KING'S HEALTH PARTNERS | Clinical Trials Office

Clinical Trial Close Out Procedure

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1. BACKGROUND AND PURPOSE

The purpose of this SOP is to cover the procedures for closing Clinical Trials of Investigational Products sponsored by King's Health Partners organisation. These procedures ensure compliance with the principles of Good Clinical Practice (GCP) and local regulations. Activities covered in this SOP include:

- Closing trial sites
- Closing central laboratories
- Preparing Investigator Site Files (ISF) Trial Master Files (TMF) and Sponsor Files for archiving

This SOP does not cover the following processes as these are covered by the referenced KHP-CTO SOPs:

- Where a trial involves blinding, the end of trial reconciliation process is described in **KHP CTO SOP 14: Emergency Code Break**.
- Data lock processes are detailed in the **KHP CTO SOP 18: Data Management**.
- Processes for notifying the Competent Authority and Ethics Committee of the end of the trial and publication of trial results are covered in **KHP CTO SOP 12: Application and Maintenance of Clinical Trial Authorisation.**
- Process for archiving are detailed in **KHP CTO SOP 4: Archiving of Clinical Trial Records**.

2. SCOPE

All CTIMPs sponsored or co-sponsored by one or more of the Kings Health Partners organisations are within scope of this SOP.

3. PROCEDURE

'Site' is used throughout this SOP: the host 'site' comprises the investigator, their delegate(s), support functions provided by the host NHS Trust, the data of the trial participants for whom they are responsible, the location(s) where trial specific activities are carried out by that investigator or their delegates and the electronic records held by or on behalf of that investigator or their delegates.

NB the processes in this SOP are not exhaustive. Depending on the risk assessment for the trial and the criticality of the data to the trial outcomes, it may be appropriate to carry out close out activities at additional locations. These will be recorded in the Chief Investigator close out report (for processes which are trial specific) and the applicable investigator site close out report (for processes which are investigator or site specific) as applicable.

3.1 Timing of site closure activities

Site closure will usually start after database lock and the end of trial notification have been submitted (refer to **KHP-CTO SOP 18: Data Management & KHP-CTO SOP 12: Application and Maintenance of Clinical Trial Authorisation**), however there may be situations where sites may be closed earlier (see section 3.1.2).

Task	Responsibility	Activity
3.1.1	Chief Investigator	**Site closure at trial completion:** Ensure that investigators and delegates are aware of planned end of protocol activities and trial closure dates (this can be face to face for local team members, email or through trial communications such as newsletters).
3.1.2	Clinical Research Associate or delegate	**Site closure prior to trial completion:** Review whether individual investigational sites can be closed before the completion of a trial for example for one or more of the following reasons: • No participants have been, or will be, recruited. • All participants enrolled at the investigational site have completed participation in the trial and all data entry has been completed and monitored in accordance with the monitoring plan. • Upon the request of the trial site. Factors in deciding whether to close out early include: • Any site which received IMP should have a close out visit. • The next scheduled monitoring visit for the site per the monitoring plan. • The timelines for the trial, in particular the planned end of trial date. • The number and severity of prior and current monitoring findings at this site. • The completeness of monitoring activities (particularly the verification of participant data per monitoring plan) • Availability of monitoring resource. • Requirements for close out visit in monitoring plan, including if partial or complete close out can be carried out early. Seek advice from CRA line manager if uncertain as to whether the site can be closed prior to end of trial.

		NB close out of individual locations may be reasonable if all trial specific activity at a particular location has been completed. For instance, pharmacy may be closed when no further IMP administration per protocol will take place if permitted by the monitoring plan.
3.1.3	Clinical Research Associate / Chief Investigator or delegate	**For sites to be close early:** Inform the investigator site prior to the site closure visit that queries on participant data are possible at any point until the final study report is completed. **Note:** In these instances, the end of trial declaration would not have been submitted. Refer to the HRA Modification Tool for guidance on site closure notification in this setting.
3.1.4	Clinical Research Associate	Carry out the close out visit in accordance with the monitoring plan (either conducted as a site visit or remotely) and complete activities in the following sections that have not already been completed at a monitoring visit.

3.2 Pharmacovigilance reconciliation

Task	Responsibility	Activity
3.2.1	Clinical Research Associate	After final participant final visit at a site and prior to that site's close out visit, review the pharmacovigilance database entries for that site: • MedDRA lower-level term and preferred term for each event is necessary (NB it is sufficient that the final version of the report has an accurate MedDRA term for LLT and PT). • Investigator signature on the final version of the event report for each event is necessary • All queries raised on the contents of event report should be answered by investigator or delegate. • The information in the pharmacovigilance database should accurately reflect the Case Report Form (CRF) entry for each event . • If there are no pharmacovigilance database entries, note this in the close out report (see 3.11). Email any outstanding actions to the investigator or delegate prior to the close out visit.

3.2.2	Clinical Research Associate	At the site close out visit: • Complete any outstanding verification of adverse event data. • Ensure the site investigator reviews any updates to serious adverse event (SAE) forms and obtain any outstanding investigator signature(s). • File final copies of SAE forms in the investigator site file (ISF). • Reconcile pharmacovigilance database with CRF data.
3.2.3	Clinical Research Associate	Ensure all signed SAE form are filed in the Trial Master File (TMF)/Sponsor File.
3.2.4	Clinical Research Associate	Record actions completed and any actions pending in the close out visit report (see section 3.11)

3.3 Source data verification, issues, deviations and data queries

Task	Responsibility	Activity
3.3.1	Clinical Research Associate	Review the last monitoring visit report, and other site correspondence with outstanding issues or follow up actions identified, and ensure these are addressed during, or prior to, site closure.
3.3.2	Clinical Research Associate	Complete any outstanding source data verification and reviews in accordance with the monitoring plan. Aim to resolve all data queries and actions in relation to issues or deviations during the visit.
3.3.3	Clinical Research Associate	Assess any new deviations or GCP non-compliances noted during the visit to determine if they meet the criteria for Serious Breach reporting (Refer to **SOP 6: Notification of Serious Breaches**)
3.3.4	Clinical Research Associate	Document any outstanding issues in the closure report (see section 3.10)

3.4 Investigational Medicinal Product reconciliation

Task	Responsibility	Activity
3.4.1	Clinical Research Associate	Where the IMP is not provided by the Chief Investigator or delegate (i.e. IMP provided from standard pharmacy stock), note this in the Chief Investigator close out report.

		A close out visit is not usually necessary for an investigator who didn't receive or administer IMP for a clinical trial. Where a close out report is generated for such a site, note that there was no IMP reconciliation. Where pharmacy activities are completed significantly earlier than end of trial date, it may be appropriate to complete pharmacy/ IMP close out activities at a site prior to the 'main' close out visit. In these cases, pharmacy close out should be recorded in a routine monitoring report which is referenced in the main close out visit report.
3.4.2	Clinical Research Associate	Per monitoring plan, complete any outstanding checks of IMP accountability and storage conditions at each site. Record activity completed and any issues in investigator site close out visit report and follow up letter.
3.4.3	Clinical Research Associate	Per monitoring plan, confirm any unused, expired, returned and quarantined IMP has been appropriately destroyed/ prepared for destruction or returned in accordance with requirements for the trial. Record activity completed and any issues in investigator site close out visit report and follow up letter.
3.4.4	Clinical Research Associate	If required, complete checks of IMP stock at central depot (accountability, destruction, storage conditions). Record activity completed and any issues in Chief Investigator close out visit report and follow up letter (see section 3.10).

3.5 Delegation log

Task	Responsibility	Activity
3.5.1	Clinical Research Associate	Ensure site delegation logs are finalised and obtain a copy of signed delegation log for sponsor records. If an investigator has not signed the final log, or further updates are necessary to record significant trial specific tasks taken on by investigator and delegates, document this issue in the close out report and follow up letter.
3.5.2	Clinical Research Associate	Provide copy of final delegation log to Chief Investigator or delegate who manages user access for trial-specific system(s) to ensure all access revoked. Ensure a copy is filed in the TMF.

3.6 Investigator Site File completeness check

Task	Responsibility	Activity

3.6.1	Clinical Research Associate	Review the contents of the investigator site file to confirm (where feasible this may be conducted remotely by providing the site with a checklist): • Ensure all records are filled according to the ISF Review Checklist template (template should reflect the KHP CTO ISF contents list and contains all ICH GCP R3 guideline essential records). • If not using the template, ICH GCP R3 C.3.3 essential records table lists the records which should be considered essential (and so retained and archived) if the records are produced for a particular trial. • Confirm with investigation site the location of any sub folders to the ISF (e.g. pharmacy file) and instruct site to either merge with the ISF or include a file note indicating the location of the file. • Ensure electronic records are printed and filed (including meta data if necessary) or if they are stored electronically the electronic storage has with restricted access, maintains data integrity and will endure for the archiving period.
3.6.2	Clinical Research Associate	List missing documents in the close out visit report and follow up letter, provide missing documents where appropriate and remind investigator site it their responsibility to ensure site files are complete.

3.7 Site laboratory close out process

Note: In the UK all human tissue/biological sample movement and analysis covered by REC approval for a trial must be completed before the end of trial is declared. After this point, samples can only be kept for data verification purposes (for a maximum of 12 months) and this should be detailed in the protocol.

Any retained human tissue/biological samples for possible future evaluation after the end of study has been declared should be with the appropriate licence and should be undertaken as described in the protocol and within the terms of consent from the donors. To ensure storage of human tissue/biological samples after the end of the trial is lawful, either:

- store the samples in an establishment with a HTA licence
- apply for ethical approval of a new project

Otherwise, the samples must be destroyed.

For further guidance refer to HRA Use of Human Tissue in research:
https://www.hra.nhs.uk/planning-and-improving-research/policies-standards-legislation/use-tissue-research/

Task	Responsibility	Activity
3.7.1	Clinical Research Associate	Record in the close out visit report for each site where there are no trial specific samples for a particular clinical trial, or where no samples were obtained by the investigator site.
3.7.2	Clinical Research Associate	Ensure all trial specific samples that require analysis at site have been analysed Ensure sample logs (e.g. processing, tracking etc) are completed and filed in the Investigator Site File.
3.7.3	Clinical Research Associate	Ensure any human tissue/biological samples remaining on site are either: - Shipped to the appropriate laboratory/designated destination with HTA licence if applicable (see note in section 3.3) and in accordance with participant consent. - Destroyed - Ensure any disposal of samples is undertaken in accordance with protocol requirements and appropriate documentation is filed in the ISF. Confirm sample tracking logs detail shipment or destruction for all applicable samples.
3.7.4	Clinical Research Associate	Where equipment, reagents, other materials were provided by the site, ensure appropriate maintenance, calibration and stock records are available for audit or inspection. These may be stored by the laboratory team, by another department e.g. medical physics and are not expected to be kept in the investigator site file (unless this is specified by trial protocol).
3.7.5	Clinical Research Associate	Ensure any trial specific equipment is treated in accordance with the trial agreement (e.g. returned to vendor, disposed of in hospital waste stream). Ensure appropriate maintenance, calibration, shipment/ disposal records are in investigator site file.
3.7.6	Clinical Research Associate	Per monitoring plan, confirm that no trial specific equipment, kits or materials remain in the investigator site laboratory.
3.7.7	Clinical Research Associate	Per monitoring plan, verify the sample tracking log entries and ensure copy filed.
3.7.8	Clinical Research Associate	List any issues relating to laboratory equipment, samples, kits, materials in the site close out visit report and follow up letter (see reporting below).

3.8 Trial Master File and sponsor file completeness check

Task	Responsibility	Activity

3.8.1	Clinical Research Associate	Before the close out visit to Chief Investigator site, review sponsor files and provide any records which should be shared with Chief Investigator or delegates.
3.8.2	Clinical Research Associate	Review the contents of the trial master file and sponsor file (files may be reviewed as part of the Chief Investigator close out visit or on a separate date. File checklists may be provided to the site to complete in accordance with the monitoring plan). • Ensure all records are filled according to the TMF Review Checklist template (template should reflect the KHP CTO ISF contents list and contains all ICH GCP R3 guideline essential records). • If not using the template, ICH GCP R3 C.3.3 essential records table lists the records which should be considered essential (and so retained and archived) if the records are produced for a particular trial. • The trial master file may be divided into several parts for the convenience of the investigator and delegates (eg study manager's working file, laboratory working file). • The sponsor file contains records which are necessary for KHP CTO to carry out regulatory oversight duties during the trial and are not usually shared with Chief Investigator and their delegates during trial delivery. This may include expedited safety reports from investigators, code break information for SUSAR reporting, monitoring reports. The Sponsor File may be merged with the TMF for archiving. • Ensure electronic records are printed and filed (including meta data if necessary) or if they are stored electronically the electronic storage has with restricted access, maintains data integrity and will endure for the archiving period. Complete the template per the monitoring plan and provide as part of the close out report (see section 3.10 reports below)
3.8.3	Clinical Research Associate	List missing documents in the close out visit report and follow up letter.

3.9 Central laboratory samples and results

Task	Responsibility	Activity
3.9.1	Chief Investigator or delegate	Where samples are analysed at the central laboratory, ensure all trial specific samples have been analysed. Sample tracking logs in TMF should confirm analysis for all applicable samples.

3.9.2	Chief Investigator or delegate	Ensure that any human tissue/biological samples held in central laboratories in the UK that will be used for future ethically approved research (in accordance with participant consent) are either: - stored in an establishment with a HTA licence (also see section 3.3). - come under the ethical approval for the new project. Arrange for any remaining samples that do not meet the above criteria to be destroyed**. No samples should remain at the central laboratory at the point the end of trial is declared unless the above criteria are met.** • Samples outside the UK should be treated in accordance with protocol, trial agreement or regulatory requirements. Sample tracking logs in TMF should confirm shipment or destruction for all applicable samples.
3.9.3	Chief Investigator or delegate	Ensure any trial specific equipment is treated in accordance with the trial agreement (eg returned to vendor, disposed of in hospital waste stream). Ensure appropriate maintenance, calibration, shipment/ disposal records are in Trial Master File.
3.9.4	Chief Investigator or delegate	Ensure any trial specific laboratory kits or materials are appropriately disposed of. Bulk supplies should be treated per trial specific requirements.
3.9.5	Clinical Research Associate	Per monitoring plan, verify the sample tracking log entries.
3.9.6	Clinical Research Associate	Per monitoring plan, confirm that laboratory results are available for analysis and reporting.
3.9.7	Clinical Research Associate	Per monitoring plan, confirm that no trial specific equipment, kits or materials remain in the central laboratory.
3.9.8	Clinical Research Associate	List any issues relating to laboratory equipment, samples, kits, materials in the Chief Investigator close out visit report and follow up letter (see section 3.10).

3.10 Records of the close out visit

Task	Responsibility	Activity
3.10.1	Clinical Research Associate	Draft the report and follow up letter • Use the appropriate report template • The visit can take place over several days and these do not need to be consecutive. If the visit dates are spread

		over more than 10 working days separate reports should be written. • Summarise activities at or related to the investigator and site since the last monitoring visit. • List any issues which require resolution before the site can be closed in the follow up letter. Send the draft report and letter to line manager or delegate for review within 10 working days of the last day of the visit.
3.10.2	Line manager or delegate	Review the report and follow up letter within 5 working days of receipt. Send comments to the CRA.
3.10.3	Clinical Research Associate	Amend the report and follow up letter to address the comments.
3.10.4	Line manager or delegate	Approve the report and follow up letter within 5 working days of receipt (i.e a total of 10 working days to review and approve the report from initial receipt from the CRA).
3.10.5	Clinical Research Associate	Send the follow up letter to the investigator and appropriate delegates, ideally within 4 weeks of the last day of the visit.
3.10.6	Clinical Research Associate	Save the report in sponsor file or TMF.

3.11 Activities after close out visit

Task	Responsibility	Activity
3.11.1	Clinical Research Associate	Ensure the site completes all actions. A proportionate approach to resolving actions may be taken: • where the action relates to participant consent, participant eligibility, participant safety or primary endpoint data integrity, follow up to completion. • where no response is received from the investigator site and the action does not affect any of the areas listed in the bullet above the site may be formally closed but emphasise to the site that the site is responsible for ensuring all essential trial records are complete and correctly filed prior to archiving.
3.12.2	Clinical Research Associate	Save the response from the investigator or delegate recording completion (or partial completion where proportionate) of actions.

3.12.3	Clinical Research Associate	Acknowledge the completion of actions and send an email or letter to confirm that the site is closed including the following details: • Plans for disseminating results to participants and when results will be published. • The timeline for archiving (if applicable indicate that they should wait to archive until after the final study results have been published which may be up to 12 months following EOT). • Any trial-specific requirements for archiving and to contact the Sponsor if they wish to destroy any records. • Source data must be retained for 25 years • Post-trial audits and/or regulatory inspections may be conducted. • That the Investigator should notify the Sponsor immediately if notified of a forthcoming inspection by a competent authority.
3.12.4	• Chief Investigator	Ensure: • The final study results are published on the public registry the trial is registered in within 12 months following the day after the end of trial is declared. • Participants are offered a summary of trials results in accordance with the REC approved arrangements *(i.e. those submitted in initial IRAS application or subsequent amendments/modifications)* Refer to **KHP-CTO SOP 12: Application and Maintenance of a Clinical Trial Authorisation**).

3.12 Confirmation of trial closure

Task	Responsibility	Activity
3.12.1	Clinical Research Associate	Update Sponsor records (i.e. EDGE) to reflect site closure status when • Actions from close out report are completed and • Trial results have been sent to investigator (where applicable) and • Confirmation of approval to archive the ISF has been sent to investigator including timelines for archiving.

3.12.2	Clinical Research Associate	Update Sponsor records (i.e EDGE) to confirm to reflect trial status: • All investigator sites are closed. • Confirmation of approval to archive TMF has been sent to Chief Investigator. • Sponsor file has been prepared for archive.

3.13 Ongoing CI responsibilities for the trial

Task	Responsibility	Activity
3.13.1	Chief Investigator	**Chief Investigator responsibilities** Inform KHP CTO if leaving KHP organisation or otherwise unable to continue CI role e.g. giving up GMC license to practice. This responsibility ends at the time that trial master files for the clinical trial are disposed of.
3.13.2	KHP CTO Non Commercial Trials Manager or delegate	Inform sponsor organisation that current CI is unable to continue delegated sponsor responsibilities. It may be proportionate to identify a new delegate only if audit or inspection is announced or in other extraordinary circumstances, as there is no day to day duty for a CI to carry out once the trial is closed. Ensure KHP CTO records are updated to confirm CI is no longer delegated any sponsor responsibilities.

4. RELATED TEMPLATES

1. Close Out Report Form template

2. Remote Study Site Close Out Checklist template

5. RELATED SOPs

1. KHP CTO SOP 14: Emergency Code Break.

2. KHP CTO SOP 18: Data Management

3. KHP CTO SOP 12: Application and Maintenance of Clinical Trial Authorisation.

4. KHP CTO SOP 4: Archiving of Clinical Trial Records

5. KHP CTO SOP 6: Notification of Serious Breaches

6. REFERENCES

1. The Medicines for Human Use (Clinical Trials) Regulations 2004

https://www.legislation.gov.uk/uksi/2004/1031/contents/made

2. The Medicines for Human Use (Clinical Trials) (Amendment) Regulations 2025
https://www.legislation.gov.uk/uksi/2025/538/contents/made

2. ICH Topic (E6) guideline for Good Clinical Practice
https://www.ema.europa.eu/en/ich-e6-good-clinical-practice-scientific-guideline

3. UK Policy Framework for Health and Social Care Research UK Policy Framework for Health and Social Care Research - Health Research Authority

4. National Archives requirements for an offsite store
https://www.nationalarchives.gov.uk/documents/information-management/considerations-for-developing-an-offsite-store.pdf

5. HRA Amendment Tool
IRAS Help - Maintaining your approvals - Amendment guidance -all review bodies

7. CHANGE HISTORY

CHANGE HISTORY			
Date	Version Number	Change details	Approved by
24 Jan 2012	2.0	Change to section 4.1.5 - Deletion of requirement to notify Competent Authority if a site closes prematurely	Jackie Powell
26 Jan 2016	3.0	Scheduled review and minor adjustment to reflect revised practice	Jackie Pullen
31 Aug 2017	4.0	Addition of requirement for Investigator to sign the delegation log, update to glossary, addition	Jackie Pullen

		of HRA requirements for end of trial notification and minor formatting changes	
01 Oct 2018	4.1	Minor amendment to include trials managed by KHP-CTO	Jackie Pullen
25 Jan 2019	5.0	Scheduled review and minor amendments to section 4.1.3 and 4.2 to reflect current practice	
05 Jan 2021	5.1	Minor amendment to include registering on a publicly accessible database	Jackie Pullen
22 Sep 2022	5.2	Scheduled review and minor adjustment to reflect revised practice	Jackie Pullen
20 Apr 2026	6.0	Move to new template, change structure to give details of specific checks required during close out and how these should be recorded rather than general principles	Ann-Marie Murtagh

8. GLOSSARY

Adverse Event (AE) - Any untoward medical occurrence in a participant who has been administered an IMP, which does not necessarily have a causal relationship with that IMP.

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 ATMPs.

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.

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 human tissue/ biological samples are managed or disposed of appropriately.

Data Lock Point – A defined point at which data are fixed against further routine change. For EoT purposes, it refers to the locking of a Clinical Trial database once data collection and cleaning are complete. For DSUR purposes, it refers to the Sponsor-defined annual safety data cut-off.

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.

Final Report (to REC) - This is a UK-wide final report for all project-based research studies that have been reviewed by a REC within the UK Health Departments' Research Ethics Service. The information contained in the final report helps the Research Ethics Service monitor whether the research was conducted in accordance with the REC favourable opinion and applicable transparency requirements.

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.

Human Tissue / Biological Samples (HBS) – Materials of human origin collected for clinical care or research purposes, which contain biological information about an individual. They typically include tissues, cells, blood, blood components, bodily fluids, DNA, RNA, and other derivatives obtained directly or indirectly from a human body.

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.

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.

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 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.

King's Health Partners (KHP) - King's College London, Guy's and St Thomas' NHS Foundation Trust, King's College Hospital NHS Foundation Trust, and South London and Maudsley NHS Foundation Trust.

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 Co-Sponsor – Where the Clinical Trial is co-sponsored, the Lead Co-Sponsor is the entity who substantively employs the Chief Investigator.

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.

New Rules Trial - A Clinical Trial where the application to approve it is submitted after 28 April 2026.

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

Old Rules Trial – A Clinical Trial where the application to approve it is submitted before 28 April 2026.

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.

Regulations – The Medicines for Human Use (Clinical Trials) Regulations 2004 (as amended).

Research & Development Department (R&D Dept.) – The NHS 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 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.

Source Data Verification (SDV) - The process by which Clinical Trial data recorded in the Clinical Trial database or CRF are checked against the original Source Records to confirm that the data are accurate, complete, consistent, and verifiable.

Source Records - Original documents or data (which includes relevant metadata) or certified copies of the original documents or data, irrespective of the media used. This may include participants' medical/health records/notes/charts; data provided/entered by participants (e.g., electronic patient-reported outcomes (ePROs)); healthcare professionals' records from

pharmacies, laboratories and other facilities involved in the Research Study; and data from automated instruments, such as wearables and sensors.

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.
Standard Operating Procedures (SOPs) - Detailed, written instructions to achieve uniformity of the performance of a specific function. SOPs are the basis upon which Quality Systems and Processes are conducted and monitored against.

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.