North Bristol NHS Trust

Standard Operating Procedure

Computer System Validation & Backup

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Document Version History

VERSION NUMBER	EFFECTIVE DATE	REASON FOR CHANGE
1.0	13-06-16	Updated to clarify the requirements for the development and validation of clinical trial databases

Adapted with the kind permission of University Hospitals Bristol NHS Foundation Trust

DO NOT USE THIS SOP IN PRINTED FORM WITHOUT CHECKING IT IS THE LATEST VERSION

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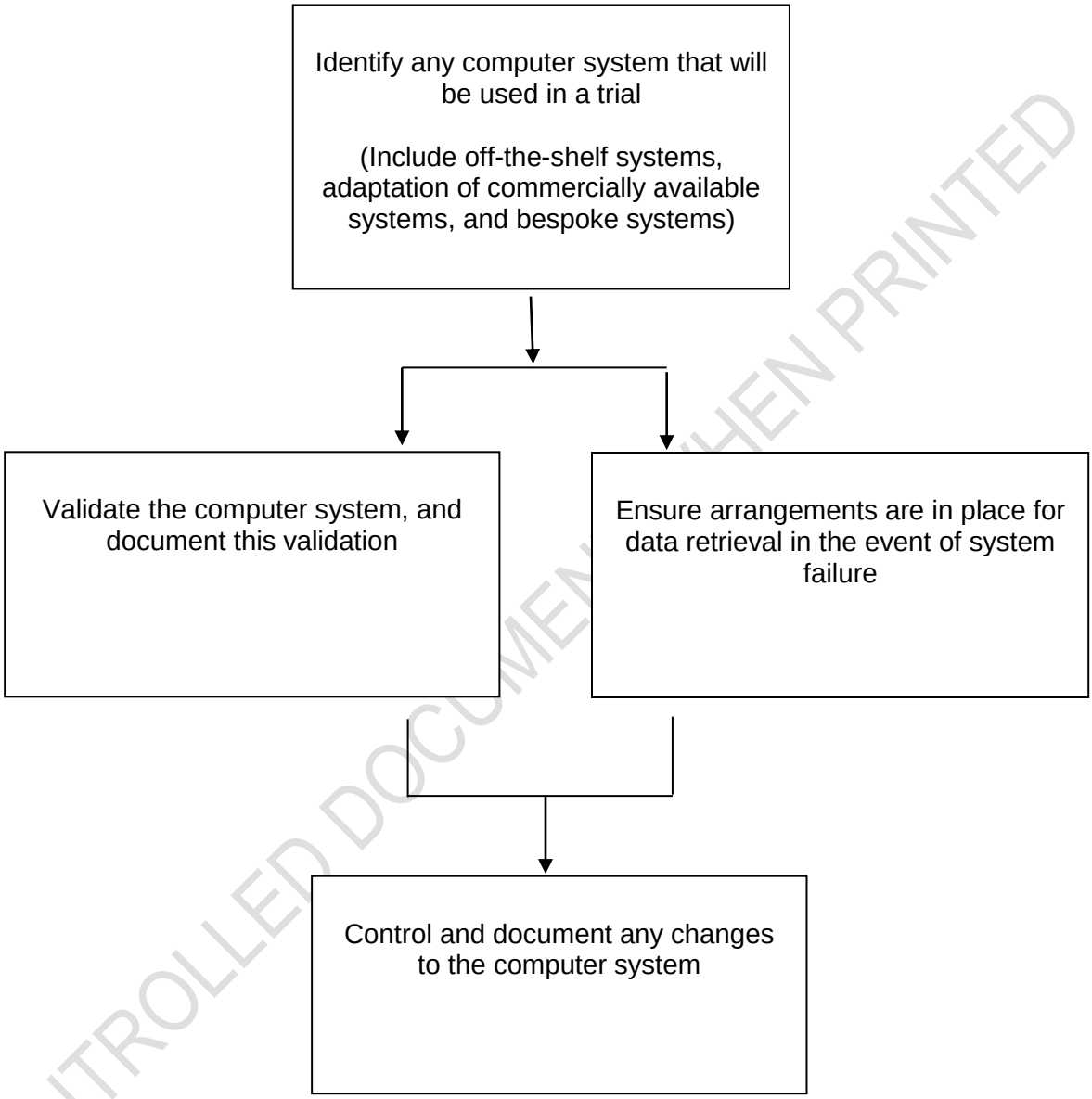
i. SOP Flowchart



1. PURPOSE AND SCOPE

The purpose of this SOP is to describe the processes which should be implemented in order to ensure that computer systems in use within CTIMPs sponsored by NBT are fit for purpose and support compliance with applicable legislation and Good Clinical Practice.

CTIMPS are subject to the Medicines for Human Use (Clinical Trials) Regulations 2004, as amended. Data must be collected, stored and manipulated using systems which support compliance with law and ICH GCP. Computer systems, both hardware and software, used in CTIMPs impact on the quality of the trial data and subject safety.

Although the focus of this SOP is NBT sponsored CTIMPs, the principles outlined in this SOP apply to all research undertaken at NBT.

2. DEFINITIONS/ABBREVIATIONS

CI	Chief Investigator
CTIMP	Clinical Trial of an Investigational Medicinal Product
DMP	Data Management Plan
eCRF	Electronic Case Report Form
ICH GCP	International Conference on Harmonisation Guidelines for Good Clinical Practice
NBT	North Bristol NHS Trust
PI	Principal Investigator
R&I	NBT Research & Innovation Office
SOP	Standard Operating Procedure
Sponsor	The individual, company, institution or organisation, which takes on ultimate responsibility for the initiation, management (or arranging the initiation and management) of and/or financing (or arranging the financing) for that research

3. WHO SHOULD USE THIS SOP

This SOP should be used by investigators, research team members, and any other staff involved in CTIMPs sponsored by NBT.

4. WHEN SHOULD THIS SOP BE USED

This SOP should be used when setting up and managing the use of any computer systems in NBT sponsored CTIMPs. This includes, but is not limited to, databases used to manage study data.

5. PROCEDURE

5.1. Identifying computer systems

Prior to starting a CTIMP, the CI must identify and document in the DMP all of the computer systems that will be used to collect and manage data for the CTIMP.

The DMP and any subsequent amendments must be agreed with the Sponsor prior to implementation in accordance with the Data Management SOP.

Certain computer systems are already used by NBT in a clinical setting, for example, ICE, PACS, EDMS, Lorenzo. Where this is the case, the system should be identified in the DMP, but a separate vendor assessment and systems validation is not required to be undertaken for research purposes.

5.2. **System validation**

All systems used in trials, whether procured from an external supplier, or developed within NBT, must be validated before use. Validation should take the form of robust controls throughout the system's use, supporting documentation (as part of the DMP) and demonstrable evidence that a computer system in use is fit for purpose.

This would include the use of test data to assess:

- Ease of system navigation and data entry.
- Ease of report generation.
- Accuracy of reports generated, including appropriately identifying 'red flags' e.g. appropriately identifying which fields should be populated.

There should be clear documented evidence of the process undertaken for system validation including the iterations and changes after feedback. The final version of the system should be approved by the CI and the Sponsor to confirm that the system is fit for purpose, prior to entering any trial data.

For activities within the scope of this SOP that are carried out by a third party, evidence of validation of relevant systems must be provided prior to their use. The final version of the system should also be approved by the CI and the Sponsor to confirm that the system is fit for purpose, prior to entering any trial data.

Examples of systems and the levels of validation required are provided in the following table:

System Type	Example System	Validation Required
Off the shelf	Microsoft excel	Cell formatting and formulae should be checked to ensure the required specification is met, and the checks made should be documented. For example, confirm that columns intended to receive a date are appropriately formatted; confirm the required number of decimal places is captured, confirm that values calculated from a number of cells are correct.
Trial specific adaptation of a commercially available off the	Microsoft access database, eCRFs	Document the agreed and approved specification, how the system will be tested (both by the users and the developers), that any issues with the system identified through testing have been resolved and the

shelf package		specification is met (validation report), instructions for use and how users will be trained, training records, how the final system will be released.
Bespoke systems	Any purpose built system solely for use in the trial	Document the process by which the decision to use a bespoke system was made and the risk assessment conducted as part of that decision making process, the agreed and approved specification (functional and user requirements), validation plan, code-testing documentation, that any issues with the system identified through testing have been resolved and the specification is met (validation report), instructions for use and how users will be trained, training records, how the final system will be released.

5.3. **Change control**

There should be suitable and proportionate audit trail functionality for the computer system. The Sponsor's approval of trial databases is conditional on the ability of the database to produce audit trails for monitoring, for example, who made the change, time, date and rationale for changes.

Any change to the system must be controlled and documented. The following information should be considered and documented:

(a) Reason for changes and person requesting changes.

(b) Risk assessment.

(c) Assessment of the changes and what actions are required.

(d) Approval of the changes (e.g. by CI and/or Sponsor).

(e) Testing.

(f) Validation report.

(g) Release documentation.

5.4. **System backup**

Arrangements should be in place to ensure that data can be retrieved if there is a computer system failure. Computer systems should be located within an infrastructure which provides for routine backups and disaster recovery in order to protect against accidental loss. Confirmation of this should be documented (on a global level if appropriate).

Local copies of different versions of data sets/databases should be retained if there is not audit software in place. These must be subject to organisational backups (as per section 5.4 of this SOP).

6. DISSEMINATION AND TRAINING

SOPs will be distributed in accordance with the SOP on Preparation of Research SOPs (RI/QMS/SOP/001).

This SOP and any associated templates and forms will be uploaded to the Trust website (www.nbt.nhs.uk/research) and the Managed Learning Environment (MLE) system on the Trust intranet shortly after having been released.

All staff whose activities are subject to this SOP should ensure that they read and understand the content of this SOP.

The training log within the Investigator Site File/Trial Master File should be completed to document that members of staff have read and understood the content of this SOP.

7. RELATED SOPS AND DOCUMENTS

- UK Government
  Medicines for Human Use (Clinical Trials) Regulations 2004
  www.legislation.gov.uk