UK DCTN Guidance on inclusivity and diversity in dermatology clinical trials

Research for everyone means doing research with everyone

Drafted April 2025.

Health inequalities can be described as 'unfair and avoidable differences in health across the population, and between different groups within society.'[1]

Inclusive clinical trials have multiple recognised benefits, but most importantly can reduce inequalities. Research has historically not been inclusive of diverse groups, resulting in findings potentially underserving communities, overlooking issues for specific populations, and maintaining health inequalities.

To be able to understand if research is inclusive, clinical trials also need to adequately report participant characteristics. In the UK, a recent study found that UK DCTN trials have higher reporting rates of key demographic parameters than control trials, but that there was still room for improvement[2].

This guidance aims to support UK DCTN research teams to:

1) **Adequately consider inclusivity in the research design.**
2) **Adequately reporting diversity in research reports.**

1. Inclusive research design

Inclusivity needs to be considered throughout the lifecycle of research design. Using the resources in the section below, we summarise some key elements you will need to consider:

- Understanding who is affected by the condition
- Considering if the intervention is likely to affect groups differently
- Considering how different groups will perceive the intervention (e.g. are some groups more likely to be fearful of it or find it unacceptable?)
- Considering if you will plan to disaggregate the data to look at different population groups if it is believed they may be impacted differently
- Considering how you will ensure recruitment of different population groups, including location of sites and novel methods for recruitment
- Considering diversity and inclusion within Patient and Public Involvement (PPI) activities
- Considering how to reduce burden and ensuring accessibility to people taking part, including novel methods for data collection
- Consider how you will explain to participants why you are collecting their demographic data and how you plan to use them

- Considering how you will monitor for diversity and inclusion during recruitment and review and adapt recruitment strategies if not meeting inclusion targets
- Considering inclusivity in how you plan to implement the intervention after the study and mobilise knowledge from the study
- Considering the cost implications for ensuring inclusion and diversity and costing your research funding proposals accordingly
- Use relevant resources available to support you to consider inclusion and diversity.

RESOURCES

The NIHR INCLUDE project[3] have developed (and are continuing to develop more) frameworks for research teams to consider how to make it easier for certain groups to take part in a trial. So far, they have the following frameworks to consider:

-Ethnicity

-Impaired capacity to consent

-Socioeconomic disadvantage

NIHR have guidance to follow when applying for funding[4]

The NHS HRA and MHRA have draft guidance on inclusion and diversity[5]. You can submit a Plan when developing a clinical trial.

The UKRI MRC have policy and guidance on diversity and inclusion[6].

NHS England have good practice guidance for engaging underrepresented groups in research[7].

NIHR Research Support Service Leicester and Partners have a EDI Toolkit to support researchers[8].

2. Consistent reporting of diversity

We recommend the following participant demographics should be collected and reported for every UK DCTN clinical trial where appropriate:

- Age
- Sex
- Gender (separately from sex, inclusive of alternative options beyond man/woman)
- Skin tone (important to think about using an instrument to measure skin tone that distinguishes beyond ‘white/black’)
- Ethnicity
- Socioeconomic status

RESOURCES

NIHR have a comprehensive list of characteristics of undeserved groups that you may want to consider reporting too[9].

Wellcome Trust DAISY guidance provides recommendations and suggestions on how to ask inclusion and diversity questions in research[10].

Key references and links:

[1] https://www.england.nhs.uk/about/equality/equality-hub/national-healthcare-inequalities-improvement-programme/what-are-healthcare-inequalities/

[2] https://doi.org/10.1093/ced/llaf141

[3] https://sites.google.com/nihr.ac.uk/include/home

[4] Inclusive research funding application guidance | NIHR

[5] https://www.hra.nhs.uk/about-us/news-updates/hra-mhra-guidance-developing-and-submitting-inclusion-and-diversity-plan/

[6] https://www.ukri.org/who-we-are/mrc/our-policies-and-standards/embedding-diversity-in-research-design/

[7] https://www.england.nhs.uk/aac/wp-content/uploads/sites/50/2023/02/B1905-increasing-diversity-in-research-participation-v2.pdf.pdf

[8] https://www.rssleicesterresources.org.uk/edi-toolkit

[9] https://www.nihr.ac.uk/improving-inclusion-under-served-groups-clinical-research-guidance-include-project

[10] https://edisgroup.org/resources/practical-tools-and-guidance/diversity-and-inclusion-survey-daisy-question-guidance-v2/

Who has developed this guidance?

Dr Laura Howells, UK DCTN Trial Development Manager

Prof Beth Stuart, UK DCTN Network Chair

Dr Carron Layfield, UK DCTN Network Manager

Ms. Maggie McPhee, UK DCTN Research Coordinator

This guidance has been reviewed by the UK DCTN Executive Committee and Dr Hannah Wainman (UKDCTN CESR Fellow 2021).

Further work nationally and internationally is needed (and ongoing) to establish best practice guidance for diversity and inclusion in clinical trials and this document will need to be updated in due course. UK DCTN intend to review the document every 2 years.