

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: STAR-TREK

Rectal cancer

STAR-TREK (rectal cancer) <https://www.isrctn.com/ISRCTN14240288>;
<https://www.cancerresearchuk.org/about-cancer/find-a-clinical-trial/a-trial-looking-at-surgery-or-different-types-of-radiotherapy-for-rectal-cancer-star-trec#undefined>

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**. The data available on prevalence and severity were not good enough to suggest anything else.
- There was also support for **oversampling of ethnic minority groups** but which groups to target in particular was unclear because of poor prevalence and severity data.

General comments from the panel:

1. This trial starts with people having already made a decision that they would like to keep some of their rectum. The trial results will be relevant for those individuals who have decided to consider options to retain part of their rectum and they may be ethnically different to all people with rectal cancer but we have no data to say whether they do or not. The trial team should monitor who says yes and no to taking part to see if the two groups are ethnically different.
2. Collecting ethnicity information for people who say no to taking part in a trial is likely to present both practical and ethical approval challenges. The key point is that it is important to consider how closely the diversity of the trial population matches the population the trial team decided it needed prior to starting recruitment and retention. Doing this may not need to know the ethnicity of those who said no: a comparison of those who said yes against the target population may be enough.
3. This point made by the panel also highlights that the difference between intervention and comparator may be far less clear to potential participants than it is to the trial team. People considering major surgery for cancer may see little difference in alternative surgical approaches: from the potential participant's perspective it's all surgery.



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: STAR-TREK

Rectal cancer

General comments from the panel:

4. Trial teams could routinely embed checking of intervention/comparator understanding, something that is likely to be a potential issue for participants of all ethnicities.
5. The choice mentioned above (i.e. to retain part of the rectum) could also differ by other characteristics such as age and gender. These too should be monitored.

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.