Setting up clinical trials: Draft guidance for Sponsors, Sites and Pharmacy Departments

Draft guidance for amendments, changes and adding sites

Changes can be necessary throughout the lifecycle of a study.

During set-up it is important to be clear about any changes that affect the information that was previously given at site selection. For information affecting Pharmacy this should be communicated to both pharmacy and the R&D department/co-ordinating function.

Once sites are selected it is important that sites and sponsors work together to accommodate changes so that only major impacts or new blocks to set-up and delivery affect the study timelines. There should be excellent communication between sites and sponsors throughout particularly if a change might impact a site's ability to continue

This guidance is for use during the ECMC/HRA Pharmacy Set-up pilot. It aims to help Sponsors and sites in the pilot understand what is expected when changes are made and it does not alter current guidance for Changes that affect the Pharmacy Assurance.

1. Changes made before regulatory approval

If a change is made before and during regulatory submission that affects the information provided in the pharmacy technical review form, the sponsor should liaise with the HRA technical assurance team pharmacy.assurance@hra.nhs.uk to ensure the changes are reflected in the information provided to sites. This includes changes made after the pharmacy assurance is issued.

Sponsor action: work with the HRA technical assurance team who will advise on next steps to make depending on the change. This might be an update to the technical review form or a site notification form. In some cases (for example if a change to the IMP) the Sponsor may be advised to submit for a new review.

Site action: use the updated technical review form and instructions from the Sponsor/HRA to start planning and setting up the study.

2. Changes made after regulatory approval that affect the pharmacy technical assurance information for sites

Any change that affects information within the pharmacy technical review form after regulatory approval is an amendment for Pharmacy Assurance.

For changes that impact the pharmacy assurance technical review information but do not constitute a regulatory amendment Sponsors should complete the site notification form and send it directly to sites

Any amendments that affect the pharmacy assurance should be highlighted to the participating pharmacy department by the sponsor. The sponsor should complete and share the pharmacy assurance amendment site notification form with the sites in addition to the amendment documentation.

Please note Pharmacy assurance will not review any amendments to a trial and the sponsor is responsible for updating and communicating with sites. Many trials have amendments; these may or may not affect pharmacy.

Sponsor action:

- Check if the change is a regulatory amendment by using the amendment tool.

If a regulatory amendment

- complete and submit an amendment for the study IRAS Help - Maintaining your approvals - Amendments for projects conducted in NHS/HSC
- complete a pharmacy assurance amendment site notification form
- share the pharmacy assurance amendment site notification form with the amendment documents at site by sending them to the R&D coordinating function and the pharmacy team.
- ensure this has been received by the site pharmacy team.

If not a regulatory amendment but a change to the pharmacy assurance information

- complete pharmacy assurance amendment site notification form
- share the Pharmacy assurance amendment site notification form with the R&D coordinating function and the pharmacy team, together with any associated documentation. Ensure this has been received by the site pharmacy team

Site action:

- R&D coordinating function to ensure all documentation has been received by the site pharmacy team

- Pharmacy to use the technical review form plus the site notification form and regulatory documents to implement the changes or the amendment.

3. Adding new sites to a trial that has already been through Pharmacy Technical Assurance

If a new site is being added to an open trial (where the new site hasn't yet had the lead technical review form) the sponsor should provide the site with the lead pharmacy technical review form plus any site notification form(s) of any previously submitted amendments that affect pharmacy

Sponsor action:

- share the lead technical review form and any pharmacy assurance site notification forms with the new site via the R&D coordinating function and the pharmacy team

Site action:

- R&D coordinating function to ensure all documentation has been received by the site pharmacy team

- Pharmacy to use the technical review form plus the site notification form and regulatory documents to set-up as a site.

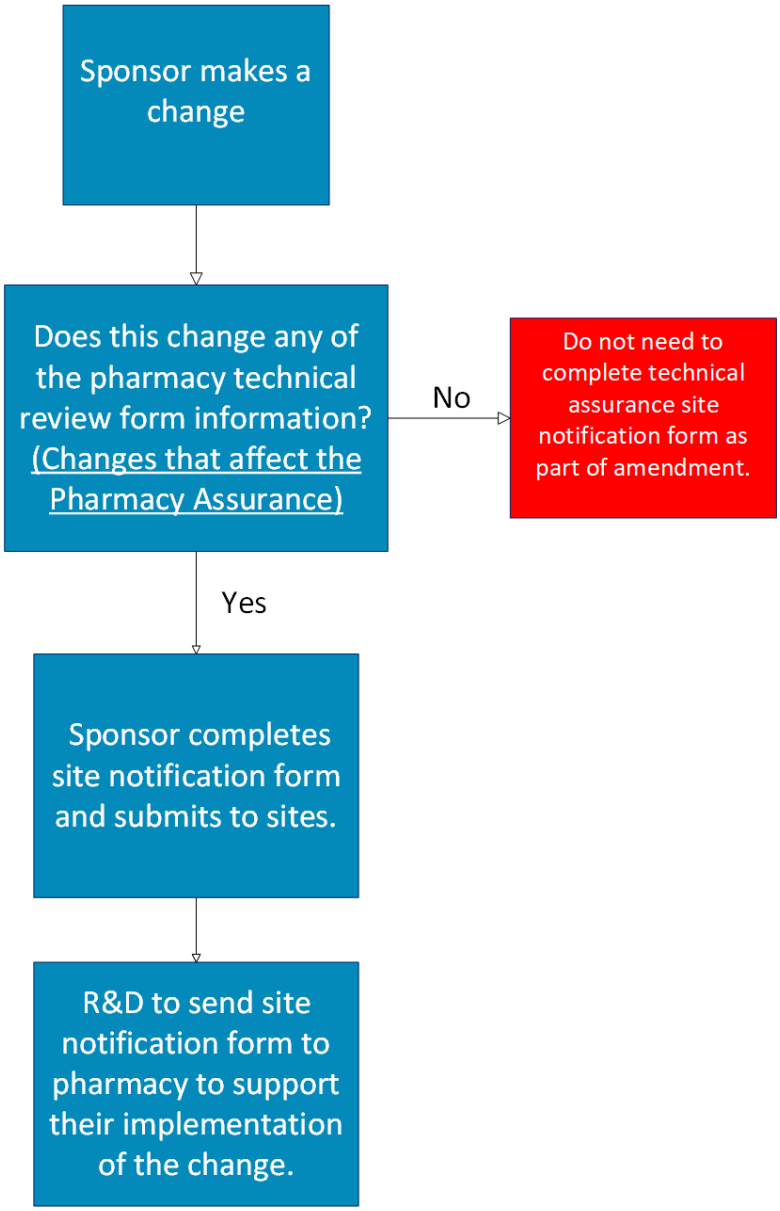

Figure 1. Pharmacy technical assurance change process