

GD008 User Acceptance Testing (UAT)

User acceptance testing (UAT) is an important part of the validation of a study specific eCRF system. This is the formal testing stage of the data repository build and audit log, it is the stage when users of the system can test the system in a real-world environment. The purpose of UAT is to discover potential errors in the data repository; this includes checking variables, visit layouts and functionality. Having FRM049 (UAT) open as you read this may assist in the understanding of this document.

There are two types of UAT, the UAT type chosen, and reasoning should be specified in the Data Management Plan (DMP):

Full UAT (for all CTIMP studies, and for multisite non-CTIMP studies): Full UAT tests the content and flow of the eCRFs, as well as the built-in data validation. For each eCRF in the study, a script will be created containing the data to be entered and expected outcomes of each, including the expected error messages. A test of the ranges, hide and show functionality and built in logic checks should be included in the script for as many variables as possible. At each stage there should be an option to say if the eCRF passed or failed that step and room for comments.

Fast Track UAT (for non-CTIMP studies): Fast track UAT has a checklist for each eCRF rather than a full script. Each eCRF should still be tested, but with the testers deciding what data to enter and test.

Process:

- 1 The UAT script is written electronically by the data management lead (DML) using the template found in FRM049 User Acceptance Testing.
- 2 All UAT documentation is stored in the \OpenClinica\Studies\\UAT documentation folder, this is currently on the s:\shared drive. This folder is filed in the eTMF/TMF at the end of the study.
- 3 The UAT should be performed by 1-3 users, depending on the complexities of the study. These users should include the data manager lead (DML) and possibly other members of the data team, and the main users of the eCRF system. For the members of the study team, it is best that these are staff that know the protocol well and include staff that have been less involved in the design of the CRFs. This is so they are new to the CRFs but still knowledgeable of the study and are more likely to pick up issues. Often the earlier rounds are done by the data team, and the later rounds by the study team. The tester should go through the script and initial the first page of UAT form (FRM049), then return it to the DML.
- 4 The UAT should be repeated until there are no errors.
- 5 The UAT can test specific areas of the data repository build, although at least one complete UAT should pass successfully to confirm the whole system is working correctly.
- 6 The first round of UAT is called UAT 1, with each round getting the next consecutive number.
- 7 After each round the DML should:
 - a. Save a copy of the testers feedback, this is usually done, by printing the UAT documentation to pdf. This should be saved along with the other files in the UAT folder.
 - b. Review the UAT result and respond to any issues.
 - c. If required, the DML should make the corrections in the data repository.

- d. Sometimes the UAT script contains the error, in which case the script will be corrected.
- 8 In addition to the documented UAT, it is also recommended that a test patient (with dummy data as similar as possible to a study patient) is entered to catch any problems that may not have appeared in the UAT script, such as a blood test having the wrong number of decimals. Ideally this would be completed by the research staff that would be entering the data into the live database. This can be done by looking at an example patient and changing the value slightly, whilst keeping the same format and number of decimal places (for example, changing 0.2 to 0.3). This ensures no real data is entered without consent. It is recommended this process is completed for all studies, regardless of whether a Full UAT or Fast Track UAT was completed.
- 9 The UAT should also include testing of the study audit log. This only needs to be completed by the DML once UAT has been completed. The DML should review the subject audit log to ensure it provides documentary evidence of the sequence of activities completed. This should be documented under the Audit log tab on FRM049.
- 10 The UAT should also include testing of the export method by selecting a sample of patients and checking the export matches the data entered. This only needs to be completed by the DML once UAT has been completed. This should be documented under the Export tab on FRM049.
- 11 Once the UAT has been completed and no errors are found, the eCRF system can go live.
- 12 After system go live, a UAT should be performed on the live site by the DML to ensure there were no problems moving the study from the test site to the live site. Tests patients used for UAT on the live environment should be created in a test site within the live environment (e.g. NOTACS test), to keep them separate from real patient data. These test patients can be named Test001 or ZZZ001 etc, depending on the study's numbering system. However, these test patient records should be deleted before database lock.
- 13 If a design change is made during the live phase, it will be tested. It is at the discretion of the DML to decide if the design change needs a formal UAT with a script, or testing on a test patient is sufficient. How it was tested would be documented in FRM037.