



## The Creation and Maintenance of Trial Master Files and Essential Records

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# 1. BACKGROUND AND PURPOSE

Regulation 31a of the Medicines for Human Use (Clinical Trials) Regulations 2004 (as amended by the Medicines for Human Use (Clinical Trials) (Amendment) Regulations 2025) requires that a Trial Master File (TMF) is established and maintained. The TMF must be readily accessible and contain the Essential Records relating to the Clinical Trial, demonstrating compliance with the principles of Good Clinical Practice (GCP) and permitting evaluation of the conduct of the trial and the quality of the data produced.

The UK Policy Framework for Health and Social Care Research has similar requirements which should be met by all researchers in the NHS.

## 2. SCOPE

This SOP is applicable to all clinical trials of investigational medicinal products (CTIMPs) sponsored or co-sponsored by one or more of the King’s Health Partner organisations.

## 3. PROCEDURE

### 3.1 Trial Master File (held by CI)

**General requirements for a TMF:**

The TMF should be set up as a clearly labelled physical folder containing paper documents and held in an area (office, filing cabinet etc) with access restricted to the Chief Investigator (CI) and delegated members of the trial team. Records may be maintained in an electronic repository (with access restricted to the CI and trial team), however unless the system is a validated eTMF these do not constitute the TMF and should be printed and filed in the physical TMF periodically, at a minimum in the event of monitoring, audit, inspection and archiving. Data held in validated electronic systems do not need to be printed and filed e.g Case Report Forms (CRFs) and Serious Adverse Events but the location should be indicated on the TMF index or via a file note.

A validated electronic TMF may be used if approved by the KHP-CTO Non-Commercial Trials Manager.

Task	Responsibility	Activity
3.1.1	Chief Investigator or delegate	<p>Establish a Trial Master File upon receipt of confirmation of sponsorship and no later than the date of the kick off meeting (refer to <b>KHP CTO SOP 13: Initiation of an Investigator Site</b>).</p> <p>Use of the KHP CTO template TMF index is recommended. Required TMF sections are:</p>

		<ul style="list-style-type: none"> <li>• Table of contents</li> <li>• Correspondence</li> <li>• Protocol (initial and modifications)</li> <li>• Combined review (<i>covering all regulatory submissions and approvals and including R&amp;D capacity and capability</i>)</li> <li>• Financial and legal documentation</li> <li>• Study staff</li> <li>• Study related supplies (including case report form)</li> <li>• Participant facing documents</li> <li>• Pharmacovigilance</li> <li>• Monitoring</li> <li>• Clinical laboratory</li> <li>• Pharmacy</li> <li>• Investigator brochure/ SmPC</li> </ul>
3.1.2	Chief Investigator or delegate	<p>Amend the standard file index/ contents as appropriate for the nature and design of the trial:</p> <ul style="list-style-type: none"> <li>• Remove sections which will be empty.</li> <li>• Add extra sections or subsections as necessary (eg for blinded trials, trials with sites outside UK).</li> <li>• Determine the requirements for retention of email, and responsibility for filing. It is recommended that emails which related to key decisions chains are filed once (at the end) and that emails are categorised.</li> </ul>
3.1.3	Chief Investigator or delegate	<p>Where records are held outside the central trial master file location during the delivery of the trial (for instance in a central laboratory or by a vendor who is delegated a trial specific duty by the Chief Investigator):</p> <ul style="list-style-type: none"> <li>• List in the main trial master file where these records are held.</li> <li>• List in the main trial master file who is responsible for maintaining the records including contact details for monitoring and audit visits.</li> </ul>
3.1.4	Chief Investigator or delegate	<p>Maintain the trial master file, in line with the principle that records should be 'inspection ready' at all times.</p> <ul style="list-style-type: none"> <li>• Records should be easy to navigate, with clear index</li> <li>• Ensure new and updated documents and records are filed in a timely fashion.</li> <li>• Records should be accurately filed. Hard copy documents in the expected section. Electronic records identifiable from file name and saved to appropriate folder/ category/ tag.</li> </ul>

		<ul style="list-style-type: none"> <li>Records should be version controlled when appropriate and include authors, reviewers and approvers with date and signatures where necessary.</li> <li>Keep superseded versions of essential records. These should be clearly labelled/ placed in a separate section of the file to avoid confusion. These records include but are not limited to protocol, reference safety information, participant information sheet, consent form.</li> </ul>
3.1.5	Chief Investigator or delegate	<p>For multi-centre clinical trials, some records for each investigator will be held in the trial master file. These include but are not limited to:</p> <ul style="list-style-type: none"> <li>Confirmation of capacity and capability issued by host Trust Research and Development department(s)</li> <li>Investigator contact details.</li> <li>Investigator CV and evidence of training e.g. GCP certificate</li> <li>Delegation log or other record of site team delegation, for managing accounts for trial eCRF and other systems.</li> </ul>
3.1.6	Chief Investigator or delegate	Make the TMF available for monitoring, audit and inspection as requested.
3.1.7	CRA	At end of trial, complete final TMF review and document in accordance with <b>KHP CTO SOP 6: Clinical Trial Close Out Procedure</b> and the monitoring plan.
3.1.8	CRA	Follow <b>KHP CTO SOP 4: Archiving Clinical Trial Data</b> and ensure TMF is archived.

### 3.2 Sponsor file (held at CTO)

The Sponsor file is the primary location for storing KHP-CTO documentation about a trial.

The Sponsor file may contain Essential Records, **but the sponsor file does not constitute the TMF**. Any Essential Records stored in the sponsor file should also be filed in the TMF (or in the ISF for the lead site if applicable), but for some records this may not be until the point of archiving as detailed in 3.2.3.

Task	Responsibility	Activity
3.2.1	Set up specialist CRA or delegate	<p>Create a sponsor file no later than the kick off meeting for the trial. Hard copy file should be held in the locked sponsor file cupboards in the KHP CTO office.</p> <p>Electronic file should be in the SharePoint site which is restricted to CTO staff.</p> <p>Amend the standard file index/ contents as appropriate for the nature and design of the trial.</p>

3.2.2	Set up specialist CRA	Ensure sponsor file is maintained until end of site set up phase. Sponsor file maintenance passes to trial lead CRA when trial set up concludes. Email to confirm handover of duty is saved in sponsor file.
3.2.3	Lead CRA or delegate	Ensure sponsor file is maintained during trial delivery. Filing of documents and records should be completed in a timely fashion <ul style="list-style-type: none"> <li>• Filenames of electronic records should facilitate identification of record contents</li> <li>• Monitoring reports are usually held in sponsor file and not main TMF as monitoring is not delegated to the CI</li> <li>• Unblinding reports are usually held in the sponsor file and not main TMF as unblinding is not delegated to the CI. This also maintains the blinding of CI and study manager if applicable.</li> <li>• SUSAR reports to MHRA are usually held in the sponsor file and not main TMF as these reports are submitted by KHP CTO CRA team. This also maintains the blinding of CI as SUSAR reports are only submitted for participants who receive IMP.</li> <li>• Some documents and records may be held in both TMF and sponsor file for administrative convenience.</li> </ul>
3.2.4	Lead CRA or delegate	Review the sponsor file to ensure records are accurate, legible, contemporaneous, original Complete the review checklist as appropriate.
3.2.5	Lead CRA or delegate	Follow SOP 4. Archiving Clinical Trial Data when preparing sponsor file for archive. Make a reasonable effort to remove duplicate records and documents prior to archiving.

### **3.3 Investigator Site File (held by investigator)**

Task	Responsibility	Activity
3.3.1	Chief Investigator or delegate	Remind sites of the requirements for establishing and maintaining an ISF as part of site set up processes and send trial documentation e.g. protocol, trial approvals etc  Note: Use of KHP CTO ISF template is recommended.  Investigators and their teams may use a local template if sections include: <ul style="list-style-type: none"> <li>• Table of contents</li> <li>• Correspondence</li> <li>• Protocol and protocol modifications</li> </ul>

		<ul style="list-style-type: none"> <li>• Combined review (<i>covering all regulatory submissions and approvals and including R&amp;D capacity and capability</i>)</li> <li>• Financial and legal documentation</li> <li>• Study site staff</li> <li>• Study related supplies</li> <li>• Participant facing documents</li> <li>• Screening and enrolment logs (randomisation if applicable)</li> <li>• Pharmacovigilance</li> <li>• Monitoring</li> <li>• Clinical laboratory</li> <li>• Pharmacy</li> <li>• Investigator Brochure/ SmPC and safety alert updates</li> <li>• Data management</li> <li>• Final study report</li> </ul> <p>A validated electronic ISF may be used by sites if this is reviewed and approved by the KHP CTO Non-Commercial Trial Manager.</p>
3.3.2	CRA	Provide the site KHP-CTO templates that should be maintained during the trial (e.g. delegation log, training log etc) for inclusion in the ISF. These may be sent as part of the site initiation visit.
3.3.3	CRA	<p>Review site file contents during monitoring visits according to the monitoring plan. Ensure all subsidiary files are also reviewed (e.g. Pharmacy) and the location of these files is clearly documented in the ISF.</p> <p>Ensure access to the site file is only available to authorised trial team members. Note: for electronic records, access should be restricted by system access settings. Records of access and page views etc should be available for monitoring, audit and inspection. For paper records, access should be restricted in a locked cabinet or room in a secure area.</p>
3.3.4	CRA	<p>Follow the process in SOP Close Out when reviewing ISF contents after end of trial. Ideally all subsidiary folders should be merged with the ISF (e.g. pharmacy file) but if this is not feasible this should be clearly documented in a file note held in the ISF</p> <p>Follow process in SOP Archiving Clinical Trial Data when reviewing ISF prior to archiving.</p>

## 4. RELATED TEMPLATES

- Trial Master File index

- Trial Master File review checklist
- Investigator Site File index
- Investigator Site File review checklist

## 5. RELATED SOPs

KHP CTO SOP 3: Clinical Trial Monitoring  
 KHP CTO SOP 13: Set up and initiation  
 KHP CTO SOP16: Clinical Trial Close Out Procedures  
 KHP CTO SOP 4: Archiving Clinical Trial Data

## 6. REFERENCES

1. The Medicines for Human Use (Clinical Trials) Regulations 2004  
<https://www.legislation.gov.uk/ukxi/2004/1031/contents/made>
2. The Medicines for Human Use (Clinical Trials) (Amendment) Regulations 2025  
<https://www.legislation.gov.uk/ukxi/2025/538/contents/made>
3. ICH Topic (E6) guideline for Good Clinical Practice  
<https://www.ema.europa.eu/en/ich-e6-good-clinical-practice-scientific-guideline>
4. UK Policy Framework for Health and Social Care Research [UK Policy Framework for Health and Social Care Research - Health Research Authority](#)

## 7. CHANGE HISTORY

CHANGE HISTORY			
Date	Version Number	Change details	Approved by
09Nov2010	2.0	Transfer to Kings Health Partners livery and inclusion of archiving details	Jackie Powell
27Feb2013	3.0	Change JCTO to KHP CTO and other administrative changes	Jackie Powell
24Jun2013	4.0	TMF Index amended and inclusion of TMF check prior to archive	Jackie Powell

28Nov2016	5.0	Update of Glossary, scheduled review, inclusion of a section for HRA in the TMF, inclusion of TMF File Review template	Jackie Pullen
01Oct2018	5.1	Minor amendment to include trials managed by KHP-CTO	Jackie Pullen
18Dec2019	6.0	Scheduled review, minor updates and renaming of TMF table of contents to TMF index and subject to participant	Jackie Pullen
03Mar2023	6.1	Scheduled review, minor updates	Jackie Pullen
20Apr2026	7.0	Terminology changes in line with updates to UK Clinical Trial Regulations and ICH GCP E6 R3 throughout (modification for amendment, location for site, record for document) SOP moved to new SOP template	Ann-Marie Murtagh

## 8. GLOSSARY

**Blinded Trial** - A Clinical Trial in which treatment allocation is concealed from one or more parties involved in the Clinical Trial (e.g. participant, investigator, Sponsor staff), in accordance with the protocol and randomisation procedures.

**Blinding** - A procedure used in a Clinical Trial to withhold information about treatment allocation from one or more parties (e.g. participants, investigators, Sponsor staff) in order to minimise bias in Clinical Trial conduct, assessment, and reporting. 'Blind' and 'Blinded' to be construed accordingly.

**Case Report Form (CRF)** - A printed, optical or electronic document designed to record all of the protocol-required information for each trial participant, to be reported to the Sponsor.

**Chief Investigator (CI)** – The overall lead researcher for a Clinical Trial (Outside the UK the term 'Coordinating Investigator', 'Principal Investigator' or 'Investigator' may be used for the overall lead researcher for a Clinical Trial). Chief Investigators are responsible for the overall conduct of a Clinical Trial.

**Clinical Research Associate (CRA)** – A staff member employed by the KHP-CTO who conducts monitoring activities for a Clinical Trial, including but not limited to the initiation phase, routine phase, and close down phase. Delegate monitors (appointed in exceptional circumstances) are included in this definition.

**Clinical Trial of an Investigational Medicinal Product (CTIMP)** - Any investigation in human participants (other than a non-interventional trial) intended to discover or verify the clinical, pharmacological and/or other pharmacodynamic effects of one or more medicinal products and/or to identify any adverse reactions to one or more such products and to study absorption, distribution, metabolism and excretion of one or more such products with the

object of ascertaining the safety and/or efficacy of those products. Includes clinical trials of ATIMPs.

**Clinical Trial Authorisation (CTA)** – Authorisation from the Medicines and Healthcare products Regulatory Agency (MHRA) to conduct a Clinical Trial. No Clinical Trial can commence in the UK without both a CTA and a favourable ethical opinion. Applications to the MHRA and the Research Ethics Committee (REC) may be made in parallel.

**Clinical Trials Administrator** - A staff member employed by the KHP-CTO who conducts administrative activities for a Clinical Trial.

**Close Out Visit (COV)** - A monitoring visit conducted at the end of a Clinical Trial at a Trial Location to confirm that all Clinical Trial activities have been completed in accordance with the protocol and regulatory requirements. It typically includes verification that essential documents are complete and archived, investigational product accountability is resolved, outstanding data queries are addressed, and any remaining HBS are managed or disposed of appropriately.

**Co-Sponsors** – Two organisations that take responsibility for the initiation, management and financing (or arranging of the financing) in relation to a Clinical Trial. The Co-Sponsors agree how the Sponsor functions for the Clinical Trial are divided between themselves and document this accordingly.

**Combined Review** - The UK system under which a Sponsor submits a single CTA application that is reviewed jointly by the MHRA and REC, and results in one combined regulatory decision.

**CTA Submission Package** - The CTA submission form and all necessary supporting documents for the CTA submission.

**Curriculum Vitae (CV)** - A summary of a person's education, professional history and job qualifications.

**End of Trial (EoT)** – The end of the Clinical Trial as defined in the protocol. The end of the Clinical Trial is typically expressed as a condition-based event, not a predetermined date.

**Essential Records** - These are records that permit and contribute to the evaluation of the conduct of a Clinical Trial in relation to the compliance of the Principal Investigator and the Sponsor with Good Clinical Practice (GCP) and the Regulations and the reliability of the results produced. For a full list of the records considered to be Essential Records, see ICH GCP E6 (R3) Appendix C.

**Good Clinical Practice (GCP)** - An international ethical and scientific quality standard for designing, conducting, recording, and reporting Clinical Trials that involve human participants. It ensures the safety, well-being, and rights of participants are protected while maintaining the credibility and accuracy of trial data. GCP is crucial for safeguarding participants and ensuring Clinical Trials produce reliable, scientifically valid results.

**Health Research Authority (HRA)** – The national body in England responsible for protecting and promoting the interests of patients and the public in health and social care research.

**ICH E2F** - The International Council for Harmonisation (ICH) guideline that defines the structure, content, and timing of the DSUR for IMPs. It sets out how Sponsors should prepare an annual, cumulative safety evaluation at IMP level, including requirements for the reporting period, Data Lock Point, analysis of AEs and SAEs, assessment of emerging risks, and requirements for an overall benefit–risk evaluation across all ongoing and completed Clinical Trials for each IMP.

**ICH GCP E6 (R3)** – The International Council for Harmonisation – Good Clinical Practice, Guideline E6 (Revision 3). This is an internationally recognised ethical and scientific quality standard for the design, conduct, oversight, recording, and reporting of Clinical Trials.

**Important Medical Event (IME)** - An Adverse Event or Adverse Reaction that may not immediately result in death, be life-threatening, or require hospitalisation, but which, in the judgement of a medically qualified individual, may jeopardise the participant or require medical or surgical intervention to prevent one of those serious outcomes.

**Informed Consent Form (ICF)** - A document by which a participant formally records their voluntary agreement to take part in a Clinical Trial, having been provided with and understood the information set out in the Participant Information Sheet.

**Integrated Research Application System (IRAS)** - The online application system used to apply for most permissions and approvals for research in health and social care in the UK.

**Investigational Medicinal Product (IMP)** – A pharmaceutical form of an active ingredient or placebo being tested or used as a reference in a Clinical Trial. This includes products with marketing authorisation when used in a way different from the approved form, for an unapproved indication, or to gain further information about an approved use.

**Investigator’s Brochure (IB)** - A Sponsor-prepared reference document that compiles the clinical and non-clinical data on an IMP that are relevant to its use in a Clinical Trial. It's intended to provide Clinical Trial staff with sufficient information to understand the rationale for the Clinical Trial, the known and potential risks and benefits of the IMP, including Adverse Reactions, and the appropriate management of participants. Where the IMP has a Marketing Authorisation, an SmPC will be available and it will supersede the IB as the RSI.

**Investigator Site File (ISF)** – The Trial Location-specific set of essential documents held at the Trial Location by the Principal Investigator, demonstrating how the trial was conducted at that particular location and that the investigator complied with the protocol, Sponsor instructions, and GCP.

**KHP-CTO Director** – The most senior member of the KHP-CTO.

**KHP-CTO Non-Commercial Team** - Comprises the Non-Commercial Trials Manager, CRA(s), Clinical Trial Administrator(s), Training Executive(s), Operations Lead and Operations Manager.

**KHP-CTO Training Team** - The team at the KHP-CTO responsible for determining, and meeting, the mandatory training requirements of KHP staff and students involved in Clinical Trials. The KHP-CTO Training Team are also responsible for delivering elective training courses to KHP staff and students involved in research involving patients (non-Clinical Trials).

**King's Health Partners Clinical Trials Office (KHP-CTO)** – The department established by King's College London, Guy's and St Thomas' NHS Foundation Trust, King' College Hospital NHS Foundation Trust, and South London and Maudsley NHS Foundation Trust to 1) undertake the set up and financial Management of commercial research hosted by one or more of the KHP Partners, and 2) undertake the regulatory submissions and oversight, as well as monitoring activity for non-commercial research studies sponsored by one of the KHP Partners.

**Lead CRA** – The CRA providing Sponsor-level oversight of monitoring activities for a Clinical Trial, with responsibility for coordinating and supervising CRA activities across Trial Locations, ensuring consistent implementation of the Monitoring Plan, identifying and escalating emerging risks or trends, and supporting the Sponsor in maintaining oversight of participant safety, data integrity, and compliance with GCP and applicable regulations

**Licensing Authority** - The licensing authority is responsible for the grant, renewal, variation, suspension and revocation of licences, authorisations, certificates and registrations under the regulations. The MHRA is the UK's licensing authority.

**Marketing Authorisation** – A regulatory approval granted by the competent authority that permits a medicinal product to be placed on the market, confirming that its quality, safety, and efficacy have been adequately demonstrated.

**Medicines & Healthcare products Regulatory Agency (MHRA)** – The UK government agency responsible for regulating medicines, medical devices, and Clinical Trials. In the context of Clinical Trials, the MHRA i) acts as the licensing authority for Clinical Trials, ii) reviews the scientific, quality, and safety aspects of a Clinical Trial application, iii) issues CTAs, iv) oversees GCP and GMP inspections, v) monitors pharmacovigilance and safety reporting, and vi) enforces compliance with UK medicines legislation.

**Monitoring Plan** - A Sponsor-approved document that sets out how Clinical Trial monitoring will be conducted, managed, and documented, using a risk-based approach to ensure participant safety, data integrity, and compliance with the approved protocol and applicable regulations.

**Non-Commercial Trials Manager (NCTM)** – The most senior member of the KHP-CTO Non-Commercial Team.

**Non-Investigational Medicinal Product (NIMP)** - Any medicinal product (licensed or unlicensed) used in a Clinical Trial for reasons other than testing its safety or efficacy.

**Participant Information Sheet (PIS)** - A document provided to potential Clinical Trial participants that clearly explains the purpose, procedures, risks, benefits, and practical

implications of taking part in a Clinical Trial, enabling them to make an informed decision about participation.

**Partner Trusts** – Guy’s and St Thomas’ NHS Foundation Trust, King’s College Hospital NHS Foundation Trust, and South London and Maudsley NHS Foundation Trust.

**Principal Investigator (PI)** – The individual at a Trial Location who has primary responsibility for the conduct of the Clinical Trial at that Trial Location.

**Reference Safety Information (RSI)** – The authoritative document used to determine the expectedness of SARs occurring during a Clinical Trial. It defines which SARs are considered expected for the IMP, based on the safety information available at the time, and is used by the Sponsor to assess whether a SAR qualifies as a SUSAR. If the IMP has a Marketing Authorisation, the SmPC will be used as the RSI. If the IMP does not have a Marketing Authorisation, the IB will be used as the RSI.

**Regulations** – The Medicines for Human Use (Clinical Trials) Regulations 2004 (as amended including The Medicines for Human Use (Clinical Trials) (Amendment) Regulations 2025).

**Research & Development Department (R&D Dept.)** – The department at a Trial Location that’s responsible for research and development at that Trial Location.

**Research Ethics Committee (REC)** – A national independent body consisting of healthcare professionals and non-medical members, whose responsibility is to protect the rights, safety and well-being of human subjects involved in a Clinical Trial, and to provide public assurance of that protection by, among other things, expressing an opinion on the Clinical Trial protocol, the suitability of the investigators and the adequacy of facilities, and on the methods and documents to be used to inform Clinical Trial participants and obtain their informed consent.

**Senior Clinical Research Associate (sCRA)** – A staff member employed by the KHP-CTO to undertake advanced CRA duties, including the line management of CRAs.

**Serious Adverse Event (SAE)** - An Adverse Event that results in death, is life-threatening, requires inpatient hospitalisation or prolongation of existing hospitalisation, results in persistent or significant disability or incapacity, or consists of a congenital anomaly or birth defect.

**Serious Adverse Reaction (SAR)** - An Adverse Reaction that is both serious and suspected to be causally related to an IMP. In other words, it is an untoward and unintended response to the IMP that results in death, is life-threatening, requires or prolongs hospitalisation, results in persistent or significant disability or incapacity, involves a congenital anomaly or birth defect, or is otherwise judged to be a medically important event.

**Serious Breach** - Under Part 4, paragraph 29A of the Medicines for Human Use (Clinical Trials) Regulations 2004 (as amended), a serious breach is defined as a breach of the conditions and principles of good clinical practice, or of the approved clinical trial protocol (as amended in accordance with regulations 22 to 25), which is likely to affect to a significant degree either the safety or the physical or mental integrity of trial participants, or the scientific

value of the clinical trial. Where such a breach occurs, the sponsor is required to notify the licensing authority in writing within seven days of becoming aware of the breach.

**Site Initiation Visit (SIV)** - A formal visit conducted by the Sponsor or their representative before a Trial Location begins participant recruitment, to confirm that the Trial Location is fully prepared to conduct the Clinical Trial in accordance with the approved protocol, regulatory requirements, and GCP.

**Sponsor** - The person or body who takes on ultimate responsibility for the initiation, management and financing (or arranging of the financing) of a Clinical Trial. The Regulations allow for two or more persons or bodies to take on responsibility for Sponsor functions.

**Summary of Product Characteristics (SmPC)** - A regulatory document approved by the MHRA that provides authoritative information for healthcare professionals on the safe and effective use of a medicinal product. It includes details on the product's composition, indications, dosing, contraindications, warnings and precautions, interactions, pharmacological properties, and known Adverse Reactions, and forms part of the product's Marketing Authorisation. Where a medicinal product does not have a Marketing Authorisation (i.e. an unlicensed IMP), an SmPC will not be available, and the equivalent safety information is provided through the IB, which serves as the RSI for pharmacovigilance and safety reporting.

**Suspected Unexpected Serious Adverse Reaction (SUSAR)** - A Serious Adverse Reaction to an IMP that is unexpected, meaning that the nature or severity of the reaction is not consistent with the applicable product information according to the RSI.

**Trial Location** - Means a hospital, health centre, surgery or other establishment, or facility or premises at or from which a Clinical Trial, or any part of such a Clinical Trial, is conducted.

**Trial Master File (TMF)** - A standard filing system which contains all essential documents which individually and collectively permits the evaluation of the conduct of a Clinical Trial and the quality of the data produced. The filing system can be in the form of a single project file or a number of files/filing cabinets, depending on what is deemed most appropriate for a particular Clinical Trial given its size and complexity. The regulatory documents and approvals within the TMF will be maintained alongside Case Report Forms and Source Records.

**UK Policy Framework** – The UK Policy Framework for Health and Social Care Research.