

# INCLUDE

**Better healthcare through more  
inclusive research**



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# Which of these terms are routinely used in your work environment?

- Hard to reach
- Under represented
- Marginalised
- Seldom heard
- Disadvantaged
- Under-served



# About INCLUDE

## Innovations in Clinical Trial Design and Delivery for the under-served

### Phase I - We developed an understanding of who is under-served, the barriers to inclusion and innovations to enhance inclusion

- Researched the **under-served** in clinical trials; professionals working on trials; and those taking part in them
- Collated the **barriers** and **challenges** that contribute
- Identified **innovations** in trial design and delivery to **enhance inclusion**

### Phase II – We developed a Framework to improve inclusion (including roadmap and objectives with work streams)

- Produced the Framework: **a roadmap** suggesting intervention points to improve inclusion and core objectives and work streams
- Identified the importance of working with **funders**, **regulators** and other **stakeholders** to implement INCLUDE
- Working with stakeholders to decide routes to **implementation** and ways to **evidence** impact

### Where we are now:

#### Phase III – Implementation and Evidence

- Disseminating the **INCLUDE Guidance** (including **COVID-19 specific guidance**)
- Continuing **engagement** and seeking opportunities to **raise awareness**
- **Measuring success and impact**

**Which groups, in your experience, are underserved by health and care research?**



# Who are the under-served groups?

There is **no single definition of what it means to be under-served**. It is **highly context specific**. However, some key characteristics common to several under-served groups are:

- Lower inclusion in health research than one would expect from population estimates
- Higher healthcare burden not matched by the volume of research designed for the group
- Important differences in how a group responds or engages with healthcare interventions compared to other groups, with research neglecting to address these factors

## **Example underserved groups by geo-demographic factors**

Age extremes (e.g. under 18 and over 75); Black and African-, Asian- and Caribbean-heritage individuals; male/female sex (depending on trial context); those living in remote areas; those experiencing poverty e.g. those on low income; individuals with low education levels; LGBTQ communities; religious minorities

## **Example underserved groups by social and economic factors**

People in full time employment; people in alternative residential circumstances (e.g. migrants, asylum seekers, care homes, prison populations, traveller communities, the homeless and those of no fixed abode); carers; the digitally excluded; those who do not access health services; stigmatised populations; looked after children

## **Example underserved groups by health condition**

Mental health conditions; people who lack capacity to consent for themselves; cognitive impairment; learning disability; people with addictions; pregnant women; people with multiple health conditions; physical disabilities; visually/ hearing impaired; obese individuals; those with rare diseases and genetic disease sub-types

# Why is it important to include under-served groups in clinical research?

- Research that does not reflect the population it seeks to help will not lead to improved healthcare
- Research that is not inclusive will not command the confidence of patients or clinicians
- It is morally the right thing to do

“I didn’t know this was a thing. I would have liked to take part in research to help myself or my baby or to just be part of helping learn stuff for other women, for my future daughters, you know. If the research is about women, then all women should be involved. From all walks of life and cultures. Otherwise, it is not about all of us. Just some.”

Black African participant in MBRRACE UK PPIE project



**In your experience, what barriers to research do under-served groups experience?**



### **Intrinsic Barriers**

Feeling unqualified to take part (e.g. due to lack of education)  
Specific cultural barriers  
Specific health fears (e.g. hospitals, needles)  
Lack of interest in research  
Lack of trust in trials  
Negative attitudes to the concept of research



Community engagement and development  
communications strategies  
Information sharing  
Peer networks  
Research visibility in community places and spaces  
Community endorsement for research

### **Extrinsic Barriers**

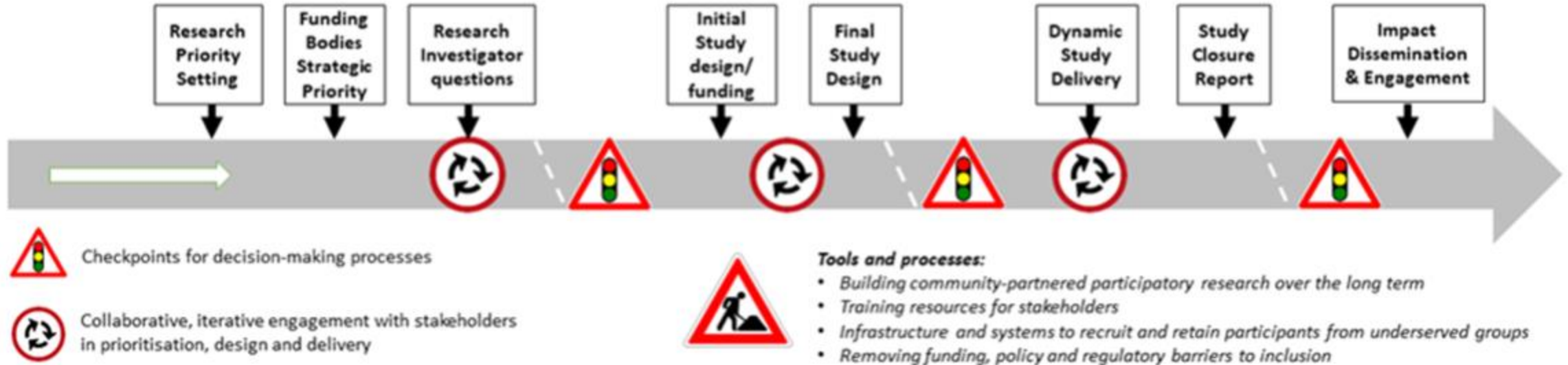
Barriers related to disability  
Difficulties in consenting for another person  
Lack of available trials / poor trial promotion  
Lack of effective incentives for participation  
Negative financial impact  
Potential participants refusing to accept their health condition  
Poor consent procedures  
Requirement for additional carer time to aid participant  
Participant risk perception  
Treatment centres not set up for research  
Trials asking too much for participation



Involvement of under-served groups in research design and delivery  
Funder requirements and expectations  
Workforce capacity and confidence  
Research design  
Research questions



Involved stakeholders: Patients, public, funders, clinicians, researchers, regulators, industry, policymakers



- 1) Develop training resources
- 2) Build infrastructure, tools and processes for research design and delivery
- 3) Remove barriers in funding, regulation and policy



## Our partners



# Examples of progress so far

NIHR Research Standard Application Form & Guidance

Updated Wellcome clinical trials policy

# Resources

INCLUDE Guidance

INCLUDE COVID-19 Guidance

Published *Trials* article

Published BMJ article

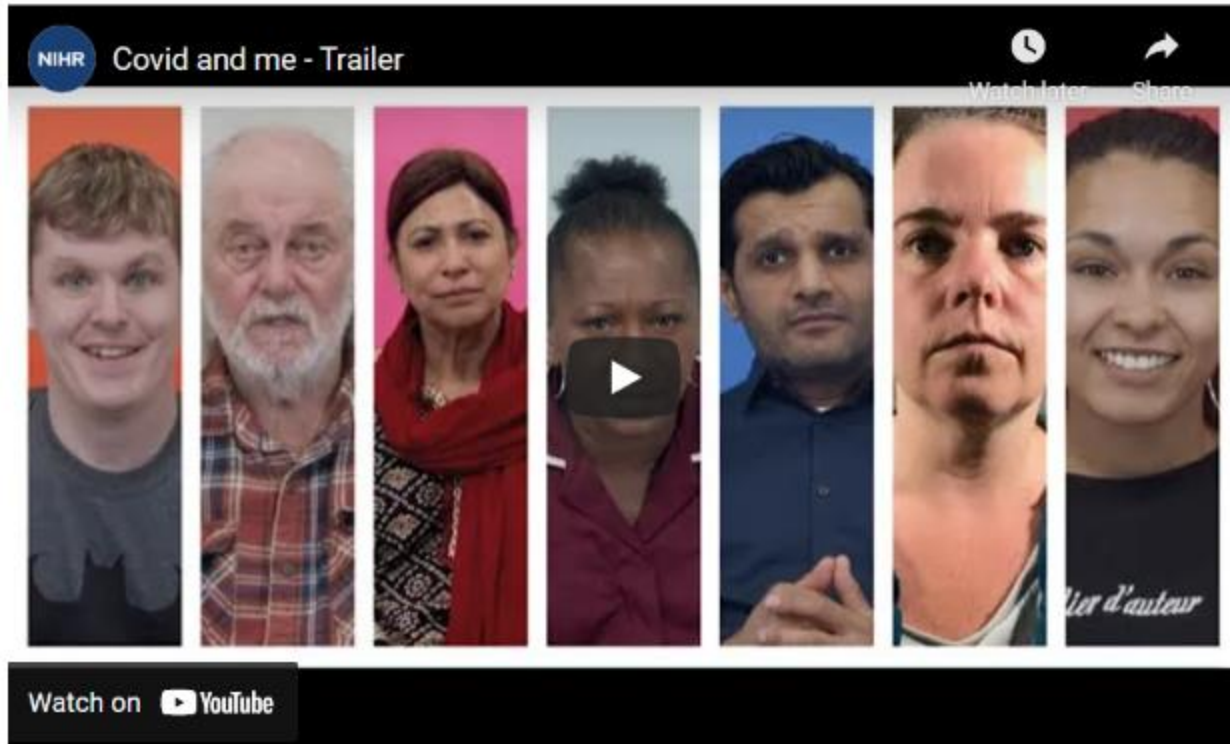
INCLUDE Ethnicity Framework

INCLUDE resource tracker

INCLUDE course on NIHR Learn

# COVID and Me

Take part to help the NHS find the solution



# Questions to guide research teams in designing inclusive research

1. What are the characteristics/demographics of the population which your research looks to serve?
2. How will your inclusion/exclusion criteria enable your trial population to match the population that you aim to serve?
3. Justify any difference between your projected trial population and the population you aim to serve
4. How will your recruitment and retention methods engage with under-served groups?
5. What evidence have you that your intervention is feasible and accessible to a broad range of patients in the populations that your research seeks to serve?
6. Are your outcomes validated and relevant to a broad range of patients in the populations that your research seeks to serve?



# Questions to guide delivery teams in considering how to improve inclusion of under-served groups

1. Who are the under-served groups within our delivery area? (e.g. geographical or disease area that the delivery team operates in)
2. What are the barriers to including these groups in research in our area?
3. What actions can we take to overcome those local barriers?
4. What tools, training and resources do we need to implement these actions successfully?

# Any questions?

# THANK YOU

**website**

<https://sites.google.com/nih.ac.uk/include/home>