

CRDC UK Network:

National Research Inclusion Strategy

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1. Introduction

Research inclusion is one of the four cross-cutting themes of the CRDC UK Network. As commercial clinical research continues to drive the development of most new medicines, devices and vaccines, it is essential that clinical research delivery and participation reflect the full spectrum of people who will ultimately use new therapies. This strategy sets out a national approach for the CRDC UK Network to BRIDGE the gap between those who bear the greatest burden of disease and those who currently deliver, participate in or benefit from commercial clinical trials. We are confident that harnessing the possibilities of inclusive research will increase the speed and robustness of recruitment to commercial trials and ensure the data is generalisable and therapies are efficacious and acceptable across a wide range of population.

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2. Executive Summary

Research inclusion is fundamental to the scientific integrity, ethical conduct, and commercial success of modern clinical trials. As the global population becomes increasingly diverse, it has become crucial that trial populations mirror more than just a narrow subset of patients. There is a clear commercial imperative for rapid recruitment, which can be facilitated in populations that have a higher prevalence of disease and are traditionally under-represented. There is also an ethical imperative to ensure that the benefits of research are shared fairly across the population and communities.

Differences in genetics, physiology, social determinants of health, and disease manifestation across age, sex, race, and ethnicity can all influence how individuals respond to medical interventions. Without representation from diverse groups, trial results may fail to capture variations in efficacy and safety, undermining both scientific validity and patient trust. Inclusive research ensures that the evidence generated is generalizable rather than limited to a narrow subset of participants. This increases the likelihood of that trial results are replicable in the wider population influencing uptake and adherence. Within the UK, addressing disparities in research participation—particularly among underserved communities, rural populations, and areas of high deprivation—is critical to improving health outcomes and reducing longstanding inequalities in care.

In recent years, regulatory authorities around the world have strengthened their expectations for diversity and inclusion in clinical development. In addition, from a business perspective, inclusive research delivers significant advantages. By demonstrating that a medicine is effective and safe across diverse populations, companies can build greater confidence among prescribers, patients, payers, and policymakers globally. Moreover, by engaging underserved communities through intentional, transparent practices, sponsors contribute to rebuilding trust in the research enterprise—an investment that yields long-term benefits in recruitment, retention, and public perception.

Ultimately, the pursuit of research inclusion is a scientific necessity, underpinned by strong commercial and moral rationale. To achieve this we need clarity, focus, and a structured plan for increasing trial recruitment and accelerating delivery of innovation across the UK.

3. Mission, Tagline and Overarching Objective

3.1 Mission:

We believe that every person deserves to be seen, represented, and valued in commercial clinical research. Our mission is to conduct commercial clinical trials that include all communities affected by disease, from trial conception through to delivery and implementation, enabling medicines that work for everyone. Through intentional inclusion in both delivery and participation, we strive to build trust, reduce disparities, and implement innovations that truly serves humanity.

3.2 Tagline:

BRIDGE the gap – from awareness to access, from data to diversity.

3.3 Overarching Objective:

Research Inclusion as a BRIDGE for “making trials more inclusive for participants and the workforce that supports them”

4. Why Research Inclusion Matters

4.1 Scientific imperative

Most new medicines are commercially developed, and trial data are the foundation for regulatory approval and clinical use. When older people, women, certain ethnic groups and people with disabilities are under-represented in commercial trials, we create evidence gaps at the point of approval, where safety and efficacy in these groups are less certain. Differences in genetics, physiology and social determinants of health mean that one size does not fit all, and generalisability of findings to real-world populations truly matters.

Research inclusion strengthens the scientific integrity of trials by ensuring that outcomes reflect the diversity of those who will receive the interventions in routine care. It also reduces the risk that important benefits or harms in specific groups remain undetected until after widespread adoption. There are many examples where understanding why an investigational medicinal product performs differently in a sub-population has led to improvements for all populations.

4.2 Commercial imperative

For industry sponsors, speed is of the essence. The patent clock, the high cost of running open trials (median \$50m for Phase III), competitive positioning and investor pressure all depend on timely recruitment and robust data. Recruitment delays, high screen failure rates or failure to demonstrate value in key subgroups carry significant commercial and reputational risk. Understanding how an investigational medicinal product performs in UK minority populations (for example those of Chinese or Indian ethnicities) could be valuable for launching the drugs in markets elsewhere (for example in China and India). Generating evidence in underrepresented groups—such as older adults with multiple comorbidities, patients from socioeconomically deprived backgrounds, or those in rural and underserved areas—can also be critical, as these populations often reflect real-world treatment settings and may respond differently due to factors such as access to care or disease severity.

Inclusive research supports:

- **Faster recruitment** by engaging with communities with high prevalence of disease that have historically had limited access to trials and are less saturated with competing studies.
- **More representative evidence** to support regulatory and payer assessments across populations.
- **Stronger market confidence** among prescribers, patients, and payers and policymakers globally.

Inclusion and recruitment are complementary and, when implemented effectively, can be mutually reinforcing.

4.3 Ethical imperative

Clinical trials are only ethical when those who bear the burden of disease have fair access to participate and to benefit from innovation. When key groups are excluded or under-represented:

- Evidence gaps mean safety and efficacy for those groups may be unknown at approval.
- Treatments may be less effective or less safe for those not included. For example, Zolpidem clinical trials largely failed to account for sex as a biological variable, assuming drug metabolism worked the same way in both sexes.
- Erodes trust and contributes to division in society.
- The benefits of innovation concentrate where access already exists.

Inclusive practice is therefore the condition for clinical trials to be ethical - not an optional enhancement.

5. The inclusion gap: barriers and challenges

Despite growing recognition of the importance of inclusion, substantial barriers remain.

5.1 Trust and historical harms

- Legacies of unethical research, including Tuskegee and aspects of haemophilia research, have left deep scars in many communities.
- Lack of trust fuels suspicion and fear.

5.2 Practical and structural barriers

- Practical access issues such as distance to research sites, transport, time off work, caring responsibilities and childcare limit participation.
- Language barriers and lack of accessible materials, including formats suitable for different literacy levels and disabilities, exclude many potential participants.
- Low awareness of clinical trials, limited understanding of preferences within communities and complex information about risks and benefits all reduce engagement.

5.3 Infrastructure and concentration of research

- The traditional model concentrates research infrastructure and experienced investigators in a limited number of centres, often far from communities with the highest disease burden.
- These high-burden communities may have fewer competing studies, but also fewer opportunities, leading to an inclusion gap and missed recruitment opportunity.
- There are differences between the four nations, for example 'Be Part of Research' uptake is higher in England compared to Scotland due to front-page promotion by the NHS App.

Addressing these barriers requires coordinated action across communities, clinical teams, sponsors and research infrastructure.

6. Bridging the Gap – a UK-wide Inclusion Infrastructure

The CRDC UK Network provides a national inclusion infrastructure, connecting 35 CRDCs across the four nations through a single coordinated 'front door' approach.

What the Network brings to inclusion:

- A single front door: One coordinated route for sponsors to set up inclusive trials at pace.
- Data-driven site selection: Equitable feasibility assessment that places trials where need is the greatest.
- Reach into communities: Extending trials beyond big city hospital hubs to primary and community care settings.
- Access to a diverse population: The NHS gives a route to the UK's full diversity of patients

Inclusion is one of four supporting themes in the CRDC UK Network including PPIEP, Marketing, Events and Communications and Skills, Training and Workforce Development.

7. Our strategy – the BRIDGE Framework

Our strategy uses the BRIDGE framework: six themes with one shared goal - making trials more inclusive for participants and for the workforce that supports them.

7.1 Strategic Aims

B – Build trust with communities and the workforce

R – Reach under-represented populations

I – Industry trial placement

D – Data and insights across key diseases (e.g. Cancer, Cardiovascular, Vaccines)

G – Guarantee equitable access to research benefits

E – Engage diverse stakeholders



7.2 BRIDGE in practice

Theme	Focus	Objective Summary
B – Build Trust	Establish transparent, long-term partnerships with underrepresented communities and public contributors.	- Develop, adapt and/or implement participatory toolkits for specific communities. - Build ambassador networks with patients and community groups. - Insight survey, engagement activities that address gaps identified.
R – Reach Populations	Extend the Network's offer to underserved and geographically isolated populations.	- Pilot engagement in remote geographies urban diverse populations. - Partner locally – e.g., care home and carer access initiatives such as WATCH. - Co-produce interventions with communities to address local barriers.
I – Industry	Trial placement, database of research-ready communities, data-driven insight.	- Develop or adapt data-driven targeting tools to enable intelligent site selection. - Set impactful, measurable inclusion targets. - Advocate for inclusion in early protocol design and feasibility
D – Data and Insights	Focus on inclusion in areas of national strategic importance.	- Highlight initiatives in cancer, cardiovascular and vaccine trials. - Embed equality impact assessments into study
G – Guarantee Access	Ensure equitable access to the benefits of commercial research.	- Develop guidance for multilingual consent materials in industry research. - Promote flexible and inclusive trial designs. - Utilise data-driven targeting tool for study placement. - Raise awareness e.g., NHS app, Be Part of Research
E – Engage diverse stakeholders	Integrate inclusion into workforce, systems, and governance.	- Collaborate across NIHR and NHS infrastructure to demystify industry-sponsored research. - Appoint BRIDGE Fellows as regional champions. - Embed inclusion metrics in workforce development plans.

8. Implementation Plan and Metrics

To operationalise the BRIDGE framework, the CRDC UK Network has identified six cross-cutting objectives, each with defined key actions and performance indicators.

Objectives	Key Actions	Performance Indicators
1. Standardise inclusion approaches across CRDCs	- Align with national key stakeholders across four-nations around the BRIDGE inclusion framework. - Complete survey of current research inclusion initiatives at each CRDC. - Appoint BRIDGE Fellows as champions to promote benefits of industry-sponsored research regionally. - Deliver two BRIDGE dissemination events per year (e.g., Scotland and London). - Survey industry partners to ensure research inclusion strategy meets needs.	- Completion of baseline survey of inclusion initiatives across CRDCs. - Evidence of patient involvement and engagement to co-produce aspects of both research inclusion and PPIEP strategy (Year 1). - Co-leads join UK Inclusion Strategy group. - Feedback from industry partners on the usefulness and relevance of the strategy.
2. Extend the Network offer for underserved populations	- Partner with local organisations (e.g., national care home and carer access initiatives such as WATCH, community settings leads) to extend the Network offer and access to industry trials for underserved populations. - Identify and co-produce interventions with communities to address local barriers.	- Agree minimum dataset to be collected by all CRDCs (Year 1). - Increased participation from underserved populations and geographies. - Evidence of co-produced solutions adopted more widely across CRDCs.
3. Identify inclusion gaps and share best practice examples	- Conduct a survey identifying challenges with participation in industry-sponsored trials. - Agree core demographic dataset for inclusion monitoring. - Include an inclusion dashboard on the CRDC UK Network website to track inclusion metrics - Collect and showcase inclusion innovations (e.g., multilingual consent materials, exemplar specialities like HIV). - Disseminate innovations through BRIDGE events, website, and publications, NHS App, and Be Part of Research.	- Publish survey results and an associated action plan (end of Year 1). - Increased adoption of shared tools and practices across CRDCs. - User feedback from dissemination activities. - Data indicators, e.g., % of demographics reported. - Set targets based on gaps identified.
4. Advance commercial research inclusion	- Audit and review current toolkits for demystifying research in communities to identify gaps. - Refine and co-produce bespoke community engagement toolkits for research engagement or implement existing effective toolkits more widely. - Share toolkits and guidance through CRDC UK network and NIHR RRDN.	- Number of workshops delivered and toolkits produced. - Uptake of toolkits across CRDCs. - Documented improvement in community engagement outcomes.
5. Promote research inclusion to industry	- Conduct industry survey to assess inclusion needs and gaps. - Develop a BRIDGE Call to Action for commercial sponsors. - Advocate for inclusion in early protocol design and feasibility discussions.	- Industry survey response rate and findings published. - Number of companies endorsing the BRIDGE Call to Action. - Documented inclusion features in commercial study designs.

Objectives	Key Actions	Performance Indicators
6. Integrate inclusion into Network systems and workforce	- Assess current inclusion status of participants and workforce via NIHR RRDN Business Intelligence. - Introduce Equality Visual Analogue Scale (EQ VAS) as a standardised tool to assess inclusion perception and implement annually. - Embed inclusion metrics in workforce development plans.	- Baseline inclusion report published. - Number of staff completing EDI training. - Improved EQ VAS scores year-on-year. - Increased representation of diverse staff in leadership roles, including secondments and placements.

9. Insights for Action: Measuring Progress and Learning

The Insights for Action element is central to this strategy and integrates with the metrics outlined above. The Network will:

1. **Agree core dataset**

Agree a core demographic and inclusion dataset through Network collaboration, patient consultation and industry engagement.

2. **Track reporting completeness**

Monitor the % of commercial trials reporting complete demographic datasets at baseline and yearly.

3. **Develop an inclusion (BRIDGE) dashboard**

Adapt the existing CRDC dashboard to include an inclusion/ BRIDGE dashboard that:

- Monitors the data and identify where inclusion is lowest.
- Identifies underlying barriers.
- Supports tailored actions (e.g., translation services, community outreach, myth -busting).
- Incorporates and tracks workforce diversity metrics.
- Leverage BRIDGE Fellows and events.

4. **Use digital platforms to myth-bust and widen access**

Use NHS App and Be Part of Research to counter myths and increase awareness and representation, for example through a simple myth-busting quiz on the NHS App landing page.

10. Conclusion

Research inclusion is a scientific, commercial and ethical necessity for the CRDC UK Network and its partners. By recognising the barriers that create the current inclusion gap and using the BRIDGE framework, the Network can deliver commercial trials that are both faster and fairer.

This national strategy provides a clear roadmap: aligning stakeholders around a common framework, extending the Network offer to underserved populations, engaging industry through a BRIDGE Call to Action, and embedding inclusion into data, systems and workforce. Through sustained effort and transparent measurement, we will BRIDGE the gap – from awareness to access, from data to diversity – and ensure that commercial research truly serves all communities affected by disease.

11. Acknowledgements

Our strategy has been created through collaboration and stakeholder engagement. We would like to thank the Public Contributors, CRDCs and Industry colleagues who contributed to the strategy.

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