A pilot to test a mandated Pharmacy Technical Assurance process through the ECMC Network, with enhanced guidance and support

Information sheet, questions and answers

May 2025

Background

The UK is improving the way research is set-up, to be a more competitive and enabling environment for clinical research, contributing to more research happening for the benefit, health and wealth, of the UK population. This is a primary aim of the UK Clinical Research Delivery (UKCRD) Programme, a cross-sector programme to make the UK a world leader in clinical research.

We have made great progress to streamline and recover the research portfolio since the COVID 19 pandemic, but whilst we have made significant improvement to regulatory timelines, set-up at site remains a challenge.

Latest figures in the UKCRD Key Performance Indicator Report suggest most commercial studies still face delays in setting up once regulatory approvals are obtained.

Streamlining the study set-up pathway in Pharmacy

Clinical pharmacy services can be stretched for capacity, and this has an impact on clinical research. The Health Research Authority (HRA) and partners in devolved nations introduced radiation and pharmacy technical assurances to help this but we have learned our technical reviews are not always used, accepted or reaching relevant teams in ways that maximise their benefit.

Led by the HRA, Workstream 2 of the UKCRD study set-up plan sets out a commitment to improve this by reducing any unnecessary site-level duplication of UK pharmacy technical review and study-wide approvals. This work will also lay some of the groundwork for existing programmes to deliver transformative improvements enabled by digital technology.

What does this work aim to achieve?

We want to help by supporting Sponsors to provide the right information to the right people at the right time for an agreed purpose and to enable sites to focus on the parts of set-up that only they can do, removing any unnecessary duplication where we can.

Overall, we aim to:

- simplify and standardise the site selection and set-up process for both sponsors and sites
- understand and make clearer the information needed from sponsors and sites, when that is best provided and in what standard format.
- remove duplication of UK study-wide review by sites and improve the use and impact of pharmacy technical review information
- test further ideas for removing duplication of tasks at site where possible and to help sites in setting up trials.

We do <u>not</u> aim to:

- replace important local set-up, quality assurance and compliance activities, with central services.

About the pharmacy pilot

This pilot will test a streamlined study set-up pathway and mandated UK Pharmacy Assurance process within early-phase oncology trials via the ECMC Network, starting from June 2025.

We are piloting a framework of additional guidance and support, to help sponsors and sites work together in a consistent way. The ECMC Network and sites will encourage sponsors to request Pharmacy Technical Assurance for their trials. Sponsors who take part in the pilot will also be asked to follow the guidance when selecting and setting up sites. Sites are expected to accept technical assurances and the set-up studies in the way set out in the guidance.

The pilot will begin by using the current technical assurance process, but we are making some small changes before we start to make sure it works as well as it can during the pilot.

<u>These initial improvements to the technical assurance process include:</u>

- ensuring that sponsors only choose lead reviewers from sites planned to participate in the trial, so that reviewers do not spend time on studies they are

not going to set-up themselves and so that lead reviewer fees can be added to the study contract for that site.

- setting out in guidance the information, to be provided by the Sponsor at site selection, in addition to the pharmacy technical review form, which is sent afterwards

- ensuring that site R&D teams are part of early site selection conversations and that they bring pharmacy into these. That site R&D receives the technical review form from sponsors at the right time and that this is passed directly to pharmacy

- improved sections in the technical review form, to include more information for ATMPs and GMO studies and transport requirements for studies that will be delivered across several locations

- support to improve the submission of amendments

Training and support in the new study set-up guidance for sponsors and ECMCs starts from May 2025. Training in the technical assurance processes can also be accessed

What trials are in scope of the pilot?

- Early-phase oncology trials that are going through an ECMC network centre are in scope of this pilot. Trials of healthy volunteers are not in scope and are excluded.

- Trials that have previously been set-up using pharmacy technical assurance can enter the pilot for any amendments

- Commercial and non-commercial trials

What should Sites and Sponsors do now?

ECMC Network Centres

From May - June 2025

1. All ECMC sites are expected to have at least one trained technical reviewer and to use Pharmacy Technical Review, when a Sponsor chooses to enter the pilot from June. Here is where you will find information on becoming reviewers : Can I become a HRA-registered pharmacy reviewer? - Health Research Authority

2. Engage in and attend any training and support events being set-up to support the pilot. Help us to improve them by feeding back. We will let you know when they are going to be.

3. Identify early-phase oncology studies that could be setting up from June. Support and encourage them to come through the pilot. Provide them with details of the pilot contact address so we can get in touch and support them. The pilot contract address is: pilot.testing@hra.nhs.uk referencing ECMC pilot or you can contact the ECMC network via ecmcadmin@cancer.org.uk

4. Be ready to act as a lead technical reviewer if selected as a site.

5. Be ready to set-up studies coming through the pilot, in accordance with the new guidance, training and support and using the technical review form

June 2025 onwards

1. Set-up studies that are in the pilot in the way the guidance and training set out and using the information in the technical review form to do this.

2. Feedback and engage in the evaluation of your experience

3. Help us to improve technical assurance, the guidance and the support offered until the pilot is completed.

Sponsors

Expressing an interest

Sponsors who are interested in taking part in the pilot can express interest by emailing pilot.testing@hra.nhs.uk referencing ECMC pilot. or you can contact the ECMC network via ecmcadmin@cancer.org.uk

A member of the pilot team will then contact you to find out whether you have a suitable study and arrange a time to talk through the new guidance.

Taking part in the pilot

Sponsors who agree to take part in the pilot will be expected to

1. Engage in and attend an online training session (approximately 1 hour*) and support available for the pilot. Help us to improve them by feeding back. If Sponsors are unable to attend a pre-arranged session then we can agree convenient times

2. For sponsors who have not used technical assurance before, additional training on top of this is available.

(training in the guidance will be available from May 2025 onwards)

From June 2025 onwards

1. Select sites and set-up studies in the way the guidance and training set out.

2. Feedback and engage in the evaluation of your experience

3. Help us to improve technical assurance, the guidance and the support offered until the pilot is completed.

In the future

Improving study set-up is complex and will require many initiatives. Future developments of this workstream may include:

- combining technical review with NCVR
- ideas to support standard information sets and dispensing guides
- UK standard drug accountability template for all Sponsors to use

Additional questions and answers

Who have we consulted to fully understand the issues?

The HRA Study Set-up Advisory Board has worked with the ECMC network and the UKCRD Programme partners consulting widely across the sector, to identify the root causes of delay and experience during set-up across the UK.

We have conducted conversations and combined them with reports, papers and findings from others who are working on this problem. Analysis of our work and a file of evidence is available to support our findings. A recent HRA survey (Feb 2025) shows set-up remains complex and that there are opportunities to make efficiencies for all.

Through this work we know that there is both duplication of review and communication differences in language and interpretation, causing problems for sites and sponsors alike. There are also known capacity issues in pharmacy where we should focus our efforts.

Conversations were conducted by the ECMC network to understand key blockers in pharmacy operations for early phase cancer studies, through the ECMC pharmacy working group. We continue to work with expert groups to identify, iterate and refine our solutions.

Pharmacy groups we have spoken to, and continue to work with include:

- NIHR pharmacy working group
- ECMC pharmacy groups
- Four nations technical assurance expert group
- Barts health

Other groups include

- HRA Study Set-up Advisory Board (UK wide representation)
- HRA/cCOG joint Site ID working group (R&D, industry ops, UK wide)

- UKCRD Programme Advisory board
- HRA R&D Champions
- Birmingham Health Partners R&D Leads
- ImPACT (initiative for Multi-stakeholder Partnership to Accelerate Children's Cancer Trials)
- Commercial Clinical Operations Group
- NHS R&D Forum and UKRD Leaders
- UKCRC CTU Network
- Four nations operational leads group
- MHRA GCP Inspectorate

NB: Pharmacy technical assurance was originally developed with pharmacists in 2015 and has been overseen by an expert pharmacy group since inception. An evaluation of technical assurance was conducted before it was launched, which showed a reduction in burden on NHS staff, and a reduction in timelines

Why can't we just mandate the manuals, they have everything sites need?

We are unable to mandate the final manuals at regulatory submission as we are assured by global sponsors this information is not always ready in time. Our industry colleagues also tell us other countries, who are often faster to set -up, do not require them at regulatory submission or to start the set-up process and they do not mandate them. Mandating manuals at regulatory submission would therefore set us apart and create a perceived barrier to trial set-up in the UK.

We will always ask for the draft manuals as part of technical review and these are often provided. Our evidence shows that where these are submitted to the technical review process questions from the lead reviewer are nearly always asked, strengthening the technical information for sites and supporting sponsors with their final manual. The technical review also helps to translate draft manuals received from global companies into a UK standard technical information set. Where a draft manual is not available, the technical review form provides information in place of it.

Some sites currently choose to wait until they receive the final manual before starting to set-up. Doing so prevents those sites receiving information that would allow them to proceed with set up in parallel to regulatory review and to be ready to offer their patients the earliest opportunity to participate in research. Manuals are finalised very late in the process and without the technical review, does not allow for any planning or early arrangements to be made.

It is part of our pilot evaluation to see if using the technical review form with our enhanced guidance and support, helps the process to be more efficient, reducing

duplicative queries and reviews, and making it easier to finalise set-up, once the final manuals arrive.

How will you make sure this won't slow us down? Our centre already sets trials up quickly and doesn't use pharmacy technical review.

A key aim of this pilot is to create a standardised and predictable process for everyone to make it easier to set up research in the UK.

This is a pilot looking to make sure we have the very best way to set-up studies in the UK. We are testing the improved use of Pharmacy Technical Assurance and will evaluate. There may be other ways.

During the pilot, if you are a selected as site then you should take part using the technical review and share with us your lessons learned. The technical review aims to help early planning and set-up arrangements and so we think it unlikely that this will slow you down. We will ask you whether the new process improved your set-up and we will ask Sponsors for their feedback.

Why should I spend my time as lead reviewer? What will it mean for my capacity

Lead reviewers will only be identified if they are already selected as a site. This means that you will be setting up the study in any case and need the information you are requesting from Sponsors. It should not take more time than you would spend in your historic site processes and will reduce your time for studies where you accept the lead review information.

Your organisation will be paid for your time if the study is put through the HRA managed route.

What is the value of the Pharmacy Technical Assurance to me as a Sponsor. Why should I use it and take part in this pilot?

Ultimately, we aim to improve the speed and experience of study set-up for both sponsors and sites. Our initial evaluation of Technical Assurance, and the ongoing feedback we collect, shows that it can and does help timelines and experience when setting up a study at site, but it is not well used in ECMC centres or for early-phase trials.

Pharmacy Technical Assurance aims to save time and resources at site because it provides one standard set of technical information that Pharmacy departments need

to confidently plan, prepare and begin the set-up of their trials once they are selected as a site and before a final manual can be provided.

Pharmacy technical assurance is UK-wide. Submitting through pharmacy technical assurance will provide you with early expert pharmacy support and advice to enable you to develop your draft manuals further and to create information that will reduce the number of queries, later and across the UK.

Submitting through this pilot will provide you with additional support to set-up your study in pharmacy. You will help us to refine a process that has previously been shown to improve set-up times

What is the value of the Pharmacy Technical Assurance for sites and NHS pharmacy teams?

Our initial evaluation of Pharmacy Technical Assurance and the ongoing feedback we collect, shows that Pharmacy Technical Assurance can and does help speed up timelines and improves experience when setting up a study, but we are also open to make improvements.

The Pharmacy Technical Assurance aims to save time and resources at site because it provides one standard set of technical information that Pharmacy departments need to confidently plan, prepare and begin to set-up trials once you are selected as a site.

We know that this technical information is not always provided to pharmacy teams early enough in the process and may not be included in study documentation. Providing a standard set of peer-reviewed technical information once means we can reduce duplication of information review and the number of requests and queries back to sponsors

After site selection there is a commitment to set up a trial. Providing the technical review form after this stage but before regulatory approval means any issues with set-up can be ironed out early in the process and arrangements put in place where that may otherwise prevent delays.

Using the technical review information, pharmacy teams can focus on putting things in place before receiving the manual. For simple routine trials this may mean set-up can begin in a straightforward manner. For complex trials this gives time for sites to arrange processes, systems and ensure oversight is going to be in place.

Does it cost for sponsors and what does it pay for?

There is a fee of £500 for pharmacy technical assurance if you submit through the HRA managed route. If you submit through a self-managed route this is not required.

The fee pays for the time of the lead reviewer to support you in the development of your standard technical information to sites and for their time collating the data. This fee will be added to their site contract and does not go to the HRA.

Would all sites in the study need to be part of the ECMC network for us to join the pilot?

Having sites that are not ECMC centres should not preclude you from taking part in the pilot as long as you do have some ECMC centres. NHS organisations who are not ECMC network centres can also choose to take part in the pilot.