Clinical Trial Computer Systems

POLICY DETAILS	
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Originally Prepared by	Matthew Simpson, Senior Clinical Trials Systems Executive
Reviewed by	Sophie Espinoza, Quality Manager
Approved by	Ann-Marie Murtagh, Director KHP-CTO
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Relevant regulations/legislation/guidelines	Statutory Instrument 2004 no 1031 Statutory Instrument 2006 no 1928 *(as amended from time to time)*

CHANGE HISTORY			
Date	Version Number	Change details	Approved by
13 Jan 2015	2.0	Branding change to KHP-CTO, consistency check of Glossary and scheduled review.	Jackie Pullen
28 Nov2018	3.0	Substantial amendment to update Glossary terms, clarification of responsibilities, previous wording in section 4 has been re-worded and some sections amalgamated and re-titled.	Jackie Pullen
9 Feb 2023	3.1	Minor updates to wording	Jackie Pullen
21 OCT 2025	3.2	Scheduled update	Ann-Marie Murtagh

Table of Contents

1.0 BACKGROUND AND PURPOSE

The purpose of this SOP is to describe the minimum requirements for computer systems used in the conduct of clinical trials sponsored by King's Health Partner Organisation(s), or clinical trials where the sponsor responsibilities are managed by King's Health Partners Clinical Trials Office (KHP-CTO).

Provision of documented assurance to the integrity and validity of computer systems will ensure that the partner organisations meet the fundamental requirement of GCP as stated in UK legislation.

2.0 SCOPE

All trial specific computer systems, including auto-calculation tools, used in the conduct of clinical trials sponsored by one or more of King's Health Partner Organisations, or clinical trials where the sponsor responsibilities are managed by KHP-CTO.

Where the computer system is entirely trial data specific or is a novel system that is outside the native IT departments remit, an assessment should be conducted by the KHP-CTO Systems Manager (or delegate). If the required level of expertise is outwith the capabilities of the Systems Manager the KHP CTO will outsource this activity to a suitably qualified person/company.

Where KHP-CTO internal computer systems are required/used or non-trial data storing computer systems are required/used, the KHP-CTO Systems Manager or delegate should conduct an assessment, overseen by the KHP-CTO Quality Manager or delegate, based on the risk associated with the system to be used.

3.0 PROCEDURE

Participant data collected for a clinical trial that are stored on networked computers, laptops or other digital storage devices must be stored in an anonymised format. Identification keys must be kept on separate systems, either electronic or paper. Users are required to protect the confidentiality of any information which they might access through the Partner Organisation networks in the course of legitimate employment activities or through academic studies.

Participant identifiable data must be stored on NHS systems unless the participant has given explicit consent for it to be stored outside the NHS Trust. This will also need to be highlighted and justified in the ethics application. Any system holding identifiable data should be sufficiently secure and should be assessed by the departments Data Protection Officer and comply with the organisations data protection policy.

3.1 Responsibility

It is the responsibility of the Chief Investigator (CI) in the clinical trial to ensure that any computerised system used during a trial complies with the relevant Partner Organisation(s) or company policies.

The responsibility for ensuring that any computerised system used during the trial complies with UK legislation remains with the trial Sponsor(s) but the management of this responsibility is delegated to the KHP-CTO.

It is expected that grant awards include the cost of provision of a fully validated clinical trial database and data management services if not already available within the Investigator research team.

The Partner Organisations' IT services are responsible for the development and delivery of IT and information systems within their respective organisations. This includes the email service, software applications, and student and staff computing on and off-site.

The KHP-CTO on behalf of the sponsor(s) will maintain oversight of the vendor process for database or system provision. All contracts and agreements will be managed by the Partner Organisation contract teams. As a minimum the following are required:-

- A fully executed Contract/agreement is in place prior to database provision, which clearly details the delegated tasks, duties and functions between the Partner Organisations acting as sponsor or co-sponsor, the CI and the vendor.
- All documentation relating to validation, including user acceptance testing, to be filed in the TMF with copies in the Sponsor File. This includes documentation relating to amendments.
- Copies of relevant vendor SOPs to be provided and filed in the Sponsor File. Relevant SOPs include those that detail disaster recovery and system back up.

3.2 Data Capture System

The trial team should decide on the type of data capture instrument most appropriate for the trial. This decision should be taken as early as possible to allow time for design, review and printing/programming. Some trials may require several different data capture systems to allow the capture of different types of trial data.

When selecting a data capture system, consideration should be given to how the data will be extracted from the system into a format suitable for analysis. Where a paper instrument (such as a questionnaire) is used then the data may need to be input into a database or other electronic format to facilitate analysis. Transfer of data between formats or systems should also be validated prior to use.

The database or system should only capture data required by the protocol. The data capture instrument should not be finalised until after the protocol has been finalised to ensure that all data required by the protocol are included.

In order for the KHP-CTO Clinical Trials Systems Manager or delegate to assess the database for compliance with the current relevant legislation, the vendor should be requested to complete an EDC Provider Specifications document. The level of risk associated with the system and mitigating factors will be documented in the trial specific risk assessment.

The Chief Investigator, Statistician, Trial Manager/Co-ordinator and Data Manager; should all be involved in the design and validation of the database.

3.3 Validation

The CI should ensure when using electronic trial data and/or remote electronic trial systems that the system is fully validated and conforms to established requirements for completeness, accuracy, reliability and consistent intended performance.

Validation key features include:-

- Appropriate controls of the system are in place throughout the system's lifetime
- Documentation is available to support the application of the controls.
- The system is fit for purpose and performs reliably and consistently as intended.

User acceptance testing is a critical part of the validation process designed to meet the "fit for purpose" function detailed above.

In most circumstances, a "test" database will be utilised to input dummy participant data for all stages of the trial and into all data collection points to ensure that the database meets the protocol requirements. Additionally, the statistician should ensure that the data is extractable from the database prior to the system going "live". Documentation relating to user acceptance testing should be filed in the TMF.

The process of validation should be documented at each stage including any amendments that are subsequent to the testing and the system going "live".

The system vendor should supply full system validation declaration plus supporting documents, as applicable, for the system provided.

All validation documentation should be filed in the TMF with copies sent to the KHP-CTO CRA for the Sponsor File.

3.4 Change Control

The system vendor should have a documented mechanism in place to ensure full version control of the system or application with a formal process to manage any changes that may arise as a result of a protocol amendment, to ensure that the system remains in a validated state. After a substantial amendment user acceptance re-testing may be required.

Version control is essential for tracking changes made to programs and associated documentation, to provide a complete history of the software.

3.5 Computer System Decommissioning Plan

The System vendor is expected to have a detailed plan in place for the decommissioning of the system.

If decommissioning of one system is due to the introduction of a new system, the Decommissioning Plan will outline the process for data transfer of clinical data.

The Plan should include measures to ensure archived databases can be accessed and read upon requirement, with documented governance for long-term data integrity, traceability, and auditability

3.6 Access to Database System

Access should be limited to authorised individuals. Each system user is provided with an individual username and secure password to access their own account.
A record of authorised personnel and their access privileges should be kept in the TMF.

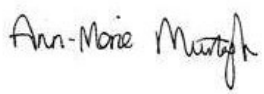
3.7 Training

Evidence should be recorded in the TMF or ISF (multi centre trials), of staff training in the use of the database.

4.0 Related Templates

4.1 EDC Provider Specifications Checklist (provided by the KHP-CTO Quality Manager)

5.0 APPROVAL and SIGNATURE



_____ ___21/10/2025_____

Ann-Marie Murtagh Date
Director, KHP-CTO

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 Trial of an Investigational Medicinal Product (CTIMPs) – 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.

Computer Systems – For the purpose of this SOP, computerised systems are defined as systems (software) that collect data in electronic form and create, modify, maintain, archive, retrieve, or transmit that clinical data.

Co-Sponsors – Where two or more organisations take responsibility for the initiation, management and financing (or arranging the financing in relation to) a clinical trial. Co-Sponsors should decide which organisation will assume responsibility for carrying out the Sponsor functions of that trial and document this accordingly.

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

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

KHP 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 Quality Team - Comprises the Quality Manager, Clinical Research Associate(s), Clinical Trial Administrator(s), Systems Executive and Clinical Trial Training Executives.

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

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.

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