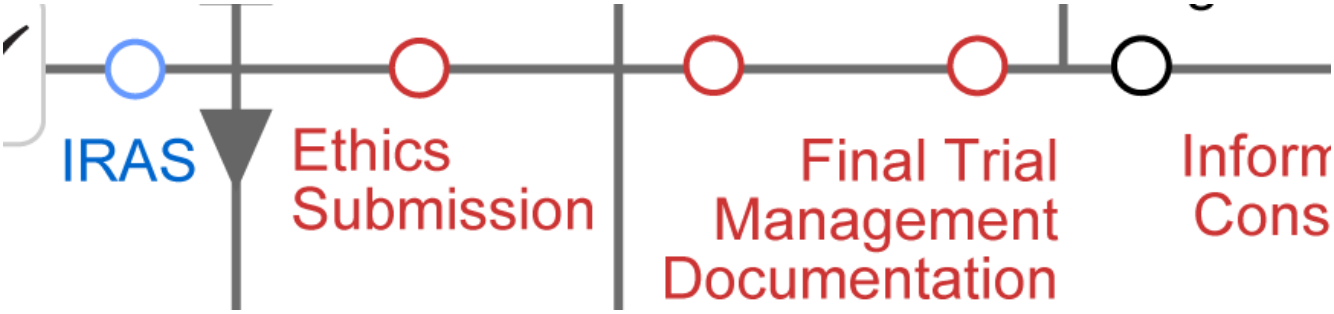
Routemap

Final Trial Management Documentation



Trial Approvals Phase

Final Trial Management Documentation follows the Permissions & Approvals Obtained station and precedes either the Trial is Abandoned or Trial Begins stations. The Final Trial Management Documentation is a legal requirement which is relevant to all trials. This station is part of the 'trial approvals phase' group of stations.

A trial cannot begin until all the relevant permissions and approvals have been obtained. For Clinical Trials of Investigational Medicinal Products (CTMIPs), Regulation 13 of The Medicines for Human Use (Clinical Trials) Regulations requires specific documentation to be in place before a Investigational Medicinal Product (IMP) can be released.

Before commencing the trial, the Chief Investigator in conjunction with the sponsor, will ensure that all trial documentation has been prepared and version controlled. For multi-site trials, the Chief Investigator will ensure that each Principal Investigator is provided with all relevant, version-controlled documents before commencing recruitment.

Final Documentation Checklist

The following list is a suggested guide for Chief Investigators relating to documentation that should be in place at the main site before a trial begins. This list is not exhaustive and local documents may also be applicable.

- Confirmation of Sponsorship letter
- Final approved trial protocol signed by all parties according to local requirements
- Transparency information relating to the processing of personal data under GDPR in accordance with sponsor/HRA Guidance
- Final approved participant information sheet(s) and consent form(s) and GP letter
- Final approved other written participant information e.g. diary card(s)
- Final approved participant recruitment advertisement (if relevant)
- Research ethics committee (REC) approval
- NHS Permission or HRA/HCRW Approval
- Clinical Trial Authorisation (CTA)* with any stated conditions addressed (if appropriate)
- Final approved risk assessment document and any monitoring plan
- Sign off from a statistician (if required)
- Signed off/finalised case report forms (CRFs)
- Signed off/finalised clinical database (if required by local policy)
- Systems for managing safety data (e.g. in pharmacovigilance database) agreed and finalised
- Details of any data monitoring committee or trial steering or management group (if not in protocol)
- Access to all relevant standard operating procedures (SOPs)
- Investigator's Brochure or Summary of Product Characteristics
- Signed agreements including operational and financial arrangements
- Statement of insurance to document compensation to participants for trial-related injury (non NHS)
- CVs and other evidence of relevant training (e.g. GCP/Regulation/protocol) and qualifications for the investigator(s) and local study team members
- Normal values/ranges for laboratory/medical/technical tests/procedures
- Laboratory accreditation(s)
- Pharmacy documentation/file
- Decoding procedures for blinded trials
- All records for Investigational Medicinal Products(s) procurement/supply (e.g. shipping)
- Template logs including delegation logs, screening/enrolment logs, participant identification log, randomisation logs (where applicable)

- Trial start-up/initiation report or confirmation that site initiation activities have been completed.

In addition please refer to relevant stations for more information.

During the review process, regulatory and governance bodies may request alterations to trial documentation before final approval is given. The Chief Investigator should ensure that once the approval process is complete, the same version of each document has been approved by all relevant bodies (e.g. MHRA, REC and NHS R&D offices).

* *Clinical trials that qualify for the MHRA notification scheme do not require a CTA if the submission has been acknowledged as valid and 14 days have elapsed since then. In this instance, the acknowledgement letter will act as authorisation.*

Further reading:

- EMA: Guideline on the content, management and archiving of the clinical trial master file (paper and/or electronic) 6 December 2018 (.PDF).