SOP number	**50.020**	Version	**2.0**
Title	**eCRF User Acceptance Testing (Glasgow Clinical Trials Unit)**		

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Released by Signature	Julie Brittenden Date

SOP category	NHS GG&C General
Staff category	

Staff Category	**R**	**A**	**C**	**I**
R&I QA Manager		X		
Chief Investigators	X			
Sponsor Research Co-Ordinator	X			
Sponsor Pharmacy	X			
Clinical Trials Monitor	X			
PV Manager	X			
Project Managers	X			

1. Scope

This procedure applies to the acceptance of an eCRF produced by the relevant data management centre. This procedure does not override any existing procedures in place with the data management centre relating to User Acceptance Testing but should instead be used in tandem to document the actions taken in completing the activity. In the event a trial is managed through the CRUK CTU, the relevant SOPs will take precedence over this SOP.

2. Purpose

The purpose of this SOP is to describe the steps to be taken before official acceptance is given for an eCRF. A sufficient level of User Acceptance Testing (UAT) must be conducted in order to ensure that the provided eCRF meets the needs of the trial.

3. Procedures

When an eCRF is provided by a Data Management Centre for review and acceptance on initial release, a complete and comprehensive review of the content and functionality must be carried out by the end users in order to verify it is fit for use. It must be possible to evidence this review at a later date to show that the correct level of due diligence has been taken prior to acceptance and release. This acceptance testing will take place in addition to any testing and verification carried out by staff of the data management centre, this level of testing is intended to evidence that as the user of the system it has been verified it meets the needs of the trial. As it is traditionally the Chief Investigator, or their delegated authority, that has the responsibility to accept the eCRF for release, it is their responsibility to ensure UAT has taken place before giving this acceptance to the data centre.

When an eCRF is made available for UAT will be a decision made by the Data Management Centre in agreement with the CI or delegated authority, they will also agree a reasonable timescale for this which will be communicated. Any issues with the proposed timescale may be discussed at this initial point of contact.

3.1. Selecting Reviewers

It is of vital importance that the correct groups are consulted in this process and the makeup of this group will depend on the nature of the trial. When notified that an eCRF is ready for UAT, the Sponsor Research Co-Ordinator will select the appropriate reviewers and notify them that testing is required while copying the CI into all correspondence. Some key examples would be:

Pharmacy

In a CTIMP trial, any sections of the eCRF relating to the IMP should be reviewed by a relevant member or members of the Sponsor Pharmacy team as they are the experts in this field.

Pharmacovigilance (PV)

Any areas of the eCRF relating to PV, should be reviewed and receive the correct level of scrutiny from the PV office.

Monitoring Team

The Monitoring Team will be key users of eCRFs and as such should be given the opportunity to review and feedback on this prior to acceptance.

Project Managers

Project Managers may make use of data from the eCRF for project critical information (e.g. reporting and payment milestones) therefore their review of the eCRF is required.

Site Users

The site staff will be the main users of the eCRF and as such will be integral to the testing of any successful eCRF. This may need to be a mix of medical, nursing and site pharmacy staff.

Chief and Principal Investigators

In addition to other members of the trial teams at sites, it is recommended that the relevant investigators review the eCRF prior to acceptance and test the relevant sections to ensure functionality. This may include a selection of Principal Investigators if relevant but this is not necessary as long as the system is reviewed by the Chief Investigator or their delegated authority.

This is a list of just a few examples, proper consideration should be given to the specifics of each trial and each eCRF on who will interact with it and its contents.

3.2. Conducting User Acceptance Testing

All of the selected reviewers should investigate the use of the functionality of the eCRF and attempt to model as many scenarios as is possible to ensure it meets their individual needs. This is an opportunity to highlight any issues or inconsistencies to try and correct them before official acceptance is given. The feedback from those testing will be emailed to the Sponsor Research Co-Ordinator and if not already copied into the correspondence, this will be sent to the CI.

A list of typical types of test that can be conducted during User Acceptance Testing are listed below, this list is not exhaustive and all may not be applicable for every scenario. If deemed appropriate, all those involved in the UAT can develop test scenarios together or individually, the following should be considered as a starting point.

1. Compare the eCRF with any original requirements or specifications that were agreed in advance of its development. Does the eCRF capture all of the required information?

2. For the fields that are present, do any of the required values have ranges? For example, if a value can be between a set range, what happens when a value outside of the range is entered? If a value should be between 3 and 7, try entering a series of numbers inside, outside and on the limit of this range:

Position	Value
Outside	1
Just Outside	2.9
Lower Limit	3
Inside	5
Upper Limit	7
Outside	10

3. If it is a requirement to declare a number to a particular degree of accuracy, i.e. 2 decimal places, what happens when a value is entered to 1 decimal place? Or to 3?

4. Are values to be entered in a particular unit listed correctly, i.e. for a weight is it in lbs, KG, Grams?

5. You will also want to check how fields will manage different types of values, for example what happens if you enter text in to a number field? Are negative numbers acceptable? Can special characters be entered into text fields? (# @ " ! & %) etc.

6. Are there any restrictions in place on who can enter information? There will be certain functions that should only be completed by certain individuals, are there any blockers in place to prevent this? Are different roles, requiring different access types (e.g. restricted access) being considered and do they match the tasks as specified in the trial delegation log?

7. If there is a link between certain fields which makes use of logic, this will need to be tested. For example, if the applicability of a question is linked to the answer of a previous then this should be tested. If by answering "No" to a previous question details are not needed in the next, this should be tested. Likewise for all other uses of logic, if a value between certain ranges acts as a trigger, or a selection from a drop down list, the resulting outcome should be tested for correctness.

8. Likewise with above, if you answer No to a limiting criteria does the system alert you, i.e. if you select No to a patient providing consent.

9. When a list of multiple options are presented for selection, the logic behind whether this is a "one" or "many" selection should be tested, i.e. if you are only supposed to select one, are you only allowed to select one? Likewise if multiples are required.

10. For any drop down menus it is important to make sure all the correct options are present.

11. Can an incomplete record be submitted? What happens if a field (or several) are left blank?

12. What read/write access do users have to records? Can existing records be edited or deleted? If so, who by. It should not be possible for users to delete records and this should be confirmed.

13. Try to complete an end to end scenario as you would expect when using the eCRF in a real world setting. This will allow you to test how the eCRF will function when you come to use it. This is an opportunity to get a feel for how it operates and if you notice anything that could cause you an issue.

14. Does the information entered in to the eCRF correctly save and is it then retrievable?

15. Are all the requirements of the Protocol represented? This may be an extensive list and 100% inspection may not be feasible, but of a sample selection are the required data captures points required of the protocol addressed?

16. If a substudy is involved ensure one of these sites participating in the sub-study is available to drop down and ensure the data fields match the protocol, ensure all other sites not participating do not have access to these fields.

3.3. Limitations of Testing

In the event that an eCRF is released for UAT in advance of all features being available due to time constraints on the project, these limitations will be noted by the Data Centre and remedial action may be taken following acceptance of the eCRF when the features are available by users to verify the are sufficient.

3.4. Final Approval of eCRF

Final approval for the release of the eCRF is the responsibility of the Chief Investigator, R&I require that before this approval is granted that an appropriate level of UAT is conducted and documented. When completed, if not already notified the CI will be informed by the Sponsor Research Co-Ordinator that UAT has been completed and the Data Management Centre may be given approval to release the eCRF. All correspondence on UAT and approval of the eCRF will be stored in the TMF as evidence of this process. Issuing approval for the release of an eCRF prior to end user testing may result in unknown issues being present in the eCRF at the start of trial, causing delays in trials and need for future amendments, this should therefore be avoided.

3.4.1. Feedback to the Data Centre

In the event that findings have been raised during the User Acceptance Testing, this will be compiled by either the Sponsor Research Co-Ordinator, the CI or by the CIs delegated authority to send to the data centre. This will be in the form of a single document or email which combines all other sources of feedback and has been reviewed by the CI or their delegated authority to agree that the issues should be resolved, i.e. the CI will determine if the correction is required or not before sending.

3.4.2. Feedback from all Testers

As a timeline for the review period will be set, if those invited to undertake User Acceptance Testing have not responded within this time window, approval may still be granted by the CI to release the eCRF with the understanding it has been agreed with the Sponsor after discussions at the relevant TMG. It will be the judgement of the CI, Sponsor and the TMG as to whether or not sufficient UAT has taken place, but must still take place to some degree, i.e. if one or two reviewers cannot respond in time this may be acceptable but it there has been no review this would not be acceptable.

3.5. Subsequent changes to the eCRF

It is only a requirement to carry out UAT on the initial release of an eCRF, in the event substantial changes are made to an eCRF as a result of an amendment to a trial protocol, the Data Centre may request input and review by end users. This review will be captured by the processes of the Data Centre and documented within the relevant section of the TMF they hold.

4. Referenced documents

- N/A

5. Related documents

- N/A

6. Document history

Version	Date	Description
1.0	2/10/2020	First Release
2.0	20/12/2023	Removal of forms for capturing UAT, additional detail on coverage.