STANDARD OPERATING PROCEDURE (SOP)

Title: User Acceptance Testing (UAT)

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Reviewed and Approval

This reviewer agrees with the technical content of the document and that this document is approved for implementation at the Melbourne Children's.

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Document History

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Laura Galletta	04/SEP/2026	New Issue

CONTENTS

1. PURPOSE

This document can be used as a guide and training tool when planning for and conducting User Acceptance Testing (UAT) of data acquisition systems. It provides guidance on the process of performing UAT to ensure that the system is fit for purpose and operating as expected prior to release date.

2. BACKGROUND

User acceptance testing, or UAT, is a software testing process that generally takes place at the last stage of software development to test whether the software handles the day-to-day scenarios for which it was designed and to confirm it is ready for production. The primary purpose of UAT is to assess how well the software can provide the intended features to the target audience (i.e., the users).

ICH E6 (R3) promotes a quality-by-design approach to data systems. UAT plays a critical role at the end of the validation lifecycle, serving as the final confirmation that a system is "fit for purpose" by ensuring usability, functionality and alignment with the trial protocol. UAT serves as the final quality check, minimising the risk of post-launch defects, and helping to identify and address any issues or improvements necessary to achieve user satisfaction.

ICH E6 (R3) sets clear expectations for sponsor oversight in relation to data systems and data quality. Sponsor-Investigators must:

- Confirm that all data acquisition systems are fit for purpose and properly validated prior to being used in the trial
- Ensure that deviations, defects and issues are logged, resolved, and risk-assessed before go-live date
- Maintain inspection-ready documentation of all UAT activities.

Moreover, if the data acquisition system supports regulated clinical trial activity, the sponsor must be in control of its readiness. GCP reinforces the importance of complete, contemporaneous, and traceable documentation:

- Test scripts must map to functional and user requirements
- All UAT results must be signed, dated, and stored in a GCP-compliant environment
- Deviations, defects and issues must be documented, resolved, and closed out prior to go live date
- UAT evidence must be readily available to auditors and inspectors upon request.

For sponsors, this means UAT is not just a technical activity to confirm system readiness: it is a regulatory deliverable.

3. SCOPE

This guidance applies to all clinical trials sponsored by the Murdoch Children's Research Institute (MCRI) and is applicable to all MCRI researchers involved in clinical trials, including Sponsor-Investigators, Statisticians, Database Programmers/Developers, Data Managers, Clinical Trial Managers/Trial Coordinators, Clinical Trial Assistants, Data Assistants and those holding Honorary positions within MCRI.

4. ROLES & RESPONSIBILITIES IN USER ACCEPTANCE TESTING (UAT)

Role in Trial	Responsibilities
Sponsor-Investigator	- Has overall accountability of UAT - Reviews and signs off UAT plan to provide acceptance that the proposed changes meet the change requirements (scope and objectives of the change). - Review test evidence and approves deployment of data acquisition tool to production.
UAT Lead (e.g. Database Programmer / Manager, Data Manager)	- Document and track set-up of UAT approach - Develop and manage the overall UAT test plan - Obtain sign-off from UAT plan from Sponsor-Investigator (or delegate) - Gather setup requirements for UAT - Coordinate development of UAT scripts - Implements the required changes in the UAT environment - Prepares the UAT database environment for execution of UAT scripts - Coordinate and assist in the execution of UAT scripts (note: UAT should be performed by personnel who were not directly responsible for the configuration or programming being tested) - Orientate UAT Team Members in UAT execution, reporting and resolution process - Triage reported defects from UAT Team Member/s and forward to Sponsor-Investigator (or delegate) for resolution - Coordinate tracking of UAT progress and results management - Coordinate resolution and re-test of defects/issues - Manage central repository of UAT documents, script, and UAT outcomes. - Ensure filing of required documentation in the TMF.
UAT Tester	- Performing assigned test cases according to the approved test scripts

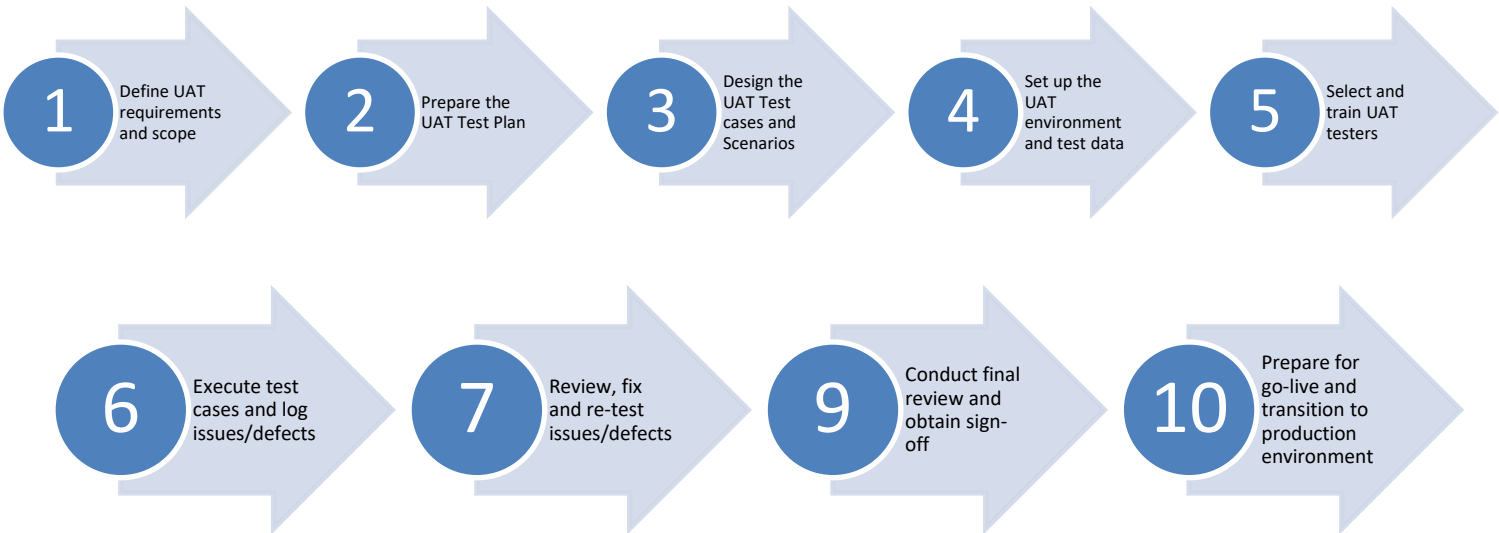
Role in Trial	Responsibilities
(e.g. Sponsor-Investigator, Clinical Trial Manager, Statistician, Study Coordinator/ Research Nurse, Trial Assistant, other stakeholders)	- Recording actual results accurately and contemporaneously - Providing appropriate test evidence - Documenting defects/issue via UAT Log - Undertake re-testing to confirm resolution of defects/issues UAT should, where practicable, be performed by personnel who were not directly responsible for the configuration or programming being tested.

5. UAT Procedure

UAT in clinical research typically focuses on the study database design, including electronic Case Report Forms (eCRFs), and any features of the chosen database which require validation before data collection commences. During the UAT phase, users or designated stakeholders will test the data collection software to validate whether it meets their requirements and expectations.

Any issues, discrepancies, defects, or possible improvements identified during UAT should be addressed before the software is officially launched (i.e., before any real data are collected in the database). UAT helps the research team ensure that the software is ready for deployment and will deliver a positive user experience, ultimately contributing to improved data quality and success of the project.

5.1. UAT Workflow



5.2. UAT Planning

The following describes the planning steps to take in preparing for UAT:

Task Description		UAT Planning Description
1.	Stakeholder engagement	• Identify and involve key stakeholders from different groups, including Sponsor-Investigator, Clinical Trial Manager, Data Manager/s, Statistician, and end-users (e.g. site staff). • Define their roles and responsibilities in the UAT process (Refer to Section **Error! Reference source not found.** for roles and responsibilities of UAT).
2.	UAT scope and objectives	• Clearly define the scope of UAT and test requirements, including which Case Report Forms (CRFs), form features or functions will be tested and any specific scenarios to be covered.
3.	UAT environment setup	• Ensure that the 'test' environment is representative of the 'production' environment and contains realistic, anonymised, but dummy data.
4.	UAT case design and data preparation	• Develop comprehensive test cases that reflect protocol requirements, or typical patient scenarios and/or other processes. • Prepare relevant and realistic test data that reflects different user scenarios. • Ensure that test cases cover both positive and negative test scenarios, e.g., if testing branching logic, test a scenario where it should show the affected field, and a scenario where it should not.
5.	Communication and training	• Communicate the UAT plan to all stakeholders involved. • Provide training or guidance to end-users on how to perform UAT effectively.
6.	Defects and issues tracking and reporting	• Set up a clear process for reporting and documenting defects and/or issues identified during UAT, including the format, severity, and steps to reproduce.

		• Determine how defects will be tracked and monitored throughout the UAT cycle. • Refer to MCTC236 Template | User Acceptance Testing (UAT) Log for an example UAT Log
7.	Exit criteria and sign-off	• Define the criteria that must be met for UAT to be considered successful. • Specify who has the authority to provide sign-off for production release based on UAT results.
8.	Schedule and timeline	• Establish a realistic UAT timeline that allows sufficient time for testing, defect/issue resolution, and re-testing.
9.	Feedback and Iteration	• Plan for feedback collection and incorporate iterative testing cycles as needed based on UAT results.

5.3. UAT Process Phases

The following describes the different phases of UAT:

Task Description		UAT Process Description
1.	Requirements analysis and test planning	• Identify and involve key stakeholders, such as Sponsor-Investigator, Clinical Trial Manager, Data Manager/s, Statistician, and end-users (e.g. site staff). • Understand the scope and objectives of UAT, including the criteria for success. • Create or review the UAT test plan, which outlines the testing strategy, scope, schedule, resources, and exit criteria.
2.	Test case design	• Develop UAT test cases based on real-world scenarios that end-users will encounter. • Test cases should cover both functional and non-functional aspects of the application.
3.	Test environment setup	• Prepare the UAT environment with the necessary hardware, software, and data. • Ensure that the UAT environment closely mimics the production environment.
4.	Test execution	• UAT is completed (refer to MCTC236 Template | User Acceptance Testing (UAT) Log for example UAT Log) • Stakeholders verify that the application works as expected, meets business requirements, and aligns with user needs. • End-users perform the defined test cases according to the test plan. • Issues and/or defects are logged using MCTC236 Template | User Acceptance Testing (UAT) Log
5.	Defect reporting and management	• If any defects or issues are identified, end-users report them with detailed information. • The development team reviews and addresses these defects, releasing fixes as needed. • Issues/defects are retested by end-users to confirm resolution

6.	Regression testing	• Conduct regression testing to ensure that fixes or changes haven't introduced new issues/defects. • Retest previously validated functionality to ensure it remains unaffected.
7.	Sign-off and exit criteria	• Stakeholders evaluate whether the application meets the defined acceptance criteria. • If the application passes UAT, Sponsor-Investigator provides final sign-off for production release.
8.	Documentation	• Document UAT results, including testing results, issues, defects, resolutions, and any additional user feedback. • Maintain UAT documentation for reference and auditing purposes. • UAT documentation must be filed in the data management section of the Trial Master File (TMF).

UAT is not only about identifying defects and issues, but also about ensuring that the data acquisition system aligns with user expectations and protocol requirements.

Effective UAT planning and execution contribute to a successful software release that satisfies end-users and stakeholders.

5.4. UAT Acceptance Criteria

UAT may be considered complete when:

- All planned test cases have been executed
- Expected results have been achieved
- Critical and major defects have been resolved and successfully retested
- Remaining minor defects have been assessed and appropriately documented
- Required regression testing has been completed
- UAT deviations have been assessed and resolved or accepted
- Required test evidence is complete
- UAT results have been reviewed
- Appropriate approval/sign-off has been obtained.

5.5. UAT Following System Changes

Additional UAT shall be performed following changes that may affect validated or previously accepted functionality. Examples include:

- Changes to CRFs
- Changes to edit checks
- Changes to calculations
- Changes to workflows
- Changes to user roles or permissions
- Changes to integrations or interfaces
- Changes to reports or exports
- Changes to electronic signatures
- System upgrades that may affect trial functionality.

The extent of additional UAT shall be based on a documented risk assessment of the change and its potential impact.

5.6. Support

Researchers are encouraged to contact MCRI system administrators with questions or queries regarding best practice when conducting User Acceptance Testing (UAT):

REDCap related enquiries	REDCap assistance can be requested via the MCRI REDCap Helpdesk: https://redcap.mcri.edu.au/community/post.php?type=question&space=9
OpenClinica related enquiries	Research Teams should contact OpenClinica@mcri.edu.au for assistance with OpenClinica.

6. COLLABORATORS

Name / Role	Department / Group	Affiliation
Richard Hall	*Melbourne Children's Trial Centre (MCTC)*	*MCRI*
Billy McMahon	*Cancer Therapies*	*MCRI*
Luke Stevens	*Clinical Epidemiology & Biostatistics Unit (CEBU)*	*MCRI*
Sri Joshi	*Clinical Epidemiology & Biostatistics Unit (CEBU)*	*MCRI*

7. RELATED DOCUMENTS

- MCTC236 Template | User Acceptance Testing (UAT) Log
- MCTC231 SOP | Case Report Form (CRF) Design and Development
- MCTC232 Guidance | CRF Design and Development

- MCTC233 SOP | OpenClinica Change Management
- CEBU SOP | REDCap Project Change Control (Clinical Trials)
- CEBU SOP| REDCap Project User Management for Clinical Trials
- MCTC195 Template | Data Management Plan
- MCTC076 Guidance | Electronic File Naming Conventions

8. GLOSSARY

Case Report Form (CRF):
Data collection tool used to record all the protocol required information to be reported to the sponsor on each research/trial participant. The CRF may be paper or electronic.

Clinical Trial
The World Health Organization (WHO) definition for a clinical trial is: 'any research study that prospectively assigns human participants or groups of humans to one or more health-related interventions to evaluate the effects on health outcomes'.

Data Acquisition System/Tool
Data acquisition tools in clinical trials are specialised, validated technologies—primarily Electronic Data Capture (EDC) systems, ePRO, eCOA, and wearable sensors—designed to collect, manage, and store study data securely in compliance with GCP and regulatory standards. These tools reduce manual errors, enable real-time data monitoring, and improve efficiency by replacing paper-based methods with digital, automated, and often remote, data entry solutions.

Data Dictionary
A data dictionary is a centralised repository of metadata that provides definitions, attributes, and descriptions for data elements within a database. It acts as a reference guide for data, explaining things like data types, allowed values, and relationships, to ensure a consistent and accurate understanding of data across teams and applications.

Essential Documents
Documents which individually and collectively permit evaluation of the conduct of a study and the quality of the data produced. These documents serve to demonstrate the compliance of the Investigator, Sponsor and monitor with the standards of Good Clinical Practice (GCP) and with all applicable regulatory requirements. Filing essential documents at the Sponsor site and participating trial sites also assists with the successful management of the trial.

Good Clinical Practice (GCP)

A standard for the design, conduct, performance, monitoring, auditing, recording, analyses, and reporting of clinical trials that provides assurance that the data and reported results are credible and accurate, and that the rights, integrity, and confidentiality of trial participants are protected.

International Conference on Harmonisation (ICH)
The International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH) is unique in bringing together the regulatory authorities and pharmaceutical industry to discuss scientific and technical aspects of drug registration.

Investigator
A person responsible for the conduct of the clinical trial at a trial site. There are four types of Investigator roles used to describe Investigators with different levels of responsibility for the conduct of clinical trials. These are described below.

Associate Investigator
Any individual member of the clinical trial team designated and supervised by the Principal investigator at a trial site to perform critical trial-related procedures and/or to make important trial-related decisions (e.g., associates, residents, research fellows). May also be referred to as sub-investigator.

Coordinating Principal Investigator (CPI)
If a study is conducted at more than one study site, the Principal Investigator taking the additional responsibility for coordination of the study across all sites in a region is known as the Coordinating Principal Investigator (CPI). This role applies to externally sponsored studies where the Sponsor may be a collaborative research group, commercial Sponsor or an institution. The Principal Investigator at each site will retain responsibility for the conduct of the study at their site.

Principal Investigator
The PI is the person responsible, individually or as a leader of the clinical trial team at a site, for the conduct of a clinical trial at that site. As such, the PI supports a culture of responsible clinical trial conduct in their health service organisation in their field of practice, and is responsible for adequately supervising his or her clinical trial team.

The PI must conduct the clinical trial in accordance with the approved clinical trial protocol and ensure adequate clinical cover is provided for the trial and ensure compliance with the trial protocol.

Sponsor-Investigator
An individual who both initiates and conducts, alone or with others, a clinical trial, and under whose immediate direction the investigational product is administered to, dispensed to, or used by a participant. The term does not include any person other than an individual (e.g., it does not include a corporation or an agency). The obligations of a sponsor-investigator include both those of a sponsor and those of an investigator.

Investigator-Initiated Trial (IIT)
A clinical trial which is initiated and organised by an Investigator, i.e., an individual, rather than a collaborative group, company, or organisation. In these cases, the Investigator will take on the role of the trial sponsor and will then be responsible for the extensive GCP and regulatory requirements associated with both the management and conduct of the trial.

Melbourne Children's
The campus encompassing all staff from The Royal Children's Hospital, Murdoch Children's Research Institute and Department of Paediatrics University of Melbourne who initiate or carry out research under one or more of these institutional affiliations.

Melbourne Children's Trials Centre (MCTC)
Melbourne Children's Trials Centre (MCTC) is a collaboration between the Royal Children's Hospital, The Murdoch Children's Research Institute, The Royal Children's Hospital Foundation and The University of Melbourne. This Centre brings together expertise in research, clinical practice, and education and incorporates anyone who initiates or carries out research under one or more of these institutional affiliations.

Murdoch Children's Research Institute (MCRI)
An Australian paediatric medical research institute located in Melbourne, Victoria, affiliated with the Royal Children's Hospital and the University of Melbourne. The institute has six research themes: cellular biology, clinical sciences, genetics, infection and immunity, population health, and data science.

Patient-reported outcomes (PROs):
PROs are health outcomes reported directly by the patient without clinician interpretation, providing insights into their health status, quality of life, symptoms, and daily functioning. These are collected using standardised questionnaires called patient-reported outcome measures (PROMs) to inform healthcare providers, improve decision-making, and drive service improvements from a patient-centred perspective.

Protocol
A document that describes the objective(s), design, methodology, statistical considerations, and organisation of a trial.

Sponsor
An individual, organisation or group taking on responsibility for securing the arrangements to initiate, manage and finance a study. For investigator-initiated trials, MCRI or RCH will act as the Sponsor but delegate many sponsor responsibilities to the Coordinating Principal Investigator. In this case the CPI has the role of both Sponsor and Investigator and hence the MCTC has adopted the term **Sponsor-Investigator** to reflect the dual role of the CPI in investigator-initiated trials.

User Acceptance Testing (UAT)

User Acceptance Testing (UAT) is the process where the Sponsor (or delegate) validates that the system meets their business and protocol requirements and is ready for use in a live clinical study.

9. REFERENCES, LEGISLATIONS AND STANDARDS

- ICH-GCP (http://www.ich.org/); in particular ICH-GCP R6 (E3)
- Australian Commission on Safety and Quality in Health Care. The National Clinical Trials Governance Framework and user guide for health service organisations conducting clinical trials. Sydney: ACSQHC; 2022
- NHMRC Australian Code for the Responsible Conduct of research (2018)
- NHMRC National Statement on Ethical Conduct in Human Research (2025)
- Data Protection Act 2018:https://www.legislation.gov.uk/ukpga/2018/12/contents/enacted
- OpenClinica: How to create and modify Case Report Forms
- MCRI's Data Governance Framework defines minimum standards for Data Management and Data Governance practices when collecting and handling data
- OpenClinica: User Acceptance Testing (UAT): The One Test Every Data Manager Should Try to Fail

DOCUMENT END