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Health Research Authority

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

May 2025

UK CLINICAL RESEARCH DELIVERY

Objectives

- ✓ Improve capacity in busy clinical services focussing on Pharmacy,
- ✓ Improve the experience and efficiency of study set-up
- ✓ Improve the impact of study-wide and technical reviews on set-up
- x **not** removal of important set-up and compliance activities

Right Information, Right Time, Right Purpose

Publish new guidance for site-selection and set-up

Starting with pharmacy, understand and set-out purpose of each step

- information needed
- decisions
- actions
- expectations and commitment
- for sites, pharmacy teams and sponsors
- in common language

Do Something Once Where-ever Possible

- Make clearer how technical assurances and study-wide review help set-up in this way
- Provide support and training for people to follow the path
- Test ideas for further removing duplication of tasks at site where possible
- Evaluate benefits (for example, better information resulting in less queries for sites)

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Set-up of clinical trials
Draft guidance for Sponsors, R&D and Pharmacy

May 2025

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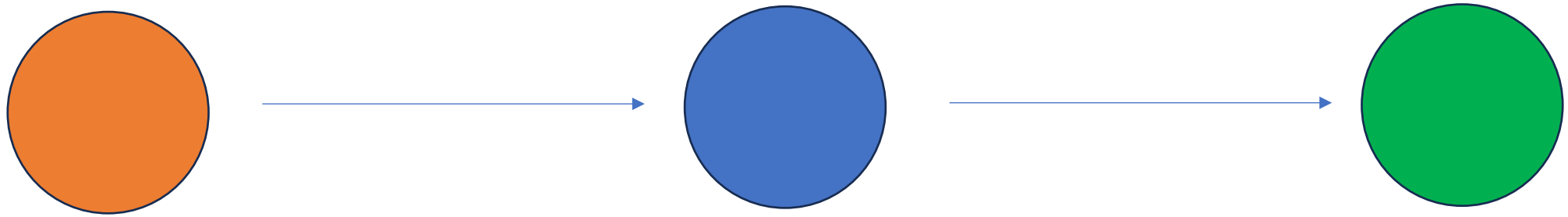
Clear steps for sponsors, sites and pharmacy teams

Guidance covers 3 key stages of identifying and setting up sites



Assessing feasibility
- Site ID
- Site Selection

Planning and arranging set-up
Confirmation of set-up via signed contract exchange

Site initiation
Sponsor green light to open

Focussed on collaboration, communication and expectations

Who has helped

Pharmacy groups (formed a guidance writing group)

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

Other groups include

- MHRA GCP Inspectorate
- Barts Health Pharmacy team
- 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

Remember this is the first draft for testing!

Study set-up pathway overview

UK Placement	Feasibility	Regulatory approvals, set up and initation

Country Assessment (study/generic)

Study synopsis

Country Assessment (protocol)

Draft protocol

Site Identification

Near final protocol/ synopsis

Site Selection

Near final protocol

Regulatory submission NCVR

Technical assurance submission

Site planning and set up

As available technical assurance review form shared

Confirmation of site set up

LIP Shared Including local site price

Sponsor greenlight

Regulatory Approval

Regulatory approval requirements accomodated

Assess capability and known blocks to capacity

Plan and arrange. Put everything in place to start

Early UK advice

Early site feedback

Early site planning

Site set-up

Site open

How best to optimise for the UK?

Who to approach?

Where could we do it?

Assess possible sites.

Where to select?

Can we do it in principle? Can we commit to set-up?

Agree site selected

Get ready to do it

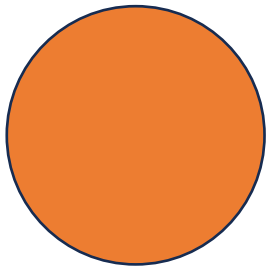
How shall we do it? Can we contract to deliver. Do we have green light to start?

Plan, prepare, arrange and commit to delivery. Assure and initiate

Site and Sponsor commitment to set-up

Site and Sponsor contracted to deliver

Feasibility



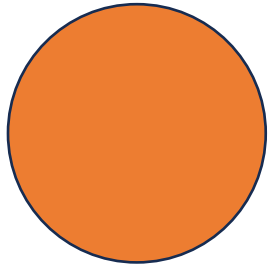
Where could we do it?

Site identification: Who to approach?

Sites/pharmacy

- ensure generic capability information is available, visible and updated when required (e.g., aseptic unit capabilities, licenses held).
- information that is unlikely to change (likely to be coordinated via R&D or networks like ECMC or RDN)
- use the ECMC network feasibility tool

Feasibility



Site selection
all parties

- ✓ assess known capability and blocks to capacity
- ✓ involve pharmacy in this step
- ✓ Sponsors provide near final protocol and known information to sites
- ✓ use the guidance

Can we do it principle?

Can we commit to set up?

Commit to set-up sites that are selected

Guidance for site selection step (draft)

Assess known trial requirements, capability and known blocks to capacity,

e.g.

- IMP handling
- staff needs
- oversight
- equipment
- blinding requirements,
- IMP logistics, and special handling (e.g., gene therapy).

Table 2: Example pharmacy protocol-specific site feasibility assessment for selection

Pharmacy assessment	Sponsor	Pharmacy
Assess any known blocks to capacity When is it likely?	• **Provide** proposed dates when aiming to start at the site. If the site is unable to commit to the timeframe, inform them of any flexibility around this i.e. can they open earlier or later than the proposed dates. • **Review** information of any studies the site informs you they already have open/committed to open which may be a competing trial and decide whether they are acceptable to run alongside.	• **Decide** whether you are likely to have capacity to undertake this trial within the proposed timeframes? • **Consider** anything else on the horizon which may prevent you being able to take part. • If you are unable to commit to the proposed timeframe, **inform** the sponsor if you could do it within a different timeframe e.g. "we would be unable to open in June due to other open studies, but we could open in September, would this work for you?" • **Inform** the sponsor of any studies you already have open/are committed to open which may compete with the proposed trial or required resource e.g. aseptic unit/gene therapy suite etc
Assess specialism, licenses and numbers required.	• **Inform** the site of how many (a range) of participants they would be expected to recruit? • Any required licencing information e.g. what licences are required.	• Consider whether capacity exists to support intended dosing schedule (e.g. weekends, 24/7 recruitment expectations etc) • **Confirm** all licenses are in place

Guidance for site selection step (draft)

A guide, not a ‘must have’ checklist:

Assess approximate resources and essential IMP management requirements	**Provide** information on essential IMP management requirements, equipment, expertise and approximate resources needed to help the site decide if they are likely to be able to comply with the protocol. Including details on: • **IMP** - is there anything unusual about the drug/drug regime? • **Stability requirements of the IMP**- If less than 4 hours can this be safely delivered at bedside? If the IMP needs to be made up at the bedside - what are the potential hazards? Or is it required to be made up in pharmacy? • **Any specific transport requirements** if preparation location is different to the participant location. For example, some organisations prepare drugs at one hospital site and transport to different hospital sites across the local area. • or in surgery, can the ward staff or surgeons administer it? • **Any known staff requirements**: For example, if IMP is to be given on the ward • **If preparation/ administration** is to be performed by unblinded/blinded staff, what will this require?	**Decide and confirm**: • you could safely manage the type of IMP detailed by the sponsor. • you could safely manage the stability requirements of the IMP detailed by the sponsor. • PI and pharmacy could safely manage any dose escalation(s) detailed by the sponsor. • you have likely capability to comply with any known blinding requirements. • if supply is from own source that this would be possible. • any specific storage requirements could be put in place e.g. -80 freezer • you could comply with any specified aseptic preparation requirements. • you could comply with the accountability requirements. • you could comply with any known details of specific equipment or resources. • if pharmacy will be responsible for IMP dispensed or administered elsewhere, can you (and relevant departments, where relevant) comply with protocol requirements.

Technical assurance submission

IRAS Help - Preparing & submitting applications - Pharmacy Assurance

Planning and set-up

How shall we do it?

Can we contract to deliver?

Site set-up – get ready

all parties

- ✓ get everything ready and in place to initiate
- ✓ **use the lead technical pharmacy review** to get-ready early (they have asked lots of pharmacy-related questions of the sponsor)
- ✓ use the regulatory documents and manual when they are available. Sponsors confirm any changes impacting pharmacy
- ✓ assure compliance with protocol and regulatory documents
- ✓ agree site initiation arrangements

Guidance for planning and set-up (draft)

Plan and arrange how the study will run

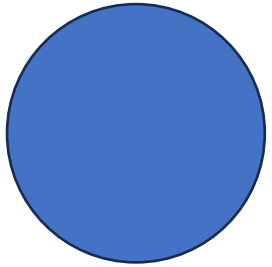
e.g.

- drug supply chain
- storage space
- randomisation procedures
- labelling,
- accountability and oversight systems.
- build prescriptions,
- localise documents,
- train staff,
- assure compliance with protocol and regulatory documents

Table 3 Examples of planning and set-up activity to be arranged

Pharmacy arrangements	Sponsor/Technical Review Form	Pharmacy
Set up and put in place how we will do it:	**Provide and arrange:** • Final document set including any pharmacy-specific documentation • **Supply:** delivery details/requirements to the site. (if supplying the IMP) • **Labels:** labelling details and requirements. • **Assembly** and reconstitution **Randomisation and blinding** information requirements including the process for **emergency Unblinding:** who is responsible for both randomisation and unblinding. How will this information be communicated to pharmacy? • **Systems and log-ins.** ensure the site has access to any required systems, the appropriate user type and access permissions and the appropriate number of log ins.	**Arrange:** • **Supply:** If you will be using local supply of the IMP ensure arrangements for this are in place to begin dispensing when required. If the sponsor is providing the IMP supply, ensure the sponsor is aware of the organisation delivery address and any local delivery requirements e.g. deliver to pharmacy loading bay. • **Digital systems:** Load/create label into local system. Load into prescribing systems, aseptic unit production system etc. • **Dispensing procedures**: Use the following information to form local working/dispensing instructions: ➢ assembly and reconstitution method(s) any randomisation and blinding instructions (including emergency unblinding process)

Planning and set-up



Site set-up – confirmation

all parties

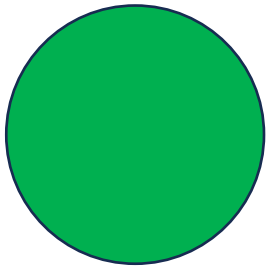
- ✓ Communicate
  - any changes (new vendors etc)
  - communicate unforeseen changes or delays
  - communicate progress
- ✓ Confirm ready to start initiation via exchange of signed contracts

Can we contract to deliver?

Are we ready to initiate?

Commit to deliver to time and target

Site initiation



all parties

- complete initiation tasks specified by the Sponsor
- confirm everything is in place
- assure compliance with regulatory documents
- initiate dispensing procedures

Is everything in place to open?

Do we have Sponsor green light?

Confirm Sponsor “green light” for the site to open

Guidance for planning and set-up (draft)

Conduct agreed final set-up and compliance activity
E.g.

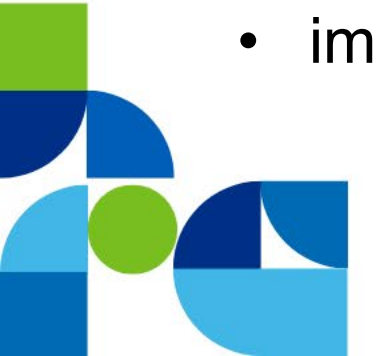
- Site initiation visit
- IMP shipment
- training
- process initiation (dispensing, systems, IT)

Table 4: Examples of pharmacy site initiation activities

Pharmacy initiation	Sponsor	Pharmacy
Final set-up and compliance	• Undertake any relevant training with the site. • Ensure shipment of any required IMP, devices and equipment. • Hold site visit (if required). Check set-up and compliance. • provide QP certification for each IMP batch / or assurance statement that all IMP supplied for the trial will be fully QP released • Confirm Sponsor green light	• Arrange for the relevant staff to undertake any sponsor required training. • Hold required site initiation visit and ensure the relevant staff are available. • Receive IMP and any relevant equipment and ensure any relevant activity is completed e.g. stored in the relevant area ready for dispensing. • Activate trial within internal systems/processes e.g. regimens available for selection within electronic systems, pharmacy staff notified of trial go-live etc
Pharmacy confirms to site R&D Coordinating function everything is in place		

Technical assurance updates

- updated technical review form (GMO, ATMP, Travel between sites)
- Lead reviewers will only be sites selected for this pilot
- amendments process will be supported so that the sponsors communicate updates and changes
- make sure Sponsors are aware new information is communicated to all sites
- improvement ideas collected



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What now?

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ECMC Sites

- review the guidance - training and support throughout as needed
- consider your own processes (pharmacy and R&D)

  what might you need to do or change to set-up in this way?
- ensure you have 1-2 technical reviewers trained
- be ready to set-up in this way if a Sponsor comes through the pilot
- take part in the evaluation and provide feedback

Sponsors

- express interest in taking part (early phase but not healthy volunteers)

- training in the guidance and process

pilot.testing@hra.nhs.uk referencing ECMC pilot or you can contact the ECMC network via ecmcadmin@cancer.org.uk

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What next?

hra.nhs.uk

Future improvements for testing

Considering and collecting other ideas for testing

E.g.

- combining technical review with NCVR (as in Scotland)
- UK accountability log
- Ideas to support standard information sets and dispensing guides

Keep in touch and informed

ECMC website

Pharmacy Assurance Pilot: Streamlining Study Setup in Early-Phase Oncology Trials | ECMC

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Thank you, any questions

Help us to make set-up better for everyone

pilot.testing@hra.nhs.uk

referencing ECMC pilot

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