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The Academy of Medical Sciences

Innovative clinical research: delivering trials in the community

Monday 17 November 2025

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Innovative clinical research: delivering trials in the community

FORUM workshop on Monday 17 November 2025

Contents

All web references were accessed in March 2026.

Executive summary

In November 2025, the Academy of Medical Sciences, the Association of the British Pharmaceutical Industry (ABPI) and the National Institute for Health and Care Research (NIHR) Research Delivery Network (RDN) jointly organised a FORUM workshop focusing on decentralised methods of clinical trial delivery.[1] The workshop involved approximately 60 participants including people with relevant lived experience, and representatives from healthcare, academia, regulation, funding, industry and government. Participants examined the components required to facilitate decentralised trial delivery and agreed that decentralised methods could better support the needs and preferences of people taking part in clinical trials. However, there is a need for clearer guidance, training, and shared learnings to increase uptake. **Discussions highlighted the following suggestions:**

1. Early engagement in trial design

1.1 **Engage and involve trial participants and healthcare staff early in trial design.** Early engagement and involvement could identify activities that would be most beneficial to decentralise, and enable trial participants to ask for their needs and preferences to be considered in trial design, such as through decentralised approaches.

1.2 **Obtain clearer regulatory guidance on decentralised clinical trial approaches.** This could be coordinated by regulators and research communities. It will also be important to compare and coordinate guidance with other countries.

1.3 **Embed research within trials to evaluate decentralised activities and build an evidence base.** Evaluation frameworks should include mechanisms to feed back on what does and doesn't work. 'Pilot studies' and publications that assess the benefits and impacts of different decentralised activities and models should be encouraged.

2. Awareness and knowledge-sharing

2.1 **Increase awareness on decentralised approaches with the public and research community.** Researchers should engage patient networks and community groups on decentralised methods, particularly underserved groups. Awareness amongst the research community could be built through forums and networks.[2]

2.2 **Establish resources for sponsors and trial teams to share knowledge on decentralised approaches.** These resources could build on evaluation frameworks, pilot studies and published research on decentralised methods to collate evidence on the benefits and impacts of decentralising activities. Mechanisms to support decentralised delivery could also collate case studies that share learnings, including on technologies and software.

3. Systems and delivery

3.1 **Map the skills and training needed to support decentralised trial delivery.** Decentralised activities may require training around safeguarding, data, quality control, logistics and digital systems. Clarity will be needed on staff roles, responsibilities and accountability.

3.2 **Ensure systems and processes are fit for purpose to support decentralised activities.**

a. Design and review approaches to contracting and costing to account for the complexity of trials that include decentralised trial activities (particularly trials offering parallel remote and site-based activities).

b. Establish how neighbourhood health services, and primary, secondary and community care service, including the commercial research delivery centres (CRDCs) could support decentralised activities.

c. Establish clearer interoperability standards for software platforms and central vendors.

[1] This report uses 'decentralised' or 'remote' methods of trial delivery to describe trials where some or all activities occur at locations other than the main investigator site, particularly if said activity is delivered or accessed closer to the trial participant (e.g. at home). This workshop did not explore whether the term 'decentralised clinical trial' is appropriate, or whether there is better, alternative terminology.

[2] e.g. The UK Trial Managers Network and the UK Clinical Research Collaboration Clinical Trials Unit (UKCRC CTU) Network.

Introduction

There is an opportunity for the UK to be a global leader in the field of digital or decentralised approaches to clinical trials.[3] Decentralised or remote methods of clinical trial delivery are considered by many a means of delivering more accessible and more inclusive patient-centred trials.[4] These can be fully remote and outside secondary care settings or contain only some decentralised activities.

Generally we define decentralised methods as containing activities that differ from more traditional methods of identifying and recruiting participants, obtaining consent, providing and administering the intervention [e.g. investigational medicinal product (IMP) or drug], and providing baseline or outcome data (e.g. which may take place at a trial participant's home, or at local community or healthcare facilities). There is a growing ambition amongst many researchers and organisations to increase uptake of decentralised clinical trial activities in the UK and this is reflected in initiatives such as the National Institute for Health and Care Research (NIHR)'s Remote Methods of Trial Delivery Project,[5] and the Trials@Home research consortium's recommendations and toolkits.[6]

In November 2025, the Academy of Medical Sciences, the Association of the British Pharmaceutical Industry (ABPI) and the NIHR Research Delivery Network (RDN) jointly organised a FORUM workshop to discuss how to further facilitate adoption and scale-up of decentralised and remote methods of clinical trial delivery in the UK. The workshop involved people with relevant lived experience, and representatives from healthcare, academia, regulation, funding, industry and government.

The workshop was developed with input from an expert steering group and co-chaired by **Professor Paula Williamson FMedSci**, Professor of Medical Statistics at the University of Liverpool, and **Professor Isla Mackenzie**, Professor of Cardiovascular Medicine at the University of Dundee.

By reducing geographical barriers, decentralised activities could improve trial accessibility, inclusivity, and participant diversity. In turn, this could better support recruitment and continued participation of people in trials and ensure trials better reflect real-world populations. By reducing travel and potentially the number of physical trial sites needed, decentralised clinical trial activities could also result in improved environmental sustainability.[7]

The COVID-19 pandemic necessitated a rapid and radical shift towards the remote delivery of clinical trials and has provided insights into best practices and examples of enablers.[8,9] However, including decentralised and remote activities within clinical trials can be challenging. Challenges

[3] Office for Life Sciences (2023). *Commercial clinical trials in the UK: the Lord O'Shaughnessy review – final report.* https://www.gov.uk/government/publications/commercial-clinical-trials-in-the-uk-the-lord-oshaughnessy-review/commercial-clinical-trials-in-the-uk-the-lord-oshaughnessy-review-final-report
[4] NHS Heath Research Authority (2026). *Decentralised trial methods position statement.* https://www.hra.nhs.uk/planning-and-improving-research/policies-standards-legislation/clinical-trials-investigational-medicinal-products-ctimps/decentralised-trial-methods-position-statement/
[5] National Institute for Health and Care Research. *Remote methods of trial delivery*. https://sites.google.com/nihr.ac.uk/remotemethodsoftrialdelivery/home/about
[6] Trials@Home. https://trialsathome.com/
[7] EMJ Gold. *Decentralised clinical trials: going green*. https://www.emjreviews.com/emj-gold/article/decentralised-clinical-trials-going-green/
[8] Masoli JA *et al*. (2021). *NIHR Remote Trial Delivery Working Group. A report from the NIHR UK working group on remote trial delivery for the COVID-19 pandemic and beyond*. Trials **22**, 911.
[9] Evans P *et al*. (2024). *NIHR Clinical Research Network. The PANORAMIC study of COVID-19 treatments in primary care: a review and learning exercise.* NIHR Open Res **4**, 46.

can include those related to data accuracy, regulation, equity of access, patient engagement, acceptability and risk, logistical complexity, infrastructure and workforce, and best practice guidelines.

Decentralised clinical trial delivery reflects the UK Government's commitment to shift care closer to the community and improve the speed and efficiency of clinical trials.[10,11] In her opening remarks at the workshop, **Dr Alice Mortlock, Deputy Director for Research Capacity and Growth at the Department of Health and Social Care (DHSC)**, discussed some of the opportunities presented by decentralised clinical trial delivery. She highlighted how decentralised activities align with the UK Government's commitment to build an NHS fit for the future, both as part of the move from hospital to community and from analogue to digital, and by helping to drive forward a focus on prevention by overcoming geographical health inequities. Decentralised clinical trial activities also reflect the NIHR's four priorities: impact, inclusion, innovation and investment.

"There is a need to do more faster and to respond as a community working together." *– Dr Alice Mortlock*

Following Dr Mortlock's opening remarks, the event continued with scene-setting talks from:

- **Professor Kerry Hood**, Professor of Trials and Dean of Research & Innovation, Cardiff University and Director of the UKCRC CTU Network.
- **Professor Caroline Wroe**, National Associate Director of Health and Care Research, NIHR RDN and Honorary Professor of Research Delivery Systems, Newcastle University.

An expert panel discussion then examined the opportunities of decentralised and remote methods of clinical trial delivery. The panel involved:

- **Professor Kerry Hood**
- **Valerie Jarvis-Evans**, Senior Director Clinical Site Operations, Pfizer
- **Professor Matthew Sydes**, Head of Data-Driven Clinical Trials, NHS England
- **Farheen Yameen**, Public contributor with experience as a trial participant
- **Professor Mira Zuidgeest**, Associate Professor, UMC Utrecht and Scientific Lead, Innovative Medicines Initiative (IMI) Trials@Home project

[10] UK Government (2025). *Life Sciences Sector Plan.* https://www.gov.uk/government/publications/life-sciences-sector-plan
[11] UK Government (2025). *10 Year Health Plan for England: fit for the future*. https://www.gov.uk/government/publications/10-year-health-plan-for-england-fit-for-the-future

Assessing the landscape

In clinical development, the sponsor is the legal entity that takes responsibility for the funding, initiation and management of a trial. Sponsors can include pharmaceutical companies, academic institutions, charities and NHS trusts. Clinical trials are traditionally carried out in secondary care or specialist clinical centres, but they can also include academic research centres, commercial clinical research sites, general practices, pharmacies, community health centres, and mobile research units.

In her remarks, Dr Mortlock suggested that a research-active workforce will be key to increasing uptake of decentralised activities, alongside taking advantage of data resources, such as the new Health Data Research Service (HDRS), which could enable those designing clinical trials to identify, engage and involve the most suitable participants for a study, regardless of where they live. In addition, Dr Mortlock spoke about how collaboration and building partnerships will be particularly important to facilitating decentralised trial activities. The National Neighbourhood Health Implementation Programme (NNHIP) aims to bring care closer to where people live by linking up local health and social care services and may also present opportunities to facilitate decentralised trial activities.

Dr Mortlock summarised that research needs to be everyone's business. People should be able to participate in research regardless of geography. Research needs to be visible and valued by healthcare professionals, with flexible career and training opportunities and in-built capacity. Proportionate governance, and rapid set-up and delivery, will be essential to supporting decentralised trial activities. In addition, impact, metrics and learnings will need to be shared, and commercial income reinvested back into supporting research into what decentralised activities work.

Decentralised trials are different to community-based trials, which are run in sites such as general practices, community health centres and mobile research units (Table 1). However, community-based trial sites can support decentralised clinical trial activities. For example, the ESTEEM trial allows women to self-refer to join the trial via their GP, after which they receive either testosterone gel or placebo for menopausal symptoms.[12] The outcomes will be measured through access to electronic health records and selected participant interviews. Many trial activities that typically take place in a central site, such as conversations about consent, sample collection, monitoring visits and some assessments, can be decentralised if appropriate.

[12] Centre for Trials Research. *ESTEEM*. https://www.cardiff.ac.uk/centre-for-trials-research/research/studies-and-trials/view/esteem

Models of clinical trial delivery

Traditional models are where the central clinical trial team and/or site staff interact with the trial participant. In traditional trials, site staff identify, approach and screen participants. Consent is obtained in person, and the intervention is provided or administered by the site or local pharmacy. Samples are taken or collected by the site and shipped to the laboratory. Case report forms (CRFs) and patient-reported outcomes (PROs) are collected at the site.

Fully decentralised models involve interaction between the central trial team and the trial participant, without site staff. In fully decentralised trials, trial participants can self-identify and refer themselves to a remote central clinical team or they might be identified and invited through electronic health records. The intervention is shipped directly to the trial participant and self-administered, and trial participants self-sample or have samples taken at a community venue. PROs are returned to the clinical team, as well as any other relevant health service data. Safety monitoring is conducted through direct reports from trial participants, health systems data or via healthcare professionals.

Hybrid models can involve a mix of traditional and decentralised activities, but often the intervention is provided by site staff or local pharmacy and self-administered at home. CRFs are often collected by site staff, while PROs are often reported directly to the central clinical team. Safety monitoring and reporting is the carried out by site staff, supported through direct reporting from trial participants.

A model that assesses which trial activities are most useful to decentralise, and has a blend of both site-based and remote trial delivery, can be a beneficial approach for both trial participants and trial teams. In her talk, Professor Hood described how a fully decentralised clinical trial is rare, because fully removing sites for clinical trials involving drug development is difficult. Decentralising trial activities can depend on whether the characteristics of the IMP or drug are compatible with decentralisation. For example, sensitive temperature-monitoring requirements may make decentralisation difficult. The phase of the trial can also affect which activities can be decentralised, with Phase 1 trials often dependent on a hospital setting for patient safety. Professor Hood emphasised that choosing which activities could be decentralised when beginning to design the clinical trial is easier than making these choices during the trial. To increase uptake of decentralised trial approaches, there is a need to provide recent case studies and examples on what works, and guidance on which activities can usefully be decentralised.

Table 1. Examples of trials with decentralised activities

Activity	PANORAMIC trial[9,13]	ESTEEM trial[12]
Identification and recruitment	Self-identification on website, identification by GP practice	Self-identification on website, identification by GP practice
Informed consent	Consent on the telephone or in person	Consent on the telephone or in person

[13] PANORAMIC. https://www.panoramictrial.org/

IMP management	Shipped directly to trial participant's home	Sent directly to trial participant's home
Samples and tests	Pregnancy test shipped with IMP, self-administered nasal swabs returned by post	Pregnancy test shipped with IMP, blood samples at home or local pharmacy
Data collection	Online or telephone diary completion and electronic health record	App or telephone data collection
Safety and monitoring	Self-reported, but proactive contact in first few days	Self-reported and proactive contact alongside blood test results

Table from Professor Kerry Hood's presentation.

Surveying decentralised trial activities and challenges

The NIHR RDN has various projects on supporting decentralised clinical trial activities, including the Remote Methods of Trial Delivery Project launched in 2020. In her talk at the workshop, Professor Wroe, National Associate Director of Health and Care Research at the NIHR RDN, highlighted the importance of: embedding trial participants as central to research; supporting regulatory bodies to facilitate industry engagement; and supporting and enabling the workforce to deliver decentralised activities.

In 2026, the NIHR RDN ran an implementation survey that sought to understand remote trial methods usage across the Network, including key findings, adoption trends and implementation barriers. The survey was disseminated to the workforce through the regional RDNs and received 293 responses. The survey found that:

- Communication activities are commonly carried out remotely. Recruitment, consent and continual engagement activities were varied, but the most popular remote method for recruitment was pre-screening. Eligibility alerts and web-based sign-up was significantly underutilised, pointing to missed opportunities for digital outreach and initial engagement of trial participants.
- Quality assurance was commonly carried out remotely, except for equipment certification, which was frequently considered 'not applicable'.
- Remote methods of intervention or drug delivery were rarely used. Professor Wroe reflected that this could imply that safe and regulatory-compliant delivery of intervention materials is a critical and unresolved bottleneck.
- There was mixed usage of remote methods for measuring outcomes, with a preference for low-tech remote data collection, such as using existing data and remotely collecting patient-reported outcome measures (PROMs). Remote methods relying on new technology or logistics, such as home-based sensors, were often not used. Professor Wroe suggested that more infrastructure and training may be needed to support the effective use of sensor and app-based outcome measures.

The survey also identified top barriers to remote methods of clinical trial delivery:

- Lack of available or reliable IT infrastructure and resources (e.g. equipment).
- Implementation of decentralised activities viewed as too difficult or challenging.
- Lack of awareness that remote methods are a possibility, including of which activities could be decentralised.
- Uncertainties around regulatory acceptance.
- Perception that remote methods would be too difficult for trial participants to utilise.

The following skills were highlighted as important to the effective deployment of remote clinical trial methods:

- IT and digital literacy skills, so that staff can support trial participants and troubleshoot common issues. Key competencies include proficiency with e-Clinical technologies such as e-Consent, electronic data capture (EDC) systems, telehealth platforms, and remote monitoring tools.
- Interpersonal skills, including effective communication for continually engaging trial participants in a virtual setting.
- An understanding of regulatory and ethical requirements related to data privacy, remote consent, and compliance.
- Adaptability, openness to innovation and the ability to respond to challenges unique to decentralised methods of delivery.
- Operational skills and logistics management, such as the delivery of the intervention to trial participants, remote site coordination, and data integrity through remote monitoring and quality assurance.

Professor Wroe summarised that overcoming these implementation challenges requires a multi-pronged strategy that addresses barriers around technology and infrastructure, regulatory clarity, and user-friendly design for both staff and participants. To support uptake of decentralised and remote trial activities, it will be important to understand where we are now and what has been achieved.

Establishing best practice

Workshop participants identified a research gap around best practice for decentralised clinical trial activities. Beyond the experience of vaccine trials during the COVID-19 pandemic, research staff need guidance on which activities can safely and appropriately be done at home versus on site, and how sample collection, processing and shipping will be managed. An updated systematic review of what has been tried, what has worked and what hasn't, costs and challenges, and where standardisation is appropriate, would be very helpful in accelerating and streamlining adoption of remote trial activities, and could provide an evidence informed foundation for decentralising trial activities.

Participants called for precompetitive collaboration to develop shared methods and guidance, and were overwhelmingly in favour of creating a central resource for knowledge-sharing around decentralised trial activities. This could include example protocols, templates and risk assessments and outcomes from methodology studies and proof-of-concept/pilot trials to test and scale care-at-home approaches. The information would build confidence on what works, including seeking early regulatory guidance and obtaining site involvement. Multinational forums that convene cross-sector stakeholders and research groups were considered particularly valuable for surfacing issues early, reducing repetitive development of technologies and tools, and facilitating shared learning across countries. Participants suggested that trade associations could help convene these forums and assess the confidence of industry organisations for adopting decentralised activities.

Suggestions:

1. Create resources for sharing case studies on decentralised activities and guidance on what works, including publications on methods, example protocols, templates and risk assessments.
2. Establish funding for proof-of-concept/pilot studies to test and scale care-at-home approaches.
3. Convene multinational stakeholders (potentially via trade associations) to surface issues early and reduce duplicate development of remote technologies and tools.

Designing clinical trials around choice and need

The growing use of healthcare data in the UK, and the ability to identify patients through anonymised GP record screening, makes it feasible to find potential trial participants by searching population-level data and using tools (such as heatmaps built from disease codes) to align clinical trial activity to need and burden. This approach to recruiting people into trials 'where they are located' could drive recruitment based on density of relevant patient populations rather than proximity of patients to a single central site. Understanding different population group needs, such as working patterns, personal routines, childcare or caring responsibilities and cultural norms, and then shaping the trial accordingly, can increase trial inclusion and diversity and prevent widening of inequalities.

Designing a clinical trial that can respond to participant needs requires a flexible model of delivery. Workshop participants agreed this can be challenging with the demands of the clinical trial protocol, which is the 'blueprint' or manual for the study that ensures all sites adhere to the same eligibility criteria, methodology, treatment plans and outcomes and safety monitoring. Participants emphasised that adaptive protocol design and tailoring of decentralised activities to different participants and populations needed to be built into trials from the outset. Engaging with participants early in the design phase ensures protocols reflect real-world needs.

The 'gold standard' is for sites to be capable of delivering both decentralised and traditional trial models, to avoid excluding individuals and groups, and create equality of opportunity. For example, hybrid visit schedules can reduce participant burden by shifting selected visits out of the clinic while engaging those who require in-person assessment. Participants at the workshop emphasised that offering meaningful choice, such as the ability to choose home versus site-based visits and procedures, can enhance trial inclusivity, participation, and continued engagement, e.g. enabling participation for those with limited mobility or access to transport. The importance of retaining the option for face-to-face care alongside expended options for home-based care was highlighted. However, risk proportionality and feasibility will need to be considered, as it might not be possible to factor participant choice safely and efficiently into all trial activities.

The geography and culture of different regions in the UK can further shape the decentralisation of trial activities. In some cases, mobile trial buses or local drop-off points for samples can support decentralisation, while in others long distances between trial participants or variations between available staff in different regions can make these options impractical. Some people may be disadvantaged by decentralisation, e.g. those who are digitally excluded, lack capacity or have no fixed abode. An additional burden may also fall on those with caring responsibilities in supporting home-based activities. Mapping these contextual factors early and tackling practical barriers such as constraints within local health systems, inequities in digital access and local infrastructure will be important, as will tailoring decentralised methods to different populations. For example, decentralised activities will need to consider how to overcome language and cultural barriers, and account for people who may prefer not to be visited by staff at home, or those who lack confidence using digital technologies.

Finally, decentralised activities may require training around safeguarding, data, quality control, logistics and digital systems.

Some participants highlighted that with greater use of e-consent and challenges with ID verification in remote recruitment there is a risk of fraud, such as self-selection by 'rogue' participants, as well as risks around social media and fraudulent advertisements to take part in clinical trials. It was suggested that an easy-to-access, easy-to-search, UK-wide, public-friendly clinical trials directory could provide a 'front door' to research opportunities, showing which trials are open and how to join. This would be beneficial to both the public and researchers, as self-referral to a trial can connect with people who are less likely to present to health services. The NHS England Long Term Plan envisages the NHS app as a 'front door' to NHS services by 2028, with linkage to research opportunities.[11]

"South Asian communities want to take part in research, but they face various barriers. Decentralised clinical trials are a real opportunity for inclusion, but they need to involve community voices early on to shape how studies are designed, communicated and delivered" *– Farheen Yameen.*

The role of trust is essential when considering how decentralisation can enable better recruitment and continual engagement of trial participants. Workshop participants noted there is a persistent perception amongst some sections of the public that clinical trials are risky and should be avoided. Participants noted that public awareness of research, alongside trust in the trial team, the organisation and the wider health system, affects willingness to participate in trials. Consistency in staff (e.g. the same nurse visiting a trial participant) is often preferred. Participant understanding of the impact of taking part in a trial, for example through receiving information on its conclusions, was also suggested as an important part of engagement. Professor Hood noted that trust in research can be built centrally but may need to be built locally as well. Community-level education and engagement initiatives and working with community groups, leaders and local healthcare staff can help build trust and ensure that trial activities align with people's lives.

While decentralised approaches can help improve the continual engagement of trial participants in a study, they may risk making participation feel transactional, rather than supportive. Participants may also feel they are taking on more responsibility, which may be empowering for some, but a source of pressure for others. Professor Hood highlighted that there is a risk that trial participants feel isolated when taking part in a decentralised trial.[14] Practical engagement strategies in trials with decentralised components include interfaces that help participants follow trial protocols, consistent messaging on why the trial matters, and regular touchpoints (phone calls, newsletters, video links, texts, short videos) tailored to participant preferences. Behavioural science techniques can be used, such as points-based rewards or gamification for younger participants, to sustain engagement. In traditional trials, participants may be reimbursed for their cost and time of travelling to sites, and this model will need to be revisited to ensure remote trial participants are fairly reimbursed for their participation and time. Managing some aspects of a trial without having to attend a hospital can enable more people to take part, but the loss of a direct relationship with a central clinical team may affect trust and commitment, and maintaining a sense of human connection will be essential.

"...we need to let go of the idea that trial participants must come to the site. We need to understand what is best for participants, and how we can best collect the data we need. We shouldn't claim to know what participants and sites can do, and what they want." *– Professor Mira Zuidgeest.*

[14] For example, see https://sites.google.com/nihr.ac.uk/remotemethodsoftrialdelivery/home/public

Suggestions:

1. Engage and involve trial participants and researchers on whether decentralised activities can be considered early on in trial design.
2. Map practical and contextual barriers to decentralising activities, such as rural locations, digital access, and constraints in local health systems and infrastructure.
3. Increase the awareness and trust of the public in trials and decentralised activities and methods through community groups and patient networks.
4. Explore practical engagement strategies supporting participants to stay on the trial, understand why it matters, and maintain a sense of human connection, including gamification for younger participants.

The requirements of sponsors

Although there is increasing interest among pharmaceutical company sponsors to adopt decentralised approaches, momentum has slowed since the COVID-19 pandemic because of concerns around complexity, perceived regulatory uncertainty and potential risk. Decentralised activities are often perceived as more expensive than traditional models, and, in her talk, Professor Hood explained how set-up and training times are currently longer for trials with decentralised elements because of lack of familiarity with the approach. Sponsors often find it challenging to demonstrate the direct benefits and advantages of various decentralised approaches and evidence of value – detailed case studies, financial analyses and transparency around efficiency gains – are needed to justify cost. Evidence on possible incentives, such as increasing diversity and inclusivity of trials and better reflecting real-world populations, could also aid industry uptake.

Workshop participants cited several barriers to decentralisation, including operational complexity related to payment models and contracting/legal processes, reduced revenues and perceived lower quality of home trial procedures. Specifically, fixed-price contracts between sponsors and sites can discourage the adoption of new activities such as telemedicine and remote monitoring because of unpredictability in cost, while decentralising trial activities can increase the number and complexity of contracts, placing greater strain on legal teams and slowing trial delivery.

Participants called for standardised contracting approaches and suggested it may be necessary to review traditional payment models to support uptake of decentralised activities, such as adopting flexible budget models to enable experimentation of costs adjusted to usage. Sponsors also need early and detailed assurances from RDNs and lead sites on technical and practical feasibility before agreeing on clinical trial protocols with decentralised elements. A clear early 'front door' offer, setting out what is possible, would help sponsors consider decentralisation before protocols are finalised.

A recurrent theme at the workshop was the need for clear national guidance on decentralised trial activities. While recent international guidance, such as from the European Medical Agency,[15] was welcomed, there was a concern that up-to-date UK guidance is limited. Without clear and up-to-date guidance from regulators, decentralised approaches are often treated as high risk by default. Sponsors are often cautious, and require clear, robust and confidence-building guidance to adopt different approaches and processes. A key concern was the need for clarity on whether decentralised activities are in alignment with the positions of inspectorates. Even if regulators have approved a protocol, there could be a disconnect with metrics and frameworks used by inspectors that ultimately determine regulatory compliance.

Regulators could help increase uptake of decentralised activities by setting out clearer expectations on risk, responsibilities, and accountability. This guidance could be combined with practical examples of end-to-end decentralised approaches. Guidance should update expectations around adverse-event reporting and clarify responsibilities for each step of decentralised delivery. Sponsors could then better manage risk, particularly with additional clarity on the requirements of Medicines and Healthcare products Regulatory Agency (MHRA) inspectorates and home health vendors. Participants also highlighted the value of early and informal regulatory engagement for derisking decentralised approaches.

[15] European Medicines Agency (2022). *Facilitating decentralised clinical trials in the EU*. https://www.ema.europa.eu/en/news/facilitating-decentralised-clinical-trials-eu

"In different geographies, there are different challenges. Coming from a global pharmaceutical company perspective, the solutions specific to the UK can be different to solutions in other countries." *– Valerie Jarvis-Evans.*

Global collaboration will also be essential to scaling the adoption of decentralised clinical trial activities. Multinational decentralised trial activities require alignment around risk and regulatory expectations in different jurisdictions, as well as flexible protocols that account for diverse contexts. For example, patient-centric blood sampling can vary in acceptance according to different jurisdictions.[16] Globally predetermined protocols are often orientated towards US requirements, which can make it difficult for individual countries or sites to influence trial design. There is an opportunity for learnings and case studies to be shared systematically, particularly between the UK, Europe, and the USA, to help sponsors understand and learn from collaborator best practices and how different decentralised trial delivery solutions work in various locations.

Suggestions:

1. Review approaches to contracting and costings to support uptake of decentralised trial activities.
2. Establish a 'front door' offer for sponsors, providing early and detailed assurance from RDNs and sites on feasibility of decentralising activities before protocols are finalised.
3. Obtain clearer guidance from regulators on decentralised activities with end-to-end examples and clear roles and responsibilities for decentralised delivery.
4. Foster early engagement with regulators to derisk decentralised approaches.
5. Collaborate globally to share learnings and case studies of what works in different countries, with a view to developing flexible protocols that account for diverse risk and regulatory expectations in different jurisdictions.

[16] Maass KF *et al*. (2022). *Leveraging patient-centric sampling for clinical drug development and decentralized clinical trials: promise to reality.* Clin Transl Sci **15(12)**, 2784–95.

Delivering decentralised trial activities

While decentralised trial delivery is working in certain scenarios, coverage and coordination across the UK remains uneven. It will be essential to balance flexibility around trial participants' needs with what staff and sites can reasonably deliver. Redefining what is considered as a 'site' and mapping site resources alongside training needs and pathways will be necessary as clinical trial models with decentralised elements evolve.

RDNs can play a pivotal role in facilitating decentralised trial activities, but regional variability in available skills and technologies means that consistent systems are needed. Standardising site workflows and skills could help ensure consistent quality in the delivery of decentralised trial activities across different settings, such as in high-street venues, e.g. pharmacies. The network of commercial research delivery centres (CRDCs) established across the UK as part of the Voluntary Scheme for Branded Medicine Pricing, Access and Growth (VPAG) could present an exciting opportunity for adopting decentralised activities in commercial clinical trials. Sites that can support decentralised activities now, such as some GP practices, could be integrated into research pathways now so that research-aware staff are built into each local ecosystem.

Staff training, wellbeing and career development

There was broad recognition at the workshop that engaging with sites about decentralised activities and building the confidence of staff to deliver these activities was pivotal. Some site teams decline to adopt decentralised trial activities due to capacity, contracting burdens, and unfamiliarity, and site staff may need reassurance that sufficient time will be allocated to deliver decentralised activities. Clinical trials that follow trial participants through different care pathways can also face barriers when treatment continues outside the original site. Continuity of relationships between site-based teams and home-delivery teams will be crucial and requires clear responsibility and communication frameworks.

Decentralised trial activities also require unique considerations around workforce wellbeing and safety, with staff, often nurses, working independently in community settings and potentially encountering challenging situations with isolated or vulnerable participants. Clear escalation pathways, support mechanisms and recognition for extended visit times will be essential, while ensuring staff felt valued beyond financial incentives was also seen as important. Strategies such as regular team meetings, buddying systems, supportive supervision, and recognition schemes can strengthen morale and engagement.

There is a need to embed decentralised trial delivery into job descriptions with clarity on roles and responsibilities and to protect staff time for training. Workshop participants viewed a well-trained workforce that feels both equipped and empowered to adopt and deliver decentralised trial activities as central. Training should be up to date to reflect the latest innovations and governance, and support staff to develop new skillsets, such as those required for face-to-face or video-based appointments and the use of different technologies. Some participants suggested that linking training to Good Clinical Practice (GCP) certification[17] would help mandate participation. Workshop participants emphasised the building of IT skills, and suggested there is a need for more IT training at non-NHS and contract research organisation (CRO) sites, alongside clear ongoing IT and helpdesk support for both staff and participants. One suggestion was to train teams as part of research studies so that staff can use those skills to inform care going forwards.

[17] GCP certification is an accreditation required for anyone working on a clinical trial of a medicinal product, aligned with guidance from the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH).

Workshop participants agreed that career development opportunities for staff delivering decentralised trial activities should be explicit. Competency frameworks, consistent feedback, and clear measures of success could help build staff confidence. Core competencies, such as community phlebotomy and certifying GPs as 'research ready' for decentralised trial activities, could also be embedded among staff.

Technology and data

The use of technology, and an integrated and effective digital infrastructure, were seen as key enablers for the adoption and delivery of decentralised trial activities. Use of electronic health records and home-based technologies can better enable decentralised activities. Participants described how remote consent via video or telephone can work well when supported by clear information, adequate time for consideration, and safeguards against pressure. During decentralised trial delivery, e-diaries, monitoring technologies, and apps that include features like a 'panic button' where certain side-effects reported by a trial participant will trigger immediate site follow-up, can be useful.

When looking to set up and deliver a clinical trial with decentralised activities, early assessments on the feasibility of introducing a technology alongside careful platform selection are needed. These assessments should incorporate user experience, and participant-facing tools should account for device constraints (e.g. phone storage, different operating systems) and offer alternatives and solutions, such as web-based access. In addition to standard process pathways, standardised software systems may also be required.

However, workshop participants suggested that current digital infrastructure systems can be complex to navigate, with clinical trial platforms taking too long to deploy, and different systems often requiring multiple logins. Decentralised trial platforms frequently need to be built from scratch, and clinical trial sites can face platform proliferation with multiple sponsor-specific tools, creating burden. While a single unified IT system may be unrealistic, participants supported reducing duplication, removing unnecessary layers of complication, and simplifying workflows. Some participants suggested that duplication could be reduced by adopting single-sign-on systems and developing interoperable interfaces between platforms (such as between-site systems and trial management tools). Central vendors, streamlined access, and clearer interoperability standards were viewed as important enablers to efficiency and cost savings for teams delivering decentralised trial activities.

> ***"One part of improving clinical trials is safe, secure, and ethical access to NHS datasets, and to take the burden of data collection off sites and participants. We need to understand what makes a prospective trial participant, so that we can increase diversity and improve reaching out to these groups."*** *– Professor Matthew Sydes.*

Moving forwards, it will be important to gather evidence to clarify which decentralised practices and processes did or did not work. Mechanisms for capturing lessons from all staff involved in decentralised trial delivery, including clinical trial units, site staff, community healthcare providers or home-health providers, should be embedded from the outset. Routinely collecting feedback from staff and trial participants at the end of studies would build a stronger evidence base for what does or does not work.

Suggestions:

1. Raise awareness of decentralised trial delivery among the research community and healthcare staff through relevant forums and networks, e.g. Trial Managers Network UK.
2. Map the skills and training needed to support decentralised trial activity.
3. Explore how neighbour health services, and primary, secondary and community care services including the CRDCs can integrate into research pathways and support decentralised approaches.
4. Embed decentralised activities into job descriptions, with clear roles, responsibilities, accountability and escalation routes, and support mechanisms for staff safety and wellbeing in community settings.
5. Provide clear career development opportunities or designated decentralised trial 'champion' roles.
6. Develop training on delivering decentralised activities, including skills around safeguarding, data-sharing, quality control, logistics and digital systems, reflecting the latest innovations in remote healthcare.
7. Evaluate the feasibility of new technologies for delivering decentralised trials early on, considering user experience, device constraints, and interoperability between different platforms.

Conclusion

Decentralised trials deliver patient-centred studies that can overcome challenges experienced in traditional trials, leading to improved participant recruitment, trial accessibility, inclusion and diversity. With the NHS and UK-wide clinical trial networks, population-wide health data, and the government's commitment to shift care closer to the community, the UK could become a global leader in the field of digital or decentralised clinical trials. Workshop participants highlighted that there are still major knowledge gaps about decentralised clinical trial activity processes and outcomes. It can be difficult for researchers to understand where and how to implement decentralised clinical trial activities for the first time. For example, there is a need for clear guidance on which trial activities can and cannot be carried out in a home setting, and how sponsors and sites should plan for logistics such as transport, shipping and sample processing. Sponsors are also hesitant to try decentralised activities without a full understanding of the benefits and how to mitigate any risks. They may need reassurance about the feasibility of decentralising activities, and advice from regulators that decentralised trial activities remain compliant.

Key priorities include establishing resources for sharing best practices and learnings, and collating publications on methods, tools and guidance on decentralised activities. Research to evaluate decentralised activities should be embedded in relevant trials, to help build an evidence base. Awareness should be raised among the public and research communities, so that decentralised trial activities are considered as an option within trial design. The workforce will need support to deliver decentralised activities, including relevant training and clarity on responsibilities. There is a need for updated UK regulation on decentralised activities, to help derisk decentralised approaches and increase their uptake. By supporting the uptake of decentralised and remote trial activities, the UK can reach its potential as a globally leading hub for clinical trials and drug development.

Annex 1: Attendee list

Co-chairs

Professor Isla Mackenzie, Professor of Cardiovascular Medicine, University of Dundee
Professor Paula Williamson FMedSci, Professor of Medical Statistics, University of Liverpool

Workshop participants

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Professor Andrea Manfrin, Deputy Director Clinical Investigations and Trials, MHRA
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