



ECTU Central Office SOP ECTU_IT_02: Feature Development

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Authorship and Approval			
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Ronnie Harkess, Senior Software Developer	Approver	27-Feb-2026	 R Harkess (27-Feb-2026 14:28:44 GMT)
Tanya Tharakan, QA Manager	QA Authorisation	03-Mar-2026	 Tanya Tharakan (03-Mar-2026 15:10:26 GMT)

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
4.0	27 Mar 2026	Added sections 4.3, 4.4 and 4.7. 4.6 Version control edited to include format as per current process (1.0, instead of 1_1). Associated documents added to the QMS and referenced where appropriate. Minor formatting changes.

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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. The IT011 Training and Description document will be saved along with the validation document in section 9 (3 for partial service studies) of the TMF.

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.

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The document includes a column to 'Pass' or 'Fail' each item listed and is designed to be completed by the person fulfilling the validator role. The IT012 Validation document is version-controlled.

4.2 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

4.3 For studies, where a scheduled task is used to issue questionnaires to participants to complete online, each time the scheduled task is run a summary email will be sent to the trial inbox. This will allow the trial management team to confirm that questionnaires are being issued as expected.

4.4 For every new study that is adopted by ECTU, Multi Factor Authentication (MFA) must be incorporated where NHS patient data will be recorded. If the use of MFA is not feasible, sufficient mitigation must be in place. This may include but not limited to, strong password (a minimum of 14 characters with a special character), password resets required biannually and/or account locking processes.

Exceptions must be discussed with the line manager and where required, with the NHS Lothian Information Security Project Manager, for example, large scale studies where the budgets would not support this feature. In such cases a risk assessment may be carried out by the Information Security Project Manager.

4.5 Version Control

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

4.5.2 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).

4.5.3 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.

4.5.4 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.

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4.6 Validating the feature using the documentation

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

4.6.1 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.

4.6.2 The Training and description document and the validation document will be provided to the person performing the validator role for the feature.

4.6.3 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.

4.6.4 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 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.

4.7 Publishing the feature

4.7.1 The feature that has been validated will be published with no major changes being made to the code. Any changes that are required following validation must be assessed for severity.

4.7.2 Major changes for example, removing user interface visibility must be validated following the process mentioned above.

4.7.3 Minor changes for example, removing spaces etc which have no effect on the performance or functionality of the study database maybe actioned by the programmer without resubmitting for validation.

Figure 1 below depicts the process mentioned in this SOP.

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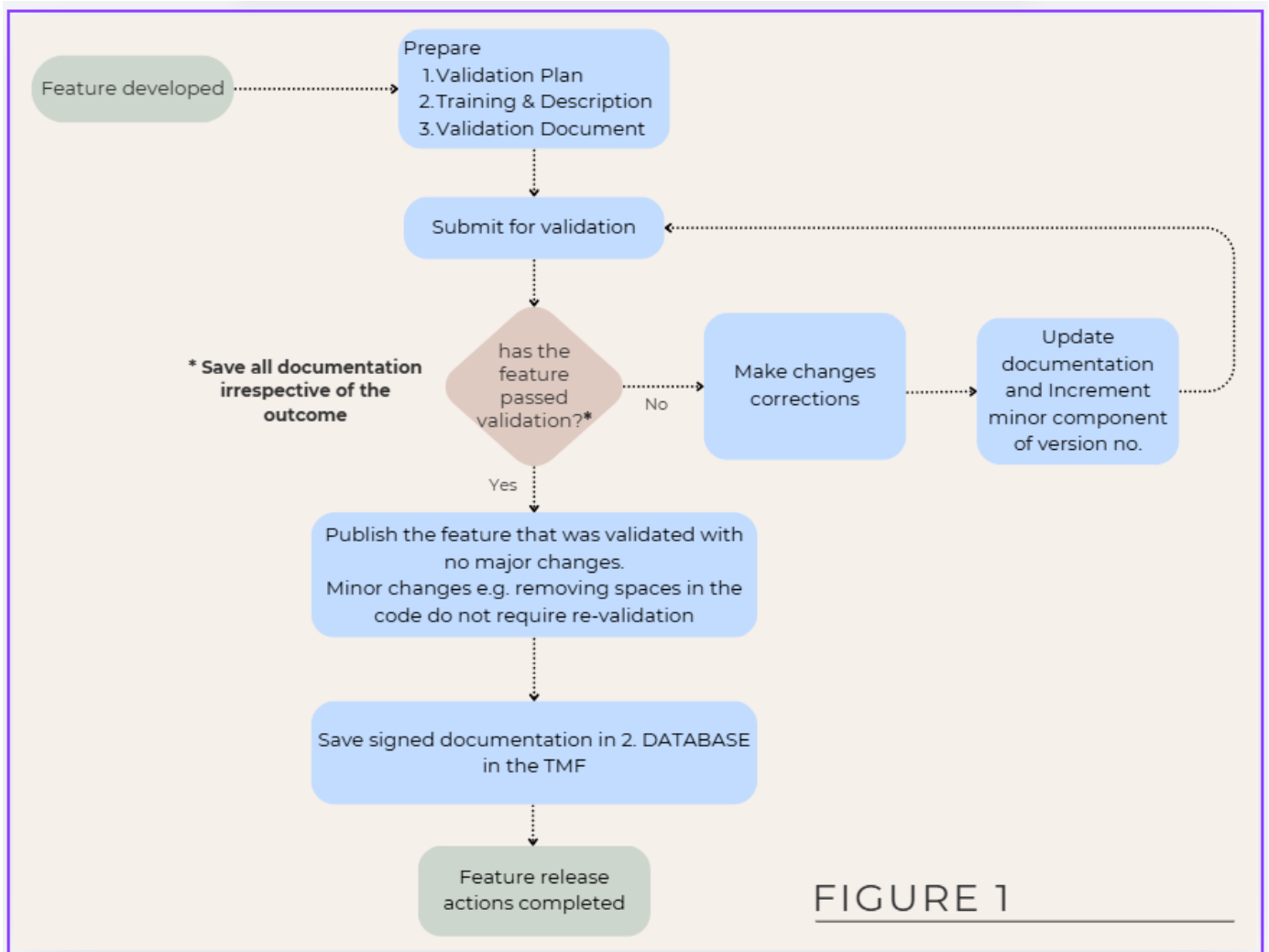


FIGURE 1

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
- IT010 Training and Description template
- IT011 Validation Document template
- IT012 Validation Document

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ECTU_SOP_IT_02 Feature Development v4.0 and associated documents


Final Audit Report

2026-03-03

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-  Document created by Tanya Tharakan (tanya.tharakan@ed.ac.uk)
2026-02-27 - 13:31:10 GMT- IP address: 192.41.114.230
-  Document emailed to Garry Milne (g.milne@ed.ac.uk) for signature
2026-02-27 - 13:33:41 GMT
-  Document emailed to ronan.collins@ed.ac.uk for signature
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-  Email viewed by Garry Milne (g.milne@ed.ac.uk)
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-  Document e-signed by Garry Milne (g.milne@ed.ac.uk)
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-  Email viewed by rharkess@exseed.ed.ac.uk
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-  Signer rharkess@exseed.ed.ac.uk entered name at signing as R Harkess
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-  Document e-signed by R Harkess (rharkess@exseed.ed.ac.uk)
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 Document e-signed by Tanya Tharakan (tanya.tharakan@ed.ac.uk)

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 Agreement completed.

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