UK Health Data Research Alliance

Alliance Clinical Trials Stakeholder Prioritisation Forum

Meeting Summary – 11th September 2024

Introduction

On 11th September 2024, the UK Health Data Research Alliance (the Alliance) convened its third Clinical Trials Stakeholder Prioritisation Forum, chaired by Dr Macey Murray and Associate Professor Marion Mafham. The forum was attended by over 25 stakeholders from diverse sectors including clinical trialists, regulatory bodies, data custodians, funding organisations, clinicians, and academic researchers.

During the previous forum meeting, there was a consensus on the need to address three priority areas.

- Standardising the procedures used to assess study consent in relation to use of healthcare systems data and streamlining the approval process while ensuring compliance with regulatory requirements
- Improving the incorporation of patients and the public voices in streamlined decision making
- Building capacity and expertise within trials teams

The session aimed to achieve the following objectives:

- To explore and address administrative burdens/challenges that trialists face navigating complex legal/information governance frameworks and varied regulations across regions. In particular, when obtaining and maintaining approvals during data application processes.
- To begin drafting a green paper to articulate the need for and describe potential approaches to streamline the approvals process that will be of use to policy makers and key decision makers.
- To identify a working group of stakeholders to support the development of this paper.

Macey Murray and Marion Mafham | Alliance Clinical Trials Stakeholder Prioritisation Forum

The chairs introduced the forum, the key aim, which is to bring together key stakeholders (data providers, users, funders, regulators, patients, and the public) to discuss and prioritise solutions to challenges in using healthcare data for trials, including data quality and regulatory compliance. Macey emphasised that the forum's objective is to generate actionable recommendations, rather than simply discussing issues. The forum is one of eight workstreams in the Transforming Data for Trials Infrastructure programme.

The chairs then elaborated on two related groups: the Transforming Data for Trials Public Advisory Group, which includes public and patient representatives, and the Trials Community Insight Group (TCIG). The TCIG aims to link the clinical trials community with the programme, ensuring that its

outputs meet the needs of researchers designing and running trials. It welcomes members from clinical trial teams, and others that have used, or are interested in using, healthcare systems data (HSD).

The presentation also summarised progress made by the forum in identifying three key priority areas, as seen in the slides, as well as highlighting the objectives detailed above.

The slides from this session can be found here.

Isla Mackenzie |Maintaining data access approvals – Experience from three UK clinical trials

Challenges faced by clinical trial teams in obtaining timely data access during three decentralised trials (FAST, ALL-HEART, and TIME), particularly concerning safety data like hospitalisations and deaths was highlighted. She explained that although the trials had been approved by data providers for access, they experienced significant delays in receiving linked data, especially initial releases for as long as 2-3 years, and then intermittent releases thereafter. Patient and health professional reports helped to fill some of the gaps, but the lack of timely data from key data providers caused significant issues. Isla pointed out that this issue was especially problematic for trial steering committees and Data Monitoring Committees (DMCs), who were responsible for ensuring the safety of trial participants. Several DMC chairs expressed concerns about not receiving enough data to make informed decisions about the safety of the trials. This lack of data created uncertainty around trial safety, which was a concern for both the trial teams and patient representatives.

One example described a data provider approving data access for a trial, and after some time deciding that the wording in the trial's consent form was not considered good enough. This meant further approval was required from the Confidentiality Advisory Group for section 251 support, even though participants had consented to the study. This added significant administrative burden to the trial team.

The involvement of patient representatives was crucial in bringing this issue to light. Isla noted that patients were shocked by the bureaucratic delays and the number of approvals required for accessing essential data. They found it difficult to understand why such an evidently beneficial action (obtaining data for safety monitoring) was so obstructed by administrative processes.

The discussion that followed Isla's presentation echoed the urgency of the issue. Attendees expressed alarm at the situation, suggesting that a lack of timely data flow jeopardised the safety of clinical trials. They advocated for a shift in perspective, prioritising safety through consistent data access. The co-chairs noted how crucial it is to maintain a sense of urgency around data flow, particularly when it impacts patient safety.

The slides from this session can be found here.

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Key Issues in Consent Procedures and Data Access Approvals for Clinical Trials

Fragmentation and Complexity

One of the key challenges highlighted in both Breakout Rooms was the fragmentation and complexity of the current data access approval system for clinical trials. Trialists often face delays due to the need for multiple approvals from different committees and organisations, which creates administrative burdens and slows down the progress of important research. This situation was compared to the ethics review process that existed in the past, where individual ethics committees provided separate opinions for trials, resulting in similar inefficiencies. The reforms in the ethics review process led to a centralised system that significantly improved efficiency, suggesting that a similar approach could be beneficial for data access approvals.

Variation in Requirements Between Access Committees

Another issue is the variation in requirements between access committees, particularly in the assessment of the adequacy of consent for linkage with healthcare systems data. Without a standardised framework, different committees or individuals may arrive at varying conclusions on whether a research project aligns with the consent provided by trial participants. This variation can create inconsistencies and can lead to delays in approving projects, while also undermining the trust that patients and participants place in researchers and institutions. Furthermore, attendees expressed concerns about risk aversion, particularly from both legal advisors and patients, which can result in “default no” decisions on consent approvals. These overly cautious decisions limit researchers’ access to data and lead to missed opportunities to use patient data for beneficial research, thereby impacting health outcomes.

Capacity Limitations

The issue of capacity limitations within organisations like NHS England was also a key concern. Approval committees are often under-resourced, leading to significant delays in processing data access requests. Furthermore, when there is staff turnover, the handover process often leads to further delays, as new colleagues need time to familiarise themselves with existing applications. Navigating different legal frameworks across various data custodians adds to the burden, as trialists must contend with varied regulatory environments, which further complicates and lengthens the approval process.

Retroactive Application of New Standards

In addition to the administrative challenges, there was concern about the pitfalls of retroactive application of new consent standards. Applying new frameworks to past decisions could erode the trust that participants have placed in trials, particularly if prior research is retroactively deemed non-compliant with new consent guidelines. This could severely damage relationships between researchers, data custodians, and trial participants, as it could call into question the validity of previously conducted research.

Lack of Trial Participant Voices

Finally, the lack of trial participant involvement in the data approval process was seen as a missed opportunity. While participants are directly affected by how their data is used, they are often excluded from high-level decisions. This exclusion can lead to decisions that do not adequately reflect the concerns or priorities of trial participants, further eroding trust in the system.

Ways Forward: Suggestions to Improve Consent Procedures and Data Access Approvals

To address the challenges highlighted within the breakout rooms, several solutions were proposed to improve the standardisation of consent procedures and streamline the data access approval process.

Overarching, objective body for assessing the adequacy of consent for healthcare systems data release

A key suggestion was the creation of an overarching, objective body to assess the adequacy of the consent processes used in the trial requesting access. This standardisation would provide clear, consistent interpretation for both researchers and data controllers, ensuring that there is no ambiguity about what participants have consented to. A standard approach would reduce the current variation between different data access committees and build public trust by making the consent process more transparent. Importantly, any new framework should be forward-looking to avoid the pitfalls of retroactively invalidating past research decisions.

A Centralised Data Access Approval System

In line with the improvements seen in the ethics review process, attendees discussed the need for centralising the data access approval system. Establishing a national body to oversee data access approvals could reduce fragmentation, duplication, and bureaucracy. This centralised body could serve as a single point of contact for trialists, ensuring that approvals are consistent across different data custodians. Such a body would also play a critical role in maintaining transparency and accountability, helping to build trust with both researchers and the public. However, creating a national body would require a significant investment in public trust, ensuring that it operates in the best interests of participants and trialists alike.

Preset Approval Pathway for Common Datasets

Streamlining the approval process also requires creating a preset approval pathway for common datasets and purposes in clinical trials. Establishing clear guidelines and timelines for decisions would ensure that data access requests are handled efficiently and fairly. Improved collaboration between different approval bodies would reduce duplication and ensure that trialists do not need to submit multiple applications across various organisations, which would significantly cut down on the administrative burden. This would allow researchers to focus on the trial itself rather than navigating complex and fragmented approval systems.

Capacity Building

Another proposed solution was capacity building within approval committees and key organisations like NHS England. By investing in training and upskilling data access teams, approval bodies can be better equipped to navigate the legal frameworks related to data access. Addressing capacity shortages by providing more resources and staff would help alleviate the bottlenecks that currently slow down the approval process.

Trials Participant Involvement

Involving trial participants more directly in the approval process was seen as another essential step. Including patient representatives with experience or knowledge of clinical trials on data access committees would ensure that participants' concerns are reflected in decision-making, fostering a more participatory environment where trial participants feel that their voices are being heard. Engaging participants early on and educating them about the data approval process could also help mitigate concerns about data misuse, while increasing public trust in clinical trials.

Balancing Risk Aversion and Efficient use of Data

Lastly, balancing risk aversion with the need for efficient data use was emphasised as critical to improving health outcomes. Overly restrictive interpretation of the guidelines and legal frameworks, especially when applied to consent procedures, may protect against data misuse but come at the cost of missed opportunities for beneficial research. Attendees suggested using educational tools like infographics to communicate the trade-offs between the risks of data misuse and missed data use. This would help both patients and researchers understand the broader implications of their decisions, leading to more informed and balanced consent governance.

Conclusion

In conclusion, both breakout sessions highlighted the urgent need to standardise procedures for evaluating the study consent processes and streamline data access approvals for clinical trials. Establishing a national body for data access, creating an objective consent framework, and building capacity within approval committees are all critical steps forward. Involving trial participants more directly and balancing the risks of data misuse with the potential benefits of data use would ensure that the clinical trial process is both ethical and efficient. These solutions would not only enhance the efficiency of clinical trials but also build the public trust necessary for future advancements in medical research.

Next steps

- Begin drafting a green paper to articulate the need and describe potential approaches that will be of use to policy makers and key decision makers.
- Reach out to volunteers to form a working group of stakeholders to support the development of this paper.

Future meetings have been scheduled as below.

- Tuesday 10th December 2024 (13:00 – 14:30)

UK Health Data Research Alliance

An agenda and Eventbrite registration link for the next meeting will be shared with all attendees shortly. If you have suggestions for discussion topics, please share your ideas with us.

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Appendix

Contributing Organisations
Cardiff University
Clinical Trial Service Unit & Epidemiological Studies Unit (CTSU), University of Oxford
EMIS Health
Health Data Research UK (HDR UK)
Health Research Authority (HRA)
Medicines and Healthcare products Regulatory Agency (MHRA)
Medical Research Council (MRC), UK Research and Innovation (UKRI)
NIHR BioResource
NHS England
Optimum Patient Care
The Royal Marsden NHS Foundation Trust
UK Kidney Association
University College London (UCL)
University of Dundee
University of Southampton