

Clinical Trial Computer Systems

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CHANGE HISTORY			
Date	Version Number	Change details	Approved by
13 th Jan 2015	2.0	Branding change to KHP-CTO, consistency check of Glossary and scheduled review.	Jackie Pullen
28 th 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 th Feb 2023	3.1	Minor updates to wording	Jackie Pullen

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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 Trial of an Investigational Medicinal Product (CTIMPs) - Any investigation in human subjects, 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.

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) - as defined in the Regulations.

King's Health Partners - 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.

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

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.

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. 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. As amended from time to time.

Sponsor - The organisation who takes responsibility for the initiation, management and financing (or arranging the financing) in relation to a clinical trial, The Sponsor organisation has responsibility for carrying out the sponsor functions of that trial (as defined in the Regulations).

2.0 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 Organisations, or clinical trials where the sponsor responsibilities are managed by 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.

In addition, this SOP will provide a consistent, risk-based method to determine if a computer system used in a CTIMP adheres to the Regulations.

3.0 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 of the native IT departments remit, an assessment will be conducted by the KHP-CTO Systems Executive (or delegate). Where KHP-CTO internal computer systems are required/used or non-trial data storing computer systems are required/used, the KHP-CTO Systems Executive or delegate will conduct an assessment, overseen by the KHP-CTO Quality Manager or delegate, based on the risk associated with the system to be used.

4.0 PROCEDURE

Patient data collected for a clinical trial that are stored on networked computers, laptops or other digital storage devices will be stored in an anonymised format. Identification keys will be kept on separate systems. 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.

Patient identifiable data must be stored on NHS systems unless the patient 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.

4.1 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 EU and UK directives 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.

4.2 Data Capture System

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

When selecting a data capture instrument, consideration must be given to how the data will be extracted from the instrument 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.

The database or system must only capture data required by the protocol. The data capture instrument's design must 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 Systems Executive or delegate to assess the database for compliance with the current relevant legislation, the vendor will 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; will all be involved in the design and validation of the database.

4.3 Validation

The CI will 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 can be defined as three key features:-

- 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.

Normally, a "test" database will be utilised to input dummy patient 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 will ensure that the data is extractable from the database prior to the system going "live". Documentation relating to user acceptance testing will be filed in the TMF.

The processes above will be documented at each stage including any amendments that are subsequent to the testing and the system going "live".

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

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

4.4 Change Control

The vendor should have a 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. Strict version control is essential for tracking changes made to programs and associated documentation, to provide a complete history of the software.

4.5 Computer System Decommissioning Plan

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

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

The Plan will include the measures used to ensure that archived databases can be accessed and read upon requirement.

4.6 Access to Database System

Access must be limited to authorised individuals. For most practical purposes this will involve each researcher being provided with an individual authorised 'log-on' and secure password to access their

own account. A record of authorised personnel and their access privileges will be kept in the TMF.

4.7 Training

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

5 RELATED TEMPLATES

5.1 EDC Provider Specifications checklist

6.0 APPROVAL and SIGNATURE



09 February 2023

Jackie Pullen
Director, KHP-CTO

Date