

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: REPOSE

Type 1 diabetes

REPOSE (type 1 diabetes) <https://www.isrctn.com/ISRCTN61215213>;
<https://www.journalslibrary.nihr.ac.uk/hta/hta21200#/abstract>

The panel noted:

- **South Asian and Black individuals must be involved** because the risk and severity of potential complications of type 1 diabetes are known to be greater for individuals from these ethnic groups.

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 for **inclusion of the specified ethnic groups should be 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 for **inclusion of the specified ethnic groups should be 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.



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: REPOSE

Type 1 diabetes

General comments from the panel:

1. The trial team would need to carefully consider how they would collect ethnicity data from participants.
2. Younger people of all ethnicities, especially those under 18, are often excluded from diabetes trials. Whether exclusion is appropriate should be carefully considered by the trial team.
3. The panel recognised that interventions targeting people under the age of 18 may need to be different to those targeting older people and a single trial of both would therefore be inappropriate. Nevertheless, there was a belief that exclusion was often more related to a perceived difficulty with consent or ethical procedures rather than whether the intervention could benefit younger people.
4. The trial team would need to carefully consider the language support that may be needed to ensure that members of the ethnic groups important to the trial can actually participate. This requires consideration of both written translation and interpretation.

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.