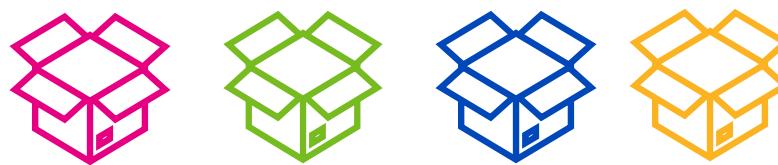


Pink, Green, Blue, and Yellow: Little Boxes All The Same



Dr Heidi Green



Director of Health Equity Innovation, Researcher in Residence



drheidirgreen@gmail.com



What's with the title?





What's with the title?

- Written and composed by Malvina Reynolds in 1962
- Folk music as an artistic tool for social satire based on the development of suburbia and associated conformist middle-class attitudes





The plan

- **Who?** A minor existential crisis
- **Why?** Consciously building boxes
- **What?** Figuring out what you need
- **How?** The INCLUDED project
- **Where?** Reporting data helpfully





Who are you?



Your identity in:

- A paragraph
- A sentence
- 3 words



Who are you?



Your identity in:

- A series of 4 boxes





Did you fit perfectly into each box?



Was this process
straightforward for you?



How did it make you feel?



Which boxes felt most
uncomfortable, and why?



What was missing?



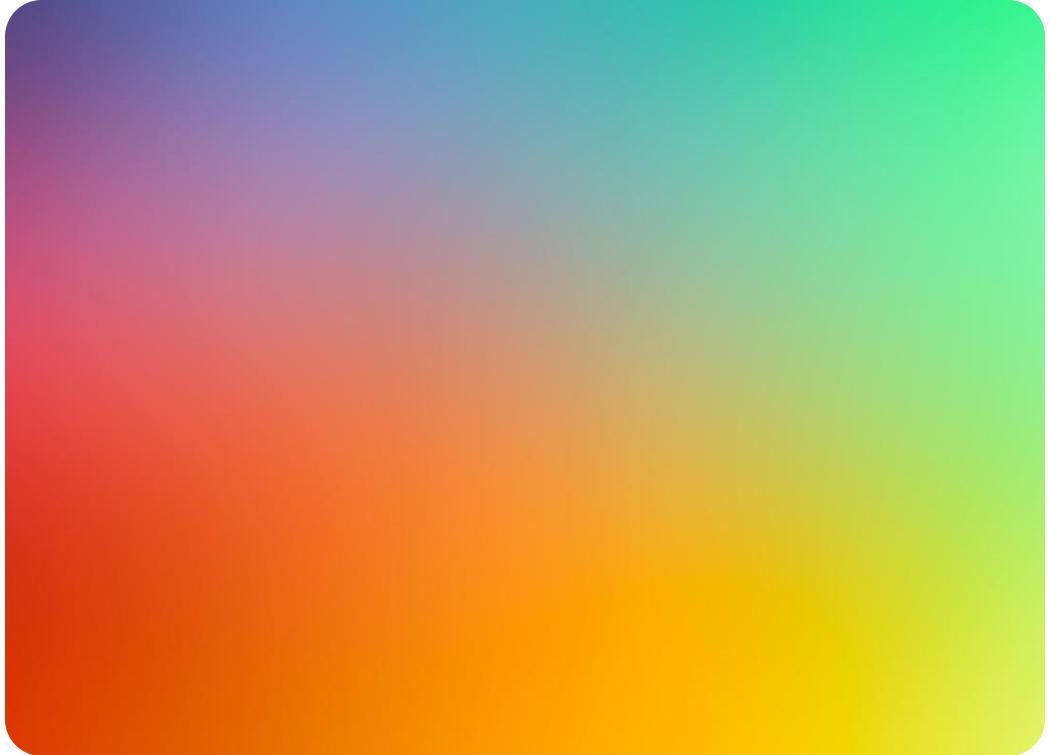
We should just ask people, right?

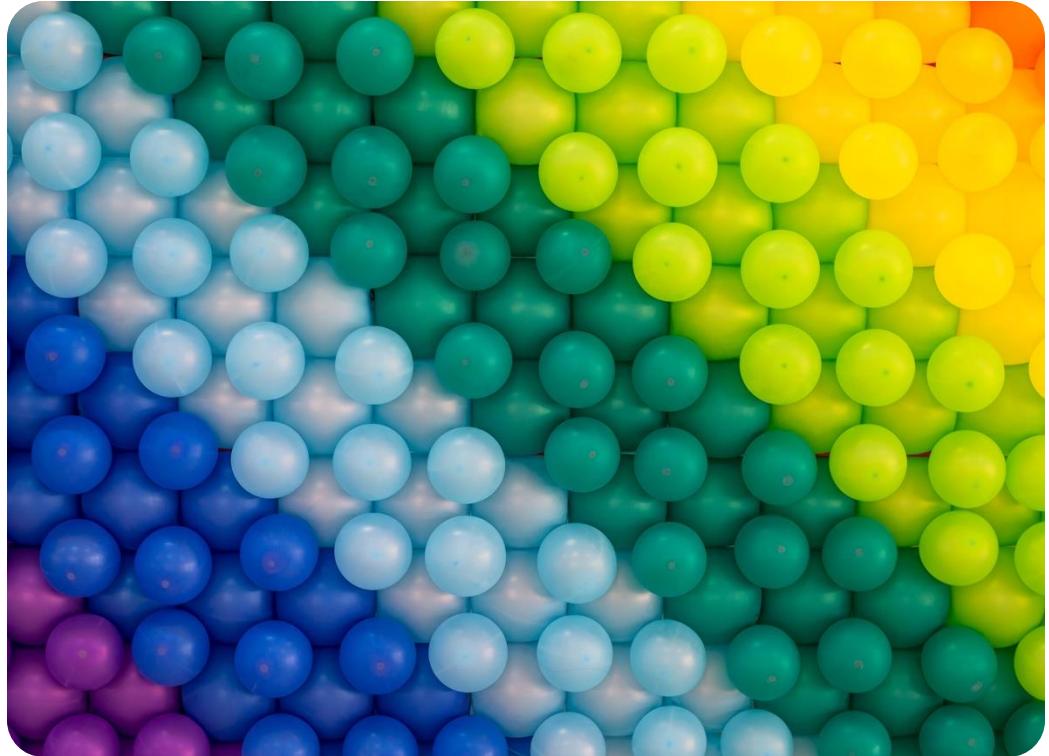




To get to grips with these data,
we need to introduce some order.









Rebuilding the boxes



The questions



The options



The language



Anything else?



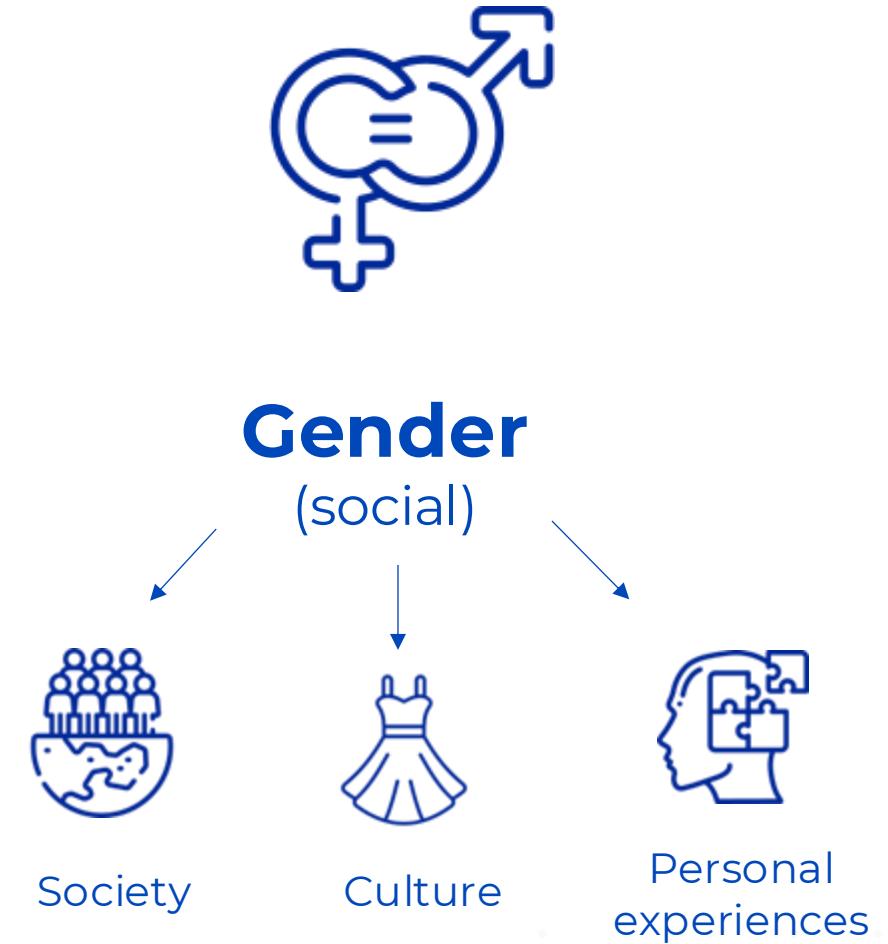
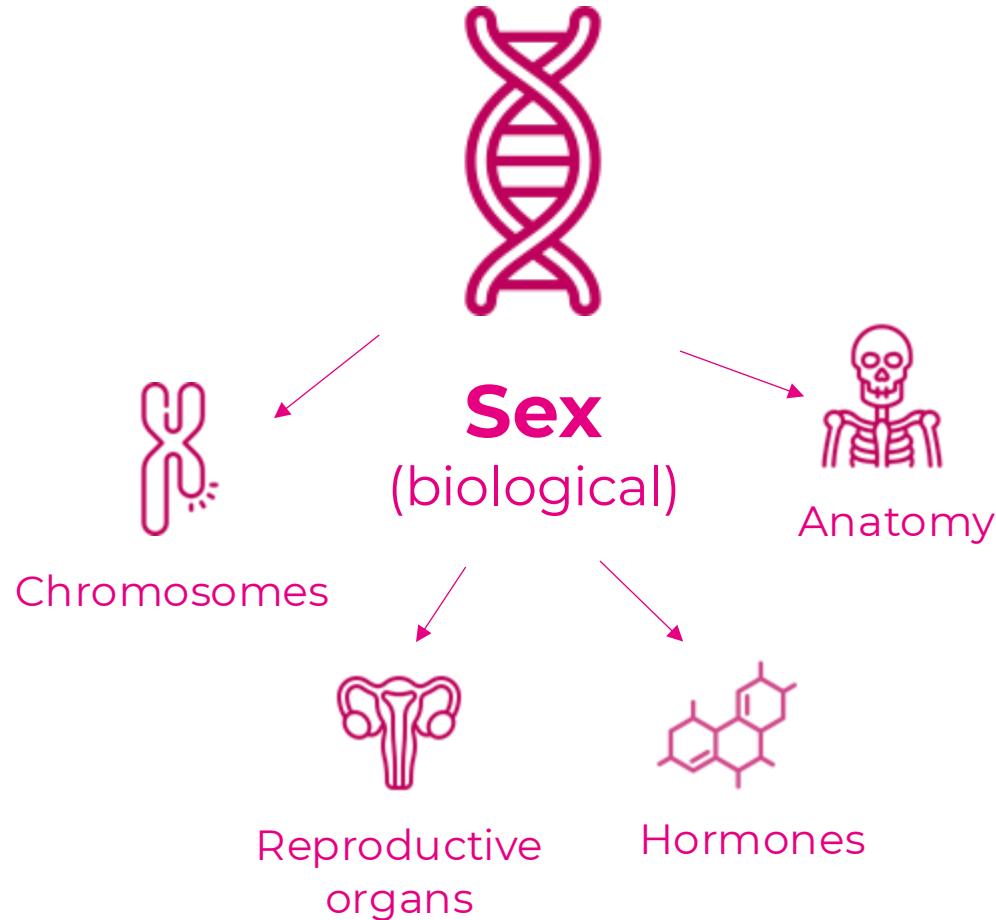
What data do you need?

- “To make sure my participant population is diverse” is not enough
- Some may be specific to your trial
- Some data should be collected across the board
 - Sex
 - Gender
 - Ethnicity
 - Age
 - Disability



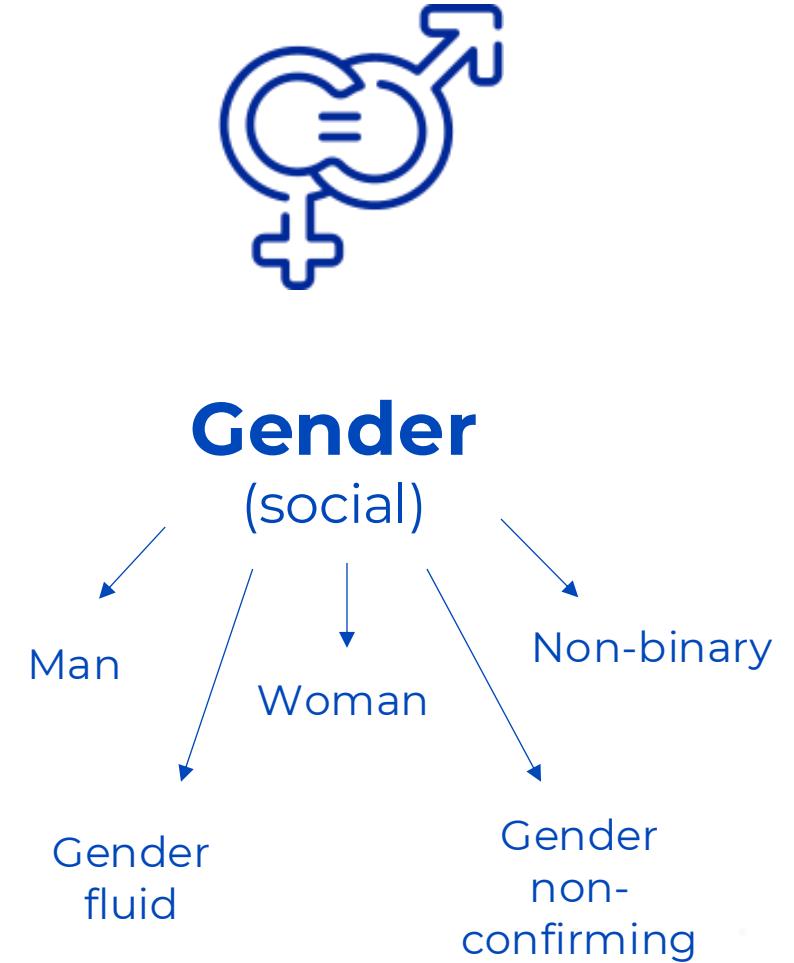
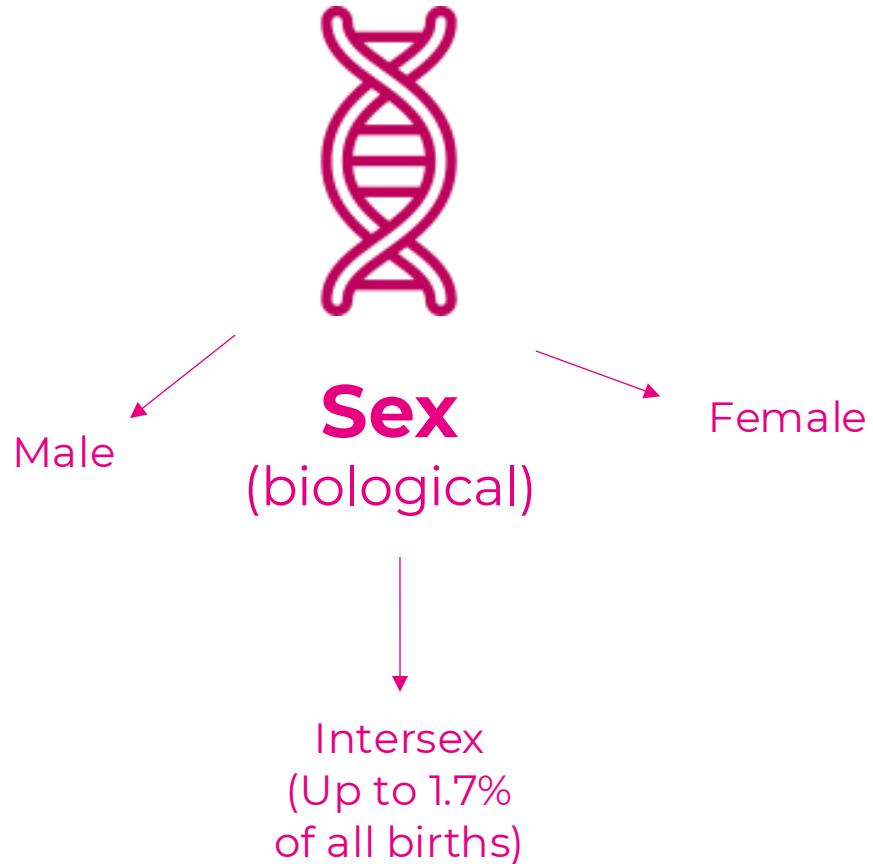


Sex and gender are not the same





Sex and gender are not the same

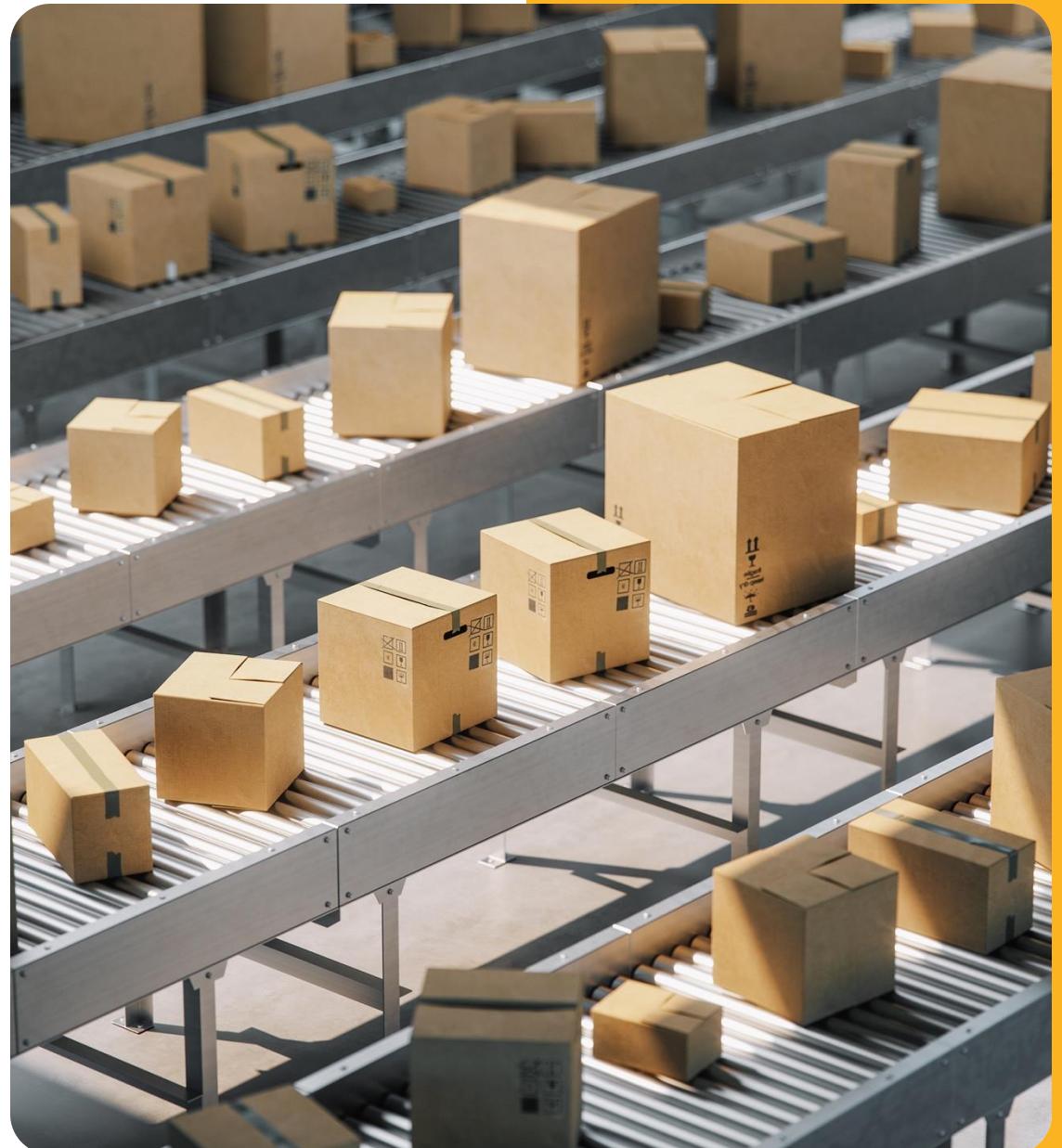


...and more.



Collecting ethnicity data

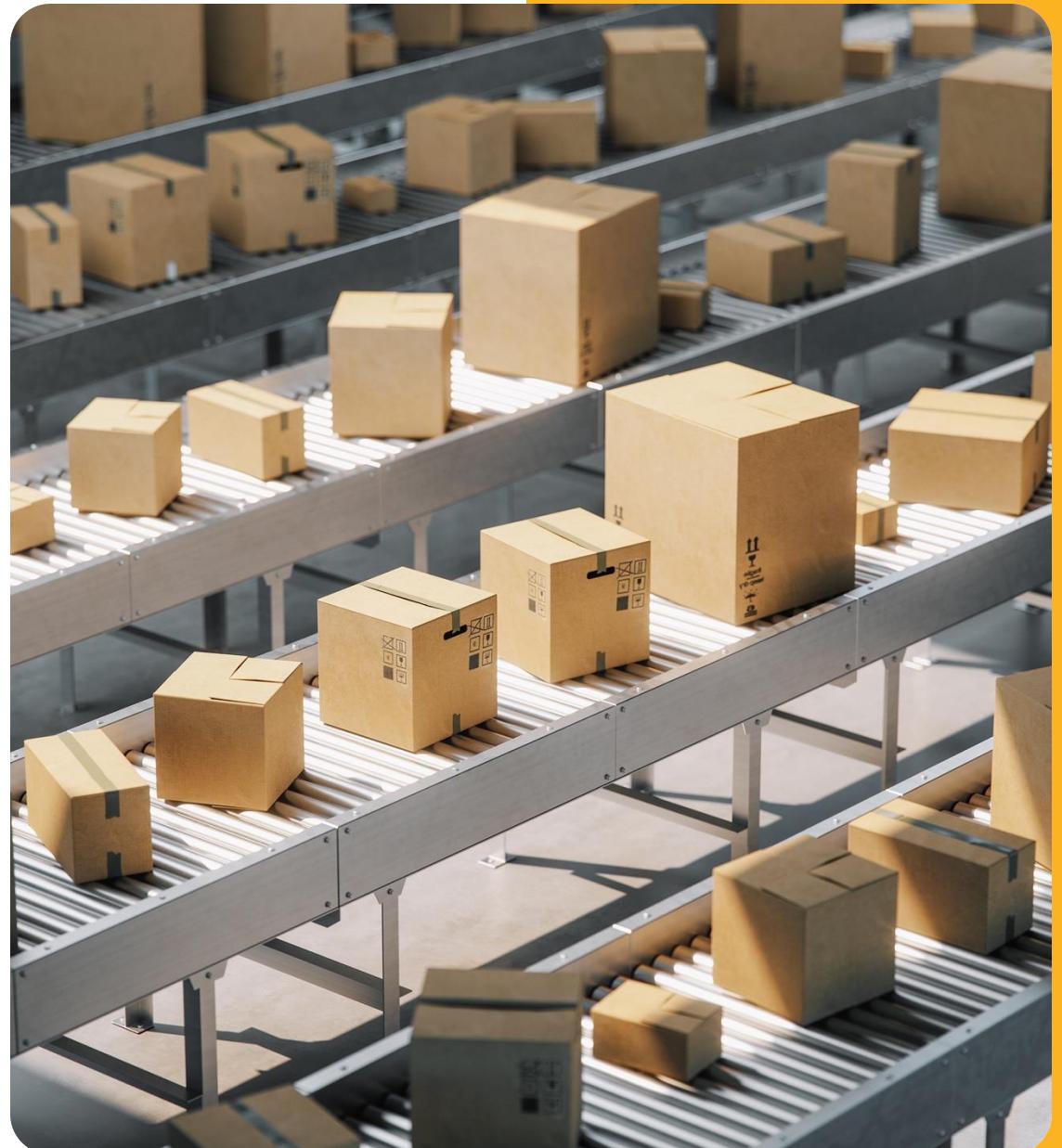
- The INCLUDED project:
INCLUsivity through improving the practice anD utility of Ethnicity Data collection in trials
- Queen Mary University of London, with the universities of Keele, Aberdeen, Oxford, and Edinburgh
- Equality Health, Social Action for Health, South Asian Health Action, Caribbean and African Health Network, Race Equality First, and a Latin American Feminist group





Collecting ethnicity data

- Allowing people to self-describe is the minimum
- Make a conscious decision about whether a list of pre-defined categories should be used in addition
- 13 recommendations:
<https://www.trialforge.org/trial-diversity/how-to-collect-ethnicity-data/>





Reporting

- 407 RCTs published in the NIHR Journals library, 2016 and 2021
- Focus on:
 - **What?** Ethnicity
 - **How?** Recording
 - **Where?** Reporting



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Journal of
Clinical
Epidemiology

METHODOLOGICAL CONSIDERATIONS RELATED TO EQUITY, DIVERSITY, AND INCLUSION IN CLINICAL EPIDEMIOLOGY

Underrecording and underreporting of participant ethnicity in clinical trials is persistent and is a threat to inclusivity and generalizability

Neil Wallace^a, Stacey O'Keeffe^a, Heidi Gardner^b, Frances Shiely^{a,c,d,*}

^aTRAMS (Trials Research and Methodologies Unit), HRB Clinical Research Facility, University College Cork, Cork, Ireland

^bHealth Services Research Centre, University of Aberdeen, Scotland, UK

^cSchool of Public Health, University College Cork, Cork, Ireland

^dHRB Trials Methodology Research Network (TMRN), University College Cork, Cork, Ireland

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Abstract

Objectives: People from ethnic minority groups are underserved by randomized trials, and poor representation of these groups reduces generalizability of results. There is no guidance on which ethnicity categories are appropriate for use in trials and thus inconsistency exists. The purpose of this study is to establish, in a large sample of trials, if participant ethnicity is recorded, how it is obtained (categories used), and if its reporting varies from its recording.

Study Design and Setting: We reviewed trial documentation for 407 randomized controlled trials published in the UK National Institute of Health Research library from 2016 to 2021. We extracted data on the recording (if it was recorded and the categories used) and reporting (if the categories remained the same as those obtained, or not) of ethnicity for each trial along with demographics. In the analysis we categorized the manner of recording and reporting of ethnicity in the trials according to UK Census ethnicity categories.

Results: Ethnicity was recorded in 67.3% ($n = 274$) of trials. The location in the trial report where ethnicity was recorded was available for 42% ($n = 116$) of trials. The details on how ethnicity was collected (predefined categories or self-defined) was available for 54/274 (20%) of trials and details on the specifics of the categories recorded was available for 44 (16%) trials. Of the 44, 6 of those did not go on to report on ethnicity in the trial report. Of the remaining 38, only 13 reported ethnicity exactly as it had been recorded. Taken as a whole from the 407 trial reports examined 9.3% (38/407) of trials demonstrated exactly how they both recorded, and reported, ethnicity. Authors made reference to whom results were relevant in terms of ethnicity in 80/407 (19.7%).

Conclusion: Ethnicity is underrecorded and underreported in clinical trials. This is a threat to the generalizability of the findings and needs to be improved. © 2023 The Author(s). Published by Elsevier Inc. This is an open access article under the CC BY license (<http://creativecommons.org/licenses/by/4.0/>).

Keywords: Randomized trials; Underserved groups; Trial methodology; Ethnicity reporting; Inclusivity; Trial reporting



Reporting

- Ethnicity recorded in 274 trials
- Ethnicity reported in 258 trials
- 38 trials (9.3%) demonstrated exactly how they recorded, and reported, ethnicity
- Reported in the same way that it had been recorded in 13 trials



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6 tips to keep you on track



Before:

- Who should be included, and why?
- What exactly do you need to know about them?



During:

- Create data collection forms that allow for self identification
- Communicate with participants: why, what, when, how



After:

- Report as transparently as possible
- Connect demographics with results where possible



Takeaways



Easing that existential crisis from earlier



Boxes will never fit everyone



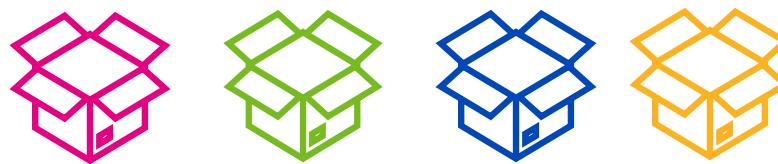
Progress over perfection



Let's work together to make the boxes better



Thank you.



Dr Heidi Green



Director of Health Equity Innovation, Researcher in Residence



drheidirgreen@gmail.com