

Which ethnic groups should be in the trial and at what proportion?

Which ethnic groups should be in the trial?
V1 13/3/2023 Trial Forge

Trial: SCOT

Colorectal cancer

SCOT trial (colorectal cancer) <https://www.isrctn.com/ISRCTN59757862>;
<https://doi.org/10.3310/hta23640>

The panel concluded:

- The minimum target for diverse ethnic involvement should be that the trial **involves different ethnic groups at the proportions found in the most recent census data for the geographical areas where recruitment is being done**. It is important to note that demographics are changing and that e.g. census data may be old and that targets should aim to take account of current and future demographics, not past demographics.
- There was also support for **oversampling Black African Caribbean and South Asian individuals** because of a current paucity of trial data for these groups and because data show the Black African Caribbean people are often diagnosed at a younger age and are more likely to present with Stage IV disease.

General comments from the panel:

1. Over-sampling of minority groups should be the default as this is unlikely to affect the applicability of results to the majority population but will provide more data than we generally see at present for ethnic minority groups.
2. The statistical analysis for the trial should always consider ethnicity. In other words, there should be an analysis that explores the potential for ethnicity-related effects. Without this more diverse ethnic group inclusion becomes a largely descriptive exercise.
3. The source data used to make decisions about the ethnic groups to be involved and at what proportion should be clear in trial reports. The level of uncertainty of these data should also be made clear.
4. This is important to avoid poor quality data effectively hard-wiring discrimination into future trials.
5. The generally poor quality of ethnicity data with regard to prevalence and disease severity was noted.



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6. Criteria linked to the ethnic groups to be involved should be part of the formal trial eligibility criteria. This would raise the importance and the attention given to non-clinical eligibility criteria.
7. Trial teams should use the most detailed census data that they can get hold of and these can be very local and detailed. This will also help to plan where to place trial recruitment sites.

NB. Completed by Shaun Treweek, University of Aberdeen, based on a discussion with an external panel brought together for this purpose as part of the STRIDE project (<https://www.abdn.ac.uk/hsru/what-we-do/research/projects/stride-supporting-recruitment-and-retention-improvements-for-diverse-ethnicities-283>). None of us was involved in this trial, we did not discuss the information below with the trial team.

Given the above, the information below may not be a proper reflection of what the trial team itself may have considered the ethnic groups needed by their trial. The information is therefore intended to be illustrative, not definitive.