

# Co-designing patient facing interventions to increase ethnic representation in Clinical Trials

Jacqueline Nuttall<sup>1</sup>, Liz Allaway<sup>1</sup>, Megan Lawrence<sup>1</sup>, Alannah Morgan<sup>1</sup>, Jeny Mathew<sup>1</sup>, Aleksandra Kusinska<sup>1</sup>, Armando Lobete Ejeleri<sup>1</sup>, Kate Henaghan-Sykes<sup>2</sup>, Sonia Newman<sup>2</sup>, Rashmi Kumar<sup>3</sup>, Emily Lam<sup>3</sup>, Gareth Griffiths<sup>1</sup>, Cherish Boxall<sup>1</sup>

1. Southampton Clinical Trials Unit, University of Southampton; 2. Primary Care and Population Sciences, University of Southampton; 3. Lay Members



## INTRODUCTION AND BACKGROUND

Recruiting ethnically homogenous populations to clinical trials creates a gap in evidence for optimal treatment in minority groups and potentially harmful consequences for their health and widens existing health disparities.

Recruitment for several Southampton Clinical Trials Unit trials does not reflect the ethnicity of the populations affected by the diseases under investigation.

- UNIVERSAL (respiratory) study, **96.9%** of the **661 participants** identified as **White**, while a more **representative sample** would be around **85% White**.
- ATTACK (kidney disease) study has a **97.0% White** among its **4,397 participants**, whereas a **more accurate representation** would be closer to **80%**.

This project aimed to improve ethnic representation in clinical trials by developing strategies to identify and remove bias in trial materials, increase accessibility, and foster trust within ethnic minority communities.

- **Stage 1** aimed to co-design an evaluation framework to apply to patient-facing trial material for subsequent testing in a cross-CTU study.
- **Stage 2** aimed to co-design an online safe space for the public to ask questions about research

## METHODS

### 1. Participation

- Diverse ethnic representation with a broad range of experiences and perspectives invited via social media and existing community groups.
- Person centred and inclusive.



**CO-Design & Co-Facilitated by PPI**

### 2. Development

- facilitated face-to-face and online workshops.
- Interactive & engaging content.
- Verbal prompts through open ended questions.
- Creative licences were given.



### 4. Outcome and Intent

- Clear vision of outcomes were conveyed from the outset.
- Realistic expectations were set.

### 3. Ownership & Power

- Ice brakers.
- Venues participants' felt comfortable in to enable the sharing of power were chosen.
- Power imbalances were addressed early on.

## STAKEHOLDER GROUPS

### DEMOGRAPHICS



With huge thanks to all the stakeholder members who contributed to this project.

## RESULTS

### PATIENT FACING MATERIAL & THE FRAMEWORK

#### Representation

- Can you add images that show representation?
- Can you provide data on ethnic group and relevance and outcome?
- Can you design the material in a way that demonstrates all ethnic groups are invited?



#### Inclusion

- The correct language can destigmatise, enable respectful relationships, and build trust
- Can you make the participant feel valued - that their involvement matters?
- Is there a thank you for taking part (i.e incentive)?
- Will you share the results with them?.



#### Culture

- Avoid anything that makes The participant feel like they are a "Guinea Pig".
- Consider whether there any religious practices or cultural traditions that needs to be respected
- State if there has been diverse representation in the study design and docs.



#### Empowerment

- Is it clear the participant can chose whether to take part?
- Is it clear that participants can ask any questions and are in control of their involvement?
- Are research ethics explained in a way that makes the participant understand it is there to protect them?



#### Safety

- Are there flexible ways to get in contact – email, phone number, etc?
- Consider explaining how participants often get monitored more than on standard care – this can be reassuring.
- Explain NHS health systems – not all ethnic groups understand British healthcare systems.

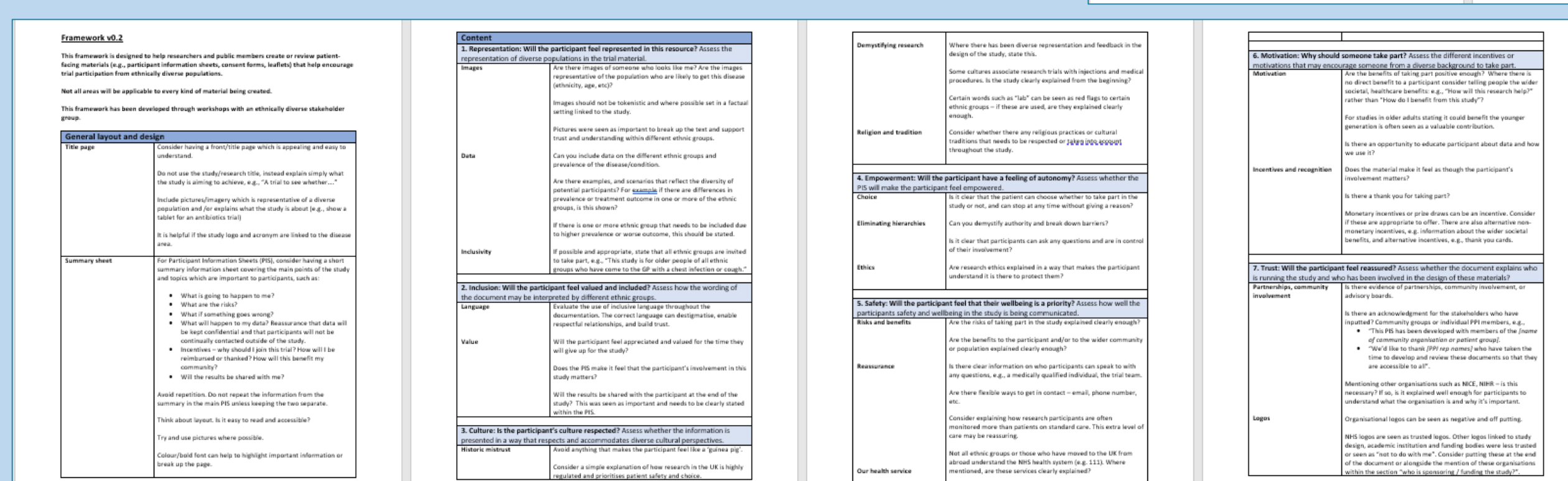
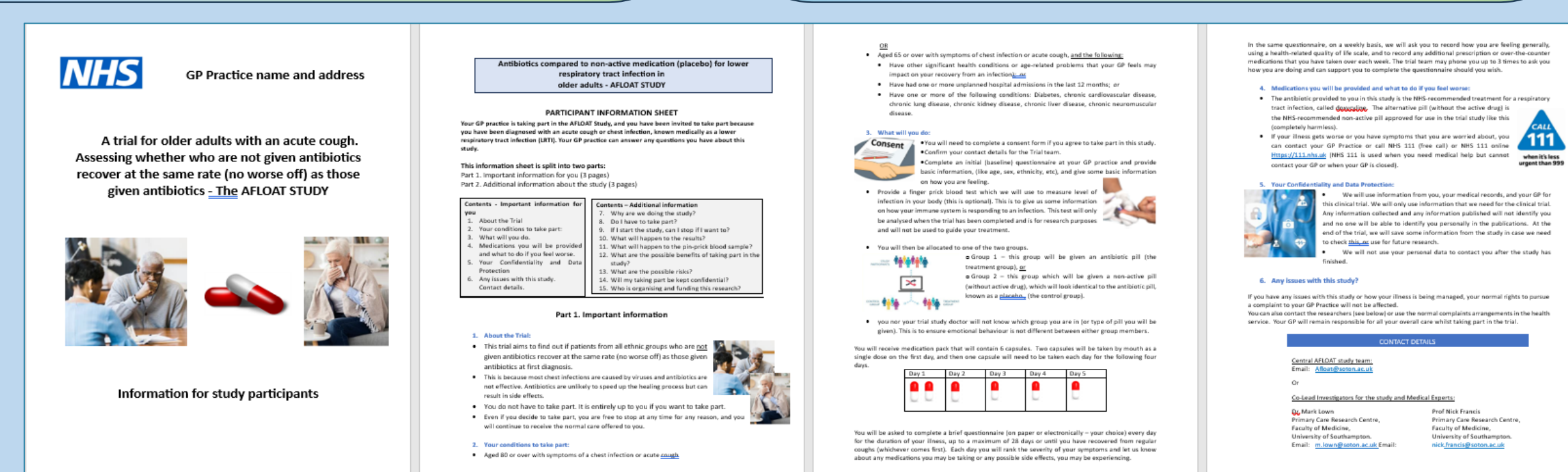


#### Trust

- Is there evidence of partnerships, community involvement, or advisory boards?
- NHS logos are trusted - other logos are less trusted. Consider putting these at the end of documents.
- Acknowledge if developed with PPI. "This PIS was developed with patients and the public"



Co-designed patient information sheet



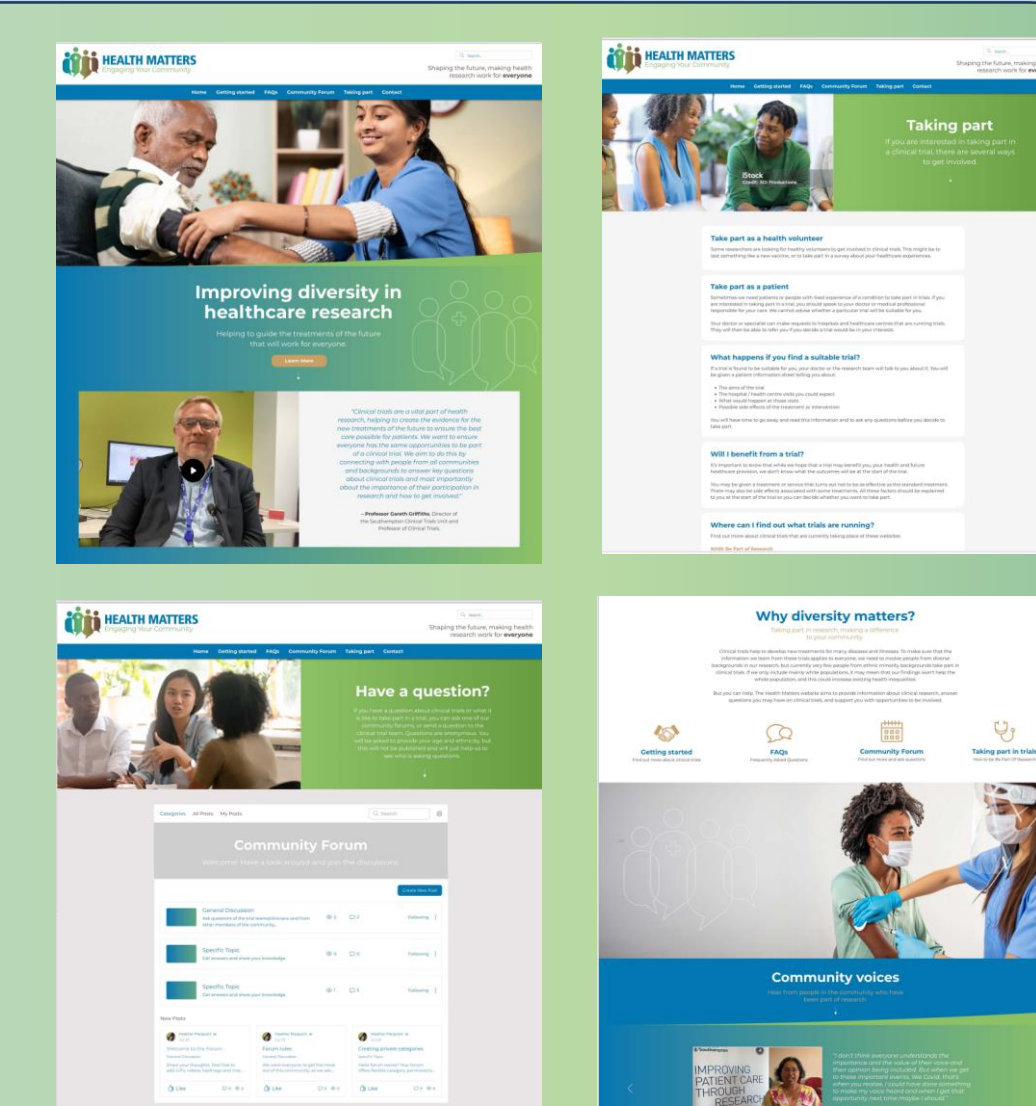
Framework to apply to patient facing documents

Keep up to date with our project outputs – register here



## ONLINE SAFE-SPACE

- Connect more – forum to ask question (1:1, Group, online) invite researchers to meet communities
- Real life stories – videos of those who have been Involved in trials
- Education on trials and frequently asked Questions
- How to get involved in trials including questions to ask if invited to take part in a trial



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Fund. Contact: [rmgroup@soton.ac.uk](mailto:rmgroup@soton.ac.uk)  
Southampton Clinical Trials Unit, University of Southampton, UK.

## POTENTIAL RELEVANCE AND IMPACT

These co-designed interventions aim to increase the diversity of trial populations. The learnings and interventions will be applied across all SCTU studies (in SWATs where possible) and disseminated to the UK CTU community.