

INCLUDED recommendations short summary

Before the trial	Identifying and prioritising	
	1. Identify the diverse ethnic communities from which participants in the trial need to be drawn.	<p><i>Why?</i> The goal is to have representative trial participants who could benefit from the intervention being tested. Identifying the right participants is crucial to avoid excluding relevant communities or causing harm.</p> <p><i>How?</i> The chief investigator, statisticians, trial managers, data collectors, data managers, and community connectors all play important roles. Community connectors are individuals who are part of specific ethnic communities and who, because of their role and/or standing in that community can bridge the gap between their own community and researchers. They can provide valuable insights, highlighting diverse communities with varying barriers and facilitators to research participation. The INCLUDE Ethnicity Framework assists in identifying relevant ethnic communities and understanding factors impacting their involvement.</p>
	3. If possible, engage with organisations or networks that connect relevant diverse ethnic communities with the research sector	<p><i>Why?</i> Researchers struggle to connect with diverse ethnic communities, but community organizations and networks can help by promoting inclusivity and understanding. Engaging with these organizations fosters long-term relationships and aligns with recommendations for increased inclusivity.</p> <p><i>How?</i> Researchers should seek national or regional organizations like Equality Health or Grampian Regional Equality Council for support. Local organizations can be found in their areas, and guidance from NIHR's People in Research is helpful for making connections and involving the public.</p>
	4. Engage individual patient/public members in communities identified in recommendation 1	<p><i>Why?</i> Diverse ethnic communities in the INCLUDED study expressed a desire for meaningful involvement in early planning for ethnicity data collection. Community connectors emphasize consulting a wider range of individuals for diverse perspectives.</p> <p><i>How?</i> Community connectors, organizations, and networks can help identify suitable participants, and meetings in familiar and safe settings like homes, places of worship, or community hubs promote inclusivity, awareness, trust, and engagement.</p>
	Design	
	2. Clearly articulate the reason(s) for ethnicity data collection in the trial	<p><i>Why?</i> Clearly articulating reasons for collecting ethnicity data motivates participation, ensures compliance with best practices, and aligns data collection with research goals. Common reasons include generalizability, representativeness, population description, and addressing health inequalities. Using these data in analyses is less common.</p> <p><i>How?</i> Prior to grant application, focused discussions involving investigators, managers, statisticians, community connectors, and research staff help select appropriate data domains and address practical considerations. Sharing outcomes with the team, potentially during training, enhances communication and clarifies reasons for participants and stakeholders.</p>

Development of grant proposal

5. Communicate to funders in the grant application, why and how ethnicity data will be collected and disseminated

Why? Transparency in communication with funders is vital for participants in INCLUDED focus groups. It places ethnicity data collection on par with other application details and clarifies the required financial resources.

How? The Chief Investigator should ensure clarity among grant applicants regarding the importance, methodology, and presentation of ethnicity data. The earlier recommendations listed here provide a basis for including this information in the application. Depending on the funder and application type, additional discussions may be required prior to submission and decisions may need to be communicated to funders in the application.

Undertaking and managing the trial

6. On data collection forms, use a question which allows people to self-describe their ethnicity

Why? Offering self-description options for ethnicity data collection avoids difficulties with predefined lists of ethnicity categories. Current lists often fail to represent diverse communities, leading to feelings of discrimination and exclusion, and lack of engagement with the research. Allowing self-description can improve response rates and data accuracy.

How? To implement this, individuals should have the freedom to provide their own ethnicity description. Some guidance can be given, explaining the importance of collecting ethnicity data for the trial and ensuring clarity on the researchers' definition of ethnicity. Involving diverse community members in developing the question and explanation ensures relevance and understanding.

7. Make an explicit decision about whether a pre-specified list of ethnic categories will be used in the trial for data collection in addition to collecting self-described ethnicity

Why? Self-described ethnicity is recommended, but a pre-specified list may be needed on in some trials. Advantages include immediate analysis categories and comparisons. Disadvantages include the difficulty of constructing an all-encompassing list and consequent exclusionary nature of lists.

How? Discussions involving diverse communities and data experts are crucial. If using a list, explain its purpose and whether it is unique or has been used previously. Consider how to handle mixed ethnicities, ensure inclusive categories, and avoid an "other" Category. Understanding how inclusive lists can best be constructed requires further research.

8. Communicate to participants why ethnicity data are being collected, what will be collected, and how they will be used

Why? Improved communication about the purpose and use of ethnicity data is essential for engaging diverse communities in trials and research.

How? Tailored explanations in participant materials, recruitment discussions, and data collection, including videos, if possible, are key. Involving community connectors and using various approaches ensures effective communication.

9. If possible, source high quality training for the whole trial team focused on better understanding of the culture of, and building trust with, diverse ethnic communities

Why? Participants from diverse ethnic communities who took part in INCLUDED emphasized the need for more ethnic diversity in research and provided suggestions for researchers. These include learning about diverse communities, avoiding tokenism, engaging with grassroots organizations, building trust, and understanding how to widen research participation. Historical events and racism in healthcare contribute to mistrust among diverse communities.

How? To address this, trial teams should collaborate with institutions, networks, funders, and researchers to source relevant training. Cultural competence training, like that offered by [The Centre for Ethnic Health Research](#), can be helpful. Additional guidance and resources can be found in [Trial Forge's recommendations](#).

	<p>10. Talk as a trial team about inclusion and diversity</p>	<p><i>Why?</i> The trial team is responsible for diversity and inclusion. Discussing ethnicity recording improves practices. Lack of diversity in the research community was highlighted by diverse ethnic community participants in INCLUDED. To foster inclusivity, teams should reflect the diversity of engaged communities. Self-reflection helps address language barriers and engage diverse communities.</p> <p><i>How?</i> Involve individuals from diverse communities. Include inclusion and diversity in site meetings and use standard procedures/checklists. Seek input from organizations connecting researchers and community groups.</p>
	<p>11. Identify an individual or group trained in leading inclusion and diversity work who can support the inclusion and diversity work within the trial</p>	<p><i>Why?</i> The INCLUDED study highlights ways to improve inclusion and diversity in trials when collecting and reporting ethnicity data. To ensure these aspects are not overlooked, it is crucial to designate someone or a dedicated group responsible for inclusion and diversity, even if they are outside the trial team.</p> <p><i>How?</i> Assign individuals or a separate group within the trial team or outside the trial team, for example within a clinical trials unit, to handle inclusion and diversity. Resourcing challenges may arise, but the Chief Investigator should ensure clear responsibilities, overview, and that these individuals or groups can make appropriate contributions in meetings.</p>
<p style="writing-mode: vertical-rl; transform: rotate(180deg);">After the trial</p>	<p>Dissemination</p>	
	<p>12. When disseminating results, report ethnicity as transparently as possible</p>	<p><i>Why?</i> Reporting ethnicity data is crucial, yet many trials in the INCLUDED survey failed to report or collapsed detailed categories into generic ones (for example “white” and “other”). This lack of transparency needs improvement.</p> <p><i>How?</i> Report ethnicity data in the main results publication, specifying self-described ethnicity collection. Maximize transparency by reporting all collected categories whenever possible, even if it results in a longer list. Consider longer tables in supplementary material if publication challenges arise.</p> <p>When reporting self-described ethnicity, respect confidentiality and legal requirements for categories with few individuals. This may mean combining categories should only be done to ensure confidentiality, with an explanation provided for transparency. If a predetermined list was used alongside self-described ethnicity, the report should describe the categories, even if some are combined to ensure confidentiality.</p>
	<p>13. Include ethnicity data when reporting to participants, to PPIE members especially diverse ethnic community members, and to community connectors involved in designing the ethnicity data collection</p>	<p><i>Why?</i> To foster understanding and trust, share research results, including ethnicity data, with participants and community stakeholders.</p> <p><i>How?</i> Consult individuals from diverse ethnic communities on how to report and disseminate the data, using various methods such as podcasts, videos, and written documents. Refer to the NIHR Research Design Service Guidance for further guidance on result feedback.</p>