York and Scarborough Teaching Hospitals NHS Foundation Trust R&I Department
SOP
R&D/S40

Clinical Trial Computer Systems

IT IS THE RESPONSIBILITY OF ALL USERS OF THIS SOP TO ENSURE THAT THE CORRECT VERSION IS BEING USED

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	Date:	16th April 2026
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	Date:	15th April 2026

This SOP will normally be reviewed at least every 3 years unless changes to the legislation require otherwise

Version History Log

This area should detail the version history for this document. It should detail the key elements of the changes to the versions.

Version	Date Implemented	Reviewers	Details of significant changes
1.0	11th July 2023		
2.0	13th May 2026	Monica Haritakis	Updated reference from T25 to T10

Contents

1 Introduction, Background and Purpose

ICH GCP guidelines require that computer systems used for clinical trial data should be fit for purpose, provide a clear audit trail, have secure access and be protected against deletions.

Clinical trial data should be collected, stored and analysed using systems which support compliance with principles of GCP, GDPR and appropriate Trust procedures.

The purpose of this SOP is to describe how computer systems which are used in the conduct of clinical trials should be tested and how this should be documented to demonstrate that they are fit for purpose and comply with applicable legislation and principles of GCP.

2 Who Should Use This SOP

This SOP should be used by staff who are setting up and managing Trust Sponsored studies which require the use of computer systems for collecting, storing and analysing clinical trial data.

3 When this SOP Should be Used

This SOP should be used when setting up a Trust Sponsored study which will require computer systems for collecting, storing and analysing clinical trial data.

4 Procedure(s)

4.1 Computer system Validation

All computer systems used in clinical trials, particularly those that impact on the quality of the trial data and subject safety should be validated. Computer systems used in clinical trials may be:

- **Off the shelf systems**
- **Trial specific systems**
- **Bespoke systems**

When validating a computer system, a risk based and proportionate approach should be utilised when determining the level of validation that is required. Evidence of computer system validation should be documented and retained in the Trial Master File (R&D/T10).

4.1.1 Examples of levels of validation required

Off the shelf system such as Microsoft Excel
Off the shelf products (MS Excel, SPSS) are validated by the software developers before being released for sale however there is an expectation that some simple validation is done prior to use. This includes:

- Cell formatting and formulae should be checked to ensure that the required specification is met. These checks should be documented.
- Examples would be to check that the value a formula has calculated is correctly; confirm that cells that are intended to have dates are formatted correctly; checking that formulas have been entered in the correct ranges

Trial specific systems
Trial specific systems would be adaptations of commercially available off the shelf packages (e.g. randomisation systems, eCRFs). The following validation should be documented as a minimum:

- Approved specification
- Testing documentation for developers and users
- Signed validation report to confirm that all test failures have been resolved and specifications have been met
- Production of user instructions and training of users
- Documenting how the final system will be released

Bespoke systems
Bespoke systems are purpose built solely for the trial and require a more comprehensive validation. This would typically include:

- Risk assessment
- User requirements specification
- Functional specification
- Validation plan
- Code-testing documentation
- Documentation of user acceptance testing
- Validation report
- User manual
- Training records
- Records of release

4.2 Change control

During the course of a clinical trial there may be a need for changes to the computer systems used, for example due to a Protocol amendment. To maintain the validation any changes to the system must be controlled and documented. The following information should be including in the documentation:

- The request for change, reasons and details of the requester
- Risk assessment
- Assessment and actions required
- Approval of planned changes
- Testing and evidence of corrective actions taken
- Validation report
- Evidence of release of new version

4.3 System Backup

When deciding on what computer system to use consideration should be given to what arrangements are in place in case of a computer system failure to ensure that the study data is not lost.

The Trust has system back up in place for documents saved to the network however where a system is being used where the data is stored outside of the Trust network

you should confirm with the host that routine backups and disaster recovery plans are in place to protect against accidental loss. This will need to be documented in the TMF.

4.4 Access

Access to the system must be limited to delegated individuals. Each delegated individual should have an individual authorised account to access the system. A record of authorised personnel and their access privileges should be kept and filed in the TMF at the end of the study. This should be monitored regularly to ensure that staff that are no longer delegated to the study have their access to the study revoked and to check that the access levels attributed are correct.

4.5 Training

Training should be provided to staff that will be using the computer system. Any training should be documented on the Training/ Meeting register (R&D/F54) and filed in the TMF.

A ‘user manual’ or ‘user instructions’ should be provided for bespoke or trial specific systems.

4.6 Contracts

Even when purchasing a system the ultimate responsibility lies with the Sponsor. The following should be agreed and documented in the contract:

- The eSystem vendors may have expert knowledge relating to IT systems and sometimes on data protection legislation if applicable, but not necessarily on GCP requirements.
- The contract should require the vendor to work to GCP. If it doesn’t then it increases the risk of them not doing so and not retaining sufficient documentation to reconstruct essential trial activities.
- The contract should allow the sponsor access to or ensure the retention of essential non-trial specific documentation such as software/system validation documents, vendor SOPs, training records and issues log/resolutions in Helpdesk/IT Ticket system.
- The contract should require the vendor to report serious breaches either to the sponsor or the relevant regulatory authorities.
- The contract needs to be clear with regards to sub-contracting by the vendor specifically which tasks can and cannot be sub-contracted and how the sponsor will maintain oversight.

4.7 Other considerations

- System security- A list of individuals who have access to the system and their level of access should be maintained. This should be reviewed regularly.
- Interaction of different systems (for example direct electronic information/results from separate computer systems or merging of information between systems)
- Audit trails- For CTIMPs the systems that are used should have the ability to verify who entered or changed data in the system, when this was done and what was changed. For non-interventional studies if this is not

possible in the system that is being used R&D/T41 may be used to document changes.

- Continued accessibility (for the duration of the trial and the archiving period)

5 Related SOPs and Documents

T10 Database Validation Checklist

T41 Database Amendment Log