



MRC-NIHR Trials Methodology Research Partnership: Webinar recording

**The INCLUDED Project: Promoting INCLUivity through improving the practice and utility of Ethnicity Data collection in trials**

*Presented, on behalf of the UKCRC Registered CTU Network, by:*

Sandra Galvin (Bristol Trials Centre)

**16 January 2024**

The slides are available below.

For any queries, please contact [uktmn@nottingham.ac.uk](mailto:uktmn@nottingham.ac.uk)

<https://youtu.be/x05SzX01IOM>

# Promoting INCLUsivity through improving the practice anD utility of Ethnicity Data collection in trials

# INCLUDED

TMRP webinar 16<sup>th</sup> January 2024

Sandra Eldridge - Bristol Trials Centre

## Background

- Ethnicity data essential for equity and appropriate treatment
- People from some ethnic communities are underrepresented in clinical trials
- Language is important
- Strong public support for diversity in clinical trials (HRA report Nov 2023)

“...nine in ten (88%) people think a diverse mix of participants in health and social care research is important.

A majority of the public also said it's important to include a diverse mix of participants even if the research costs more money (70%) or takes more time (74%)”

Promoting INCLUsivity through  
improving the practice anD utility of  
Ethnicity Data collection in trials

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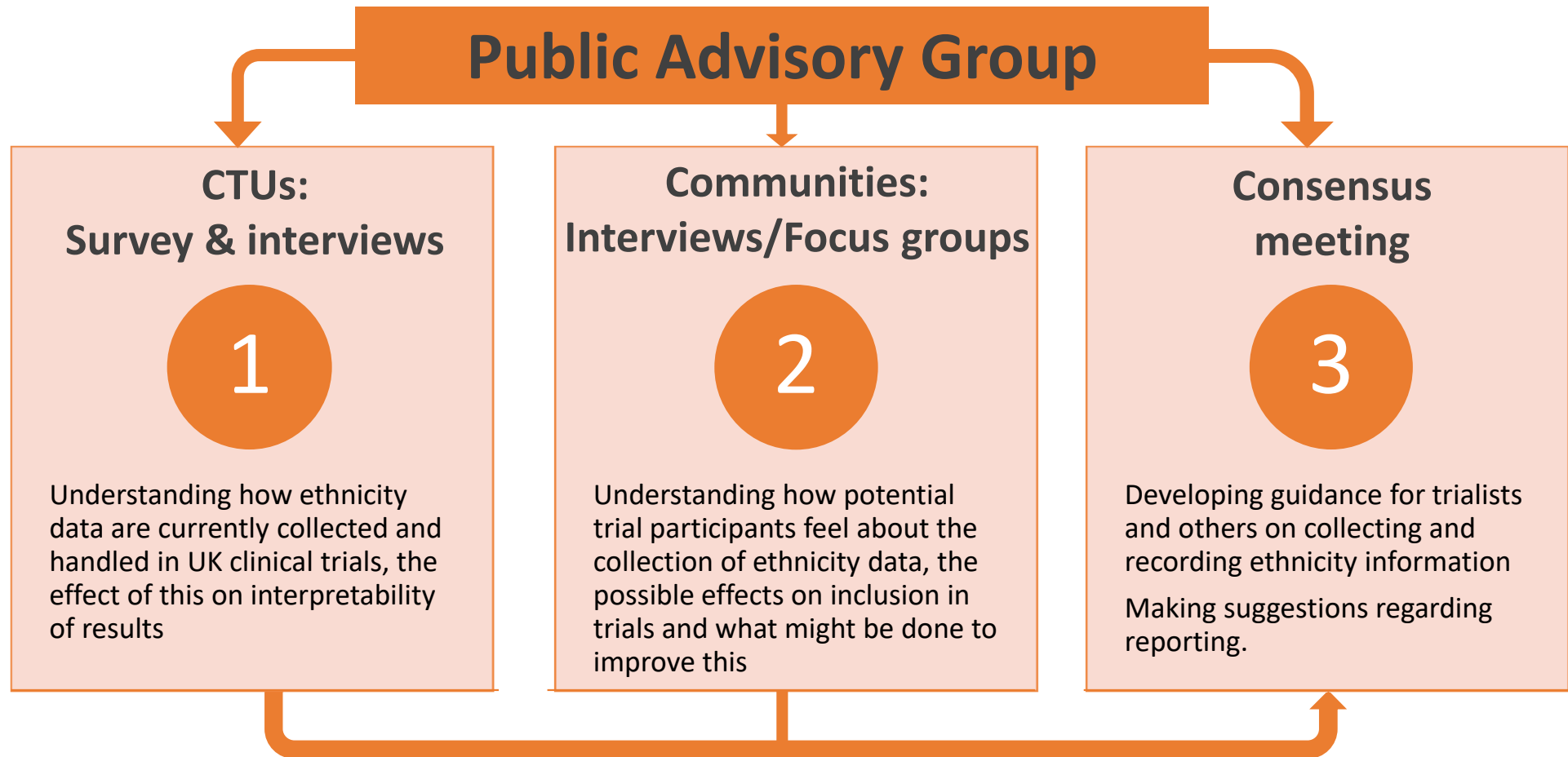
**NIHR** | National Institute for  
Health and Care Research

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The views expressed are those of the author(s) and not necessarily those of the NIHR or the Department of Health and Social Care.

Aim: to produce initial recommendations for researchers on collecting, handling and reporting ethnicity data in clinical trials.

# Research plan



# INCLUDED Team

**Queen Mary:**  
Sandra Eldridge (Chief Investigator)  
Ratna Sohanpal (Lead WP2, Co-Lead WP3)  
Sian Newton (Lead WP1, Co-Lead WP3)  
Ann Thomson (management team)  
Imran Khan (management team)  
Beatriz Ratton (management team)  
Izzy Monger (management team)

**Keele:**  
Gill Lancaster (all WPs)  
Sarah Lawton (WP1)  
Jo Smith (WP1)

**Aberdeen:**  
Shaun Treweek (all WPs)  
Heidi Gardner (management team)

**Oxford:**  
Sally Hopewell (all WPs)

**Edinburgh:**  
Tracy Jackson/Meiko Makita (PAG Lead)

**Egality Health:**  
Annette Jack (WP2)  
Ria Sunga (WP2)

**Social Action for Health:**  
Ceri Durham (WP2)  
Grainne Colligan (WP2)

**South Asian Health Action:**  
Kirit Mistry (WP2)  
Bhavna Patel (WP2)

**Caribbean and African Health Network:**  
Charles Kwaku Odoi (WP2)  
Percy Akundo (WP2)

**Race Equality First:**  
Aliya Mohammed (all WPs)

**Public Advisory Group (PAG):**  
• Clancy Williams  
• Emily Lam  
• Manoj Mistry  
• Sandra Jayacodi



## Definition

*“Ethnicity is a multi-faceted quality that refers to the group to which people belong, and/or are perceived to belong, as a result of certain shared characteristics, including geographical and ancestral origins, but particularly cultural traditions and languages. The characteristics that define ethnicity are not fixed or easily measured, so ethnicity is imprecise and fluid. Ethnicity differs from race, nationality, religion, and migrant status, sometimes in subtle ways, but may include facets of these other concepts.”*

(Raj Bhopal JECH 2004)



## Methods: Clinical Trials Units (CTUs)

### Online Survey (CTUs)

- Sent to all registered UK CTUs  
(55% response rate, 41 studies)

### Focus Groups/Interviews (CTU staff/survey respondents)

- 1 Focus Groups/2 Interviews (N=5)  
(trial manager, coordinator, research fellow, Statistician, data manager)

### Research forum feedback

- Email responses regarding views and knowledge of ethnicity data collection  
(8 responses; 4 stats, 3 trial managers/assistant, 1 data manager)



## Methods: Communities

**Terminology:** Community connectors & diverse ethnic communities

### Data collection

- 8 focus groups comprising 4-6 people in each group and 1 interview
- N=38

### Setting

- Online or face to face (or telephone)

### Selection criteria

- Members of diverse ethnic groups from across the UK
- Aged 18 years or over
- Ability to give informed consent



# Public Advisory Group Members & Community Connectors



**Latin American community**

Identification and recruitment

Planning focus group/interview

Running focus groups and interview

Analysis meetings

Community newsletters

Consider the Somali community

Video blogs in different languages

Build trust

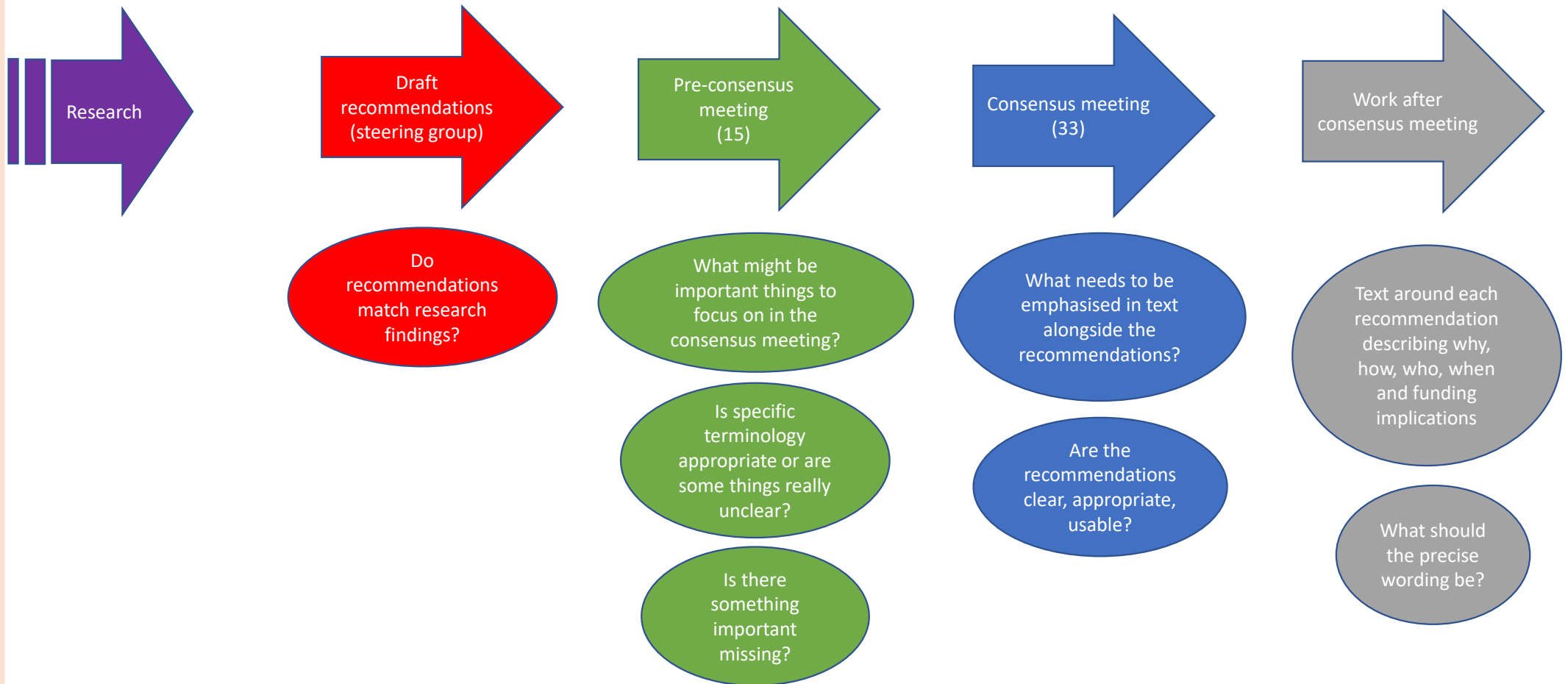
Bilingual researchers

Translation

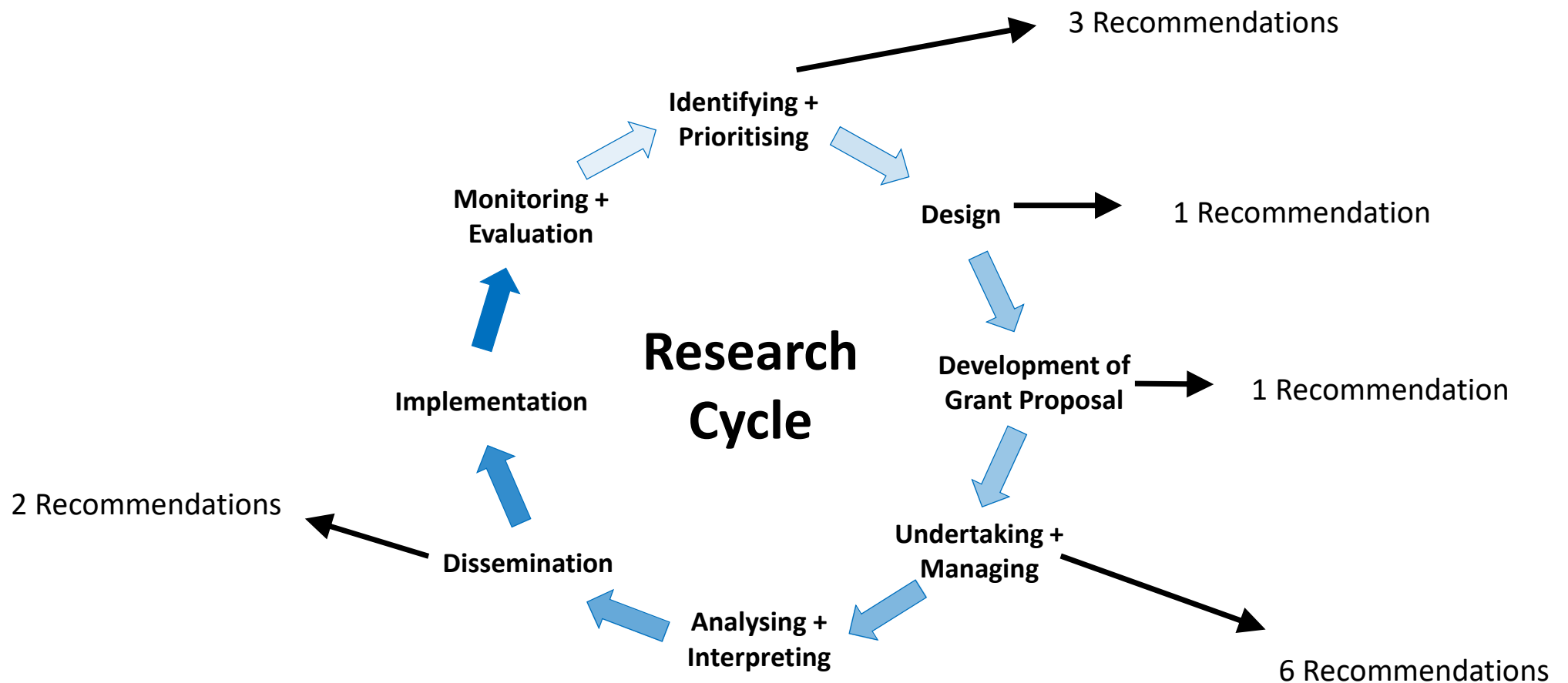


Consider the Latin American community

# Methods: Consensus



# RECOMMENDATIONS



## RECOMMENDATION 1

# Identify the diverse ethnic communities from which participants in the trial need to be drawn

### WHY?

- Representative sample
- Identify those who need to participate
- Identify appropriately inclusive collection instruments

### HOW?

- Trial team and community connectors
- The INCLUDE Framework



The INCLUDE Ethnicity Framework aims to help trial teams think specifically about which ethnic groups should be included in their trial for its results to be widely applicable, ***and what challenges there may be to making this possible.***

## RECOMMENDATION 2

# Clearly articulate the reason(s) for ethnicity data collection in the trial

### WHY?

- Comply with best practice
- Only collect necessary data
- Ensure purpose of data collection / analysis match
- Motivation to provide data
- Benefit to diverse ethnic communities

### HOW?

- Focused discussion prior to grant application
- Involving community connectors & those that provide or collect the data

## RECOMMENDATION 3

**If possible, engage with organisations or networks that connect relevant diverse ethnic communities with the research sector**

### WHY?

- Facilitate connection with multiple communities
- Ensure understanding between researchers & communities
- Longer-term relationships with diverse ethnic communities
- Benefit to diverse ethnic communities

### HOW?

- NIHR guidance on how to involve public in research (individuals)
- National organisations e.g. Equality Health
- Regional organisations e.g. Grampian Regional Equality Council
- Look for local organisations



## RECOMMENDATION 4

# Engage individual patient/public members in communities identified in recommendation 1

### WHY?

- **Diverse ethnic communities want to be meaningfully involved**
- **Obtain perspectives other than those of community connectors**

### HOW?

- **Community connectors/ organisations may identify individuals**
- **Meet individuals in places used by their communities**
- **Increase knowledge of research opportunities and improve trust**

## RECOMMENDATION 5

# Communicate to funders in the grant application, why and how ethnicity data will be collected and disseminated

### WHY?

- Transparency
- Places importance on ethnicity data collection
- Clarity regarding associated costs needed to collect data appropriately

### HOW?

- Chief Investigator
- Early discussions with trial team, community connectors and data providers/collectors
- Discuss how ethnicity data will be collected (recommendations 6-8)

## RECOMMENDATION 6

**On data collection forms, use a question which allows people to self-describe their ethnicity**

### WHY?

- Pre-specified lists can be exclusionary/discriminatory
- ONS 2021 census: missing categories
- Individuals more likely to complete
- Improves data accuracy

### HOW?

- Explain what is meant by ethnicity
- Provide explanation of why important
- Involve diverse ethnic communities

## RECOMMENDATION 7

**Make an explicit decision about whether a pre-specified list of ethnic categories will be used in the trial for data collection in addition to collecting self-described ethnicity**

### WHY?

- Use pre-specified list as well as self-description
- Pre-specified lists facilitate comparisons & synthesis, yet no consistency across trials
- Pre-specified lists - exclusive and discriminatory
- Further research needed to constructing a 'good' list

### HOW?

- Considerations specific to disease area
- Ask communities about consequences of using a list
- Discuss with data collectors, stats... about practicalities of collecting/analysing/reporting ethnicity data

## RECOMMENDATION 8

**Communicate to participants why ethnicity data are being collected, what will be collected, and how they will be used**

### WHY?

- Researchers need to do this better
- Improve trust
- Improve participation
- Increase engagement in research more generally

### HOW?

- Participant Info Sheet & during recruitment discussions
- At time of data collection (researcher or on CRF)
- Videos
- Community connectors could advise on their communities

## RECOMMENDATION 9

**If possible, source high quality training for the whole trial team focused on better understanding of the culture of, and building trust with, diverse ethnic communities**

### WHY?

- Racism in health care
- Historical abusive events within research
- Cultural/religious sensitivities
- Move away from tokenism
- Engage with communities/stakeholders
- Build trust & understanding

### HOW?

- Liaise with providers of such training
- Reflect on own culture > understand how this may influence the research
- The Centre for Ethnic Health Research
- Trial Forge

## RECOMMENDATION 10

# Talk as a trial team about inclusion and diversity

### WHY?

- Research community less diverse than UK population
- Increase understanding by reflecting on own influence on engagement
- Widen participation & include diverse ethnic communities

### HOW?

- Involve diverse ethnic communities in discussions
- Involve networks that link researchers & community groups

## RECOMMENDATION 11

**Identify an individual or group trained in leading inclusion and diversity work who can support the inclusion and diversity work within the trial**

### WHY?

- Research schedules governed by tight deadlines
- Identify someone or group to focus on inclusion & diversity

### HOW?

- Person / group outside of trial team within a research unit
- Person / group within trial team (resourcing & staff turnover issues)
- CI > overall responsibility to ensure these individuals have overview



## RECOMMENDATION 12

# When disseminating results, report ethnicity as transparently as possible

### WHY?

- Good practice!
- 18% trials didn't report ethnicity data collected
- Collapsed ethnic groups used on data forms (e.g. White & Other) with no explanation
- Maximise transparency & inclusivity

### HOW?

- In relation to the purpose for which its collected
- Be clear: self-described or pre-specified list
- Report categories as collected
- Consider longer tables or footnotes
- Be aware of DPA breaches
- CONSORT, journal-specific e.g. JAMA

## RECOMMENDATION 13

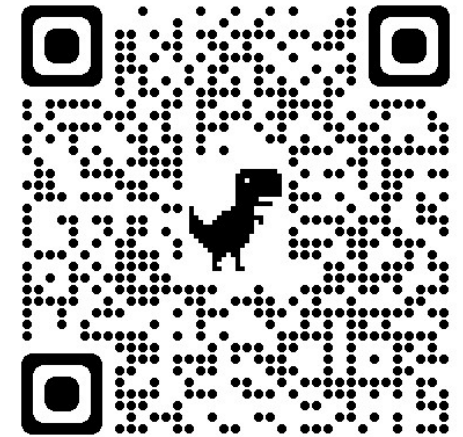
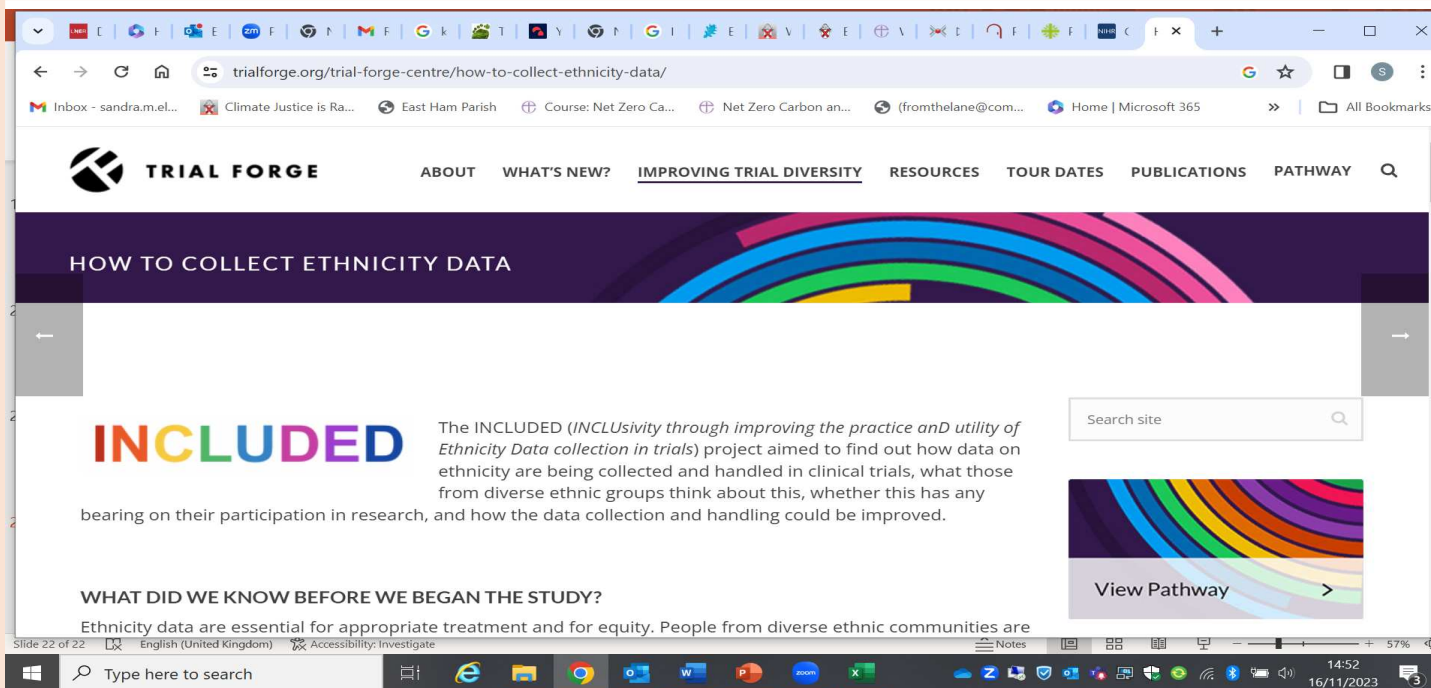
**Include ethnicity data when reporting to participants, to PPIE members especially diverse ethnic community members, and to community connectors involved in designing the ethnicity data collection**

### WHY?

- Extension of existing recommendations
- Understand how providing ethnicity data contributed to the trial
- To build trust - see the ethnic groups involved

### HOW?

- Consult community individuals: reporting & dissemination methods
- Podcasts, videos, presentations, written documents
- NIHR Research Design Service Guidance



<https://www.trialforge.org/trial-forge-centre/how-to-collect-ethnicity-data/>

[s.eldridge@qmul.ac.uk](mailto:s.eldridge@qmul.ac.uk) for fuller report

