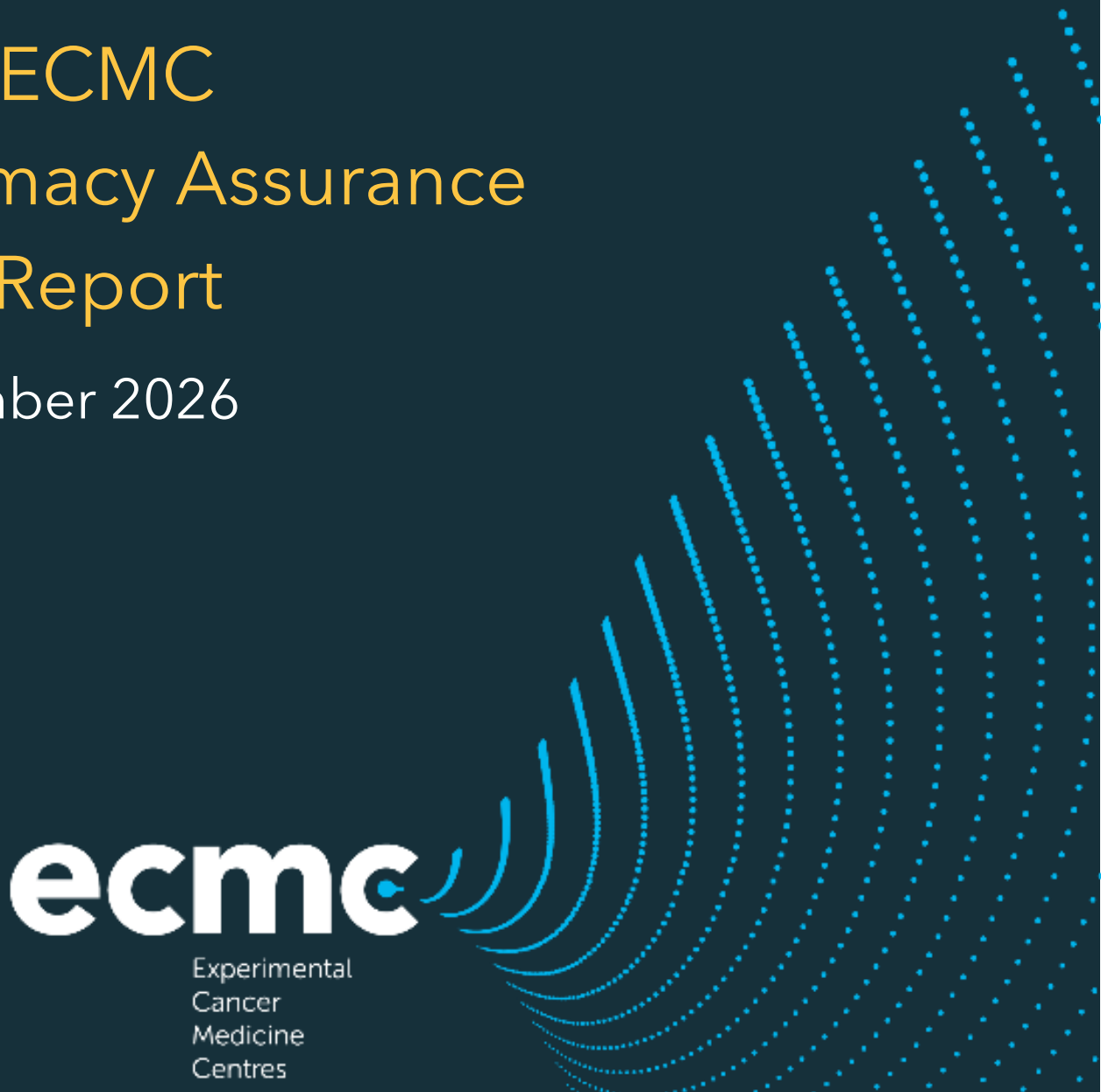
HRA-ECMC Pharmacy Assurance Pilot Report

November 2026



Background

The Experimental Cancer Medicine Centre (ECMC) Network has been delivering a programme of work to improve and speed up the set-up of early-phase oncology trials within the UK as part of the UK Clinical Research Delivery (UKCRD) programme. UKCRD is a cross-sector programme bringing together delivery partners and key stakeholders to create a faster, more efficient, more accessible, and more innovative research system (UKCRD, 2026). This includes a commitment to deliver the UK Government's target to reduce clinical trial set-up time to fewer than 150-days.

Through its national network of specialist oncology centres, the ECMC Network is uniquely positioned to identify common operational barriers affecting the delivery of early-phase cancer trials across the UK. The pharmacy workstream was established following feedback from Network sites that the pharmacy review and authorisation processes were contributing to delays in study activation.

Pharmacy Assurance (PA), managed by the HRA, "*coordinates a standardised single technical pharmacy review for eligible studies across the UK*". The "*completed review can be used by all participating NHS/HSC sites across the UK to support local capacity and capability arrangements and study set-up in their departments*" (Health Research Authority (HRA), 2024). PA Reviewers must be HRA trained and registered, ensuring consistency of review. PA aims to provide the necessary information to sites at the 'right' time to support pharmacy from Site Selection through Planning and Set-up and can incorporate any modifications made at a later stage.

Rationale for the pilot

Through delivery of the ECMC programme of work to date it was identified that PA was not being widely used for early-phase trials and that understanding of the process was inconsistent across the community. It was unclear what the impact of increased uptake of the process would be. Consultation with the ECMC Pharmacy Working Group identified few information gaps in the technical review, suggesting that information provision within PA was not the primary issue; however, several concerns within the process were identified beyond simply a low uptake overall, including the quality of assurance reviews for early-phase trials, the outputs of assurance reviews not being shared with site-level pharmacy teams by sponsors and/or Research and Development (R&D) Departments, and sponsor organisations not following the established process to update information following modifications. If sponsors choose not to follow the standardised central process they must work with each site individually to follow their specific process instead, which increases the chances of duplication across sites and often leads to unnecessary delays and uncertainty. Although there was a consensus that the process could potentially be beneficial if delivered at the right time in the broader set-up process, there were concerns raised that the information included would not be sufficient (despite there being no obvious or identified 'missing' information), and pharmacist's understanding of what PA is intended to do was variable (for example, should it be used to aid feasibility assessments only or does it act in lieu of a pharmacy manual when one is not yet available?)

The pilot formed part of a wider ECMC led programme of work to improve study set-up performance and support delivery of national clinical research objectives. Through engagement with sites, sponsors and pharmacy stakeholders, the ECMC Network identified an opportunity to evaluate whether more consistent use of Pharmacy Assurance, supported by clear guidance, could reduce duplication and support more efficient study activation.

Removing blocks to pharmacy set-up is a specific objective for the Health Research Authority (HRA), as part of the broader delivery of Workstream 2 of UKCRD, which is to "*remove duplication of activity that can be done once on a per study basis during study set-up by making it easier to understand and accept assurance from UK Pharmacy and Radiation Technical Assurances and Information Governance study-wide reviews*".

The HRA and ECMC Network Programme Office (PO) collaborated to design and deliver a pilot project as part of the improvement work within workstream 2 of UKCRD.

The project focused on piloting and testing specific set-up guidance for sponsors, sites and pharmacy teams on the information requirements and timepoints, alongside increased support and a mandated PA process for ECMC centres, in order to assess the impact on the set-up of early-phase oncology trials, with the aim of then transferring any learnings and improvements to other settings outside of early-phase oncology.

Pilot Design

A key objective of the pilot was to evaluate potential improvements within a real-world operational environment. The ECMC Network provided an established national infrastructure through which sponsors, sites, and pharmacy teams could participate in a consistent process.

Having identified that uptake of PA within early-phase oncology trials was low, and that there was a lack of familiarity with the process among key stakeholder groups, it was decided that the pilot should mostly follow the business-as-usual (BAU) PA process. This would enable baseline analysis to be made concerning the effectiveness of PA within early-phase oncology trials and enable identification of any improvements required to the BAU process. Without first testing the BAU process through a mandated system where sites are instructed to always follow the process it would not be possible to make informed decisions about how best to structure the pharmacy set-up pathway.

Following insight gathered from stakeholder groups and to allow for some known capacity concerns within pharmacy departments, some modifications to BAU were made for the pilot:

- **Detailed set up guidance which incorporated how to use the BAU PA process was generated.** The guidance was co-developed by the specifically created guidance writing group, which drew on expertise from the ECMC Pharmacy Working Group, HRA PA 4-Nations Working Party, and the NIHR Pharmacy Working Group. The newly developed guidance incorporated clear information outlining the information requirements for each stage of the set-up process and required actions for each involved party, including the modification process. The guidance, available

from the ECMC website (ECMC, 2026) includes a detailed pathway of the PA process.

- **A revised technical review form with improved sections for early-phase trials was produced**. This included more information concerning trials of Advanced Therapy Medicinal Products (ATMPs), and also information covering transport requirements for studies that are delivered across multiple locations.
- **Trials entered into the pilot by sponsors were mandated to use PA and follow the accompanying guidance**, which would allow the testing of the set-up guidance, with a mandated PA within a standardised system where stakeholders must follow the same processes.
- **The pilot incorporated direct oversight of the stakeholders involved and of the individual trials going through PA**. This included the proactive involvement of R&D teams in the early site selection conversations and ensuring that pharmacy were also engaged at this initial stage.
- **Instead of following the 'taxi-rank' PA system, allocating each new trial to the next available reviewer, a selected ECMC site was responsible for completing PA**. This was to ensure that an ECMC pharmacist was allocated the study and to enable the lead site to benefit from early involvement in the pharmacy process for a trial that they will definitely be setting up.
- **Improved guidance for modifications.** Clearer guidance for sponsors on what to do following any change to the IMP post Pharmacy Assurance.

The scope of the pilot was limited to early-phase oncology trials that were identified through existing ECMC Network processes. Trials selected could involve any sites within the ECMC Network.

Metrics for the pilot were focused on the whole process, from selection through to pharmacy authorisation. This also incorporated the timelines for the PA process. Quantitative measures included the time taken by each stakeholder to complete each step of the process. Qualitative measures included feedback from stakeholders on their experience of the process, including sponsors, site-level pharmacy teams, and the ECMC Pharmacy Working Group.

Pilot Objectives

The objectives of the pilot were:

- To pilot detailed set-up guidance, with a mandated HRA PA process for early phase oncology trials within the ECMC Network.
- To test the set-up guidance and, and to use feedback collected to make iterations and re-test where required.
- To assess the impact on the set-up of early-phase oncology trials of detailed set-up guidance, with a mandated HRA Pharmacy Assurance process.

- To determine the potential advantages and disadvantages for sponsors, sites, and the HRA of implementing a mandated HRA Pharmacy Assurance system.
- To identify any obstacles to the implementation of a mandated HRA Pharmacy Assurance process and to co-develop and test solutions to overcome them.
- To identify and test any required modifications to HRA Pharmacy Assurance to expedite and simplify the Pharmacy set-up process for early-phase oncology trials.
- To encourage sponsors to use the pharmacy assurance modifications process to allow it to be tested and changes be made if required.
- For each ECMC centre to have at least 1 HRA registered reviewer to undertake the mandated Pharmacy Assurance process review.

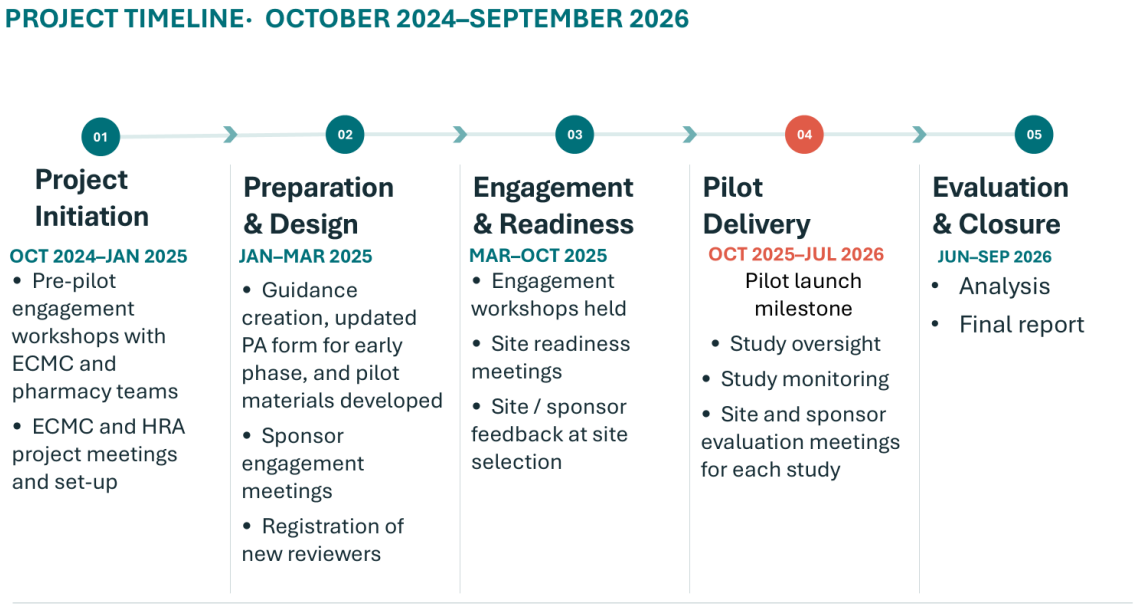
Methods

The pilot included only early-phase oncology trials that were identified through the existing ECMC Network processes. Trials could involve any sites within the ECMC Network.

Extensive engagement and training was undertaken at the following timepoints:

- **Early pilot planning** – Workshops and presentations to introduce the pilot and it's aims, and to identify experts to support the writing of the set-up guidance and information requirements
- **Pre-launch** – Further workshops with sponsors, R&D and sites to introduce the finalised guidance and ensure site readiness to take part. This re-confirmed the purpose and process for PA and highlighted the need to have HRA reviewers registered at site (this was to ensure studies could be assigned directly to a participating site without delay)
- **Launch** – Further meetings were held with both sponsors and sites (to include both pharmacy and R&D) on the requirements of the process, any difficulties with reviewer registration and to discuss studies in the pipeline
- **Study identification and submission** – Upon identification of a study, a meeting was held with sponsors re-introducing the guidance, requirements of the pilot and submission process for PA. Contact was implemented throughout the set-up lifecycle of the study to ensure difficulties and improvements to all processes could be identified.
- **Post pilot** – Separate structured interviews were held with sponsors and sites (R&D and pharmacy) to understand and collate qualitative data on their experience of the pilot, difficulties encountered, and positive impacts of a more structured and standardised study set-up process.

Pilot timeline



Pilot Status

Number of studies entered into the pilot	7
Number of studies with sites selected	6 (1 study withdrew from the UK)
Number of studies submitted to technical assurance	6
Number of studies issued pharmacy assurance	6
Number of studies with pharmacy authorisation in first site	4 (1 study on hold from MHRA and 1 study withdrawn from pilot)
Number of studies with pharmacy authorisation in all sites	4

Of the 6 studies that proceeded to set-up, 4 have completed pharmacy authorisation in all sites at the time of publication. Each trial encountered challenges that negatively impacted on the completion of set-up, and on the time taken to complete each stage of the process. Many of the challenges were study specific. For e.g., one study was held up for a substantial period following completion of the PA process due to an undeliverable request from a regulator to implement additional overnight stays in the protocol that was unrelated to the pharmacy review. Another was delayed due to complications concerning the provision of standard of care medicines (as identified through the PA review process).

Reviewer Status

Number of ECMC Centres	Centres with a reviewer	Total number of reviewers	% of sites with a reviewer
17 (Adult)	12	27	70%
12 (Paediatric)	5	8	42%

Although not all centres were able to register a reviewer, the number of reviewers (especially within the Adult Network) is significantly higher than pre-pilot. The stakeholder group of ECMC Pharmacists was not an established reviewer network prior to the pilot, meaning support and engagement was required to explain PA, publicise the registration process, and bring the group into a more collaborative structure. The ECMC Pharmacy Working Group was established as part of this process and has been a key part of engaging with the community.

Data

The mean time to pharmacy authorisation from HRA/HCRW Approval was 38 calendar days, with variation between studies, which further supports the need to have standardisation and consistency in pharmacy set-up.

Study 1 demonstrated a mean pharmacy authorisation time of 72 days following HRA/HCRW Approval. Multiple pharmacy handling, formulation and vial management issues emerged at different sites throughout set-up which were raised by one site in early feasibility discussions and not actioned by the sponsor due to a misunderstanding of the importance of the issue. These issues were identified later by other sites who had early pharmacy engagement and were handled and resolved individually over a lengthy period, highlighting the need for early engagement and greater sharing of issues raised across sites to increase efficiency in resolution.

By contrast, pilot studies 2 and 3 achieved substantially shorter pharmacy authorisation timelines, averaging 31 days and 24 days respectively. These studies were characterised by stronger pharmacy engagement during site selection and greater use of Technical Assurance information throughout set-up. The findings suggest that the value of Pharmacy Assurance is maximised when technical review findings are integrated early into site planning and when pharmacy are engaged from site selection onwards.

Full datasets can be found in Appendix 1

Pilot Findings

Beyond evaluating the practical application of Pharmacy Assurance within early-phase oncology, the pilot generated valuable evidence regarding wider pharmacy study set-up processes. The findings highlight several opportunities to improve consistency, reduce duplication and strengthen communication across the clinical research ecosystem.

Structured feedback was collected from sponsors, pharmacy teams, reviewers and members of the ECMC Pharmacy Working Group throughout delivery of the pilot, and this enabled valuable information to be gathered regarding the set-up guidance, PA and the pharmacy set-up pathway. Several clear themes emerged and numerous areas of opportunity and potential next steps for development were identified.

Impact of Early Pharmacy Engagement

A consistent finding across the pilot was that studies involving pharmacy teams earlier in site selection and feasibility discussions progressed more efficiently through set-up. Sites reported that early review of technical information enabled identification of potential barriers before formal activation activities commenced, reducing the need for later clarification requests and rework. The pilot therefore provides some evidence that pharmacy involvement at site selection is a critical success factor for efficient study set-up and should be considered a core component of future pathways.

Technical Assurance and reducing duplication

Sponsors reported that the Technical Assurance process helped reduce the duplication of technical queries and created greater consistency between participating sites when received at the right time. Sponsors highlighted that detailed early review reduced the likelihood of the same questions being raised repeatedly by multiple pharmacy departments.

Several Sponsors noted that the process created value beyond initial site activation because technical decisions and sponsor clarifications could subsequently be referenced by participating sites during study delivery.

However, feedback also indicated that the process could be strengthened further through sponsor sign-off of Technical Assurance outputs, increased clarity around key topics such as supply models, and the incorporation of commonly encountered questions into future versions of the review process.

Communication remains a barrier

Across all groups, communication and implementation challenges emerged as the most significant obstacles to efficient set-up. While technical information was generally available, there was variation across organisations in how information was shared, actioned and communicated to pharmacy teams. These findings suggest that system-wide improvements in communication pathways are likely to be as important as any changes made to Pharmacy Assurance itself.

Examples included:

- Technical Assurance forms not reaching pharmacy departments promptly.
- Modifications not being communicated consistently.

- Sponsor responses to queries not being cascaded to all participating sites.
- Reliance on CRO intermediaries delaying query resolution.
- Lack of access to sponsor subject matter experts when technical decisions were required.

Strong Support for Centralised Knowledge Sharing

One of the most consistent findings from both sponsor and site interviews was the repeated escalation of similar technical questions at multiple sites. Stakeholders identified a lack of mechanisms for sharing solutions, resulting in unnecessary duplication of effort.

There was broad support for development of a national platform through which:

- Technical queries could be logged.
- Sponsor responses could be shared.
- Frequently asked questions could be maintained.
- Technical Assurance updates could be distributed.
- Sites could access prior decisions and clarifications.

This represents a significant opportunity to increase consistency and reduce repeated work across the UK.

Challenges Around Drug Supply Models

Drug supply arrangements emerged as one of the most frequently discussed challenges during feedback interviews.

Sites and sponsors reported confusion concerning central versus local supply arrangements, inconsistent interpretation of regulatory requirements, uncertainty around modification requirements and substantial operational consequences when supply models changed after set-up had commenced.

Several examples from the pilot demonstrated that Technical Assurance reviews successfully identified inconsistencies between protocol documentation and operational requirements, allowing issues to be resolved early on. However, this benefit is only realised when the Technical Review Form is received and used by pharmacy teams. For one pilot study where the form was not utilised by a couple of sites, the pharmacy team was unable to identify an inconsistency that had already been flagged by the Technical Assurance reviewer. As a result, the site proceeded with the expectation that local drug supply could be used, when in fact the study required central supply only. This misunderstanding led to

operational issues and delays much closer to site activation, highlighting the importance of ensuring the review form is distributed and used.

Stakeholders concluded that clearer national guidance and earlier sponsor decision-making would be required to address these challenges fully. This issue, along with other recurring challenges, highlighted the need for more accessible and coordinated early pharmacy advice within the UK.

Workforce constraints and reviewer recruitment

Workforce capacity continued to influence study timelines throughout the pilot. Pharmacy stakeholders reported that increasing workload, reviewer shortages and variation in organisational structures all affected implementation.

The pilot also demonstrated the ability of the ECMC Network to establish and mobilise a community of Pharmacy Assurance reviewers where one did not previously exist. Through the creation of the ECMC Pharmacy Working Group and targeted engagement activity, the Network substantially increased reviewer participation and generated a foundation for future improvement work.

Initially, some site pharmacist teams were reluctant to take part in the pilot process or only wanted to commit to specific parts of it (for example, only completing reviews for studies where they would be lead site, not as part of the 'taxi-rank' system; this was amended for the pilot process to allow the selected site to complete the review directly). A combination of the lack of awareness of the reviewer requirements and concerns about whether it would negatively impact on workloads and capacity understandably created hesitancy initially.

Positive engagement from the HRA and ECMC PO to support the onboarding of new reviewers was successful in registering pharmacists from most ECMC sites. The process for registering new reviewers was slower than hoped for. This was in part due to a lack of understanding of the process for registration. Funding has been secured from the Voluntary Scheme for Branded Medicines Pricing and Access (VPAG, see below) to support this in the future, which will make it easier to increase the pool of PA trained pharmacists which in turn will enable a higher volume of studies to utilise PA. Ultimately, this will hopefully enable pharmacists to become more confident with PA and aware of the potential benefits as they will be more likely to be directly involved in completing a review and/or they will receive Technical Assurance outputs more regularly for their trials.

Longer-term, if PA is to be used more widely (or if PA is to be mandated for all studies/certain study types) then the initial roll-out and implementation to a broader user base must be accompanied by change-management that can work with Pharmacists and other impacted stakeholders to manage any concerns.

Nevertheless, stakeholders strongly supported the continued expansion of the reviewer network. Feedback indicated that assigning reviews to a selected participating site was viewed positively as it increased local ownership and maximised the value generated from

the review process. The traditional taxi-rank model was considered an important contingency mechanism but was generally viewed as a secondary option where no suitable reviewer could be identified.

Limited scope of pilot

Whilst the pilot was conducted within a relatively small and specialised network, it nevertheless demonstrated the feasibility of implementing a more structured and standardised pharmacy review pathway across multiple organisations. Importantly, the pilot generated operational evidence that would not previously have been available and identified practical opportunities for wider system improvement.

Although there was substantial direct management of the pilot studies, there were still challenges with implementing the pilot process and a lack of buy-in from some stakeholders, including from R&D Departments who did not all fully engage with the process. In order to be able to demonstrate to sponsors and sites that PA can be effective for all trials, and that the revised guidance and approach to site selection improves the PA process, there must be clear evidence that can be reported and shared with the community.

Further evidence is required to assess whether additional modifications to the PA process beyond those tested in this pilot would be beneficial. For e.g., the pilot has not made clear whether the current timing of the technical review completion is opportune, as the limited sample of trials has not included many where the information was available at the earliest time point. As outlined above, the study-specific challenges encountered in these trials could potentially have been dealt with more proactively (and with less impact on set-up timelines) if the review was completed at an earlier stage of the process. Early-phase oncology trials are also often particularly complex for pharmacy to set-up and deliver; more data covering later-phase and non-oncology trials may better inform the decision-making process concerning mandating PA in the future and guidance for study set up within pharmacy departments. Further testing outside of early-phase cancer/ECMC to assess the potential for a wider roll-out is essential.

General Findings

Pharmacy capacity

PA is only one step within a broader complex pharmacy set-up process, and other challenges can also influence timelines and have a detrimental effect on overall progress. This includes a lack of standardised templates for pharmacy, with multiple versions being used between sites for documents like dispensing guidance and accountability logs. Prescription building is also currently very time consuming; in some cases, this can take 60 or more days, longer than the total time sites are allocated for set-up. Communication within sites between different departments continues to impact on the initial stages of the set-up process, with site selection uncoordinated and pharmacy often not involved until a later stage.

The findings suggest that the principal challenge was not the content of Pharmacy Assurance itself but ensuring that stakeholders understood when and how to use the

outputs effectively within existing local processes. This represents an implementation challenge rather than a limitation of pharmacy expertise within participating organisations.

For GMO studies there are additional concerns. Delays with organising risk assessments via site-specific processes and a cautious approach from sponsors when setting containment levels and determining licensing requirements are creating a confused and varying process from site-to-site. The pilot has highlighted that although PA is a potentially important tool, the impact of PA on overall pharmacy set-up times will be limited unless additional measures are taken to address these other areas of the process simultaneously.

The pilot has confirmed previous findings from other related workstreams that there continue to be capacity challenges within pharmacy at most sites. It is difficult to separate some of the findings from the pilot from more general capacity concerns, especially in light of the additional process considerations outlined above, and it is clear that resource impacted the pilot in several areas. This has included reluctance to engage with the pilot process from some sites because of a lack of time and/or resource, or because of concerns that PA may not alleviate the pressures that already exist. Limited resource can also impact on the ability of sites to properly conduct the pilot activities as specified in the guidance, and delay pharmacists from registering and training to be reviewers. Pharmacy workforce and capacity concerns need to be addressed alongside improvements to the set-up process. Overall, capacity issues do not lessen the need for initiatives like PA, but they can create additional challenges for engagement and implementation. The pilot has shown that proactive work with pharmacists can help to alleviate their concerns, and that direct and continued engagement with stakeholders is a key part of delivering necessary change. One sponsor involved in the pilot confirmed that their experience was that the thorough PA review minimised similar queries arising later on during the set-up of other sites; this is an important metric when considering capacity within participating sites.

Engagement/familiarity with the process

Consultations delivered ahead of the pilot established that awareness of the process and familiarity with how to utilise PA at site-level was a substantial limitation in increasing uptake. Although PA has been an option for sponsors for several years, the low uptake of the service within early phase trials meant that many site-level stakeholders were unfamiliar with the purpose of PA or even what the PA review outputs looked like.

However, the pilot has demonstrated that in most cases this can be overcome through engaging directly with users and working through any local concerns that are raised. The pilot has shown that most stakeholders will embrace the process and attempt to work to the guidance providing there is clear justification for any changes needed within their local systems and workflows. The guidance has been generally well received by users, and feedback received has been positive.

Availability of information

For PA to be most effective, the Technical Assurance output generated by the Reviewer must be shared with the site pharmacy at the earliest opportunity. Further to this, pharmacy engagement from the outset of the site-level process (i.e., from site identification onwards)

and provision of early information from the sponsor, even in stable draft form, is key to ensuring that a proactive approach to set-up can be taken. However, as identified prior to the delivery of the pilot, engagement between R&D departments (or their equivalent) and pharmacy departments varies from site to site, and sponsors are also not always engaging pharmacy representatives directly during early set-up. There are instances where the Technical Assurance Form is not distributed to pharmacy at all by the sponsor/R&D, or it is sent too late in the set-up process for it to be useful. This is not unique to PA; the Vaccine Innovation Pathway (VIP) have reported that they have encountered similar challenges with piloting a risk assessment pathway for pharmacy. The revised guidance used for the pilot makes clear that sharing the report with pharmacy promptly is essential and that early engagement is key, and the Project Team have reinforced this message to R&D departments and sponsors involved in the pilot, as well as through the National Institute for Health and Care Research (NIHR) Pharmacy Working Group. However, this was still an issue for several of the pilot studies. For e.g., for one trial PA was issued on the 23rd of December, however by the 14th of January (3-weeks after) it had not been sent to pharmacy. Although the Christmas and New Year period may explain part of this delay, a 3-week delay will have a significant impact on overall set-up times and potentially prevent a site from meeting the mandated national metrics. Stakeholders on both sides of the process must understand the importance of distributing the information as soon as possible and of making sure that it reaches pharmacy directly. Without this level of engagement and understanding PA will not function properly.

External initiatives

The implementation of stricter national set-up metrics, accompanied by a revised NIHR Research Delivery Network (RDN) Research Delivery Funding Model of which 20% is awarded based on performance against these targets (NIHR RDN, 2026), appears to be causing sites to review and amend their local set-up processes. This should be positive overall, as it will hopefully lead to more efficiency at site-level. There are examples already of sites within the ECMC Network making substantial changes to their site-level processes to implement more efficient routes to set-up. However, there is a potential for friction if site processes shift to become incompatible with the overall PA process and the expectations detailed in the revised guidance. For PA to be effective, it is essential that change management at site-level incorporates PA into the overall process for local set-up and accounts for pharmacy involvement from the early stages of site selection.

The pilot was conducted within a fast-moving national picture where there are numerous improvement projects being undertaken within UKCRD and other programmes. This includes within Pharmacy. For example, the VIP pharmacy risk assessment process pilot has been completed, and a report was published. The Project Team are working to identify how PA could be impacted by other initiatives that are being tested and to assess whether further revisions to PA are required. Given the rapid and broad programme of work that is happening nationally for other set-up/delivery processes, any roll-out of a mandatory process would likely need to be gradual to enable sponsors and sites to manage the change alongside the multiple other modifications that are being made currently/will occur in the

future. This could impact on the speed of implementation and the realisation of positive outcomes.

Although the pilot process was broadly the BAU PA delivery, the increased levels of oversight for pilot studies increased the resource required from the HRA to manage the delivery of PA for the trials in the pilot. In addition to the management of the PA service as usual, the pilot required regular communication with sites and sponsors, and hands-on management of the process to ensure that all steps were completed as intended. There was also a need to help sites to problem solve as and when potential challenges were identified. For e.g., for one trial a costing escalation related to the National Contract Value Review (NCVR) process concerning the pharmacy dispensing fee required extensive communications with NIHR to resolve. It is hoped that this level of oversight would not be required longer-term if PA were to be mandated nationally, as sites would familiarise themselves with the process and embed it locally. Early-phase trials may also present more challenging pharmacy requirements than many later-phase studies and therefore require more hands-on support when challenges arise. However, there would still be increased resource requirements for the HRA to manage a scaled-up process, and there will continue to be complex trials that require escalation or central management to help them proceed. A mandated PA process could only deliver properly if there is sufficient accompanying resource to manage it.

It should be recognised that standardising UK processes for both sponsors and sites should be a priority for any external initiative and a core delivery message for PA. Ensuring sponsors encounter the same set-up processes from each site they are working with is the key to enabling ease of set-up.

Opportunities and potential next steps

One of the most important outcomes of the pilot is the demonstration that established research networks can provide an effective environment for testing and evaluating national process improvements. The ECMC Network has generated valuable evidence regarding pharmacy study set-up and established a framework through which future improvements can be developed, piloted and evaluated.

The pilot helped to identify numerous opportunities and/or solutions that could be implemented or explored further:

- As outlined above, **further refinement of the set-up guidance and pharmacy assurance process remains important** as the pathway and technical assurance outputs continue to evolve. The pilot has provided valuable learning on implementation, stakeholder engagement and process development. These findings are informing ongoing improvements to the pathway and service, with enhancements being iteratively tested and refined through routine implementation as development continues.
- There are opportunities to **link PA to other set-up processes more closely, including NCVR and the GMO Risk Assessment processes**. Enabling sequential steps of set-up to be done in parallel where possible could reduce the input

required from users and help to standardise and streamline the overall pharmacy process. There is also a known challenge within early-phase trials specifically with ensuring pharmacy costs are accurately represented during NCVR. Linking the lead PA reviewer in proactively to also conduct the costing process could help to reduce the number of issues that are being encountered and prevent so many trials needing to utilise the escalation pathway. The HRA is currently recruiting Technical Experts, supported by VPAG funding, to further develop and implement the study set-up pathway.

- Future digital developments **could potentially allow the PA question set and process to be undertaken digitally**. This would standardise completion of the review as part of the overall regulatory process and could also help to minimise errors in completion. The guidance could be built into a system, with additional question specific prompts and resources also made available. The potential for sharing information that arises during PA within a national platform should also be explored. Sponsor feedback confirms that queries (and subsequent solutions) that arise from the initial review are not always shared effectively across sites; digital system(s) offers an opportunity to make a log of this information available to all users more easily and reliably.
- There must be **a drive to ensure that all sites have at least one Pharmacist registered with PA**. If usage of the service is to increase there must be a sufficient pool of reviewers available to process studies at the earliest practical opportunity. This could be realised through including site pharmacy representation in the national metrics. Work is currently being undertaken by the HRA to increase the number of reviewers available, supported by VPAG investment.
- The Site Selected Email Template that was launched by the HRA in August 2026 presents an opportunity to further embed PA within the early stages of set-up. The Template includes the confirmation of whether the project will be submitted for PA. **A mandated PA process could include a requirement to use the Site Selected Email Template**, which will subsequently prompt sponsors that PA must be utilised. Additional criteria could be added to the Template to enforce that sites must engage pharmacy directly from the outset of the process and provide the relevant contact details to the sponsor.
- The pilot highlighted that although PA is a potentially important tool, the impact of PA on overall pharmacy set-up times will be limited unless additional measures are taken to address other areas of the process simultaneously. **There is a need to create UK template documents for accountability logs and dispensing guidance**. The potential for **developing a process to build dispensing guides from PA** should also be explored.
- Finally, **for GMO studies there are additional concerns.** Delays with organising risk assessments via site-specific processes and a cautious approach from sponsors when setting containment levels and determining licensing requirements are creating a confused and varying process from site-to-site. The pilot has highlighted

that although the set-up guidance and PA are potentially important tools, the impact on overall pharmacy set-up times will be limited unless additional measures are taken to address these other areas of the process simultaneously.

The pilot has demonstrated the value of partnership working between the ECMC Network, HRA, sponsors and NHS organisations to address complex study set-up challenges. Whilst further work is required, the project has generated important evidence regarding how pharmacy processes can be streamlined and standardised. It has also demonstrated the role that the ECMC Network can play as a national improvement partner, providing the expertise, stakeholder engagement and operational environment required to test innovations and support wider transformation of UK clinical research delivery.

Appendices – Data Tables

Calendar days from HRA Approval to Pharmacy Authorisation (4 studies that completed the pilot):

Study	Site	Calendar Days
1	Site 2	65
1	Site 3	75
1	Site 4	76
3	Site 1	13
3	Site 2	39
3	Site 3	41
4	Site 1	45
4	Site 2	4
4	Site 3	24
5	Site 1	-11
5	Site 2	46
5	Site 3	44

Mean Calendar days from HRA Approval to Pharmacy Authorisation by Study:

Study	Mean Calendar days
Study 1	72
Study 3	31
Study 4	24.3
Study 5	26.3