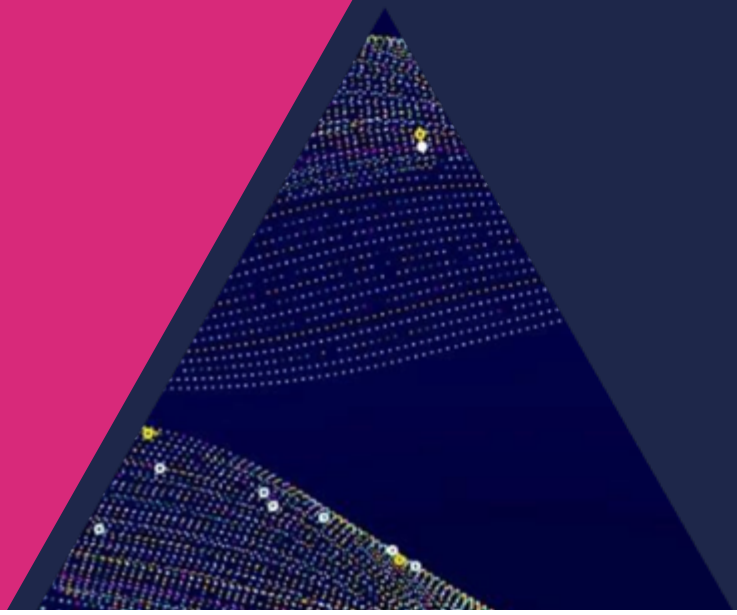
Advancing Clinical Trials

Making the UK a global leader in inclusive clinical trials

May 2025



egality
diversity in research
equality in health

PADDINGTON LIFE SCIENCES

Faculty of Pharmaceutical Medicine
of the Royal Colleges of Physicians of the United Kingdom





Executive summary

On 25 November 2024, the Faculty of Pharmaceutical Medicine, in partnership with Paddington Life Sciences and with the support of Egality, hosted a roundtable with key stakeholders in the UK research system. Attendees included regulators, sponsors, NHS Trusts, and medical research charities. The aim of the roundtable – to discuss strategies to make the UK a global leader in inclusive clinical trials.

This report summarises insights from the 2024 roundtable discussion. These are supported by a series of follow up engagements with leading national organisations, and desktop research to substantiate recommendations.

The authors acknowledge and welcome progress already made across the sector, including the work of the UK Clinical Research Delivery Programme. This report aligns with the ambition to establish the UK as a world leader in clinical trials. The recommendations aim to support stakeholders across the UK research system in advancing this shared objective.

Acknowledgements

We would like to extend our thanks to all attendees of the 'Advancing Clinical Trials – Making the UK a Global Leader in Inclusive Clinical Trials' roundtable for their valuable time and contributions. We would also like to thank the additional national stakeholders who engaged with us and provided insights following the roundtable. The collective cross-sector expertise and perspectives shared have been instrumental in informing this report.

For the full list of attendees and contributing stakeholders, please refer to page 25.

01 Introduction

On 25 November 2024, the Faculty of Pharmaceutical Medicine, in partnership with Paddington Life Sciences and with the support of Egality, hosted a roundtable with key stakeholders in the UK research system. Attendees included regulators, sponsors, NHS Trusts, and medical research charities. The aim of the roundtable – to discuss strategies to make the UK a global leader in inclusive clinical trials*.

Discussions ranged from tough ethical considerations on historical practices, to the practical changes needed to advance inclusivity in clinical trials. However, a unified message emerged:

> Being a global leader in inclusive clinical trials is a moral and strategic imperative. One that the UK is uniquely set up to deliver, building on significant progress in recent years.

However, **bold and decisive action is needed** for the UK to fulfil its potential.

The November 2024 roundtable followed an earlier roundtable held in March 2023, where leading system stakeholders convened to explore the same topic of advancing the UK's leadership in inclusive clinical trials. Since March 2023 there have been significant shifts in global policy and increasing challenges to equity, diversity, and inclusion (ED&I) initiatives.

This report summarises insights from the 2024 roundtable discussion. These are supported by a series of follow up engagements with leading national organisations, and desktop research to substantiate recommendations.

The recommendations aim to provide guidance for national and regional bodies, sponsors, and commercial/non-commercial research organisations. The report also serves as a call for bold and decisive action at a critical time for the UK and inclusive initiatives globally.

Any stakeholder in our health research system, whether from the commercial sector or the NHS, regardless of their level of experience, can play a role in establishing the UK as a global leader. You should read this report if you, like the participants at the roundtable, believe in the UK's potential and wish to take action to realise that vision.

Please note - Published on 6 May 2025, this report captures insights during a period of rapid progress. While it includes the latest developments at this time, the landscape continues to evolve.

* In this report, 'inclusive clinical trials' refers to trials that aim to ensure that research findings are applicable to diverse populations by actively including participants from various backgrounds, addressing potential biases, and promoting equitable access to treatments.

Context

Why should the UK be a global leader in inclusive clinical trials?

Inclusive trials can increase health and wealth in the UK

Inclusive trials increase health equity, as diverse trials provide more representative data which highlight varied effects of a treatment across different populations. This leads to more efficacious treatments for everyone.

Inclusive trials could drive economic growth by strengthening life sciences, creating jobs, and attracting global investment - leveraging the UK's diverse population and research infrastructure.

The UK is uniquely placed to be a global leader in inclusive clinical trials

The **UK's population** is diverse, meaning we have the potential to reach a broad range of participants for clinical trials.

The **NHS Infrastructure** has the potential to recruit across all socioeconomic and demographic groups.

The UK's comprehensive longitudinal health data, spanning from birth through to later life, is a critical asset for monitoring long-term health outcomes, and providing real-word data.

The time is now for the UK, due to national progress and global political change

The UK must **re-establish itself** as a leading destination for clinical trials, as it currently lags behind several European counterparts.

The UK has made **significant progress** on inclusive clinical trials, with the Medicines and Healthcare products Regulatory Agency/Health Research Authority (MHRA/HRA) diversity plan guidance launching this year, alongside the National Institute for Health and Care Research (NIHR) making inclusion a key condition for funding.

Global policy developments and growing scrutiny of ED&I initiatives have created a changing landscape. This is a moment for the UK to stand firm, make meaningful progress, and set a strong example for others to follow.

02 Recognising progress since March 2023 (2 years)

This section provides an overview of the progress achieved since the 2023 roundtable. The previous report outlined recommendations across four key themes, and participants in this 2024 roundtable shared examples and discussed the positive advances made in this relatively short period.

Please note, this report only refers to examples of progress discussed at the 2024 roundtable. More detail on each is available in Appendix 1.

System leadership

At the 2023 roundtable, this theme focused on strong system leadership to embed equity, diversity, and inclusion into clinical research. It emphasised ensuring inclusive research is driven from the top, with regulators, funders, and institutions setting clear expectations, aligning with international guidance. System leadership in diverse clinical trials is exactly what's needed to shift from fragmented efforts to real, sustainable inclusion in research.

Since then, the HRA and the MHRA have released draft guidance on how to develop inclusion and diversity plans that ensure clinical research is designed to include people who could be impacted by the findings, including those underserved by research. The NIHR has introduced new ED&I requirements for its funded research infrastructure, ensuring that Clinical Research Facilities, Biomedical Research Centres, and Patient Safety Research Collaborations integrate inclusion strategies into their application processes, annual reporting, and ongoing initiatives. These efforts align with national priorities to improve diversity in clinical research, as outlined in the NIHR's ED&I framework and the policy paper The Future of Clinical Research Delivery: 2022 to 2025 Implementation Plan. See Appendix 1 for further examples.

Aligning clinical and commercial priorities

At the 2023 roundtable, discussions emphasised the need to align commercial and clinical priorities, balancing data quality with speed and efficiency. Participants recognised the commercial value of diversity in trials and establishing internal processes that promote stronger collaboration between clinical research and commercial teams.

Since March 2023, a growing number of sponsors are now treating diversity as a critical success metric, requiring research sites to report on participant diversity throughout the trial process. A clear example of this in practice is Moderna pausing recruitment on a vaccine trial due to poor diversity, prioritising inclusivity as a decisive factor in trial progression.

Diverse leadership

Participants at the 2023 roundtable highlighted the critical role of diverse leadership in shaping more inclusive clinical research. The participants called for investment in diverse clinical leadership, inclusive key opinion leader (KOL) networks and support for healthcare professionals to offer more research opportunities to patients. Leaders from diverse backgrounds bring lived experiences that shape relevant goals, inclusive methods, and culturally competent recruitment. Representation builds trust and encourages participation from underrepresented communities. Diverse perspectives foster creative, context-aware research.

Since then, significant efforts have been undertaken across the UK to foster a more diverse landscape in research and medical leadership. For instance, the NIHR has part-funded the Melanin Medics Envision Med research project, which supports Black African and Caribbean students aspiring to study medicine. By providing university-style teaching, research experience, mentorship, and application guidance, this initiative is helping to create a more diverse future medical workforce. The Academy of Medical Sciences' SUSTAIN – Women in Research programme supports women in advancing their independent research careers, ensuring stronger representation in leadership roles. Additionally, the General Medical Council (GMC) has updated its Good Medical Practice professional standards, effective January 2024, to include a requirement for doctors to consider opportunities to conduct research, participate in studies, and inform patients about research opportunities.

Deep engagement

At the 2023 roundtable, discussions underscored the importance of deep and sustained engagement to build trust and increase participation in clinical research. Participants emphasised that sustained presence in underserved communities builds trust and access, calling for investment in outreach, early engagement, and clearer guidance to support inclusive research. Deep engagement in clinical research means shifting from transactional participation to true partnership.

Participants at the 2024 roundtable noted significant progress here. For example, Roche has expanded its Global Diversity Programme, originally launched in the US, into Canada and the UK. This initiative allows sponsors to establish strategic, long-term relationships with research sites to support outreach work in communities, ensuring greater inclusivity in clinical trials. Funding models like NHS England's Research Engagement Network (REN) Programme have also been developed to drive participation and involvement from underrepresented groups. Additionally, The Association of the British Pharmaceutical Industry (ABPI) Diversity & Inclusion in People-centred Research Hub, launched in 2022, continues to provide resources and best practices for improving representation in trials. The Prescription Medicines Code of Practice Authority (PMCPA) have published guidance on the use of social media which includes a section on clinical trial recruitment. Complementing this, NHS England's Health Inequality Improvement Forum brings together stakeholders from across the NHS and the wider health sector to discuss best practices and learnings, to improve health inequalities.

The progress achieved since the last roundtable reflects an increasing commitment to integrating equity, diversity, and inclusion in clinical research. However, to establish the UK as a global leader, continuous collaboration and sustained action are crucial to ensure these efforts result in lasting change.


Digital
Collaboration
space

03 Roundtable discussions

This section summarises the discussions from the 2024 roundtable across four themes and offers recommendations for specific stakeholders within the system.

3.1 Historical practices and considerations for the future

Achieving global leadership in inclusive clinical trials requires the UK to critically examine and move beyond traditional research approaches. Many long-standing systemic practices—though deeply embedded—limit progress toward greater inclusion. This moment presents a valuable opportunity for the UK to lead by example, with regulators and national bodies taking bold and decisive action.

3.1.1 The scientific question and statistical evidence

The primary purpose of a clinical trial is to determine whether a drug is clinically safe and effective. The first step is to develop a scientific question that tests a hypothesis about a certain treatment and condition. E.g. a trial might investigate whether Treatment X is more effective than the current standard of care, Treatment Y. For a medicine or medicinal product to be approved for sale in the UK, the MHRA must evaluate evidence generated from clinical trials. This evidence must demonstrate not only the clinical effectiveness of the product but also how well it addresses the scientific question posed.

Despite the clear need for greater inclusivity, participants acknowledged concern amongst stakeholders, including statisticians, that if we make trials more diverse, it will mean the trial is not homogenous enough to conclude that the medicine is clinically effective. Sponsors are also unclear on what evidence will be required by MHRA to demonstrate clinical effectiveness and an acceptable representation of diverse populations.

Recommendation 1:

The MHRA should facilitate sponsors in improving diversity and inclusion of clinical trial participants, where it is safe and scientifically appropriate to the clinical trial objectives, for example through scientific advice.

3.1.2 Guidelines and Standards of Care

The National Institute for Health and Care Excellence (NICE) develops evidence-based guidance that informs health and care. Roundtable participants, however, noted that this guidance may be based on clinical trials lacking diversity. While NICE did not participate in the roundtable, a follow-up discussion confirmed their ongoing initiatives to address this. NICE's **Transformation Plan (2021–2026)** highlights its commitment to reducing health inequalities, and its **Equality, Diversity, and Inclusion Roadmap (2020–2024)** outlines its approach. Additionally, NICE's guidelines manual instructs developers to consider equality and diversity when using trial evidence to inform recommendations.

Recommendation 2

NICE should continue its efforts to reduce health inequalities, in line with its existing transformation plan and roadmap.

3.1.3 Payments

In the UK, payment practices for clinical trial participants are inconsistent, with some trials offering financial compensation and others not. Participants highlighted a tension between two perspectives. One view advocates for reimbursement as essential to ensuring fair participation and improving representation from underserved groups. Conversely, another perspective considers financial compensation as potentially coercive, particularly for individuals from underserved communities.

This point has been explored in existing guidance including the (previous) NHS England initiative on increasing diversity in research participation and the NIHR's ED&I framework for positive action and the HRA's guidance on payments and incentives in research. Yet, despite these resources uncertainty remains, and more work is needed to provide clear guidance on fair reimbursement, and the amount participants can be paid as this varies significantly. This should be in line with the ICH Good Clinical Practice Guidance.

Recommendation 3

The **HRA** should facilitate a national discussion on payments for research participants, with a specific focus on increasing inclusion in clinical trials.

3.1.4 The role of the pharmaceutical industry and the ABPI Code of Practice

The ABPI is the organisation that represents innovative, R&D-based pharmaceutical companies in the UK. The ABPI Code of Practice sets out the requirements the industry must comply with.

Participants suggested the Code could offer clearer guidance on how companies might use innovative strategies - like social media or trust-building activities beyond specific trials - to boost diversity in recruitment. There was strong interest in seeing bolder action from ABPI, exploring how pharma can work within the Code to deliver creative, inclusive engagement. This aligns with HRA's ongoing efforts to develop guidance on inclusion and diversity in clinical research.

The ABPI, guided by its Patient Council, maintains an active workstream on Equity, Diversity, and Inclusion (ED&I). Recently, in collaboration with the Association of Medical Research Charities (AMRC), hosted a conference on ED&I in clinical trials, bringing together industry, patient organisations, regulators and research funders to explore challenges and solutions collaboratively.

Recommendation 4

The **ABPI** should build on momentum by deepening its efforts in ED&I activity. The organisation should take a bold, innovative approach to supporting companies in improving inclusivity in clinical trials, providing clear guidance on permissible recruitment and community engagement practices in alignment with the code.

3.2 System fundamentals

The recommendations in this section are longstanding and have been discussed for years. However, the roundtable discussions underscored persistent barriers to progress, on data, protocols and decentralised trials. Without addressing these fundamental challenges, the UK will struggle to achieve its goal of becoming a global leader in inclusive clinical trials.

3.2.1 Establishing a baseline of diversity data

To achieve global leadership in inclusive clinical trials, the UK must systematically collect demographic data to establish a baseline for diversity and monitor progress. With no European leader currently driving this effort, the UK has a unique opportunity to lead. Furthermore, as health outcomes decline, ensuring accurate and representative trial data is essential to effectively addressing population health needs.

Measuring progress requires two data types: (1) Standardised participant data to assess sector performance and (2) Epidemiological data to understand disease impact across groups, and recruit the right population to trials. While some epidemiological data exists, gaps remain, and trial recruitment data is poorly coordinated. No single body systematically collates this information. While there are numerous local organisations collecting data in silos, participants acknowledged the need for improved regional coordination, involving Health Innovation Networks, Integrated Care Boards, and NIHR Regional Research Delivery Networks, to centralise data.

In parallel, Commercial Research Delivery Centres (CRDCs) and Clinical Research Organisations (CROs) should share anonymised diversity data and best practices. The CRDC Network is already integrating a diversity metric as a key performance indicator, positioning it to lead in commercial trial data collection.

Recommendation 5a

A **national body** needs to take responsibility for driving the collection of trial participant demographic data across national bodies so we can build a UK-wide picture.

Recommendation 5b

Health Innovation Networks, Integrated Care Boards, the CRDC Network NIHR Regional Research Delivery Networks should drive collection of trial participant demographic data within their regions and support local trial sites to submit the right data in the right place.

Recommendation 5c

NHS trial sites, CRDCs, and CROs should share anonymised trial participant demographic data, alongside any learnings and best practices, with the appropriate regional and national bodies, and sponsors.

3.2.2 Develop inclusive protocols

A study protocol provides information on the background and rationale for a trial and outlines the study plan. Clinical trial protocols are often developed using generic 'copy-paste' inclusion and exclusion criteria. This means patients are frequently excluded from trials, based on e.g. comorbidities or concomitant medication. This limits diversity in clinical trials, and reduces the real-world applicability of results.

Roundtable participants acknowledged that commercial and non-commercial trials tend to rely on templates, reinforcing restrictive eligibility across multiple studies. The increasing reliance on AI in protocol design may also present a risk, as models derived from existing trials continue to produce protocols that lack inclusivity.

Initiatives like NIHR's ED&I framework, and the INCLUDE guidance provide guidance on protocol development. But more work is needed to ensure inclusive protocols are actively developed to increase diversity.

To note - Many UK sponsors are global companies with protocols developed outside the UK. Further work is needed globally to promote diverse protocol development on an international scale.

Recommendation 6a

HRA / NIHR should produce and/or signpost to guidance on developing inclusive protocols, e.g. the HRA/MHRA diversity action plan guidance, with a focus on exclusion and inclusion criteria to increase, not restrict diversity.

Recommendation 6b

UK research organisations and sponsors should develop more flexible, inclusive protocols, regularly reviewing and updating inclusion and exclusion criteria to reflect real-world patient populations. AI tools should be used responsibly to enhance, rather than replicate, these criteria.

3.2.3 Accessible community-based and decentralised trials

At present, much research activity is centered in major teaching hospitals. This can limit the pool of potential trial participants and lead to the consistent under-representation of certain groups. To address this, we should seek to deliver research activities through a wider range of centres and implement programmes to engage diverse and under-represented populations in research. Community pharmacists, private pharmacies, and primary care providers play a crucial role in reaching diverse patient populations. NIHR has recognised the importance of community-based research in effective trial delivery through its Study Support Services, which highlight the potential of GP surgeries, care homes, pharmacies, and other community settings in expanding trial access. The upcoming launch of Primary Care Commercial Research Delivery Centres (CRDCs) in November 2025, also present a critical opportunity to enhance community-based trial delivery in a coordinated way.

There is, however, currently no standardised framework to guide sponsors and clinical trial leads in effectively designing and implementing accessible community trials. Participants raised the need for more national guidance, and sharing of best practice, as well as the need to resource NHS research staff to raise awareness about clinical trials in the community.

Recommendation 7

NIHR should develop a toolkit for designing accessible community-based trials, incorporating defined roles for community pharmacists, private companies, and primary care providers, including Primary Care CRDCs.

3.2.4 Optimise GP engagement

Participants acknowledged that while GPs are ideally positioned to discuss clinical trial opportunities with underserved groups, this may not be possible in many appointments due to insufficient support for GPs, and the many other considerations GPs need to address within an appointment.

However, there are several ways to better support GPs in identifying suitable clinical trials for patients. These include automatic prompts during consultations, embedded systems in electronic records to generate patient lists, and existing solutions that allow GPs to invite patients outside consultations. There are also ongoing efforts to explore automated prompts to enhance trial discussions during appointments.

Participants also suggested that tailored training for GPs would help build confidence in discussing clinical trials with patients and help equip them with the knowledge and tools needed to engage with diverse populations.

Recommendation 8a

Clinical systems providers should continue work to embed clinical trial recruitment into routine clinical software systems and explore how integrated systems and prompts may best support diverse recruitment into clinical trials.

Recommendation 8b

NIHR and **RCGP** should develop and co-ordinate training for GPs and their wider multi-disciplinary teams on recruiting people from underserved communities to clinical trials.

Recommendation 8c

NIHR Regional Research Delivery Networks (RRDNs) should monitor primary care sites accessing training and funding calls, to ensure equity of access across different sites.

3.3 Engaging underserved communities

To establish itself as a world leader, the UK must build trust in clinical trials among underserved communities. A robust network of community organisations is essential for fostering trust and facilitating recruitment. A UK-wide strategy is necessary to effectively collaborate with and support these community organisations.

3.3.1 Mapping and monitoring sustained community engagement

Community organisations are critical stakeholders in advancing diversity in clinical trials. Participants highlighted the need for better tools and guidance to help identify and map these organisations near research sites, and build and monitor trust levels within communities. There was also concern that new MHRA/HRA draft guidance, and NIHR inclusion condition for funding, might lead to an increased burden on community groups with more requests to support in research.

Beyond mapping and measurement, participants agreed that long-term, sustained engagement is essential for building trust, and improving diversity in clinical trials. This means working with communities to build trust in, and awareness of, research outside of recruitment for specific trials. Existing initiatives, such as the (previous) NHS England Research Engagement Network Development Programme and NIHR's Community Research and Engagement Network (COREN), serve as strong examples of how this can be effective.

Recommendation 9a

NIHR to assess the impact of the new inclusion condition for funding on community organisations, and provide or signpost to training and guidance that promote responsible, people-centred engagement without overburdening partners.

Recommendation 9b

MHRA and **HRA** to evaluate the impact of new inclusion and diversity guidance on community organisations, and signpost to training and guidance that promote responsible, people-centred engagement without overburdening partners.

Recommendation 9c

NIHR to continue to fund and monitor the impact of the programmes above (e.g. COREN), and similar programmes. Supporting local and regional bodies to deliver trust building activities with community organisations outside of clinical research.

3.4 Sharing best practice

Initiatives to enhance diversity in clinical trials are underway throughout the UK; however, we have yet to establish an effective mechanism for sharing best practices across various sectors of the health system. To position itself as a global leader, the UK must explore new ways to facilitate the sharing of best practices across different areas.

3.4.1 Sharing best practice

While local initiatives effectively enhance diversity in clinical trials, best practices are not systematically shared across sites, leading to fragmented efforts. Participants highlighted the need for a national, pre-competitive platform to facilitate knowledge exchange.

Existing initiatives, such as the ABPI People-centred Research Hub, already promote best practices in diversity, inclusion, patient engagement, and research transparency. Additionally, the Commercial Research Delivery Centre (CRDC) Network, which is being established to coordinate UK CRDCs in commercial research, presents an opportunity to compile and share insights on inclusive recruitment strategies.

Recommendation 10a

NIHR and **ABPI** should build on existing progress by expanding access to and sharing case studies in pre-competitive spaces, with support from companies and researchers providing content.

Recommendation 10b

Once established, the **CRDC Network** should disseminate insights on inclusive clinical trials, compiling case studies and best practices from its sites and sharing them through appropriate forums and national stakeholders.

Conclusion

Ensuring the UK becomes a global leader in inclusive clinical trials requires a coordinated, system-wide approach. The insights from this roundtable, along with follow-up engagements and sector research, highlight both progress made and critical areas for improvement.

The recommendations outlined in this report aim to strengthen the UK's research ecosystem by fostering collaboration, enhancing regulatory and funding frameworks, and prioritising meaningful engagement with underrepresented communities. While significant steps have been taken, continued commitment from policymakers, industry leaders, healthcare providers, and community organisations is essential to drive lasting change.

By implementing these recommendations, the UK can not only improve inclusion in clinical trials but also enhance research quality, patient outcomes, and global competitiveness. We encourage all stakeholders to use this report as a foundation for further action, ensuring that inclusive research remains a core focus of the UK's research system.

Appendix

Previous recommendations and progress since 2023

This table sets out the recommendations from the previous 2023 roundtable, and examples of where progress has been made.

Please note, this a summary of examples discussed at the roundtable, not an exhaustive list of progress.

Recommendation	Examples on progress
System leadership	
The HRA should consider r**equiring ED&I plans as a part of the clinical trial ethics** approval process, where possible aligning with international guidance, such as that developed by the FDA.	The Health Research Authority (HRA) and the Medicines and Healthcare products Regulatory Agency (MHRA) in the UK have released a draft Diversity Plan to ensure clinical research is designed to represent a diverse population. The updated plan, following consultation is expected later in 2025.
The NIHR and other research funding bodies and charities should consider **strengthening ED&I requirements** for directly funded research projects.	NIHR has introduced a requirement for inclusion strategies from funded research infrastructure. NIHR-funded Clinical Research Facilities, Biomedical Research Centres and Patient Safety Research Collaborations have already developed and published their strategies and supporting actions. E.g., there is strong ED&I element in their initial application processes, annual reporting etc. In all research programmes funded by NIHR, there has to be costed research inclusion plans and researchers are held accountable for delivering on the plans. NIHR has a number of initiatives to tackle the barriers which lead to groups of people being underrepresented in research careers. These include a new pre-application support fund. The fund aims to help individuals who need more support in applying for NIHR career development awards.
Clinical trial registries should be audited to ensure they reflect the diversity of the UK population, and where they do not, plans should be established to address gaps.	An audit from London North West University Healthcare Trust showed that the clinical trial registry is very ethnically diverse.

Recommendation	Examples on progress
Aligning commercial and clinical priorities	
Pharmaceutical companies should embed **internal processes** which facilitate **closer working and collaboration between clinical research and commercial management** functions.	Topic not discussed at roundtable.
Clinical trial **ED&I reporting requirements** should be strengthened and standardised, to ensure that ED&I is identified as a key metric for commercial success	A number of sponsors are focusing on diversity as a key metric for success. Sites are being asked to report on their diversity metrics throughout the trial. Moderna for example have paused recruitment on a vaccine trial due to poor diversity.
Diverse leadership	
Programs should be developed by research institutes, funders, and pharmaceutical companies to **train and foster diverse communities of researchers**.	NIHR has part-funded a Melanin Medics Envision Med research project. The project aims to support Black African and Caribbean students hoping to go to university to study medicine. It gives students experience of university-style teaching and research. The project also provides mentorship and application advice
Pharmaceutical companies and other research commissioners should ensure that diverse **pools of KOLs are developed to review trial designs and protocols**, with a view to ensuring diversity in participation.	The Academy of Medical Sciences SUSTAIN – women in research programme was established. This enables women in research to thrive in their independent research careers.
Clinicians at all levels should be encouraged to **present research opportunities to patients** as a part of routine care.	The GMC Good Medical Practice Professional Standards were updated effective January 2024. These now include a standard for doctors to consider opportunities to conduct, take part in and tell patients of opportunities for them to take part in research.

Recommendation	Examples on progress
Deep engagement	
Pharmaceutical companies should work with others to support **consistent and sustained patient outreach in diverse areas about the importance of research**, particularly where populations have a higher-than-average prevalence of diseases in the research pipeline.	The Roche Global diversity programme, was started in the US and is now rolled out into Canada and the UK. The programme allows the sponsor to have a strategic, long term relationship with sites to support outreach work in communities.
Research bodies such as **the NIHR** should actively fund research into effective models for **pre-clinical community engagement** which supports diverse participation in research.	The NHS England's Research Engagement Network (REN) programme aims to increase diversity in research participation, particularly among underserved communities.
Research bodies, regulators, and industry bodies should seek to **promote and disseminate good practice in clinical study design**, development and community outreach which fosters diverse participation in research.	The ABPI people-centred research hub (launched 2022) and the National Healthcare Inequalities Improvement Network are strong examples of best practice sharing in the sector.
The **ABPI and PMCPA should produce guidance** on the ABPI Code of Practice to enable and support patient outreach in relation to research.	PMCPA social media guidance was published in 2023, and updated last year, and includes a section on clinical trial recruitment. The ABPI are also liaising with the HRA on this topic to see how they can collaborate further.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Final list of recommendations

Recommendation 1

The MHRA should facilitate sponsors in improving diversity and inclusion of clinical trial participants, where it is safe and scientifically appropriate to the clinical trial objectives, for example through scientific advice.

Responsible body/organisation:
MHRA

Recommendation 2

NICE should continue its efforts to reduce health inequalities, in line with its existing transformation plan and roadmap.

Responsible body/organisation:
NICE

Recommendation 3

The HRA should facilitate a national discussion on payments for research participants, with a specific focus on increasing inclusion in clinical trials.

Responsible body/organisation:
HRA

Recommendation 4

The ABPI should build on momentum by deepening its efforts in ED&I activity. The organisation should take a bold, innovative approach to supporting companies in improving inclusivity in clinical trials, providing clear guidance on permissible recruitment and community engagement practices in alignment with the code.

Responsible body/organisation:
ABPI

Recommendation 5a

A national body needs to take responsibility for driving the collection of trial participant demographic data across national bodies so we can build a UK-wide picture

Responsible body/organisation:
A national body

Recommendation 5b

Health Innovation Networks, Integrated Care Boards, the CRDC Network and Research Delivery Networks should drive collection of trial participant demographic data within their regions and support local trial sites to submit the right data in the right place.

Responsible body/organisation:
Health Innovation Networks, Integrated Care Boards, CRDC Network, Research Delivery Networks

Recommendation 5c

NHS trial sites, CRDCs, and CROs should share anonymised trial participant demographic data, alongside any learnings and best practices, with the appropriate regional and national bodies, and sponsors.

Responsible body/organisation:
NHS trial sites, CRDCs, CROs

Recommendation 6a

HRA / NIHR should produce and/or signpost to guidance on developing inclusive protocols, e.g. the HRA/MHRA diversity action plan guidance, with a focus on exclusion and inclusion criteria to increase, not restrict diversity.

Responsible body/organisation:
HRA / NIHR Regional Research Delivery Networks

Recommendation 6b

UK research institutions and sponsors should develop more flexible, inclusive protocols, regularly reviewing and updating inclusion and exclusion criteria to reflect real-world patient populations. AI tools should be used responsibly to enhance, rather than replicate, these criteria.

Responsible body/organisation:
UK research institutions and sponsors

Recommendation 7

NIHR should develop a toolkit for designing accessible community trials, incorporating defined roles for community pharmacists, private companies, and primary care providers, including Primary Care CRDCs.

Responsible body/organisation:
NIHR

Recommendation 8a

Clinical systems providers should continue work to embed clinical trial recruitment into routine clinical software systems and explore how integrated systems and prompts may best support diverse recruitment into clinical trials.

Responsible body/organisation:
Clinical systems providers

Recommendation 8b

NIHR and RCGP should develop and co-ordinate training for GPs and their wider multi-disciplinary teams, on recruiting people from underserved communities to clinical trials.

Responsible body/organisation:
NIHR, RCGP

Recommendation 8c

NIHR Regional Research Delivery Networks (RRDNs) should monitor primary care sites accessing training and funding calls, to ensure equity of access across different sites.

Responsible body/organisation:
NIHR Regional Research Delivery Networks (RRDNs)

Recommendation 9a

NIHR to assess the impact of the new inclusion condition for funding on community organisations, and provide or signpost to training and guidance that promote responsible, people-centred engagement without overburdening partners.

Responsible body/organisation:
NIHR / HRA

Recommendation 9b

MHRA and HRA to evaluate the impact of new inclusion and diversity guidance on community organisations, and signpost to training and guidance that promote responsible, people-centred engagement without overburdening partners.

Responsible body/organisation:
MHRA / HRA

Recommendation 9c

NIHR to continue to fund and monitor the impact of the programmes above (e.g. COREN), and similar programmes. Supporting local and regional bodies to deliver trust building activities with community organisations outside of clinical research.

Responsible body/organisation:
NIHR

Recommendation 10a

NIHR and ABPI should build on existing progress by expanding access to and sharing case studies in pre-competitive spaces, with support from companies and researchers providing content.

Responsible body/organisation:
NIHR, ABPI

Recommendation 10b

Once established, the CRDC Network should disseminate insights on inclusive clinical trials, compiling case studies and best practices from its sites and sharing them through appropriate forums and national stakeholders.

Responsible body/organisation:
Regional Research Delivery Networks, Research and Engagement Networks, CRDC Network

Roundtable attendees list

Co-Chairs

Suki Balendra | Director of Strategic Partnerships, Paddington Life Sciences

Sheuli Porkess | President, Faculty of Pharmaceutical Medicine

Attendee

Victoria Bhui | Associate Director, Investigator Engagement, Lilly

Christiana Dinah | R&D Director, London North West University Healthcare Trust

Kingyin Lee | Head of Clinical Trials, MHRA

Angela McFarlane | Vice President, Strategic Planning UK & North Europe, IQVIA

Edward Merivale | Senior Clinical Operations Lead, Roche

Louise Newport | Head of Clinical Trials Engagement & Governance, DHSC

John Ndikum | Pharmaceutical Physician, FPM

Andy Nolan | Head of Clinical Operations UK and Ireland, IPSEN

Marcia Philbin | Chief Executive, FPM

Marie Pullen | Clinical Operations Manager, MSD

Elizabeth Robertson | Director of Research and Clinical, Diabetes UK

Naho Yamazaki | Deputy Director of Policy and Partnership, HRA

Thank you also to those who were not at the roundtable, but contributed via follow-up meetings and report reviews:

Amit Aggarwal | Executive Director Medical Affairs and Strategic Partnerships, ABPI

Dr Laura Boothman | Senior Innovation and Research Policy Manager (Clinical), ABPI

Keerti Gedela | Chelsea & Westminster NHS Foundation Trust, London

Margaret Ikpoh | Vice-Chair Professional Development & Standards, RCGP

Michelle Oritsejafor | Study Participation Inclusion Senior Manager, NIHR North London Regional Research Delivery Network

Dr Zoya Panahloo | Senior Medical Director, Head of Rare Medical, UCB

Isabel Baker | Optum

Colleagues at the National Institute for Health and Care Excellence (NICE)

For questions, feedback, or more information about the roundtable, please **contact team@egality.health**

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