Computer System Validation and Backup

Division: Strategy and Transformation

Specific staff groups to whom this policy directly applies	Likely frequency of use	Other staff who may need to be familiar with policy
Staff employed by North Bristol Trust who directly or indirectly work on Clinical Research within the Trust	Role Dependant	Staff not employed by North Bristol NHS Trust who are working on Research studies sponsored or hosted by NBT

Main Author(s):	Deborah Warbrick, Research Operations Manager Sadia Khurshid, Research Compliance Manager
Consultation:	R&D Sponsorship Team
Approval Authority (Committee/ Group/ Lead Clinician):	Trust Research Group
Executive Lead (Trust-Wide only):	Tim Whittlestone
Date of Approval:	5th May 2026
Next Review Due:	5th May 2029
Version:	RD/QMS/SOP/015 Version 2.0
KEYWORDS:	Systems Validation, Audit trails, Risk assessment, data management plan, bespoke systems
Summary of changes since the previous version	Changed format to align with NBT SOP template Changed R&I to R&D Added information in relation to responsibilities when working with Clinical Trials Units. Change the naming convention of R&D SOP's Clarifications on roles and responsibilities. Editorial amendments have been made to sentence structure and wording to improve clarity, flow, and consistency across the R&D SOP's.

1. Purpose	The purpose of this SOP is to describe the processes required to ensure that computer systems used in CTIMPs sponsored by NBT are fit for purpose and support compliance with applicable legislation and ICH Good Clinical Practice. Although this SOP is written primarily for CTIMPs sponsored by NBT, its principles may also be applied to non-CTIMP research studies where computer systems are used to support research activities. For non-CTIMP studies, the level of system assessment and control must be proportionate to the nature, complexity, and risk of the study.
2. Key Messages	Computer systems used in CTIMPs have a direct impact on data integrity and participant safety. All systems used to collect, process, store, or analyse trial data must be reliable, secure, and fit for their intended purpose. NBT, as Sponsor, retains ultimate responsibility for ensuring that all computer systems used in sponsored CTIMPs comply with applicable legislation and ICH Good Clinical Practice, regardless of whether activities are delegated to the Chief Investigator, Trial Management team, Clinical Trials Units, or third-party providers. All computer systems used for CTIMPs must be subject to a proportionate, risk-based assessment and validation process to demonstrate that they perform as intended and support accurate, complete, and traceable trial data throughout the system lifecycle. Validation is not a one-off activity, but part of an ongoing system-lifecycle approach that includes appropriate controls for access, audit trails, user training, change control, backup, and disaster recovery. The identification and intended use of all computer systems must be documented in the Data Management Plan (DMP) and agreed with the Sponsor prior to use. Any subsequent changes to system use must be subject to appropriate review and approval. Systems used by third parties or Clinical Trials Units must meet equivalent validation standards, and evidence of system suitability must be available prior to their use in NBT-sponsored research. Robust backup and recovery arrangements must be in place to ensure that trial data can be protected against loss, corruption, or system failure and can be restored in a timely manner. **Abbreviations** **CI** Chief Investigator **CTIMP** Clinical Trial of an Investigational Medicinal Product **CTU** Clinical Trials Unit

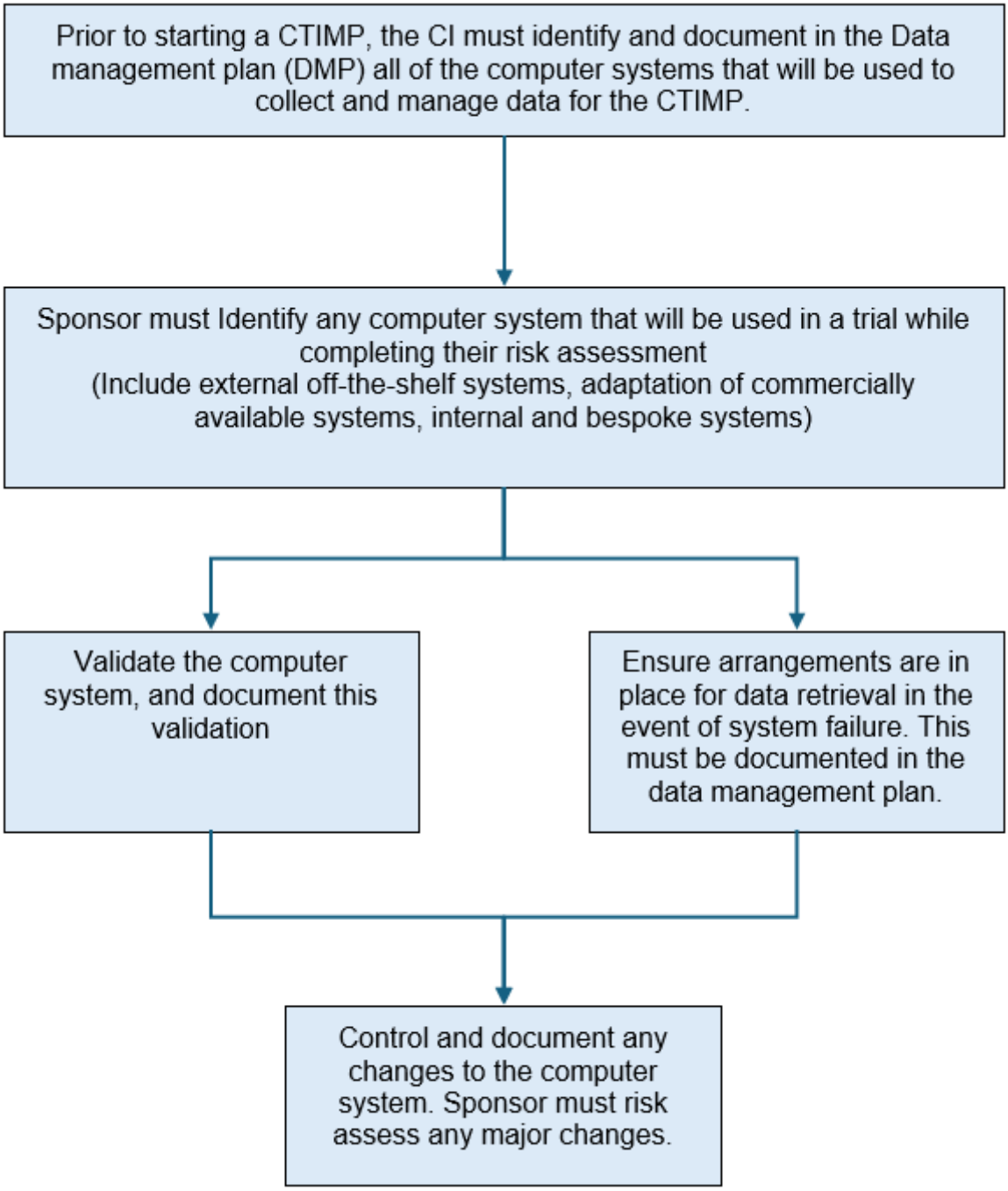
	R&D Research and Development **SOP** Standard Operating Procedure **DMP** Data Management Plan **ICH GCP** International Conference on Harmonisation Guidelines for Good Clinical practice **eCRF** Electronic Case Report Form
3. Relevant Policies & Guidance	**Policies and Guidance:** ICH Guideline for Good Clinical Practice E6 (R3) Medicines for Human Use (Clinical Trials) Regulations 2004, as amended by the Medicines for Human Use (Clinical Trials) (Amendment) Regulations 2025 UK General Data Protection Regulation (UK GDPR) and the Data Protection Act 2018, and applicable Trust Information Governance policies. UK Policy Framework for Health and Social Care Research The following NBT documents are available on the R&D website: www.nbt.nhs.uk/research **Associated SOP's and Templates:** RD QMS SOP 017 Data Management
4. Operational Areas Included	This SOP applies to all research studies sponsored by NBT, and to externally sponsored studies hosted by NBT where NBT is responsible for the selection, use, or oversight of computer systems used to support the conduct of the research.
5. Operational Areas Excluded	This SOP does not apply to computer systems used in externally sponsored studies where NBT has no responsibility for system selection, validation, or oversight.
6. Who should read this	This SOP should be read and applied by investigators, research team members, and any other staff involved in the design, conduct, management, or oversight of CTIMP and Non CTIMP studies sponsored by North Bristol NHS Trust (NBT), where computer systems are used to support trial activities.

7. Roles responsible for carrying out this procedure	**Sponsor** NBT as Sponsor, retains ultimate responsibility for ensuring that computer systems used in NBT-sponsored research are fit for purpose and comply with applicable legislation, regulatory requirements, and ICH Good Clinical Practice (GCP). The Sponsor is responsible for ensuring that appropriate, proportionate arrangements are in place for the identification, risk assessment, validation, oversight, change control, backup, and recovery of computer systems used to support research activities. Sponsor oversight responsibilities are discharged through the R&D Sponsorship Team. **R&D Sponsorship Team** The R&D Sponsorship Team provide oversight and assurance in relation to the use of computer systems in research studies. This includes: reviewing and approving the proposed use of computer systems documented within the Data Management Plan (DMP) assessing and approving validation approaches for computer systems, including systems managed by third parties or Clinical Trials Units (CTUs) reviewing evidence of system validation, audit trail functionality, change control, and backup arrangements. ensuring that risks associated with computer system use are appropriately assessed, mitigated, and documented; and maintaining Sponsor oversight throughout the lifecycle of the study. **Chief Investigator (CI)** The Chief Investigator (CI) is responsible for identifying all computer systems intended for use in the study and ensuring that these systems are documented within the Data Management Plan. The CI is responsible for implementing Sponsor-approved procedures relating to computer system use, including participation in system testing, user acceptance testing where applicable, and ensuring that systems are used in accordance with approved processes. The CI must inform the Sponsor of any proposed changes to computer systems or their use during the study and must not implement such changes without appropriate review and approval. **Trial Manager / Study Management Team (where appointed)**

	The Trial Manager or Study Management Team supports the CI and Sponsor by coordinating the operational aspects of computer system implementation. This may include: • supporting documentation of system use within the DMP • coordinating validation activities, testing, and user training records; • liaising with system providers or CTUs where systems are externally managed • escalating system issues, failures, or change requests to the CI and Sponsorship Team. **Clinical Trials Units (CTUs)** Where computer systems are provided or managed by third-party organisations or Clinical Trials Units, those organisations are responsible for maintaining systems in accordance with applicable regulatory and contractual requirements. Evidence of system validation, audit trails, access control, change management, and backup arrangements must be made available to the Sponsor prior to system use and throughout the study, as required.

8. Procedure:

SOP Flowchart – Computer Systems Validation



8.1 Identifying Computer Systems

Prior to the commencement of a CTIMP study, the Chief Investigator (CI) must identify and document in the Data Management Plan (DMP) all computer systems that will be used to collect, manage, store, or analyse trial data.

The DMP, and any subsequent changes to the identified systems or their intended use, must be reviewed and approved by the Sponsor prior to implementation, in accordance with the Data Management SOP.

Where computer systems already in routine clinical use at NBT (for example ICE, PACS, EDMS, Careflow, or REDCap) are proposed for use in a research study, these systems must be documented in the DMP and subject to a documented, risk-based assessment to confirm their suitability for the intended trial use. Where existing controls are sufficient, full revalidation may not be required, subject to Sponsor agreement.

8.2 Systems Validation

All systems used in trials, whether procured from an external supplier, or developed within NBT, must be validated before use. Validation must provide demonstrable evidence that the system is fit for its intended purpose and supports compliance with applicable legislation and Good Clinical Practice.

All computer systems used in clinical trials, whether procured from an external supplier or developed within North Bristol NHS Trust (NBT), must be subject to validation prior to use. Validation must provide demonstrable evidence that the system is fit for its intended purpose and supports compliance with applicable legislation and Good Clinical Practice.

Validation should be proportionate to the nature, complexity, and risk of the system and must be supported by appropriate documentation, including within the Data Management Plan (DMP). This may include the use of test data to assess system functionality such as usability for data entry, report generation, accuracy of outputs (including identification of mandatory fields or exception flags), and the ability to generate and extract audit trails.

The validation process, including any testing undertaken, issues identified, and system changes made in response to feedback, must be clearly documented. The final version of the system must be reviewed and approved by both the Chief Investigator (CI) and the Sponsor prior to the entry of any trial data.

Where activities within the scope of this SOP are carried out by third-party organisations or Clinical Trials Units, appropriate evidence of system validation must be provided and reviewed before the system is used for trial purposes

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

System Type	Example System	Validation Required
Off the shelf systems (low-risk use only)	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. Use of spreadsheets must be proportionate to risk and complexity, and subject to Sponsor approval.

Trial specific adaptation of a commercially available off the shelf package	Microsoft Access database, eCRF platforms	Documented evidence of an agreed and approved specification; defined testing approach (including user and technical testing); resolution of issues identified during testing; a validation report confirming the system meets specification; user instructions and training arrangements; training records; and controlled release of the final system. Systems must support appropriate access control and audit trail functionality
Bespoke systems	Any purpose-built system solely for use in the trial	Documented justification and risk assessment for use of a bespoke system; approved functional and user requirements specification; validation plan; evidence of testing (including code testing, where applicable); validation report demonstrating the system meets requirements; user instructions; training and training records; and controlled system release. Systems must incorporate appropriate audit trail, access control, and change management arrangements.

For

8.3 Change Control

Computer systems used in clinical trials must have suitable and proportionate audit trail functionality. Sponsor approval of trial databases is conditional on the system's ability to generate audit trails that clearly record, as a minimum, who made a change, the date and time of the change, and the reason for the change, to support effective monitoring, audit, and inspection.

All changes to computer systems must be subject to controlled change management and fully documented. The change control process must consider and record:

a) the reason for the change and the individual requesting it;

b) a risk assessment of the proposed change;

c) assessment of the impact of the change and any required actions;

d) approval of the change by the appropriate authority (e.g. the Chief Investigator and/or Sponsor);

e) testing undertaken to verify the change;

f) documentation of validation or re-validation, where required; and

g) release documentation confirming implementation of the approved change. Assessment of the changes and what actions are required.

8.4 System Backup

Arrangements must be in place to ensure that trial data can be recovered in the event of a computer system failure. Computer systems used in research should be hosted within an infrastructure that

provides routine data backup and disaster recovery arrangements to protect against accidental data loss, corruption, or system failure. Evidence of these arrangements must be documented and may be retained at an organisational or system level where appropriate.

Where computer systems do not incorporate automated audit trail functionality, local copies of successive versions of datasets or databases must be retained to support data reconstruction. These copies must be subject to approved organisational backup and recovery arrangements in accordance with this SOP.

9. Dissemination and Training

SOPS will be distributed in accordance with the SOP on Preparation of R&D Research SOPs (RD/QMS/SOP/001). This SOP and any associated templates and forms will be uploaded to the NBT website (www.nbt.nhs.uk/research) 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.