KING'S HEALTH PARTNERS | Clinical Trials Office

Oversight of Central Laboratories Processing and Analysing Human Biological Samples Collected During a Clinical Trial

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1. BACKGROUND AND PURPOSE

The Medicines for Human Use (Clinical Trials) (Amendment) Regulations 2025 clarify that the sponsor's responsibilities include the selection and oversight of laboratories involved in the analysis or evaluation of human biological samples (HBS) collected during a clinical trial. The Regulations also confirm that the conduct of a clinical trial encompasses the processing, analysis and evaluation of these samples.

The processing and analysis of HBS contribute significantly to the generation of research data, including safety data and trial outcomes. It is therefore essential that all HBS are handled in accordance with the approved trial protocol, Good Clinical Practice (GCP), applicable regulatory requirements and relevant guidance. The expected standards for laboratory processes supporting the quality and integrity of clinical trial data are described in the EMA Reflection Paper (Reflection paper on laboratories that perform the analysis or evaluation of clinical trial samples dated 05 Dec 2011)

The purpose of this Standard Operating Procedure (SOP) is to describe the processes for sponsor oversight of laboratories processing or analysing HBS in Clinical Trials of Investigational Medicinal Products, to ensure compliance with regulatory requirements and GCP.

2. SCOPE

Clinical trials of investigational medicinal products (CTIMPs) sponsored by one or more of the Kings Health Partners organisations are in scope.

Laboratories at trial locations that process HBS as a standard tests equivalent to standard NHS care are not within in scope of this SOP.

In vitro Diagnostic Devices are not within scope of this SOP.

3. PROCEDURE

3.1 Set up of Central Laboratories

Task	Responsibility	Activity
3.1.1	Clinical Research Associate or delegate	Identify central laboratories that will be performing analysis or processing HBS for this trial via: - Protocol (also refer to **KHP CTO SOP 9: Writing a GCP Compliant Protocol).** - During Kick off meeting (also refer to **KHP CTO SOP 13: Initiation of an Investigator Site).**

		- Drafting initial application for approvals (also refer to **KHP CTO SOP 12: Application and Maintenance of a Clinical Trial Authorisation** - Indicated by Sponsor R&D Contracts Manager.
3.1.2	Clinical Research Associate or delegate	Ensure that all central laboratories performing analysis or processing HBS for CTIMPs have been assessed for compliance with the requirements of GCP during trial set-up by either: 1. Confirming whether the laboratory has been previously assessed (*with no concerns raised from a completed laboratory checklist* (**Associated template 1***) or audit in the last three years*). 2. Sending the laboratory a Laboratory checklist (**Associated template 1**) to laboratory contacts (usually QA contacts) where they have not been previously assessed to complete. This may be sent as part of contract negotiation (see **KHP CTO SOP 21: Service Provider Selection and Oversight)**. Request a list of central laboratory SOPs and an organogram.
3.1.3	Clinical Research Associate or delegate	Review the completed checklist to confirm that the laboratory meets GCP requirements. Note Laboratories may also work to other regulations or guidelines such as Good Laboratory Practice (GLP), Good Clinical Laboratory Practice (GCLP) and ISO15189:2012, however, when processing and analysing clinical trial samples, it is GCP that applies. Following review : **No concerns:** When the completed checklist is acceptable, document this on the checklist and send to the Non-Commercial Trials Manager (NCTM). **Concerns:** Escalate concerns to the NCTM including: - Questionnaires that indicated lack of appropriate Quality Management System (QMS) or training - Questionnaires that have not been completed or poorly completed - Data protection issues (labelling includes patient identification data).
3.1.4	Clinical Research	Complete trial risk assessment to determine requirements for: - Training central laboratory staff

	Associate or delegate	- Ongoing central laboratory oversight including monitoring or audit.
3.1.5	Clinical Research Associate or delegate	Document process for oversight of central laboratories in the monitoring plan (also see **KHP CTO SOP 3: Clinical Trial Monitoring**).
3.1.6	Chief Investigator or delegate	Ensure fully executed agreements are in place and central laboratory assessment of compliance per steps 3.1.2 completed by KHP CTO for all central laboratories before any HBS are transferred to the laboratory.
3.1.7	Clinical Research Associate or delegate	Ensure laboratory staff are sufficiently trained to carry out their delegated duties. • Protocol training as required by protocol or contract or laboratory SOP, including processes for reporting results which may impact the safety of participant(s) or the integrity of trial data including blinding, and processes for reporting breach of protocol, GCP or regulations to KHP CTO. • Evidence of GCP training proportionate to the roles and responsibilities as required by protocol or contract or laboratory SOP. Ensure training documentation filed in the central laboratory file and Trial Master File.
3.1.8	Clinical Research Associate	Follow steps 3.1.2 – 3.1.7 when any new central laboratory is added to the trial and ensure a substantial modification is submitted (also see **KHP CTO SOP 12: Application and Maintenance of a Clinical Trial Authorisation.**

3.2 Laboratory Oversight and Close Out

Task	Responsibility	Activity
3.2.1	Clinical Research Associate	Oversee central laboratories in accordance with the monitoring plan (**KHP CTO SOP 3: Clinical Trial Monitoring**). Record issues in laboratory monitoring report (**Associated Template 2)**
3.2.2	CRA line manager	Ensure issues are recorded and escalated appropriately to KHP CTO NCTM.
3.2.3	Clinical Research Associate	Escalate any breaches of protocol, GCP or regulations likely to affect safety of participants or scientific integrity of trial (through KHP CTO SOP Notification of Serious Breach) to KHP CTO NCTM.
3.2.4	KHP CTO Non	Ensure appropriate action in response to potential or actual serious breach is taken. This may include but is not limited to:

	Commercial Trial Manager	• Modification of trial processes and systems. • Increased level and intensity of oversight such as additional onsite monitoring, central monitoring • Audit of laboratory. • Suspension of delegated activities at laboratory.
3.2.5	Chief Investigator or delegate	Ensure laboratory team are informed of and trained on modifications to the trial which may affect their delegated duties and they maintain current versions of trial documentation in the Central Laboratory File.
3.2.6	Chief Investigator or delegate	Planned trial milestone dates and any updates to plans should be shared in a timely fashion to aid resource allocation by laboratory team such as • Last participant last visit. • Deadlines for availability of primary and secondary endpoint results. • End of trial. This may be included in trial training above. Where specific updates are sent out, for instance in a trial newsletter or by email from CI or study manager, ensure these are saved in TMF.
3.2.7	Clinical Research Associate	At end of trial, complete and record close out activities per monitoring plan (**KHP CTO SOP 16: Clinical Trial Close Out Procedure).**

4. RELATED TEMPLATES

1) Laboratory Checklist
2) Laboratory Monitoring Visit Report

5. RELATED SOPs

KHP CTO SOP 3: Clinical Trial Monitoring
KHP CTO SOP 6: Notification of a Serious Breach
KHP CTO SOP 13: Initiation of a Clinical Trial
KHP CTO SOP 21: Service Provider Selection

6. REFERENCES

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

Medicines for Human Use Clinical Trial Regulations 2025 The Medicines for Human Use (Clinical Trials) (Amendment) Regulations 2025

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

European Medicines Agency reflection paper Reflection paper on laboratories that perform the analysis or evaluation of clinical trial samples dated 05 Dec 2011

7. CHANGE HISTORY

CHANGE HISTORY			
Date	Version Number	Change details	Approved by
05 Jan 2021	1.1	Update to documentation of oversight (4.3)	Jackie Pullen
17 Mar 2023	1.1	Scheduled review no changes to SOP content.	Jackie Pullen
20 Apr 2026	2.0	Updated to new SOP template Addition of Medicines for Human Use (CT) (Amendment) Regulations Title of SOP updated to reflect scope.	Ann-Marie Murtagh

8. GLOSSARY

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 Study Report (CSR) – A comprehensive, regulatory-standard document that provides a complete and structured account of a Clinical Trial's methods, conduct, results, and conclusions. It includes all analyses — efficacy, safety, and protocol deviations — and is used by regulators, Sponsors, and auditors to verify the integrity and outcomes of the Clinical Trial. For the avoidance of all doubt, academic publications and funder reports do not meet the regulatory requirements for a Clinical Study Report.

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.

Code Break – The controlled process by which the treatment allocation for an individual participant is Unblinded, typically in the event of a medical emergency, where the identity of the Clinical Trial treatment has been withheld as part of the Clinical Trial's Blinding procedures.

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.

Commercial Trials Contracts Manager – A member of the KHP-CTO Commercial Team with various duties, including arranging for commercial study contracts to be amended.

Commercial Trials Facilitator (CTF) – A member of the KHP-CTO Commercial Team with various duties, including monitoring the KHPCTOcommercial@kcl.ac.uk inbox.

Corrective and Preventive Action (CAPA) - A structured quality management process used to identify, investigate, and address the root causes of actual or potential non-compliance, deviations, or quality issues, with the aim of preventing recurrence and improving systems and processes.

Critical-to-Quality (CtQ) factors - The attributes of a Clinical Trial that are essential to protect participant safety, ensure the reliability and integrity of Clinical Trial data, and support credible interpretation of the Clinical Trial results.

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.

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.

Human 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.

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.

Modification - Any change to a Clinical Trial after initial approval that affects the information or conditions on which the Clinical Trial was authorised. Includes minor modifications, Modifications of an Important Detail (MOIDs), Route A and Route B substantial modifications.

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.

Monitoring Visit Report (MVR) – A Sponsor document completed by the CRA following a monitoring visit, which records the activities performed, observations made, findings identified, and actions required, and provides evidence of ongoing Sponsor oversight of Clinical Trial conduct, participant safety, data integrity, and compliance with the approved protocol, GCP, and applicable regulations.

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

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 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.

Risk Assessment - A structured, documented evaluation performed by the sCRA to identify and assess risks to participant safety, data integrity, and regulatory compliance in a Clinical Trial, and to define proportionate risk-mitigation and monitoring measures in accordance with the Regulations and ICH GCP E6 (R3) by extension.

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.

Setup CRA – The CRA who's responsible for Clinical Trial setup activities on behalf of the KHP-CTO.

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.

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 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.