

INCLUDE

Innovations in Clinical Trial Design and
Delivery for the Under-served



NAME

DATE

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





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



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 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



About the INCLUDE Project

The Vision:

“Better healthcare through more inclusive research”

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)

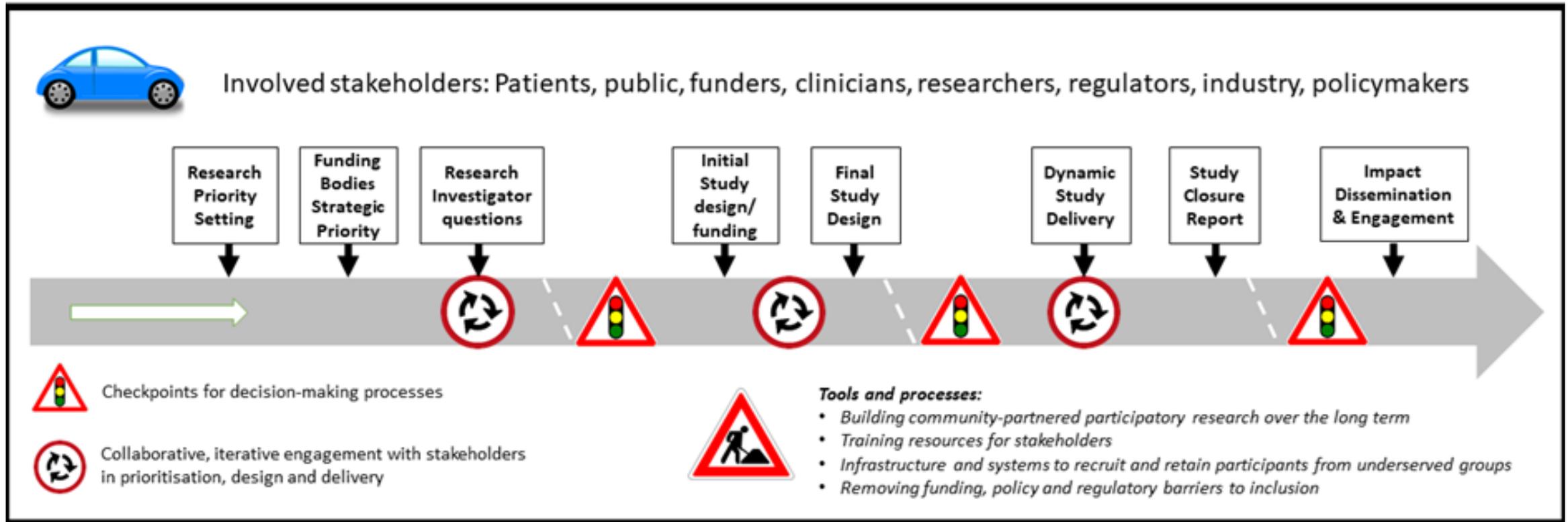
- Produced the Framework: **a roadmap** suggesting intervention points to improve inclusion and core objectives and work streams
- Identified the importance of working with **funders, regulators** and other **stakeholders** to implement INCLUDE
- Working with stakeholders to decide routes to **implementation**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

Where we are now:

Phase III – Implementation and Evidence

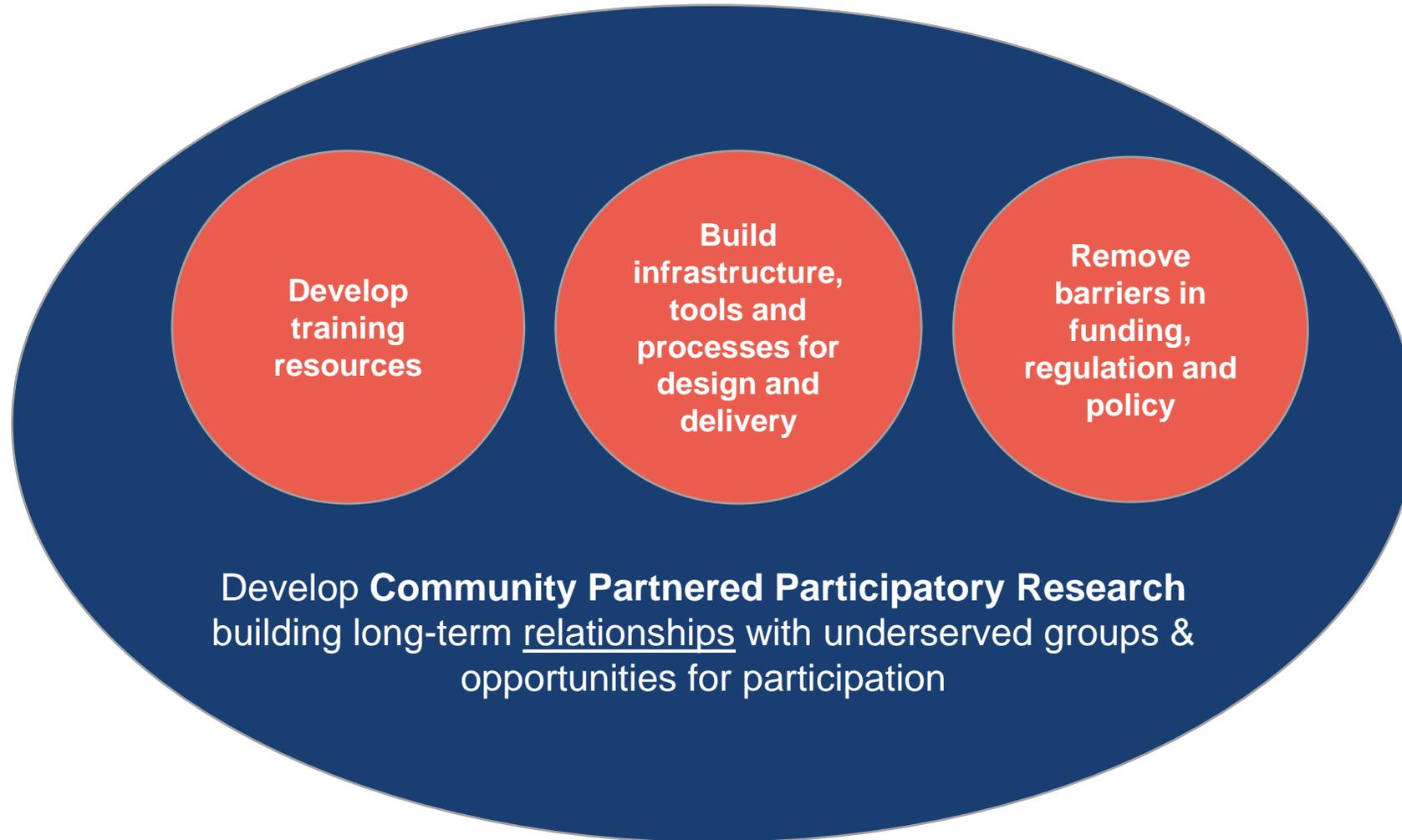
- Disseminating the **INCLUDE Guidance** (including **COVID-19 specific guidance**)
- Continuing **engagement** and seeking opportunities to **raise awareness**
- **Measuring success and impact**

The INCLUDE Framework for developing guidelines to improve inclusivity in clinical studies





INCLUDE's core objectives



INCLUDE: Outputs, resources and partnership working

Resources and slide sets from INCLUDE events



INCLUDE Guidance & COVID-19 Guidance



Published *Trials* article



Published *BMJ* article



INCLUDE Website



COVID and Me



NIHR Learn*



INCLUDE Ethnicity Framework



Updated Wellcome clinical trials policy



****Coming to a screen near you****

In February 2021, we will be launching our brand new **INLCUDE online course**, in partnership with NIHR Learn



NIHR Research Standard Application Form & Guidance



INCLUDE resource tracker

INCLUDE Resource Tracker			
Resource	Version	Published	Updated
NIHR Research Standard Application Form (SAF) - Stage 1: Application Forms & Guidance	1.0	2020	2020
NIHR Research Standard Application Form (SAF) - Stage 2: Research plan	1.0	2020	2020
NIHR Research Standard Application Form (SAF) - Stage 3: Research plan	1.0	2020	2020
NIHR Research Standard Application Form (SAF) - Stage 4: Research plan	1.0	2020	2020
NIHR Research Standard Application Form (SAF) - Stage 5: Research plan	1.0	2020	2020
NIHR Research Standard Application Form (SAF) - Stage 6: Research plan	1.0	2020	2020
NIHR Research Standard Application Form (SAF) - Stage 7: Research plan	1.0	2020	2020
NIHR Research Standard Application Form (SAF) - Stage 8: Research plan	1.0	2020	2020
NIHR Research Standard Application Form (SAF) - Stage 9: Research plan	1.0	2020	2020
NIHR Research Standard Application Form (SAF) - Stage 10: Research plan	1.0	2020	2020

INCLUDE Guidance

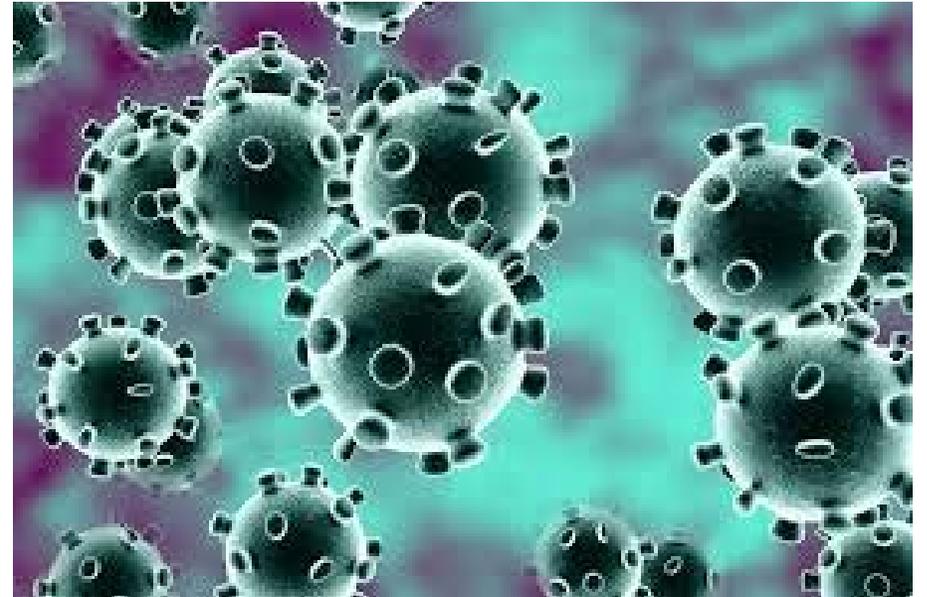
- Provides examples of under-served groups and shows that groups may fit into **multiple categories**
- Provides examples of **barriers** to inclusion
- Then works through the **research journey**
- Finishes with **three checklists** for promoting inclusion of under-served groups:
 - For **researcher's** designing studies
 - For **funders** and **reviewers** evaluating proposals and analyses
 - For teams **delivering** research projects

The **INCLUDE Guidance** was also tailored to form **COVID-19 specific INCLUDE guidance**



How have recent events accelerated this work?

- COVID-19 is not an equal opportunities disease
- It causes severe disease and death more often in certain groups:
 - Some BAME communities
 - Men
 - People living with obesity
 - People living with multimorbidity
 - Older people
- Research on COVID-19 therefore needs to include these groups but does not always do so
- COVID-19 is an exemplar of everything that the INCLUDE project is about
- Now – more than ever – is the time for action. The **INCLUDE COVID-19 specific guidance** aims to address this



Patient and Public Involvement and Engagement (PPIE) is central to the work of INCLUDE

- **Workshops** – PPIE through speakers and delegates
- **Surveys** – to gather views of patients and public e.g. what barriers might people face in clinical trials?
- **INCLUDE steering group** – Laurie Oliva Head of Patient and Public Involvement and Engagement at the NIHR CRN
- **PPIE collaborations** – e.g. “COVID and Me”
- **Supporting ‘Multiverse Lab’** – aims to engage 2,000 people in Newcastle to share their hopes and priorities for health research and ageing
- **Communication** – e.g. newsletters and workshops



What actions can you make to improve inclusion of under-served groups in research?

Your Role	Example action
Researcher	<ul style="list-style-type: none">• Use PPIE to better tailor the research questions to the target group• Talk to under-served communities to better understand them• Identify key local members of under-served groups and build relationships with them
Funder	<ul style="list-style-type: none">• Require applicants to identify steps taken to ensure recruitment of under-served populations (e.g. implementing the INCLUDE guidance)• Fund resources needed to recruit under-served populations
Industry	<ul style="list-style-type: none">• Use networks and skills of partner organisations to help reach these groups (e.g. healthcare, social care, community groups, charities)
Regulator	<ul style="list-style-type: none">• Consider what questions you need to ask to ensure under-served groups are included in research?• Put training in place for review panels to help them review appropriately to ensure adequate plans for recruiting under-served groups
Research Delivery Team	<ul style="list-style-type: none">• Change the format and language of participant information sheets – use different comms channels like video, YouTube, Braille and translations• Don't assume anyone is too old, too ill, or lives too far away to take part• Recruit across an integrated care system – health and social care

Leveraging the impact of INCLUDE through partnership working



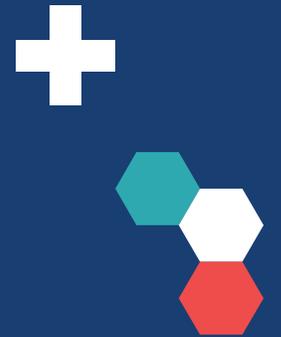
Our partners, collaborators and stakeholders



...and more



Thank you



Contact Us:

e: crnspecialtycluster@nihr.ac.uk

NIHR Clinical Research Network National Specialty Hub
Newcastle University
Biomedical Research Building (3rd Floor)
Campus for Ageing and Vitality
Newcastle upon Tyne, NE4 5PL

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

