Chief Investigator* site file: Essential clinical trial documentation for academic (non commercial) trials

The Trial Master File (TMF) is a legal requirement for clinical trials that come under the Medicines for Human Use (Clinical Trials) Regulations 2004 and major non compliance can now lead to prosecution. GGHB divides the TMF into three separate categories:

- Sponsor file
- Investigator site file
- Pharmacy file

Each category abides to a separate index which collectively represents the TMF.

This guideline has been produced by the Research and Development Department to assist the Chief Investigator in formatting their study site file.

The purpose of a site file is to contain the essential documents which reflect the conduct of the trial and is therefore a key element in trial reconstruction. The site file should be established at the beginning of the trial, be rigorously maintained and available at any time for monitoring, audit or inspection purposes.

All academic trials within GGHB will potentially be subject to good clinical practice (GCP) audit, in conjunction with routine monitoring. Additionally, academic clinical trials under the scope of the Regulations will, potentially, be subject to regulatory inspection from the Medicines and Healthcare products Regulatory Agency (MHRA).

It should be noted that the documentation in the site file will vary slightly, depending on the study type. The index therefore should be amended to reflect local activity.

It will be the responsibility of the **Chief Investigator** to ensure all relevant documentation is included within the site file.

*The Chief Investigator is the individual who has **overall responsibility** for the study.

Site File Index

Section 1: Contact information

a. Sponsor details
b. Chief Investigator details
c. Key contacts details
d. 24 hour contact number (for study participants and study site personnel)
e. Principal Investigator(s) at participating site(s) for multi-site studies

Section 2: Study correspondence

a. General correspondence: letters, faxes, emails filed in date order with most recent at the top

Section 3: Protocol and amendment(s)

a. Current, signed version of protocol, numbered and dated
b. Superseded protocol(s)
c. Amendments, numbered

Section 4: Ethics

a. COREC form, parts A, B and C
b. Ethics committee members
c. Favourable opinion letter(s): Main REC/REC
d. Amendment(s) favourable opinion letter
e. Correspondence: letters, faxes, emails filed in date order with most recent at top
f. Site closure letter

Section 5: R&D/Sponsor

a. Research and Development form
b. Management approval
c. Management approval following substantial amendment(s)
d. Sponsorship agreements and related correspondence (if applicable)
e Protocol risk assessment, signed, final version
f. Agreements with commercial organisations (if applicable)
g. Grant information (if applicable)
h. Sponsor letter (if applicable)
i. Site visit discussion log

Section 6: Regulatory (MHRA)

a. CTA application
b. Regulatory approval letter, EudraCT number
c. General correspondence
d. Periodic summary reports
e. Import licence (if applicable)
f. Annual report
g. Site closure letter

Section 7: Critical documents

a. CI/PI cv (if applicable)
b. Study team cv(s)
c. Responsibility/signature log
d. Labels (Pharmacy, case notes)
e. Schedule for study participants
f. Clinical trials pharmacy prescription form
g. Archiving log
h. Record of retained body fluids/tissue samples
i. Decoding procedure for blinded trials (emergency and end of trial)
j. Teaching/drug self administration log for subjects (if applicable)
k. Relevant study drug documentation if dispensed out with Pharmacy

Section 8: Trial documentation

a. Patient information sheet
b. Informed consent form
c. Screening log
d. Screening failures
e. Enrolment/recruitment log
f. Patient identification log
g. Signed consent form (original)
h. Master randomisation list, if applicable
i. GP letter(s)

Section 9: Pharmacovigilance

a. SAE/SUSAR reporting forms
b. Safety reports
c. SAE safety report submission letters
d. Data Monitoring Committee/Trial Steering Group (or equivalent) reports
e. Related correspondence

Section 10: CRF

a. Sample CRF
b. Complete CRF's
c. CRF completion guidelines
d. Data queries and correction forms
e. Electronic data capture - web user manual and signature log

Section 11: Laboratory

a. Laboratory manual/instructions
b. Accreditations (external laboratories)
c. Reference ranges

Section 12: GCP

a. GCP guidelines
b. Declaration of Helsinki (1996)
c. Monitoring/audit documentation/reports/action plan
d. Training information (protocol, GCP, delegation, responsibilities log)
e. File note(s)

Section13: Pharmaceutical information

a. Most current Investigator Brochure (if applicable)
b. Updates to IB
c. Related correspondence
d. Summary of Product Characteristics (if applicable)

Section 14: Standard Operating Procedures (SOP)

a. Trial specific SOP

