

Key points

- The INCLUDE Ethnicity Framework is a tool that helps trial teams to think about how disease prevalence and severity, culture, faith, language, intervention and trial design features may affect trial participation of individuals from different ethnic groups.
- A total of 40 people from stakeholder groups including patient and public partners, clinicians, funders, academics working with ethnic minority groups, trial managers and methodologists contributed to seven phases of Framework development.
- The Framework comprises two parts:
 - Part 1 has four key questions:
 1. Who should my trial apply to?
 2. Are the groups identified likely to respond in different ways?
 3. Will my study intervention make it harder for some groups to engage?
 4. Will the way I have designed the study make it harder for some groups to engage?
 - Part 2 is a set of worksheets to help trial teams address these questions.
- The Framework can be used for any stage of trial, for a healthcare intervention in any disease area.
- The INCLUDE Ethnicity Framework was launched on October 1st 2020 and is available open access at <https://www.trialforge.org/trial-forge-centre/include/>. The site also contains guidance, examples of how the Framework can be applied to trials and a video giving public perspectives on why it is important for researchers to think about ethnicity at the inception of trial planning, throughout the lifespan of the trial, and/or retrospectively.