Clinical Trials Training

Policy Details	
Document Type	Standard Operating Procedure
Document name	KHP-CTO/CT/SOP2.0 Clinical Trials Training
Version	Version 8.0 - 15 October 2025
Effective from	15 October 2025
Review date	26th April 2026
Owner	King's Health Partners Clinical Trials Office
Originally Prepared by	Sarah Ruiz, Senior Clinical Trials Training Executive
Reviewed by	Scott Vezina, Senior Clinical Trials Training Executive
Approved by	Jackie Pullen, Director KHP CTO
Superseded documents	Final v 7.0 – 7th January 2021 Final v7.1 13/04/2023
Relevant regulations/legislation/guidelines	Statutory Instrument 2004 no 1031 Statutory Instrument 2006 no 1928

Change History			
Date	Version Number	Change details	Approved by
10th May 2010	2.0	King's Health Partners Livery	Jackie Powell
30th Sept 2010	3.0	Overall update of the SOP to reflect current practice.	Jackie Powell
27th Nov 2012	4.0	Branding change to KHP CTO, Introduction of CI Responsibilities Refresher training, and review.	Jackie Powell
15th Oct 2015	5.0	Scheduled review and inclusion of new training initiatives.	Jackie Pullen

31st Oct 2017	6.0	Scheduled review, glossary updated, updated ICH GCP E6 to include R2, removal of references to GCP Assessment, changes to GCP for Pharmacy staff Accreditation and changes to GCP Refresher Course.	Jackie Pullen
19th Oct 2018	6.1	Minor amendment to include trials managed by KHP-CTO	Jackie Pullen
4th Jan 2021	7.0	Scheduled review, glossary updated, updated to include The Medicines for Human Use (Clinical Trials) (Amendment) (EU Exit) Regulations 2019,changes to courses accredited, includes updated to device regulations, updates to 4.3 to reflect remote working practices.	Jackie Pullen
13th Apr 2023	7.1	Scheduled review, minor updates. Addition of new course (Archiving Clinical Trial Data).	Jackie Pullen
15 OCT 2025	8	Schedule review –NIHR link for GCP training.	Ann-Marie Murtagh

Table of Contents

1.0 BACKGROUND AND PURPOSE

This SOP outlines the mandatory and elective clinical trials training requirements for staff and students across King's Health Partners Organisations involved in Clinical Trials of Investigational Medicinal Products (CTIMPs) and non-CTIMP research. It ensures compliance with the Medicines for Human Use (Clinical Trials) Regulations 2004 (as amended) and relevant Good Clinical Practice (GCP) standards.

2.0 SCOPE

This SOP applies to all Chief Investigators, Principal Investigators, research staff, and other personnel engaged in clinical research activities within KHP Organisations, including trials sponsored, co-sponsored, or hosted by KHP, and those managed by the KHP Clinical Trials Office.

All clinical staff who are undertaking trial-related activities in a CTIMP study **must** sign a Delegation of Duties Log and receive GCP training commensurate with their roles and responsibilities within the trial.

Completion of a Delegation of Duties Log and GCP training is recommended for those clinical staff involved in non-CTIMP studies but is not mandatory.

Members of clinical staff performing an activity that is part of their normal clinical role, which is not trial specific and does not contribute to the collection of trial specific data, will not be required to sign the Authorised Signature / Delegation of Duties Log, but may still be offered GCP training where appropriate, particularly if they spend appreciable amounts of time with participants in CTIMP studies (**see 4.1.5**).

3.0 PROCEDURE

3.1 Mandatory Training

3.1.1 Good Clinical Practice and The Medicines for Human Use (Clinical Trial) Regulations for CTIMP studies

Core aspects: Declaration of Helsinki 1996, EU Clinical Trials Directive (2001/20/EC) and UK SI 2004/1031, European GCP Directive (in particular 14 Principles and Conditions of GCP) and UK SI 2006/1928, any further amendments to SI 2004/1031, ICH-GCP E6 R2, The Medical Device Regulations SI 681 (2002) and the applicability of the Human Tissue Act 2004.

All staff performing trial-related duties in CTIMPs must complete GCP training covering UK legislation, ICH-GCP E6 R2 principles, and other relevant guidance. Training must be refreshed every 2 years or following significant regulatory updates

Mandatory training ensures that all relevant personnel possess the knowledge and skills to conduct clinical trials in accordance with GCP and applicable regulations. Training requirements vary by role and may include initial training, refresher sessions, and update briefings.

Training can be accessed from a variety of sources including:

- KHP CTO face to face or online GCP or refresher training
- NIHR online training - Good Clinical Practice (GCP) | NIHR
- Any other training provider offering the required standards as defined by the HRA

KHP CTO GCP Training: Attendance at a 4-hour training course – online or in person

Accredited by: Royal College of Physicians for 4 CPD points (regular Open courses only) and TransCelerate as meeting their minimum requirements for GCP training.

NB Although this training is acceptable for all staff, Pharmacy staff should refer to **Section 3.1.2,** and Laboratory staff should refer to **Section 3.1.3.**

Special Circumstances: New and Lapsed Staff

Where new staff joining one of the KHP Organisations have had **recent involvement** in clinical trials with IMPs and can provide **evidence of training** (must include the UK Statutory Instruments) completed **within the last 2 years**, no further action will be required until this training is 2 years old and a GCP Refresher becomes due.

3.1.2 Good Clinical Practice and The Medicines for Human Use (Clinical Trial) Regulations for Pharmacy staff

Core aspects: Declaration of Helsinki, EU Clinical Trials Directive (2001/20/EC) and UK SI 2004/1031, European GCP Directive (in particular 14 principles and conditions of GCP) and UK SI 2004/1031, UK SI 2006/1928, any further amendments to SI 2004/1031, ICH-GCP E6 R2, EU GMP Directive (2003/94/EC) and Annexe 13.

Training Method: Attendance at a 2.5-hour training course. Includes Initial and Refresher training.

Mandatory for: All KHP Pharmacy employees, pharmacy students and any other Pharmacy staff performing trial-related duties for **CTIMPs** sponsored, co-sponsored or hosted by KHP Organisations. This course is recommended for pharmacy staff and students; however, they may attend the general GCP for CTIMPs course if they so wish.

3.1.3 Good Clinical Practice for Clinical Laboratory staff analysing or evaluating clinical trial samples

Core aspects: Guidance on the maintenance of regulatory compliance in laboratories that perform the analysis or evaluation of clinical trial samples.

Training Method: Attendance at a 2.5-hour training course. Includes Initial and Refresher training.

Recommended for: All KHP clinical laboratory employees, laboratory students or any other Laboratory staff analysing or evaluating clinical trial samples for **CTIMPs** sponsored, co-sponsored or hosted by KHP Organisations. This course is recommended for laboratory staff and students; however, they may attend the general GCP for CTIMPs course if they so wish.

3.1.4 Good Clinical Practice and The Medicines for Human Use (Clinical Trial) Regulations Refresher

Core aspects: as 4.1.1

Training Method: Attendance at a 2-hour training session.

Accredited by: Royal College of Physicians 2 CPD points (regular Open courses only). Meets TransCelerate minimum requirements for GCP training if attendees review the accompanying handout.

Pre-requisite: Attendance at the Good Clinical Practice and The Medicines for Human Use (Clinical Trial) Regulations for CTIMP studies course or equivalent training provided by other organisations within the last 2 years (at KHP-CTO Trainer discretion if longer)

3.1.5 Chief Investigator's Responsibilities

Core aspects: KHP-CTO Pharmacovigilance and Safety Reporting policy and Standard Operating Procedures for Essential Documentation and other relevant activities.

Training Method: Attendance required at a 2-hour training session. These are offered as departmental or 1:1 sessions and should be repeated every 2 years whilst the CI is active in this role.

Mandatory for: All Chief Investigators conducting **CTIMPs** sponsored, co-sponsored by KHP Organisations.

Recommended for: Others with significant involvement in a **CTIMP** sponsored, co-sponsored or hosted by KHP Organisations. This training is delivered in the same session as the CI's training.

Special Circumstances: Where trials are sponsored by external parties, this training is *not* mandatory for Chief Investigators since they should follow the Pharmacovigilance policy of the external sponsor. However, if the external sponsor does *not* have appropriate policies then the Chief Investigator should follow the KHP-CTO policies and will receive this training.

3.1.6 Good Clinical Practice Update

Core aspects: Regulatory changes to any aspects listed in section 3.1.1

Training Method: Following any significant updates to any of the core aspects of GCP listed in section 3.1.1, the KHP-CTO training team will undertake to provide GCP update training to those employees for whom it is relevant in a timely manner and by the most appropriate means.

Mandatory for: All relevant KHP employees and any other staff involved in performing trial-related duties in **CTIMPs** sponsored, co-sponsored or hosted by KHP Organisations.

3.1.7 KHP-CTO Policies and SOPs

KHP-CTO employees and other staff involved in clinical trials will undergo training in relevant new or updated KHP-CTO Policies and SOPs where this is deemed necessary by the KHP-CTO Director or Quality Manager, and as reflected by the **KHP-CTO Standard Operating Procedures Training Matrix** (Section 5.1).

Training Method: Advance notice will be given to the training team of new or revised KHP-CTO Policies and SOPs, and training will be implemented in an appropriate manner prior to the intended effective date, with combined 1:1 training and a self-directed training exercise.

3.2 Elective Training

There is no legal requirement for other types of research (i.e. studies which are not clinical trials of investigational medicinal products) to be conducted in accordance with the conditions and principles of GCP.

However, it is still important that such research is always conducted in a manner that provides public assurance that the rights, safety and wellbeing of research participants are protected and that research data are reliable.

Members of the research team in such studies are expected to be qualified by education, training or experience but should not be required or expected to undertake GCP training. (HRA accessed 08/2025 Joint Statement on the Application of Good Clinical Practice to Training for Researchers (HRA, MHRA, Devolved Administrations for Northern Ireland, Scotland and Wales) - Health Research Authority)

KHP CTO offer elective GCP courses for staff working on non CTIMP studies

3.2.1 Good Clinical Practice for non-CTIMP studies

Core aspects: Declaration of Helsinki (latest version), the UK Policy Framework for Health and Social Care Research 2017 and the applicability of ICH-GCP E6 R2. The Human Tissue Act 2004, the Mental Capacity Act 2005, and other guidance which may be relevant.

Training Method: Attendance at a 3-hour training course.

Recommended for: All KHP employees, students and any other staff who are involved in performing trial-related procedures in a **non-CTIMP** sponsored, co-sponsored or hosted by KHP Organisations.

This course does not meet the minimum training requirements for CTIMP studies. Therefore, if staff start working CTIMP studies, they will need to attend the CTIMP GCP or a GCP Refresher Training Course to bring themselves up to speed.

3.2.2 Archiving Clinical Trial Data

KHP CTO Training team provide a 90-minute training session on archiving procedures across the partner organisations (KHP-CTO SOP 4 (Archiving of Clinical Trial Data) and KHP NHS R&D Archiving polices.)

3.3 Resources and Documentation

A **KHP-CTO Training Attendance Log** will be produced for each face-to-face training session and delegates will be asked to sign it to acknowledge their participation in the training. For remote training, attendance will be confirmed by the KHP-CTO trainer through the most appropriate method, including but not limited to: meeting chat box registration and attendance logs generated by Microsoft Teams. All Training Attendance Logs will be filed centrally in the **Training Attendance File**.

Once training has been completed and attendance is tracked in a central **KHP-CTO Training Attendance Tracker**, all delegates will receive a KHP-CTO Training Certificate. The Training Attendance Tracker will be annotated to indicate the version number of the slide presentation given to allow confirmation of the exact information provided to all delegates. The Training Attendance Tracker will be annotated to indicate the version number of the slide presentation given to allow confirmation of the exact information provided to all delegates.

Delegates will receive a delegate pack as specified by the core content documents, for example Quick Reference Guides summarising the Statutory Instruments, Medical Device Regulations and ICH-GCP E6 R2, and they will receive a PDF copy of the presentation via email following the training event.

Contact details for all delegates will be stored electronically by the KHP-CTO in the **Training Attendance Tracker** and will include the type of training undertaken. Information regarding GCP training completed elsewhere will also be maintained where supplied, to enable reminders to be sent when GCP training expires. In addition, all staff will maintain their own **Personal Training Record** (see Section 5.2 for an example Personal Training Record template).

3.4 Training Evaluation

A **KHP-CTO Training Evaluation Survey** can be used to obtain feedback on the delivery of the training and/or the appropriateness and usefulness of the training sessions. Training Evaluations will be collected electronically using Microsoft Forms.

4.0 RELATED TEMPLATES

4.1 Example CPD Record template

4.2 Example Personal Training Record template

5.0 RELATED DOCUMENTS

5.2 KHP-CTO Training Attendance Tracking

5.1 KHP-CTO Standard Operating Procedures Training Matrix

6.0 APPROVAL and SIGNATURE

Ann-Marie Murtagh

Ann-Marie Murtagh
Director, KHP-CTO

15/10/25
Date

Appendix 1
GLOSSARY

Chief Investigator (CI) – The chief investigator is the overall lead researcher for a research project (Outside the UK the term Coordinating Investigator or Investigator may be used). In addition to their responsibilities if they are members of a research team, chief investigators are responsible for the overall conduct of a research project**.**

Clinical Research Associates (CRAs) – A professional who organises and monitors clinical trials to assess the safety and effectiveness of new or existing drugs, medical devices, or treatments. CRAs play a vital role in ensuring that clinical trials are conducted ethically, safely, and in accordance with established protocols and regulations. CTO CRA's monitor compliance, for clinical trials where regulatory oversight has been delegated to the KHP CTO.

Clinical Trial of an Investigational Medicinal Product (CTIMP) – a type of clinical trial that investigates the safety and efficacy of a drug or other medicinal product that is not yet authorised for general use. It can also involve studying how the drug is absorbed, distributed, metabolised, and excreted, or identifying any adverse reactions.

Continuing Professional Development (CPD) – Any educational activity which helps to maintain, develop or increase knowledge, problem-solving, technical skills or professional performance standards all with the goal that physicians and other health care workers can provide better care.

Elective – training which is optional, that is available to any KHP staff and students involved in research, but is not compulsory.

Good Clinical Practice (GCP) – an international ethical and scientific quality standard for designing, conducting, recording, and reporting clinical trials.

International Council for Harmonisation (ICH) – a collaboration between regulators and the pharmaceutical industry in Europe, the United States and Japan to establish common standards for clinical trials. ICH GCP is a widely recognised standard for Good Clinical Practice in clinical trials.

Investigational Medicinal Products (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.

King's Health Partners (KHP) - King's Health Partners brings together research, education and clinical practice across three NHS Foundation Trusts - Guy's and St Thomas', King's College Hospital and South London and Maudsley - and a world-leading university, King's College London.

King's Health Partners Clinical Trials Office (KHP-CTO) – Established in 2006 by King's College London, Guy's & St Thomas' NHS Foundation Trust, South London and Maudsley NHS Foundation Trust and King's College Hospital NHS Foundation Trust to provide a streamlined approach for all aspects of trial administration. The King's Health Partners CTO has two sections: the Commercial Team which provides a single interface for those wishing to conduct trials sponsored by the pharmaceutical industries and the Quality Team that supports investigators at King's Health Partners institutions who undertake CTIMP trials where King's Health Partners are the sponsor or co-sponsor.

KHP-CTO Standard Operating Procedures (SOPs) – ICH-GCP defines as "Detailed, written instructions to achieve uniformity of the performance of a specific function," SOPs are the basis on which Quality Systems and Processes are conducted, and against which study processes and systems are monitored.

Mandatory – training which is compulsory for all or some of the staff involved in clinical trials sponsored, co-sponsored or hosted by any of the KHP Organisations.

Medicines & Healthcare products Regulatory Agency (MHRA) - the UK's regulatory body responsible for ensuring the safety and effectiveness of medicines, medical devices, and blood components for transfusion. It operates as an executive agency sponsored by the Department of Health and Social Care.

NIHR – National Institute for Health Research. Organisation responsible for providing a health research system in which the NHS supports outstanding individuals working in world-class facilities, conducting leading-edge research focused on the needs of patients and the public.

Principal Investigator (PI) – the individual primarily responsible for the conduct of a research study at a specific research site

Statutory Instrument (SI) – Legal means of implementation of EU Clinical Trials Directive into UK law. SI 1031 (2004), subsequently amended by SI 1928 (2006), SI 2984 (2006), SI 941 (2008), SI 1184 (2009), SI 1882 (2010) and SI 744 (2019). These may also be referred to as the Regulations.

The Regulations – The Medicines for Human Use (Clinical Trial) Regulations 2004 which transposed the EU Clinical Trials Directive into UK legislation, as Statutory Instrument 2004 no 1031. An amendment to implement Directive 2005/28/EC was made to the Regulations as Statutory Instrument 2006 no 1928. As amended from time to time.