A practical worksheet for trial teams

About this worksheet

This worksheet helps trial teams reflect on where intersectionality has been considered in a clinical trial, visualise strengths and gaps, and choose proportionate actions. It can be used on its own or alongside the HRA/MHRA Inclusion and Diversity Plan and one of the NIHR INCLUDE Frameworks.

- Step 1: Complete the self-check matrix
- Step 2: Plot a simple radar chart
- **Step 3:** Select proportionate actions

Before you begin

Study title:	
Chief/Principal Investigator:	
Completed by trial member/team:	
Date of completion:	

The stages of the INCLUDE Roadmap

The INCLUDE Roadmap sets out stages where inclusion can be strengthened across the trial lifecycle. This worksheet focuses on stages where trial teams should consider inclusion. There are 8 stages, but this worksheet only focuses on stages 4-7 only:

- Stage 4: Initial design and funding
- Stage 5: Final study design
- Stage 6: Delivery and monitoring
- Stage 7: Closure and reporting

The questions below map to these stages and are intended to prompt reflection and action.

A starting list of characteristics

Use these characteristics as a prompt when thinking about intersections that matter for your trial context. Drawn from **PRO EDI** (Protected, Relevant, and Other Equality, Diversity and Inclusion).

Age	Sexual identity	Level of education
Sex Race, ethnicity, and ancestry		Disability
Gender	Socioeconomic status (SES)	Location

Tip: Intersections combine these factors, for example, *older women in low-income work*, or *young men with low education*.



Step 1: Self-check matrix

For each question, select the option that best reflects your current level of consideration for each stage of the INCLUDE Roadmap.

- 1 = Not considered: intersectionality has not yet been discussed or factored into decisions at this stage
- 2 = Partially considered: some thought or early action, but not yet consistent or embedded
- 3 = Fully considered: intentional and evidenced considerations have been made

Stage (INCLUDE Roadmap)	Trigger Questions	1 = Not considered yet	2 = Partially considered	3 = Fully considered
Stage 4: Initial	Do you know which intersections are most relevant to the condition and trial context?	□ 1	□ 2	□ 3
design and funding	2. Have you identified 1–2 intersections to focus on, and are they feasible to address?	□ 1	□ 2	□ 3
Stage 5: Final study design 3. Do the eligibility criteria or processes risk excluding the priority intersections?		□ 1	□ 2	□ 3
Stage 6: Delivery	4. Will it be possible to recruit and retain participants from the priority intersections?	□ 1	□ 2	□ 3
and monitoring5. Do you have a process to act if participation gaps emerge at the chosen intersections?		□ 1	□ 2	□ 3
Stage 7: Closure 6. Will you be able to report who was reached and who was missed at the chosen intersections?		□ 1	□ 2	□ 3
and reporting	7. Do you have a plan for sharing lessons that could support other trial teams?	□ 1	□ 2	□ 3

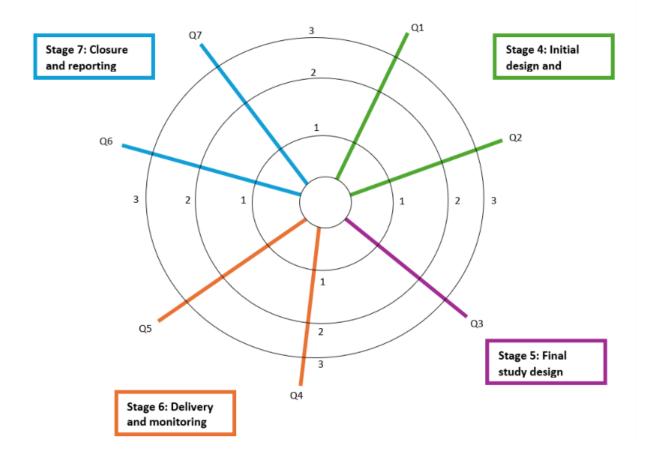
Brief justification (add evidence, notes, or decisions):		
Paste links or references to supporting documents (e.g. protocol sections, TMG minutes):		



Step 2: Radar chart (visual guide)

Plot each answer from Step 1 as a point on the matching axis (Q1–Q7). Connect the points to create a shape.

- A fuller, balanced shape suggests more consistent integration
- An uneven shape highlights where to focus first
- Use this as a guide, not a score



Notes from team discussion when reviewing the radar:



Step 3: Proportionate actions

Start with the narrowest point of the circle from the radar. For those areas, begin with **Light touch** actions. Move to **Moderate** and then **Extensive** once earlier steps are in place and capacity allows.

How to use this table

- Pick the **question numbers** that scored lowest (for example Q3 and Q5)
- Go to the **matching stage row** and consider a Light touch action first
- Record your choice and planned evidence source
- Revisit in TMG to monitor progress

The Intersectionality Action Matrix: proportionate actions to consider by INCLUDE Roadmap stages 4-7

INCLUDE Roadmap Stage	Step 1: Light touch (minimal resources)	Step 2: Moderate (more planning & resources)	Step 3: Extensive (higher commitments)
Stage 4: Initial design & funding	Add a short rationale in the protocol naming 1–2 intersections most affected (e.g. ethnicity + age, gender + caregiving); use existing epidemiological or community data to highlight why these matter.	Work with PPI contributors or community partners representing overlapping disadvantages to review whether design decisions reflect their realities; complete relevant sections of the INCLUDE Ethnicity, Socioeconomic, or Capacity Frameworks if these intersections are relevant; begin planning modest supports (e.g. transport for older adults in low-income areas).	Dedicate budget/staff to intersectionality-informed design (e.g. outreach coordinators with lived experience); co-produce protocol sections with groups most affected by multiple disadvantages; embed SWAT* to test intersectional recruitment methods.



Stage 5: Final study design	Review eligibility criteria and materials for barriers faced at intersections (e.g. digital-only consent excluding older migrants; language + literacy barriers); involve PPI contributors with lived intersectional experience.	Adapt participant materials with attention to intersecting needs (e.g. translations plus plain language; imagery that reflects ethnicity, age, gender, disability together); review recruitment strategies with intersectional PPI contributors; apply the INCLUDE Frameworks where ethnicity, socioeconomic status, or capacity to consent are part of the identified intersections.	Broaden eligibility criteria to reduce exclusions of people with multiple disadvantages; create new recruitment pathways through trusted intermediaries (e.g. services supporting women with disabilities in low-income households).
Stage 6: Delivery & monitoring	Track recruitment/retention data by overlapping characteristics (e.g. gender × socioeconomic status, ethnicity × age) rather than single axes; raise intersectional participation as a standing agenda item in trial management.	Build site-level feedback loops to detect where intersections are under-represented; adapt scheduling for groups with multiple constraints (e.g. weekend visits for carers, mobile visits for those without transport); partner with community organisations that already support intersecting groups; use relevant INCLUDE Framework outputs to inform adaptations during delivery.	Invest in outreach staff or roles specifically tasked with engaging communities at the intersections of disadvantage; develop long-term partnerships with trusted intermediaries; pilot retention strategies tailored to overlapping needs (e.g. migrant mothers balancing childcare and shift work).



Stage 7: Closure & reporting Add a note in the final report on who was reached and who was missed at key intersections; documes simple adaptations may at site level.	de of intersecting groups; reflect on use of INCLUDE	Publish structured lessons on intersectionality (case studies, methodological papers); present at conferences; advocate with funders to embed intersectionality into reporting expectations.
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Record selected actions and why:				

Optional cross-walk to plans and frameworks

If you are completing an **Inclusion and Diversity Plan**, you can use notes from this worksheet to support:

- Q1: Who is affected and where are the gaps
- Q2: How design choices include or exclude groups and why
- Q3: Recruitment goals for groups at the chosen intersections
- Q4: Operational measures to recruit, retain, monitor, and act if goals are not met



If one of your chosen intersections includes ethnicity, socioeconomic status, or impaired capacity to consent, it may be useful to complete the relevant **NIHR INCLUDE Framework** as a Moderate action.

Ethnicity = The INCLUDE Ethnicity Framework • Trial Forge

Socioeconomic = The INCLUDE Socioeconomic Disadvantage Framework • Trial Forge

Impaired capacity = The INCLUDE Impaired Capacity to Consent Framework • Trial Forge

Team reflection and next review

Team Teffection and flext feview			
What went well and what needs attention:			
Agreed next review date:	Meeting: TMG □ TSC □ Other □		
Appendix: evidence and links			
here.	ng or recruitment data summaries, or short PPI notes		

Reference for PRO EDI characteristics: <u>PRO EDI:</u> improving how equity, diversity and inclusion are handled in evidence synthesis • Trial Forge

