Clinical Trials Training

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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

Table of Contents

1.0 GLOSSARY

Chief Investigator (CI) - A Registered Physician, Dentist, Pharmacist or Registered Nurse who has overall responsibility for the conduct of the study.

Clinical Research Associates (CRAs) – Part of the KHP-CTO Quality Team. Ensure compliance with the Regulations, GCP and SOPs, by monitoring clinical trials.

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

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 can provide better health care.

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

Good Clinical Practice (GCP) - as defined in the Regulations.

International Council for Harmonisation (ICH) – Produced a series of guidelines in 1996, E6 being the guideline on Good Clinical Practice, otherwise known as (ICH-GCP). Formerly known as International Conference on Harmonisation.

Investigational Medicinal Products (IMP) - means a pharmaceutical form of an active substance or placebo being tested, or used as a reference in a clinical trial. This includes a medicinal product which has a marketing authorisation but is, for the purposes of the trial -

(a) used or assembled (formulated or packaged) in a way different from the form of the product authorised under the authorisation,

(b) used for an indication not included in the summary of product characteristics (or equivalent document) under the authorisation for that product, or

(c) used to gain further information about the form of that product as authorised under the authorisation

King's Health Partners (KHP) - King's Health Partners' Academic Health Science Centre is a pioneering collaboration between King's College London (University) and three of London's most successful NHS Foundation Trusts – Guy's & St Thomas', King's College Hospital and the South London & Maudsley.

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 Foundation Trust to provide a streamlined approach for all aspects of trial administration.

KHP-CTO Standard Operating Procedures (SOPs) – "Detailed, written instructions to achieve uniformity of the performance of a specific function," SOPs are the base on which Quality Systems and Processes are conducted and monitored against.

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) - UK competent authority responsible for regulation of clinical trials.

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) - A Registered Physician, Dentist, Pharmacist or Registered Nurse who has responsibility for the conduct of the trial at a host 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, is applicable for all Clinical trials of investigational medicinal products. This became effective on the 1st May 2004**.** An amendment to implement Directive 2005/28/EC was made to the Regulations as Statutory Instrument 2006 no 1928, which includes the Conditions and Principles of GCP. As amended from time to time.

2.0 BACKGROUND AND PURPOSE

Statutory Instrument 2004/1031, The Medicines for Human Use (Clinical Trials) Regulations 2004, transposed the European Union Directive 2001/20/EC for Clinical Trials into UK law effective from the 1st May 2004. The original UK regulations were amended in August 2006 to incorporate the EU GCP Directive (2005/28/EC) as Statutory Instrument 2006/1928.

The Regulations state that Clinical Trials of Investigational Medicinal Products (CTIMPs) **MUST** be authorised by the MHRA and conducted according to the Principles and Conditions of GCP as defined in the Regulations and any subsequent amendments.

MHRA GCP Inspectors assess compliance with the requirements of GCP by conducting inspections at the sites of pharmaceutical sponsor companies, contract research organisations, academic research organisations, investigational trial sites, clinical laboratories, GCP archives and other facilities involved in clinical trial CTIMP research. Mandatory GCP inspections will be conducted in both commercial and non-commercial organisations within the UK.

Schedule 1 Part 2 of the amended regulations defines the 14 Principles and Conditions of GCP, and number 2 states: - “Each individual involved in conducting a trial shall be qualified by education, training, and experience to perform his or her respective task(s)”, and to fulfil this obligation, the KHP-CTO will provide ***mandatory*** clinical trials training to relevant King’s Health Partner Organisation employees and any other staff involved in clinical trials sponsored or hosted by one or more of King’s Health Partner Organisations, or clinical trials where the sponsor responsibilities are managed by the KHP-CTO.

In addition, the KHP-CTO undertake to provide GCP training to any KHP Organisation employees involved in research which falls outside of the remit of The Medicines for Human Use (Clinical Trials) Regulations 2004, referred to as non-CTIMP research, with such staff electing to attend should they so wish.

3.0 SCOPE

The KHP-CTO Training Executives, assisted from time to time by the KHP-CTO CRAs and external training providers, undertake to appropriately train any and all of the following KHP Organisations employees and any other staff involved in the conduct of clinical research; including, but not limited to:

- Chief Investigators
- Principal Investigators
- Research Nurses
- Trial Managers and Co-ordinators
- Pharmacists
- Laboratory staff analysing clinical trial samples
- Data Managers
- Administrators

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

4.0 PROCEDURE

4.1 Mandatory Training

4.1.1 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.

Training Method: Attendance at a 4 hour training course.

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

Mandatory for: All KHP employees and any other staff involved in performing trial-related procedures in a **CTIMP** sponsored, co-sponsored or hosted by any of the KHP Organisations and all KHP-CTO staff on joining the organisation.

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

NB Although this training is acceptable for all staff, Pharmacy staff should refer to **Section 4.1.2,** and Laboratory staff should refer to **Section 4.1.3.**

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 equivalent 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.

Any staff with recent involvement in clinical trials with IMPs and evidence of equivalent training completed **more than 2 years** ago **may** be eligible to attend a GCP Refresher course (see section 4.1.4) and this will be decided on a case by case basis. However, where involvement in CTIMPs has been minimal during this period, and/or considerable time has elapsed since the equivalent training was completed, the GCP for CTIMP studies course will be mandatory.

Examples of GCP Training considered equivalent are the GCP training provided by the NIHR and some commercial GCP training available on-line.

4.1.2 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.

Recognised by: General Pharmaceutical Council as eligible learning towards CPD.
Mandatory for: All KHP Pharmacy employees and any other Pharmacy staff performing trial-related duties for **CTIMPs** sponsored, co-sponsored or hosted by KHP Organisations.

4.1.3 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 Issue 1 2009.

Training Method: Attendance at a 2.5 hour training course.

Accredited by: Eligible for 1 CPD point per hour of learning for participants towards the Royal College of Pathologists CPD scheme.

Recommended for: All KHP clinical laboratory employees analysing or evaluating clinical trial samples for **CTIMPs** sponsored, co-sponsored or hosted by KHP Organisations.

4.1.4 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. These are offered as Open sessions for general attendance, as Departmental sessions or as 1:1 sessions.

Accredited by: Royal College of Physicians Meets Transcelerate minimum requirements for 2 CPD points (regular Open courses only).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.

Mandatory for: All KHP employees and any other staff involved in performing trial-related duties in **CTIMPs** sponsored, co-sponsored or hosted by KHP Organisations should complete a GCP Refresher every **2 years**.

4.1.5 Good Clinical Practice Light

Core aspects: Introduction of the Regulations governing CTIMP studies. Understanding of importance of safety reporting, source data and good documentation in CTIMP studies and possible involvement in source data collection during contact with trial participants.

Training Method: Attendance at a 30 minute training session.

Mandatory for: All KHP staff who may have responsibility for an area where staff spend appreciable amounts of time carrying out normal clinical care for participants in **CTIMPs** sponsored or co-sponsored by KHP Organisations. For example, a Ward Manager or Sister.

Recommended for: All KHP staff spending appreciable amounts of time carrying out normal clinical care for participants in **CTIMPs** sponsored or co-sponsored by KHP Organisations. For example, a staff nurse. Alternatively a GCP Advice Sheet may suffice for these staff if they have minimal contact with trial participants and/or report to GCP Light trained staff.

4.1.6 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 1 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 or hosted by KHP Organisations.

Recommended for: All other employees and any other staff involved in a **CTIMP** sponsored, co-sponsored or hosted by KHP Organisations.

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

4.1.7 Good Clinical Practice Update

Core aspects: Regulatory changes to any aspects listed in section 4.1.1

Training Method: Following any significant updates to any of the core aspects of GCP listed in section 4.1.1, 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.

4.1.8 KHP-CTO Policies and SOPs

All 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 6.1).

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.

4.2 Elective Training

4.2.1 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, the Children Act 1989 and other guidance which may be relevant.

Training Method: Attendance at a 3 hour training course.

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

4.3 Resources and Documentation

To achieve standardisation in course material, a series of **Core Content** documents have been produced to ensure that while the style and format of training may differ between Trainers, the content does not. Each Trainer will produce a standard slide presentation for each of the training courses with agreed core content and these will be stored electronically in the shared drive.

These Core Content documents are available for the Good Clinical Practice and The Medicines for Human Use (Clinical Trials) Regulations for CTIMPs, and the associated Refresher, GCP

for non-CTIMPs, GCP for Pharmacy, GCP for Laboratory staff, GCP Light and Chief Investigator's Responsibilities training.

A **KHP-CTO Training Attendance Log** (Section 5.1) will be produced for each 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 trainer through the most appropriate method, including but not limited to: meeting chat box registration and attendance logs generated by Microsoft Teams.

Once training has been completed and attendance is tracked in the **Training Attendance Tracker**, all delegates will receive a **KHP-CTO Training Certificate** (Section 5.2).

Training Attendance Logs and 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. All Training Attendance Logs will be filed centrally in the **Training Attendance File**.

Delegates for the open GCP for CTIMPs and GCP for non-CTIMPs courses will receive a full delegate pack as specified by the core content documents. Delegates of all other courses will receive any relevant documentation or material at the time of the training, 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. Electronic copies of the GCP Light slide presentations will not routinely be sent to delegates after the training, as they will have been given a GCP Information sheet for reference.

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 5.4 for an example Personal Training Record template).

4.4 Training Evaluation

A **KHP-CTO Training Evaluation Form** template (Section 5.5) can be used to obtain feedback on the delivery of the training and or the appropriateness and usefulness of the training sessions.

The Training Evaluation form contains one section of mandatory information to enable metric analysis, and an optional design section for specific questions related to individual training sessions.

5.0 RELATED TEMPLATES

5.1 KHP-CTO Training Attendance Log template

5.2 KHP-CTO Training Certificate template

5.3 Example Personal Training Record template

5.4 KHP-CTO Training Evaluation Form template

6.0 RELATED DOCUMENTS

6.2 KHP-CTO Training Attendance Tracking

6.1 KHP-CTO Standard Operating Procedures Training Matrix

7.0 APPROVAL and SIGNATURE

07 January 2021

Jackie Pullen
Director, KHP-CTO Clinical Trials Office

Date