Summary Guidance for Clinical Trial Set-Up

For Sponsors, Sites, and Pharmacy Departments

About this Guidance

This document provides an accessible summary of draft guidance: Setting-up Clinical Trials. Draft Guidance for Sponsors, Sites and Pharmacy Departments, May 2005

This document sets out clear steps for setting up clinical trials, focusing on collaboration between Sponsors, Sites, and Pharmacy. It covers three key stages of the set up pathway.

1. Assessing Site Feasibility

2. Planning and Set-Up

3. Site Initiation

The draft guidance has been written following engagement with sponsors, sites and pharmacy experts in clinical trials. It is authored by the Health Research Authority (HRA) in partnership with the Experimental Cancer Medicines Centre Network (ECMC) and is being piloted with ECMC sites. Changes will be made based upon feedback from sites and sponsors who choose to take part in the pilot.

Each section outlines:

- Purpose

- Key actions for sponsors and sites

- Pharmacy role

1. Assessing Site Feasibility

Goal: Identify if a trial is possible at a site before full set-up.

Stage 1: Site Identification

Sponsor's Goal: Find and approach potential sites.

Site's Goal: Decide whether to express interest.

What to Do:

Sponsor:

- Share: basic trial information (e.g., a protocol synopsis).
- Ask: could this site deliver the trial in theory based on known capability?
- Confirm: if the site seems capable of participating at this stage pending a more detailed assessment.

Site:

- Provide: organisational capability info (e.g., aseptic unit capabilities, licenses held).
- Ask: do we have the basic infrastructure for this?
- Confirm: interest in participating based on information known at this stage and willingness to proceed to more detailed feasibility assessment.

Site pharmacy role:

Ensure generic capability information is available and updated when required (e.g., aseptic unit capabilities, licenses held). This is information that is unlikely to change and is likely to be coordinated via R&D or networks like ECMC or RDN.

Stage 2: Site Selection

Sponsor's Goal: Choose which sites to commit to set-up based on the protocol.

Site's Goal: Decide whether to commit to setting up the study.

What to Do:

Sponsor:

- Provide: near-final protocol and any known trial requirements (use the detailed guidance). Inform the site when the Lead Technical Review outcome and pharmacy manual are expected
- Ask: does the site have the capability. Are there any known blocks in capacity available to do it?
- Confirm: site selection.
- Commit: to set-up.

Site:

- Share: site capability and known blocks to capacity to deliver the study based on the protocol and known trial requirements from the Sponsor.
- Ask: do we have what we need to comply with the protocol? Can we commit to set-up? Is there any known, fundamental reason why we cannot commit to set-up?
- Confirm: site selection
- Commit: to set-up.

Site pharmacy role:

- Assess protocol-specific feasibility and known trial requirements like IMP handling, staff needs, oversight, equipment, capacity, blinding requirements, IMP logistics, and special handling (e.g., gene therapy).
- Confirm: to Sponsor (via R&D) that pharmacy is capable and has the likely capacity (there are no known blocks) to do the study (pharmacy are happy to be selected as a site

2. Planning and Set-Up

Goal: Get everything ready and in place to confirm commitment to deliver the trial.

Stage 3: Site Delivery Planning and Set-up

Sponsor's Goal: to ensure everything is ready at site to comply with the regulatory approved protocol.

Site's Goal: to plan and arrange everything at site to be ready to comply with the approved protocol.

What to Do:

Sponsor:

- Share: Lead Pharmacy Technical Review as soon as it is available
- Provide: Local Information Pack
- Ask: what does the site need to set-up and initiate?
- Confirm: Sponsor requirements for site initiation

Site:

- Plan and arrange resources, training and staffing. Begin pre-screening where possible.
- Ask: how shall we deliver this study? What needs to be in place to initiate?
- Confirm: readiness to initiate in line with sponsor initiation requirements.

Site Pharmacy Role:

- Use: Pharmacy Lead Technical Review and final approved protocol when available.
- Plan and arrange (set-up) 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

Stage 4: Site Confirmation

Sponsor's Goal: to ensure everything is ready at site to commit to opening the site

Site's Goal: to ensure everything is ready at site to commit to delivery

What to Do:

Pharmacy Confirms:

- We're ready and compliant, except for any agreed activities that can happen after initiation
- Pharmacy readiness to the site R&D coordination team.

Sponsor & Site:

- Confirm all resources are in place except any agreed post-contract actions (e.g., IMP delivery)

- Exchange signed contracts confirming responsibilities, targets and timelines.

3. Site Initiation

Goal: to confirm everything is in place and compliant with the regulatory documents, to open at site.

What to do

Sponsor:

- Deliver IMP and other resources agreed to occur at site initiation
- Confirm everything is in place
- Issue Sponsor “green light” for the site to open

Site:

- Complete initiation tasks specified by the Sponsor
- Assure compliance with the regulatory documents
- Confirm everything is ready at site to open and receipt of Sponsor green light.

Pharmacy’s Role:

- Final training if required
- Confirm equipment, drug delivery and storage
- Initiate dispensing procedures

Summary of Responsibilities

Step | Sponsor | Site | Pharmacy

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Site Identification | Share outline | Provide capability information | Provide generic information

Site Selection | Share protocol | Confirm feasibility | Assess specific feasibility

Set-Up Planning | Provide pharmacy technical review | Arrange local set-up | Implement technical details

Site Confirmation | Sign and exchange contract | Sign and exchange contract | Confirm set-up

Site Initiation | Provide green light | Open site | Begin delivery

Feedback

This guidance is draft for use in a pilot phase. It will be updated and improved based upon feedback.

To feed into the pilot and comment on this guidance email: pilot.testing@hra.nhs.uk and ecmcadmin@cancer.org.uk referencing pharmacy assurance pilot.