Clinical trials best practice guide 2024

Helping to improve clinical trial set-up processes in the UK

Developed in partnership between NHS and industry representatives.

Supported by The Association of the British Pharmaceutical Industry, The Shelford Group, and UKRD - R&D leaders in the NHS.

About the clinical trials best practice guide 2024

The need to improve clinical trial set-up processes in order to reduce timelines and increase patients' access to research has been consistently on the UK life sciences agenda for several years. It has been highlighted as an area of importance in conversations between the Association of British Pharmaceutical Industry (ABPI), Shelford Group Chief Executive and Medical Directors, and UKRD - R&D leaders in the NHS .

Last year these three partner organisations convened a working group of senior NHS Research and Development (R&D) leaders and pharmaceutical company representatives to help achieve a common understanding of where the main challenges are, and how they can be addressed.

This collaborative working group has now developed and published this best practice guide, which identifies where reciprocal improvements can be made to help improve clinical trial set-up processes in the UK.

The guide is comprised of four parts:

1 Establishing a study's feasibility

2 Confirming a site's capability and capacity

3 Escalating blockers to study set-up and delivery

4 Establishing strategic communication between sites and sponsors

About the clinical trials best practice guide 2024

This guide was developed by NHS trust and pharmaceutical company representatives, supported by the Association of British Pharmaceutical Industry (ABPI), the Shelford Group and UK Research and Development (UKRD).

The contributing organisations are as follows:

- Guy's & St Thomas' NHS Foundation Trust
- Imperial College Healthcare NHS Trust
- Leeds Teaching Hospitals NHS Trust
- Manchester University NHS Foundation Trust
- Oxford University Hospitals NHS Foundation Trust
- Royal Free London NHS Foundation Trust
- University College London Hospitals NHS Foundation Trust
- University Hospital Southampton NHS Foundation Trust
- Amgen
- AstraZeneca
- GSK
- Pfizer
- Janssen

1 Establishing a study's feasibility

Working together

Sponsors should:

- **Avoid repeatedly asking for the same standard (non-study-specific) information** from a site by coordinating internally between different study teams. This could also be achieved by sponsors storing standard information about a site's capabilities and capacity that is unlikely to regularly change (e.g. research interests).
- Customise feasibility request documents to primarily **focus on study-specific questions** about a site's capabilities and capacity.
- **Copy in Research and Development (R&D) departments** when sending feasibility requests to prospective Principal Investigators (PIs).
- Use the **model Confidential Disclosure Agreement**.

Sites should:

- Publish and **regularly update documents setting out standard information** about their capabilities and capacity, including past clinical trial recruitment data.
- **Use a shared mailbox** to receive feasibility requests.
- Encourage sponsors to **use web-based or mobile-friendly feasibility surveys** to avoid sites needing to register accounts from third-party vendors.

Managing expectations

Feasibility assessment is vital to establishing clear and realistic expectations for a study's delivery that, if met, can encourage a sponsor to return to a site in the future:

- **Underperforming against targets** set during feasibility assessment can deter sponsors from working with a site in the future, as meeting these targets is crucial to the UK's global competitiveness. Therefore, sites and sponsors should work together to **establish realistic targets**.
- Sponsors should provide as much detail regarding their study's capacity and capability requirements as possible to **enable sites to make informed decisions quickly**. If the sponsor is using a phased site selection process, then they should inform sites of this from the outset.
- Sites should attempt to decline **Expressions of Interest quickly** (ideally within 2 weeks).
- Sponsors will **not penalise sites that decline to express an interest in a study due to capacity constraints**, as this is preferable to underdelivering against targets. Likewise, if a sponsor declines to work with a site on a study, that will not impact decisions about future studies.
- Sponsors will also **not avoid sites in the future if the site declines to run a study due to concerns about its design**, and this feedback should be shared with the sponsor.

Learning and development

Sites and sponsors should pursue opportunities to learn and improve their ways of working when establishing a study's feasibility:

- **Early discussions about the availability of Principle Investigators** (PIs) are highly recommended, as they can help establish a site's suitability quickly and assist with the identification and mentoring of new Principle Investigators (PIs).
- Tools for **monitoring study feasibility timelines** should be developed and refined so sponsors and sites have a clear baseline of current performance. Examples of these tools include:
  - Shared Investigator Platforms
  - The National Institute for Health Research (NIHR) Study Support Service

2 Confirming a site's capability and capacity

Working together

Sponsors should:

- Use the Health Research Authority's (HRA) technical **radiation and pharmacy assurance processes** wherever possible when confirming a site's capacity and capability.
- Provide as much up-to-date and accurate information on their study's **imaging, radiation, and laboratory services** requirements as possible when sending the Local Information Pack (LIP) to a site.
- Use the **model site agreements** and the National Contract Value Review (NCVR) process, when able.
- **Work closely with the Chief Investigator** (CI) to ensure the study is deliverable.

Sites should:

- Accept the HRA's technical **radiation and pharmacy assurances** wherever possible, reviewing local elements of submissions only when necessary to deliver the study.
- Promote **acting as a technical reviewer** to their staff.
- In the absence of a finalised manual or technical review, sites should **give the sponsor clear and proportionate expectations for what information the site needs** to review the study and confirm capacity and capability.
- The **CI site should work closely with the sponsor** to ensure the study is deliverable.

Managing expectations

Communication between site and sponsor is vital to establishing clear and realistic expectations for a study's delivery and confirming required capacity and capability:

- Using and accepting the HRA's technical assurance processes is key to **preventing duplication of work** across sites and enabling faster patient access to research.
- The **sponsor's choice of CI** will significantly influence the quality of communication during capacity and capability confirmation:
  - The CI site can be nominated as the reviewer for the radiation and/or pharmacy assurance processes; and
  - The CI site can coordinate with the other study sites to ensure the study is deliverable, and to encourage sites to accept the technical assurances.
- Sponsors and sites should **establish clear points of contact** when confirming capacity and capability, as this process involves multiple teams across both sides.
- To maintain consistent expectations of sites, sponsors should **avoid introducing new capability requirements** when finalising the study manual.
- A site's **signing of the Clinical Trial Agreement** (CTA) indicates confirmation of its capacity and capability to deliver a study, so no further steps should be required to begin the process of site activation.

Learning and development

Sites and sponsors should find and pursue opportunities to learn and improve their ways of working when confirming a site's capacity and capability:

- **Building trust in the technical assurance processes** is critical to improving their uptake by sponsors and acceptance by sites, so adopters of technical assurance should highlight its impact to help build this trust.
- **Using a standard pro forma to collect information** from sites and sponsors could streamline capacity and capability confirmation by reducing variation in ways of working. Examples of these pro forma already exist, and sites and sponsors should share these best practices.
- Similarly, sites and sponsors should develop and share **Standard Operating Procedures** (SOP) for working with support departments (e.g. pharmacy) to confirm capacity and capability.
- Sites and sponsors should **identify any gaps in the information gathered during the technical assurance** processes and highlight these to the HRA, as filling these gaps could help build trust and streamline set-up

3 Escalating blockers to study set-up and delivery

Working together

Sponsors and sites should:

- **Provide each other with clear points of contact** for each phase of the study set up and delivery process.
- **Communicate changes to points of contact** as quickly as possible. For periods of both planned and unplanned leave, email out of offices should specify alternate points of contact.
- Sites should provide **guidance on when sponsors should liaise with the site's R&D department (administrative) or Principal Investigator (clinical)**, as misdirected queries cause delays to study set-up and delivery.
- **Use shared, rather than personal, contact details** (e.g. generic email addresses) wherever possible, as this 'futureproofs' in advance of changes in staffing or roles.
- **Identify a manager** to whom major issues or concerns with any of the regular points of contact can be escalated.

Managing expectations

It is important for sponsors and sites to establish clear guidelines about who to communicate with in order to escalate any concerns about study set-up or delivery.

- Establish and agree **expectations about how contact will be managed**, including point of contact and timeframe for a response.
- It is recommended that 'managers' are the most appropriate level of seniority for **escalating any concerns** to.

Learning and development

Sites and sponsors should find and pursue opportunities to learn and improve their ways of working when confirming a site's capacity and capability:

- **Creating a template to capture information** on points of contact and timeframe for response for each phase of the study set up and delivery process.
- This would need to be **completed by both sponsors and sites** at the start of formal site set-up activities.
- It is recommended that this is a **live shared document** accessible to both parties (only) via an online platform.

4 Establishing strategic communication between sites and sponsors

Working together

Sponsors should:

- Establish **clear points of contact** for matters of strategic communication.
- Provide clarity as to **escalation routes**, especially in Clinical Research Organisation (CRO) managed trials, to enable sites to have confidence in getting strategic questions answered.

Sites should:

- Establish **clear points of contact**, usually within the Research and Development (R&D) department or the Trust's Business Development function, for sponsors to be able to quickly communicate with Trusts.
- Produce a **clear statement to signal their research objectives and interests publicly** (e.g. on their website) and publicise their single point of contact.

Managing expectations

Strategic communication between site and sponsor is important because it enables better matching of the interests and capabilities of sponsors and sites and underpins a 'pick up the phone' mentality to joint working on commercial trials:

- Sponsors should acknowledge that many Trusts are large, complex organisations and answers to **strategic questions may require the site to involve several staff**.
- They should acknowledge that **it can be difficult for sponsors** to know which sites are interested in hosting trials and their key interests.

Learning and development

Sites and sponsors should find and pursue opportunities to learn and improve their ways of working when seeking to develop channels of strategic discussion:

- Sponsors and sites should acknowledge and respect the fact that **confidential disclosure agreements (CDAs). will sometimes be required in order to take forward strategic communications**, especially when potential new trials are under discussion.

About the Shelford Group

The Shelford Group is a collaboration between ten of the largest teaching and research NHS hospital trusts in England.

These ten NHS trusts provide a comprehensive range of services from community care for local populations, to highly specialised care for patients nationwide. Together they account for over £17 billion of the NHS budget, care for around 17 million patients a year, employ over 170,000 staff and account for almost two thirds of the country's clinical research infrastructure. Our work is co-ordinated by a central secretariat, and delivered through sub-groups of executive directors and professional leads from member trusts. We have three modes of operating, through which we aim to create value for members and the wider health system: mutual learning, policy development and system leadership.

www.shelfordgroup.org

About the Association of the British Pharmaceutical Industry (ABPI)

The ABPI exists to make the UK the best place in the world to research, develop and use new medicines and vaccines. We represent companies of all sizes who invest in discovering the medicines of the future.

Our members supply cutting edge treatments that improve and save the lives of millions of people. We work in partnership with Government and the NHS so patients can get new treatments faster and the NHS can plan how much it spends on medicines.

Every day, we partner with organisations in the life sciences community and beyond to transform lives across the UK.

www.abpi.org.uk

About UKRD - R&D leaders in the NHS

UKRD (UK Research & Development Leaders in the NHS) is a community of Research and Development Directors and senior R&D leaders in the NHS. UKRD exists to promote excellence in R&D leadership, through peer support, development and networking opportunities for our clinical and non-clinical professional membership.

In consultation with our members, we enable high quality research, develop and share best practice and clear standards, and help the financial sustainability of NHS R&D. We do this through our working groups, project work and working closely on policy and strategy with key partners such as UK Government, the National Institute for Health and Social Care, regulators, funding organisations and professional associations.

With over 200 members from 100 NHS organisations, UKRD's membership is geographically very diverse and includes academic trusts, district general hospitals, community trusts and mental health trusts, primary care and Integrated Care Systems/Boards.

www.ukrdleaders.org