment and retention in surgical trials

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Overview of seminar

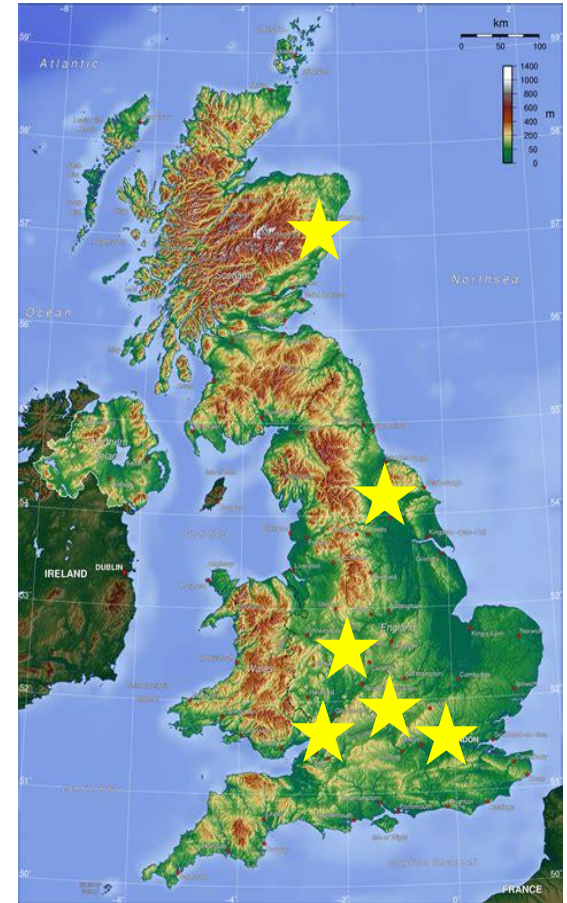
- What's the problem?
- What do we mean by 'PPI'?
- Impact of PPI on recruitment & retention in clinical trials
- Aims of PIRRIST project
- Methods
- Key findings
- PPI recommendations
- Practical guidance development
- Dissemination plans



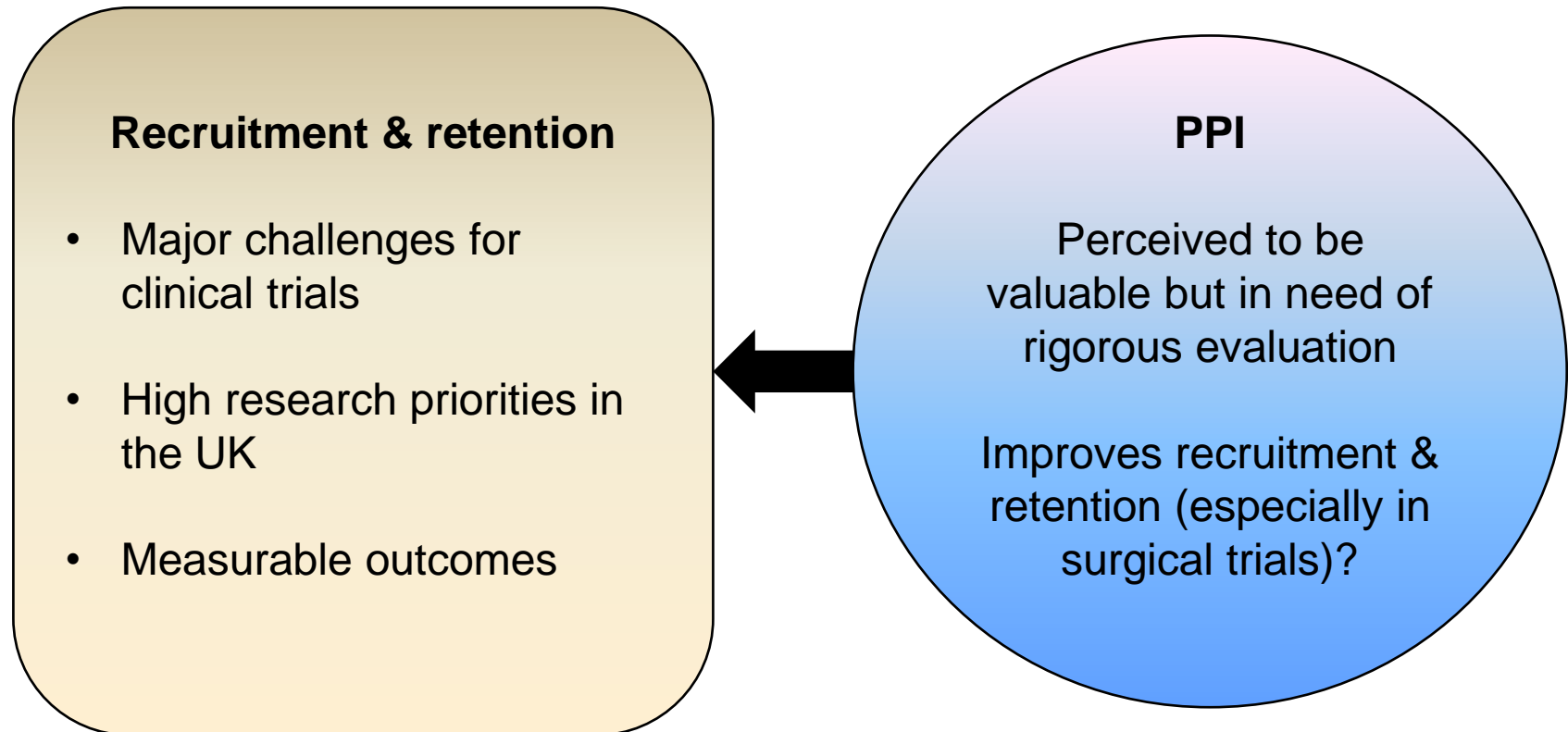
Please complete feedback forms. Thank you!

Dissemination & feedback events

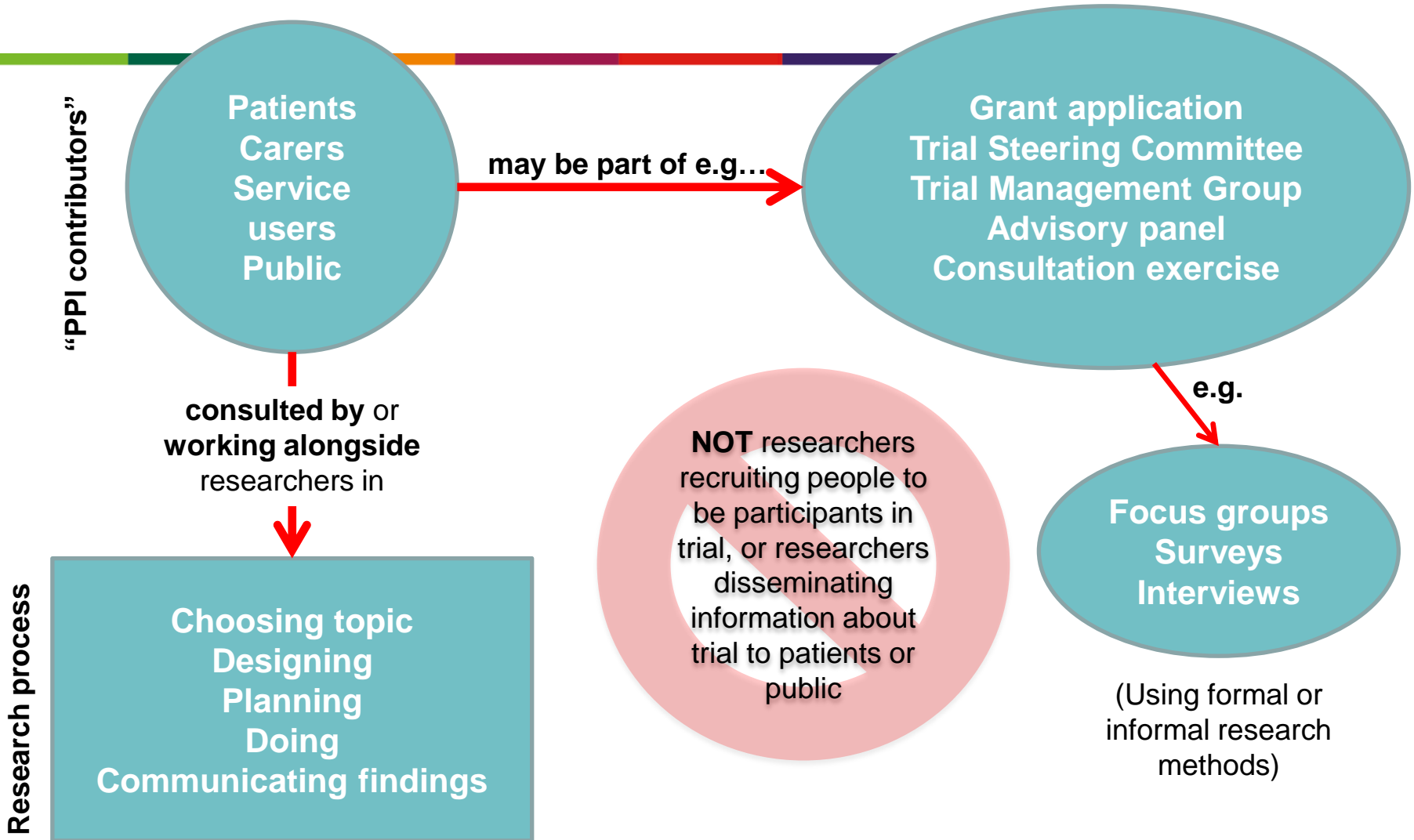
- Surgical trial centres:
Birmingham, York, Bristol,
Aberdeen, Oxford
- Patients and lay contributors:
NCRI Consumer Forum, PPI
workshop at Library of
Birmingham, webinar



What's the problem?



Definition of PPI



Impact of patient involvement in mental health research: longitudinal study

Liam Ennis and Til Wykes

- **374 studies** in the Mental Health Research Network portfolio
- Greater patient involvement associated with **achievement of recruitment targets** ($p < 0.05$)

RESEARCH

 OPEN ACCESS

 Check for updates

Impact of patient and public involvement on enrolment and retention in clinical trials: systematic review and meta-analysis

Joanna C Crocker,^{1,2} Ignacio Ricci-Cabello,^{3,4,5} Adwoa Parker,⁶ Jennifer A Hirst,⁷ Alan Chant,² Sophie Petit-Zeman,² David Evans,⁸ Sian Rees⁹

BMJ: first published

- **Eligibility criteria:** Experimental and observational studies quantitatively evaluating impact of a PPI intervention, vs. non-PPI or no intervention
- **Meta-analyses:** Average effect of PPI interventions on enrolment & retention; several exploratory subgroup & sensitivity analyses.

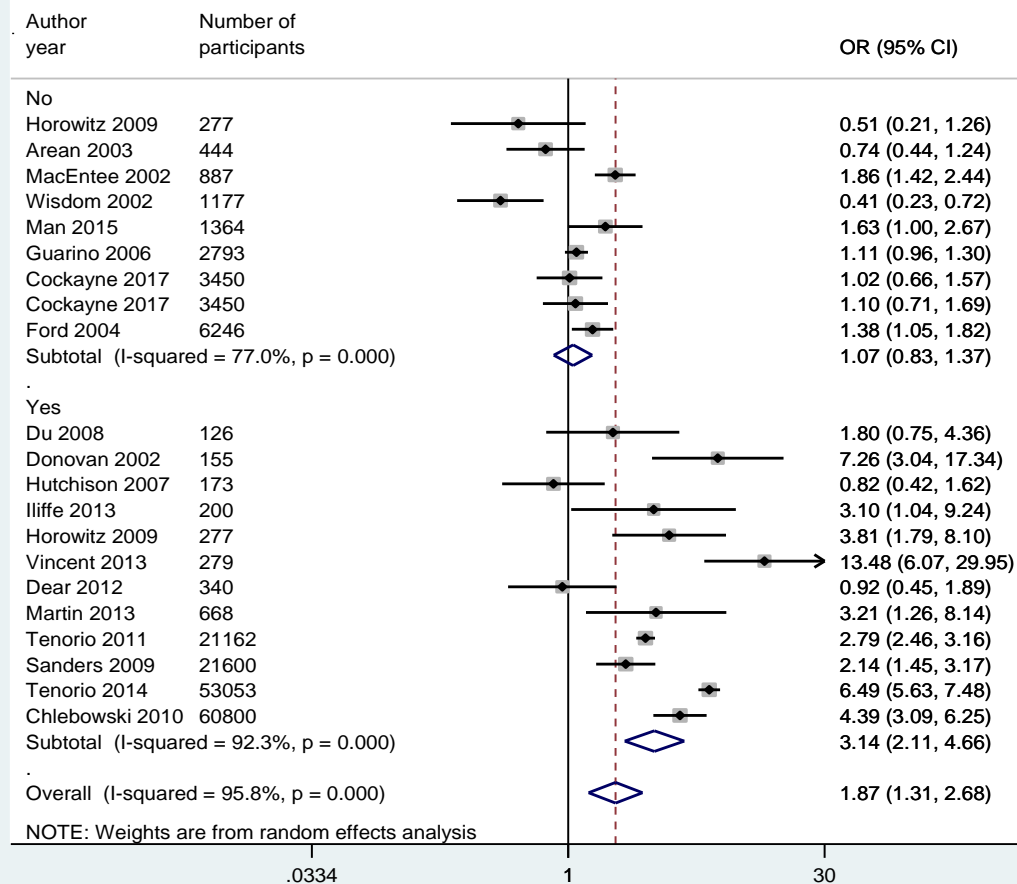
Systematic review: Key findings




- 26 studies included in review (19 eligible for enrolment meta-analysis and 5 for retention meta-analysis)
- Wide variation in PPI characteristics & effect size
- On average, **PPI interventions modestly but significantly increased the odds of participant enrolment** in our main analysis (OR 1.16 [95% CI and prediction interval 1.01 – 1.34])
- Retention findings inconclusive due to lack of studies (OR 1.20; 95% CI 0.68 – 2.12 for main analysis)

Crocker JC et al. BMJ 2018;363:k4738.

Results by 'lived experience' (n=19)



p = 0.017



To **develop a PPI intervention** aimed at improving recruitment and/or retention in surgical trials

- helping to develop our understanding of **whether** and **how** PPI might improve recruitment and retention in clinical trials
- leading to a mixed methods study to **implement** and **evaluate** the PPI intervention in UK surgical trials

Surgical trials

- ✓ Trials of a surgical intervention
- ✓ Trials in a surgical context, where surgery is involved but is not one of the interventions under evaluation

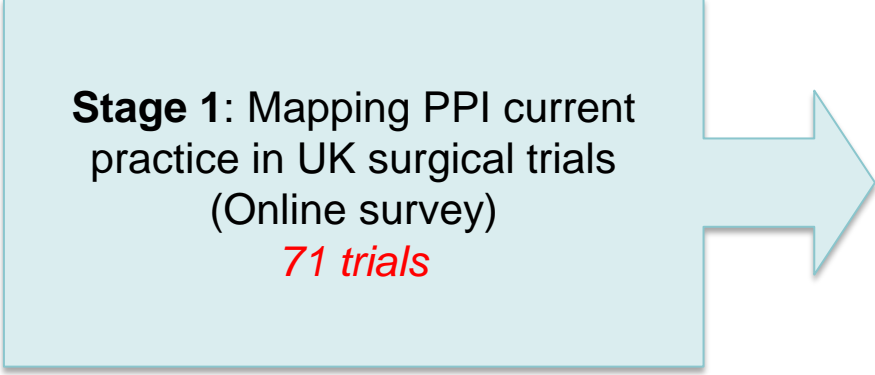


Methods: Overview

- **3 key stakeholder groups:**
 - Surgical trial staff (trial managers, investigators, administrators, research nurses)
 - Patients & members of the public involved in trials
 - PPI coordinators
- **Mixed methods:**
 - Surveys
 - Focus groups
 - Consensus workshop



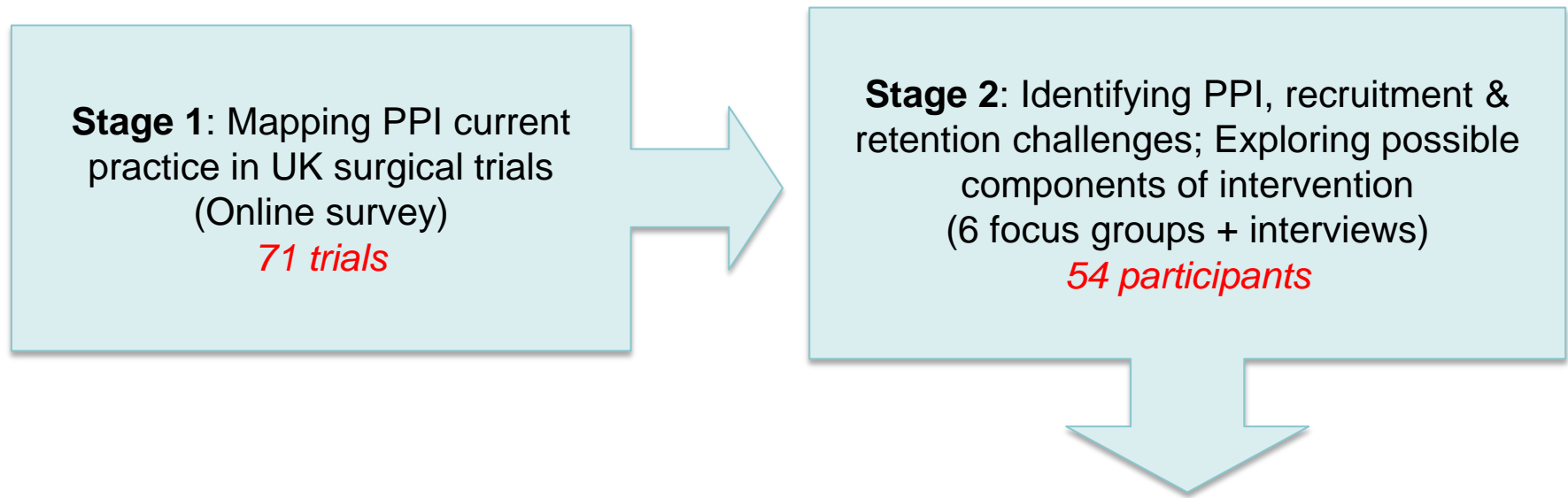
Methods



Stage 1: Mapping PPI current
practice in UK surgical trials
(Online survey)
71 trials

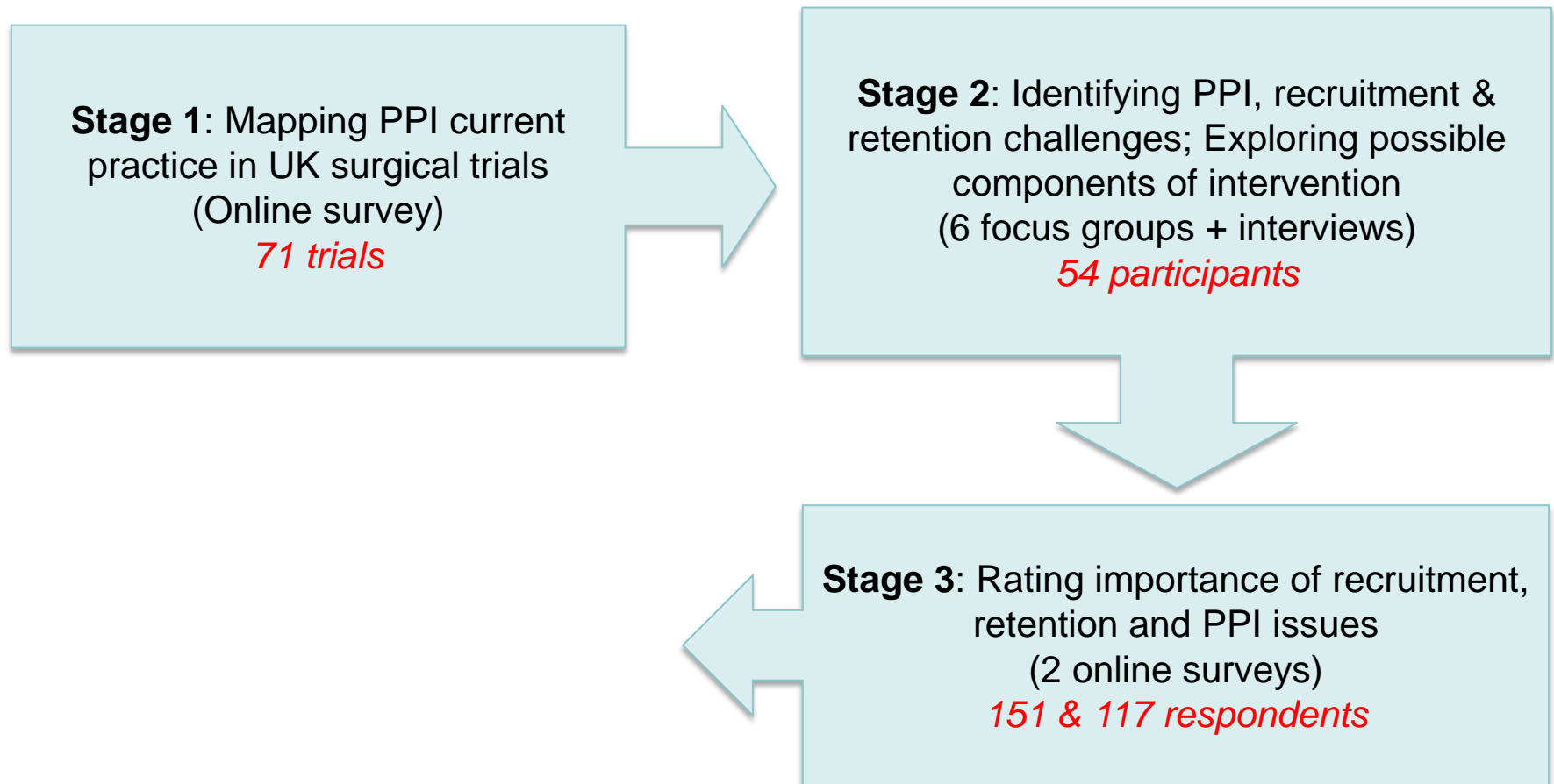
Crocker JC, et al. *Patient and public involvement (PPI) in UK surgical trials: a survey and focus groups with stakeholders to identify practices, views, and experiences*. Trials. 2019;20(1):119.

Methods

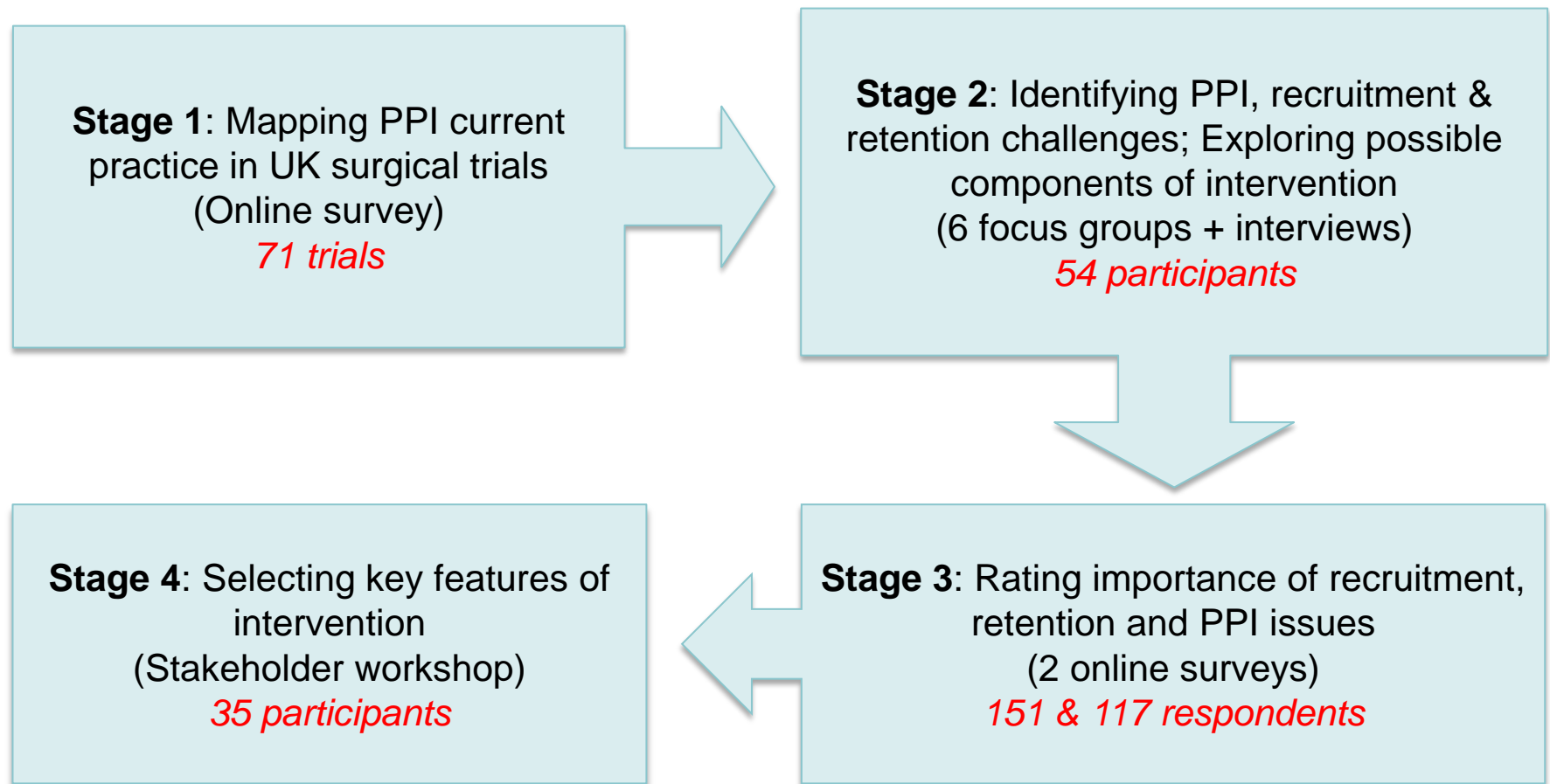


Crocker JC, et al. *Patient and public involvement (PPI) in UK surgical trials: a survey and focus groups with stakeholders to identify practices, views, and experiences*. Trials. 2019;20(1):119.

Methods



Methods



Key findings



- **92%** surveyed trials reported some kind of PPI, most commonly in **oversight (TSC)** or **advisory** roles.
- **Earlier involvement** enables more pathways to impact on recruitment & retention. PPI in **trial design** (including funding proposal) was considered essential.
- PPI should include patients/carers with **personal experience** of target health condition (although lay people can also help).
- **Two-tier** model of PPI appears effective but is uncommon.

Benefits of having a separate patient advisory group...

We found it's worked really well to have it separate actually, and you can just focus on the things that need talking about with them, rather than I suppose them having to sit through an entire meeting where maybe only certain bits of it might be relevant for them. [...]

In addition to how it helps the trial, I think patients really value coming along to a meeting of just patients and just all sharing their stories actually.

(PS24, PPI coordinator, focus group 4)

Example of PPI in designing recruitment methods...

They [PPI contributors] had the idea of using social media as a possible avenue to approach patients because of the type of patients in the trial – they were younger and they're more inclined to use Twitter and Facebook... And with their input we started to develop entries for Facebook and to use on Twitter, and our recruitment virtually tripled as a result of using that.

(PS08, trial manager, focus group 2)

Key findings



- Top **recruitment** issue = Patients preferring one treatment over another' (82%)
- Top **retention** issue = Patients failing to return follow-up questionnaires (81%)
- Top **PPI** issue = Trial staff lacking time to do PPI (50%)
- Trial staff want help **recruiting** suitable PPI contributors

Having a dedicated PPI coordinator...

And I think maybe also in order to retain both your PPI members and your participants, you need somebody who is nominated to do that... whose role is to look after them. So, all the nuts and bolts of doing PPI; all the logistical stuff which is what takes up so much time, as well as being able to answer questions.

(PP14, PPI contributor, focus group 6)

PPI recommendations

Trial design & funding proposal Trial protocol & patient-facing materials

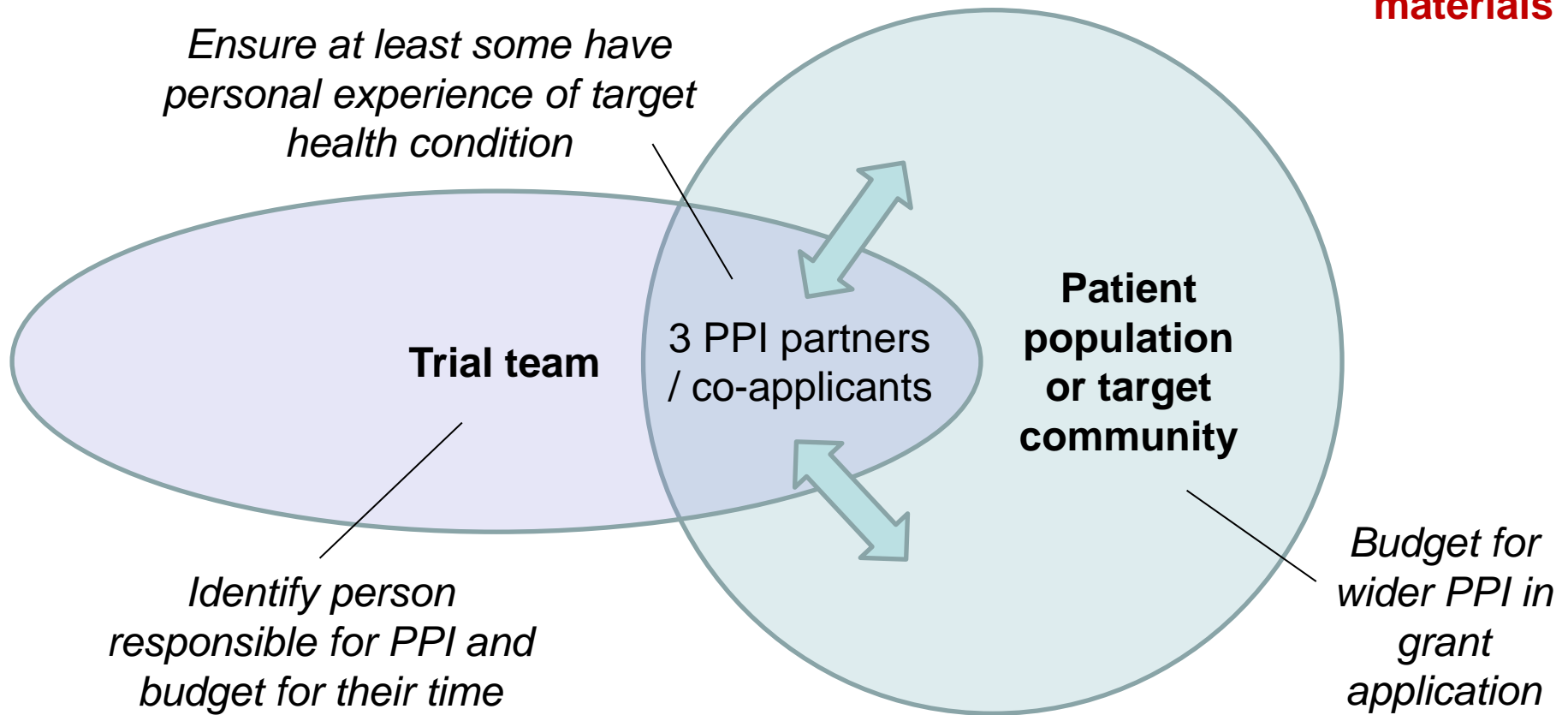
- ✓ Minimising burden on participants
- ✓ Increasing benefits to participants
- ✓ Assessing acceptability of randomisation and placebo
- ✓ Planning appropriate & effective recruitment and retention strategies

- ✓ Designing attractive/appealing recruitment materials and messages
- ✓ Improving informed consent
- ✓ Ensuring questionnaires / data collection tools are as easy to use as possible
- ✓ Communicating with participants throughout trial to keep them engaged

PPI recommendations

Trial design & funding proposal → **Trial protocol & patient-facing materials**

*Ensure at least some have
personal experience of target
health condition*



Guidance: design specifications



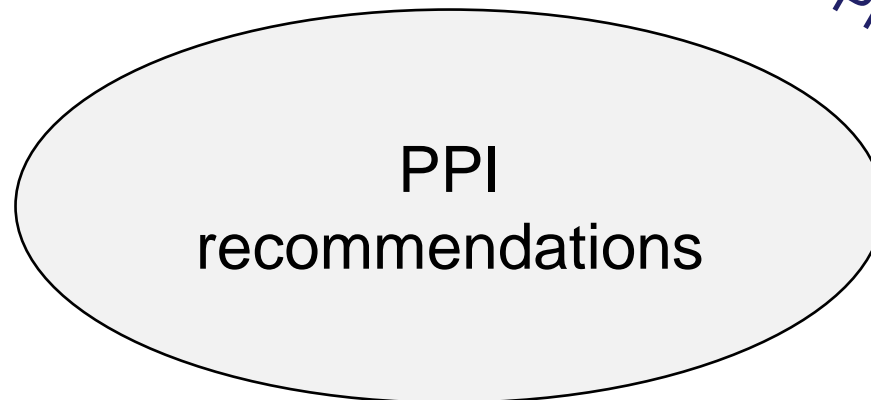
- Aimed primarily at Chief Investigators
- Persuasive (why important?)
- Able to be used flexibly or with a 'pick and mix' approach
- Succinct (2 A4 sides long)
- Practical (embedded tips & hyperlinks)
- Not re-inventing the wheel but signposting to existing resources, where available
- Structure: chronological steps?

Practical guidance: content



Tips and resources to
aid recruitment &
retention of suitable PPI
partners

Training
resources for
trial staff and
PPI partners

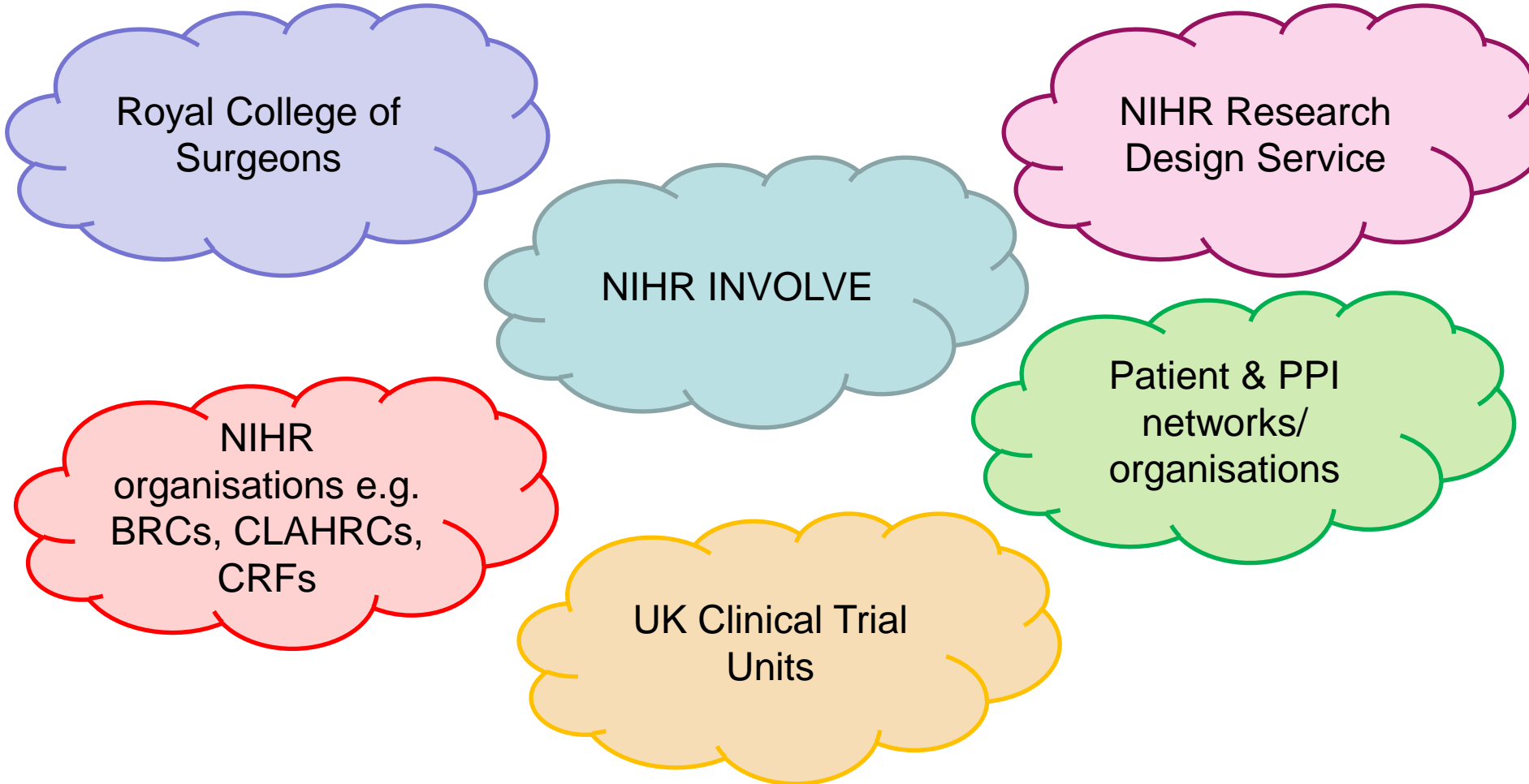


Examples of outreach
and innovative PPI

Questions to ask PPI
contributors

Resources to help
budget for PPI

Dissemination routes



Royal College of
Surgeons

NIHR Research
Design Service

NIHR INVOLVE

NIHR
organisations e.g.
BRCs, CLAHRCs,
CRFs

Patient & PPI
networks/
organisations

UK Clinical Trial
Units

Messages for funders & institutions



- Short timeframe for grant applications limits quality of PPI
- PPI needs to be well funded, including staff time & training if needed
- Need for more funding to be made available for pre-grant PPI
- Consider funding expert PPI coordinator and database of potential PPI contributors

Thank you

- All participants for their time and generosity
- Collaborators and advisors
- Funders: NIHR Oxford Biomedical Research Centre & Network of MRC Hubs for Trials Methodology Research

Email: pirrist@phc.ox.ac.uk
Website: www.phc.ox.ac.uk/pirrist

5th International Clinical Trials Methodology Conference

ICTMC

2019

Sunday 6th to Wednesday 9th October 2019
Hilton Metropole, Brighton, UK

Key Dates:

Abstract Submission Deadline: Sunday 5th May 23:59 BST

Notification to Authors: Week Commencing 17th June

Early Registration Deadline: Monday 8th July

ictmc@in-conference.org.uk

www.ictmc2019.com

