

# The INCLUDE Ethnicity Framework: Ensuring your trial is designed for all who could benefit

## Who should trial results apply to?

Trial teams need to do everything possible to make their trial relevant to the people for whom the results are intended to apply (often patients) and those expected to apply them (often healthcare professionals).

The INCLUDE Ethnicity Framework aims to help trial teams think specifically about which ethnic groups should be included in their trial for its results to be widely applicable, and what challenges there may be to making this possible. Having identified potential challenges, the trial team can then consider ways to reduce those challenges. For this to work, **the Framework needs to be used at the trial design stage before funding is in place.**

Ethnicity is a complex matter that can influence personal identity and group social relations. The specific ethnic groups that a trial should involve depends on many things, including the disease or condition targeted. However, in the UK, all trials should consider the five main ethnic categories developed by the Office for National Statistics and used in the UK census:

- Asian / Asian British
- Black / African / Caribbean / Black British
- Mixed / Multiple ethnic groups
- White
- Other ethnic group

These can be further broken down depending on the trial (see Appendix 1, which also gives more detail on why we focus on these five groups).

For trials intended to directly inform clinical decision-making, **the default position is that ethnic diversity in the trial should be similar to ethnic diversity in the affected population.** Deviations are possible but this needs to be justified by the trial team.

## The Key Questions and Worksheets

The INCLUDE Ethnicity Framework has two parts:

1. Four Key Questions.
2. Worksheets to help trial teams think through the answers to the Key Questions.

The Key Questions are general while the worksheets focus on ethnicity.

Once Key Question 1 (What groups should my trial results apply to?) has been answered, trial teams will know explicitly who needs to be in their trial. The remaining three questions ask trial teams to think through potential challenges to involving the people identified by Question 1.

Answering these questions can be tricky. To help with this we developed the worksheets, which give pointers to the sort of things to think about when answering Key Questions 2 to 4. Each trial will have its own challenges, but we think the issues on the worksheets are likely to be relevant for all or most trials.

## Who should complete the Key Questions and Worksheets?

Answering the Key Questions and using the worksheets is a team effort, not the task of an individual. Moreover, they will need input from Public and Patient Partners, in other words, people like the people the trial needs as participants.

Doing this well is not a job of an hour or so. **We have prepared a set of examples** (see resources) where we applied the Framework to a number of existing trials. At least two of us applied the Framework to each trial, and each of us spent about a day working on the Key Questions and Worksheets. We then discussed our individual responses and agreed a common position.

It might be possible for a trial team to be faster than this (the team will know their trial inside out, for example) but in the context of a trial that might run for 3-5 years and cost £1-2 million, spending a day or so thinking about ethnicity is not an unreasonable time investment, especially as it will ultimately improve the applicability of the trial results.

## Who has developed the INCLUDE Ethnicity Framework?

The Framework has been developed by people from the [National Institute for Health Research \(NIHR\) INCLUDE initiative](#), [Trial Forge](#), the [Medical Research Council-NIHR Trial Methodology Research Partnership](#), the [Health Research Board Trial Methodology Research Network](#), the [Centre for BME Health](#) and Patient and Public Partners. We have also had contributions and advice from individuals working in trials and who are not part of the above networks.

See Appendix 2 for an outline of our process and the list of people who have contributed.