

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

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V1 13/3/2023 Trial Forge

Trial: PROSPER

Breast cancer

PROSPER (breast cancer) <https://www.isrctn.com/ISRCTN35358984>; <https://doi.org/10.3310/JKNZ2003>

The panel noted:

- The panel did not make specific comments regarding the ethnic groups needed by the trial.

The panel concluded:

- The panel did not reach a conclusion with regard to particular percentages for different ethnic groups.

Where a panel cannot reach a conclusion, STRIDE suggests adopting the following default inclusion position:

- The minimum target is that **ethnic groups are included at the same proportion as is found among the population of people with the condition targeted by the trial.** The proportion is dependent on the intended reach of the applicability of trial results. A trial intending national reach should aim for national ethnic proportions by disease. A trial with more local reach could aim for proportions in its local area.

Where **disease data by ethnicity do not exist, or cannot be obtained**, STRIDE suggests adopting the following default inclusion position:

- The minimum target is that **ethnic groups are included at the same proportion as is found in the most recent census data.** The proportion is dependent on the intended reach of the applicability of trial results. A trial intending national reach should use national census data. A trial with more local reach could aim for census proportions in its local area.

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## General comments from the panel:

1. 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.
2. 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. This is important to avoid poor quality data effectively hard-wiring discrimination into future trials.
3. The range of experiences individuals from different ethnic groups have may be best obtained by good patient and public involvement during trial planning and design.
4. The panel raised the possibility of over-sampling but noted the challenge of deciding what the levels should be. Regardless of what they are, those levels should have some sort of error bar or range around them. There is plenty of uncertainty when choosing these levels.
5. If there are differences between ethnic groups, these differences are more likely to be due to ethnic minority experiences of poor care and low expectation than of biological differences between people of different ethnic groups. Different groups may not accept the treatment to the same extent and that sort of difference is what we should be paying most attention to because it will be far greater (in most cases) than any biological difference.
6. The data that are really needed (updated of breast cancer surgery by ethnicity) are lacking, which makes it hard to plan a trial of this sort. The data we have is prevalence of breast cancer, which is not the starting point for this trial.
7. Other characteristics than ethnicity (e.g. income, gender) may also be important.

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/huru/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.