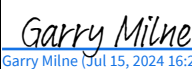

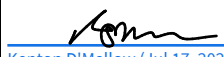





ECTU Central Office SOP ECTU_IT_02: Feature Development

Version No:	3.0
Issue Date:	17 Jul 2024
Effective Date:	31 Jul 2024

Authorship and Approval			
Name and Designation	Author/Reviewer/Approval/Authorisation	Date	Signature
Garry Milne, Senior Software Developer	Author	15-Jul-2024	 <small>Garry Milne (Jul 15, 2024 16:28 GMT+1)</small>
Tim Duncan, Senior Software Developer	Reviewer	15-Jul-2024	
Kenton D'Mellow, Data Management & Programming Team Lead	Approver	17-Jul-2024	 <small>Kenton D'Mellow (Jul 17, 2024 09:44 GMT+1)</small>
Tanya Tharakan, QA Manager	QA Authorisation	17-Jul-2024	 <small>Tanya Tharakan (Jul 17, 2024 11:41 GMT+1)</small>

Document Revision History		
Version No.	Effective Date	Summary of Revisions
1.0	14-Mar-2012	Initial creation
2.0	10-June-2016	Reflect process changes. Change title from System Component Development
3.0	31 Jul 2024	Document moved to v3 template. Changes to document to reflect new Validation plan

The user of this document is responsible for ensuring it is the current version.

1.0 PURPOSE

To describe the process for producing and validating a system feature.

2.0 SCOPE

This SOP applies to all the bespoke research support systems developed in-house by Edinburgh Clinical Trials Unit.

3.0 RESPONSIBILITIES

The study software developer, or designee is responsible for:

- Developing the feature and producing the documentation described below
- Maintaining version control of the completed documentation and filing appropriately.

4.0 PROCEDURE

This procedure describes the process of validating a system feature and the documentation to be in place before the feature can be included in the live system as detailed in ECTU_SOP_IT_01 Initial Set-Up Procedure.

4.1 Feature documentation to be produced

If the feature is part of the user interface, then the following documentation is to be produced

4.1.1 Training and Description document

This document describes how to use the feature and contains a complete set of screenshots of the feature and step-by-step instructions of how to use the feature. This document will be produced by the member(s) of ECTU staff responsible for implementing the feature. This is a version-controlled document.

4.1.2 Validation Plan document

This document contains a list of the features that require validation for the specific live system release, and an explanation of the validation process to be used -i.e. by completion of the Training and Description document and Validation document for each new or altered feature. There will be one Validation Plan per system release, stating which features require to be validated.

This document will be produced by the member(s) of staff responsible for the system release. This is a version-controlled document.

The IT009 Bespoke Study Database Validation Plan Template will be used for future trials, and may be applied for updates to existing trials, where applicable and deemed feasible.

4.1.3 Validation document

This document contains a list of the items of the feature that require validation and will include the behaviour of the feature and confirmation of the dataset. It describes the validation rules and queries applied to individual dataset fields. The document includes a column to 'Pass' or 'Fail' each item listed and is

The user of this document is responsible for ensuring it is the current version.

designed to be completed by the person fulfilling the validator role. This is a version-controlled document.

If the feature is not part of the user interface, for example, Randomisation algorithm, automated mailing, then the Training and Description document will not be produced. The validation plan and validation document will be produced. Any supporting documentation as evidence of automated testing will be referred to within the validation plan, which is signed off by the Software Developer and validation document, which will be signed off by the Validator, and saved in Section 9.2 of the TMF

4.2 Version Control

4.2.1 The Training and Description document and Validation document for each new or altered feature must have the same feature version.

4.2.2 The feature version is composed of an integer representing the major component and an integer representing the minor component, separated by an underscore. If this is the initial version of the feature then the major component is set to 1 and minor component set to 0 (i.e. 1_0).

4.2.3 If this is an update to a feature in production then the major component is incremented by 1 and remains at that value until the feature version is released to production. The minor component is incremented each time a set of Training and Description and Validation documents are produced.

4.2.4 When a new system release is put into production, the Validation Plan for the release will have its major component incremented by 1. The Validation Plan will detail which features require validation and the version of the documents used.

4.3 Validating the feature using the documentation

The documentation mentioned above will be used to validate the feature by following these steps.

- 4.3.1 The member of the system development team responsible for the feature signs and dates the validation plan. This plan is filed in the project's documentation folder in Section 9.2 of the TMF.
- 4.3.2 The Training and description document and the validation document will be provided to the person performing the validator role for the feature.
- 4.3.3 The validator returns the signed and dated Training and Description document and the validation document to the responsible member of the system development team. These documents are filed along with the validation plan.
- 4.3.4 This process repeats until the validator approves the feature for release. Each time the validator returns a validation document that fails to approve the feature for release, the responsible member of the system development team will:
 - Adjust the feature as necessary.
 - Produce updated versions of the Training and Description documents and Validation documents. The minor component of the version

The user of this document is responsible for ensuring it is the current version.



- number should be incremented by 1 from the previous versions of the document. The major component should remain unchanged.
- The Validation plan should be updated with the version number of the Training and Description documents and Validation documents that were signed as passed for release.

5.0 RELEVANT DOCUMENTS AND REFERENCES

ECTU Website:

- ECTU_SOP_IT_01 Initial Set-Up Procedure

On ECTU Shared Drive:

- IT009 Bespoke Study Database Validation Plan Template

The user of this document is responsible for ensuring it is the current version.












ECTU_SOP_IT_02 Feature Development v3.0

Final Audit Report

2024-07-17

Created:	2024-07-15 (British Summer Time)
By:	Tanya Tharakan (tanya.tharakan@ed.ac.uk)
Status:	Signed
Transaction ID:	CBJCHBCAABAAvNK_1bdr6k1tvvHG6fbSzFj4IPq09gV1

"ECTU_SOP_IT_02 Feature Development v3.0" History

-  Document created by Tanya Tharakan (tanya.tharakan@ed.ac.uk)
2024-07-15 - 16:16:57 GMT+1- IP address: 192.41.114.230
-  Document emailed to Garry Milne (g.milne@ed.ac.uk) for signature
2024-07-15 - 16:19:31 GMT+1
-  Document emailed to Tim Duncan (tim.duncan@ed.ac.uk) for signature
2024-07-15 - 16:19:31 GMT+1
-  Document emailed to Kenton D'Mellow (Kenton.D'Mellow@ed.ac.uk) for signature
2024-07-15 - 16:19:31 GMT+1
-  Document emailed to Tanya Tharakan (tanya.tharakan@ed.ac.uk) for signature
2024-07-15 - 16:19:31 GMT+1
-  Email viewed by Tim Duncan (tim.duncan@ed.ac.uk)
2024-07-15 - 16:19:56 GMT+1- IP address: 104.47.11.254
-  Document e-signed by Tim Duncan (tim.duncan@ed.ac.uk)
Signature Date: 2024-07-15 - 16:20:27 GMT+1 - Time Source: server- IP address: 82.12.80.193
-  Email viewed by Kenton D'Mellow (Kenton.D'Mellow@ed.ac.uk)
2024-07-15 - 16:22:49 GMT+1- IP address: 104.47.11.254
-  Email viewed by Garry Milne (g.milne@ed.ac.uk)
2024-07-15 - 16:27:49 GMT+1- IP address: 104.47.11.126
-  Document e-signed by Garry Milne (g.milne@ed.ac.uk)
Signature Date: 2024-07-15 - 16:28:51 GMT+1 - Time Source: server- IP address: 192.41.114.230
-  Document e-signed by Kenton D'Mellow (Kenton.D'Mellow@ed.ac.uk)
Signature Date: 2024-07-17 - 09:44:53 GMT+1 - Time Source: server- IP address: 81.78.162.163



Document e-signed by Tanya Tharakan (tanya.tharakan@ed.ac.uk)

Signature Date: 2024-07-17 - 11:41:32 GMT+1 - Time Source: server- IP address: 192.41.114.230



Agreement completed.

2024-07-17 - 11:41:32 GMT+1

