

CONFIGURATION MANAGEMENT

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Implementation plan

This Standard Operating Procedure (SOP) should be implemented within two weeks from Release Date for studies that are being set-up.

For ongoing studies applicable sections of this SOP should be implemented as far as possible immediately after the implementation date, unless impractical for the circumstances e.g. too close to the end of study.

If unsure, the BTC Director and/or Quality Assurance Manager should advise.

Note to User:

It is your responsibility to ensure that you are using the latest approved version of this SOP. Please note that versions may be superseded before their planned review date.

THIS IS AN UNCONTROLLED VERSION WHEN PRINTED.

If you are reading this document in printed form, please check that the version number and date match the most recent SOP's details. Current versions of all Bristol Trials Centre (BTC) SOPs and accompanying documents are available on the BTC Teams QA channel.

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1. INTRODUCTION AND PURPOSE

The International Conference on Harmonisation (ICH) Good Clinical Practice (GCP) regulates specific requirements for computerized systems, specifically in Section 5.5.3: “when using electronic trial data handling and/or remote electronic trial data systems:

- Ensure and document that the electronic data processing system(s) conforms to the sponsor’s established requirements for completeness, accuracy, reliability, and consistent intended performance (i.e. validation).
- Maintain SOPs for using these systems.
- Ensure that the systems are designed to permit data changes in such a way that the data changes are documented, and that there is no deletion of entered data (i.e. maintain an audit trail, data trail, edit trail).
- Maintain a security system that prevents unauthorised access to the data.
- Maintain a list of the individuals who are authorised to make data changes.
- Maintain adequate backup of the data.
- Safeguard the blinding, if any (e.g. maintain the blinding during data entry and processing).”

The purpose of this SOP is to describe the standard procedures undertaken for ensuring effective configuration management measures are in place for all software and hardware systems which fall under the direct responsibility of the BTC. SOP describes the processes and steps required in order to ensure that any required requests for or changes to software or hardware maintained within the BTC are duly logged and progressed as appropriate. This will ensure any requests, issues, enhancements and/or problems discovered during the utilization of these systems are dealt with in a timely and appropriate manner, thus ensuring the integrity of collected and stored clinical data and enhancing the functionality of data collection processes.

2. SCOPE

This SOP defines the configuration management procedures for software and hardware maintained within the BTC.

This SOP is not expected to apply to any software or hardware systems outside of this remit, for instance software or servers maintained by the University of Bristol or University Hospitals Bristol and Weston NHS Foundation Trust (UHBW).

The Chief Investigator (CI) must be made aware of this SOP and as a minimum, be signposted to the SOP by BTC.

NB: Throughout this document the terms ‘research’, ‘trial’, and ‘study’ will be used interchangeably to denote those projects which fall under the remit of the UK Policy Framework for Health and Social Care Research 2017.

3. DEFINITIONS

For definitions, acronyms and abbreviations relevant to IT please refer to the BTC-RES-IT-001 Definitions and Acronyms (IT) available on the BTC Teams QA channel.

For all other definitions, acronyms and common abbreviations relevant to research projects and general management of research refer to the BTC-RES-TM-001 Definitions and Acronyms, also available on the BTC Teams QA channel.

4. RESPONSIBILITIES

Any delegation of responsibilities should be formally agreed by all parties and clearly documented.

4.1 Research Systems Technical Developer or delegate

It is the responsibility of the Research Systems Technical Developer (or delegate) to implement an effective configuration management process, which will include the tracking and progression of logged issues within agreed timescales and the adequate documentation of software versions and hardware configurations employed within the BTC.

4.2 BTC Staff

It is the responsibility of the BTC staff using software and hardware systems deployed for the purposes of collecting, storing and processing clinical study data to document the issues, enhancements required and problems encountered during the use of those systems in a timely manner and within the defined configuration management process.

4.3 SOP author(s) or delegate

It is the responsibility of the SOP author (or an appropriately qualified/trained delegate) to:

- Generate, finalise and revise the SOP in accordance with the BTC-SOP-QM-001 Development and Management of SOPs.
- Ensure that the SOP remains fit for purpose.
- Provide relevant training and education materials to ensure that staff are aware of their responsibilities in relation to SOP content and management.

4.4 SOP user

It is the responsibility of the SOP user to:

- Ensure compliance with this document.
- Review procedures during use of the SOP and inform the QA manager of any changes required using the Change Request log on the BTC Teams QA channel.
- Undertake training on all aspects of this SOP and record training on the BTC Teams QA channel.

5. SPECIFIC PROCEDURES

5.1 Configuration Management

Issues, enhancements or problems discovered during the use of BTC software or hardware systems must be recorded in a tracking system. Each request will be raised as a ticket in the BTC ticketing system and the ticket will track the request.

The BTC Systems Team will monitor any issues logged within the tracking system and act accordingly to meet the request, resolving any issues, assigning responsibilities and timescales as appropriate and updating the status of the issue on the tracking system as it is progressed.

Certain issues cannot be logged internally via a tracking system. For instance issues relating to public facing services such as the web-site may come in from an external third party via alternative means like email. In this instance the BTC Systems Team will raise the request and copy any correspondence into the allocated ticket.

5.2 Change management process

Each change management request should be raised via a support ticket that will go through a defined process to completion:

- The ticket is categorised;
- The ticket is prioritised;
- The impact of any action and non-action is assessed and recorded in consultation with other affected parties within the BTC;
- The risk of any action and non-action is assessed and recorded in consultation with other affected parties within the BTC;
- The requirements of the request are detailed satisfactorily;
- The change or solution to satisfy the request are detailed;
- The implementation of change or solution is validated as appropriate to the level of risk that was assessed.

5.3 Change/version/release management

For proposed changes in functionality to clinical study systems developed in house, in addition to recording a request, all relevant source documentation (CRFs, field specification document etc) must be revised and a new document version generated highlighting those changes. This updated documentation will be required before changes can be implemented within the system. A reference to the documents will be added to the ticket.

The ticketing system tickets initiating the code change will be updated to document which code elements have changed. The source control system will store a ticket reference number against each code change, as detailed in section [5.4. Source Control](#).

For third party software systems it is expected that the system provider will make available appropriate release notes relating versions with a list of changes for that version.

Each server setup will have installation details and any other pertinent information recorded in an initial server configuration document. Details for changes to underlying services, e.g. server configuration, will be recorded in this configuration document for each server. This document will

list details such as operating system versions, anti-virus and firewall settings, installed services, dependencies, etc.

5.4 Source Control

During the development and subsequent maintenance of in-house software systems the source code and any dependent files must be stored and versioned within a source control system.

Before commencing any development or maintenance work on a software system held under source control, the latest 'checked-in' version of the system must be obtained from the source control system.

Following alterations to a software system held under source control, changes must be 'committed' back to the source control system, in order to ensure that the latest version is always available under source control. Any committed changes must reference the related ticket numbers for which the change is being made.

6. SUPPORTING DOCUMENTS TO BE USED

Number	Title
BTC-RES-IT-001	Definitions and Acronyms (IT)
BTC-RES-IT-002	Website References – IT SOPs
BTC-RES-TM-001	Definitions, acronyms and abbreviations relevant to research projects and management of research
BTC-SOP-QM-001	Development and Management of SOPs

7. CHANGE HISTORY

Previous version and date	New version and date	Summary of review
NIL		New document
V1, 28 Jul 2021	No change	SOP was reviewed and required no change; review date was amended but the SOP version number and date were not changed
V1, 28 Jul 2021	V2, 05 Mar 2024	Job titles amended due to BTC restructuring. Minor grammar changes. Simplifying change management process with the view of moving processes into working instructions.