

TESTING CLINICAL TRIALS SYSTEMS

SOP Number: BTC-SOP-IT-005

SOP Version: 2.0

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Release Date:	05/03/2024	Implementation Date:	05/04/2024
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Review Due:	05/04/2026
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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 Please note that versions may be superseded before their planned review date.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. PURPOSE

The purpose of this SOP is to describe the testing of the systems developed within the BTC to support research studies, in accordance with Good Clinical Practice (GCP) principles and guidelines, UK Policy Framework for Health and Social Care Research and Medicines for Human Use (Clinical Trials) Regulations.

2. SCOPE

This SOP covers the testing of the systems carried out within BTC throughout the development of systems and when changes are made as agreed between BTC and the requestor.

The SOP describes:

- The subject of testing;
- How testing is done and who does it;
- How testing is documented and signed off.

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 agreed by all parties and documented.

4.1 Requester

It is the responsibility of the Requester to:

- Engage with Developer and Tester in clarifying requirements.
- Sign off the testing.

4.2 Developer

It is the responsibility of the Developer to address issues raised during testing.

4.3 Tester

It is the responsibility of the Tester to:

- Devise a plan for testing and carry out the testing accordingly.
- Keep a record of the testing.

4.4 SOP Author or delegate

It is the responsibility of the SOP author(s) (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.

4.5 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

All work carried out must be appropriately tested and signed off.

5.1 Subject of Testing

Testing of the developed systems or modifications of the systems is carried out to check that they perform as agreed between the database team and the requester. The main types of testing that may be undertaken include:

- Testing that the system functions as expected and fulfils the agreed service request.
- Testing bespoke code functionality in detail.
- Transformation testing – testing the integrity of data for which the output is via a different system or in a different format than where or how it was originally stored (i.e. the source data).
- User acceptance testing by the requester in accordance with the respective documentation.

Following the implementation of a system or changes to a system, testing will be performed in accordance with the requirements as specified by the requester within the agreed scope.

5.2 How testing is done and who does it

A judgement will be made about the appropriate level of testing and a risk-based approach will be applied.

Testing of low-impact or low-risk service requests may be undertaken by the BTC Research Systems Team.

Higher-impact or higher-risk service requests should also be tested by the requester or delegate.

5.3 How testing is documented and signed off

Test plans and results will be recorded in existing systems.

Simple service requests can be signed off by the developer via the ticketing system. Complex service requests will be tested and signed off by the requester or a delegate.

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	Adjustments level of detail on Testing Processes and risk assessments with the view of putting detailed processes into work instructions.