Quality Control Document:

Computerised System Validation Plan

# Purpose

Any computerised systems used to support the analysis of samples for clinical trials of investigational medicinal products (CTIMPs) must be validated to ensure it meets the requirements of the trial and will maintain both data security and data integrity.

This document is designed to be used for CTIMPs but could also be used for non-CTIMP trials or studies to support best practices. It is possible to create a project specific Equipment Fitness for Use and User Acceptance Testing Record, which should contain the specifications outlined in the Laboratory Analysis SOP (UoB-CRL-SOP-004).

# Instructions

1. Remove this first instruction page.
2. Update the header to include the trial/study ID.
3. Update the footer; include a version date and retain the document reference information relating to this quality control document (QCD).
4. For each computerised system, complete the ‘system requirements’ in the table, adding additional rows as necessary. Consider the following:

* Does the system have the appropriate functionality to meet the requirements of the trial work?
* Output can be used for further analysis?
* Does the system support defined user access levels? Note that if this is not the case, extra quality control methods will need to be put in place.
* Will data be stored on a secure network and in-line with participant consent?
* Will access to the system be restricted?
* Will data be automatically backed-up to a secure location?
* Does control test data produce the expected results?
* The Laboratory member performing the validation will document whether the system meets the requirements on the form and add their name, date on which the validation was performed and their signature.

1. The validation results will be assessed, and a decision made as to whether the computerised system is acceptable. If the computerised system is found to be acceptable the Laboratory member who has approved the system for use will complete the form with their name, date and signature in the appropriate place.
2. File completed versions of this form and all related correspondence in the ‘Computerised Systems’ section of the Laboratory Master File (LMF); see quality control document (QCD) Setting Up a Laboratory Master File (UoB-CRL-QCD-001). Archive with the other trial documents when the trial closes; see Archiving SOP (UoB-ARC-SOP-001).
3. Repeat steps 4-7 following the installation of any patches or updates the computerised system.

# Related documents

* UoB-ARC-SOP-001 Archiving
* UoB-CRL-QCD-001 Setting Up a Laboratory Master File
* UoB-CRL-SOP-001 Laboratory Set Up and Management
* UoB-CRL-SOP-002 Laboratory Facilities
* UoB-CRL-SOP-003 Sample Management
* UoB-CRL-SOP-004 Laboratory Analysis
* UoB-CRL-SOP-005 Reportable Issues

UoB QMS documents can be found on the [CRCT website](https://www.birmingham.ac.uk/research/activity/mds/mds-rkto/governance/index.aspx). Internal work instructions can be obtained from the CRCT (<mailto:crct@contacts.bham.ac.uk>) and/or from the RGT ([researchgovernance@contacts.bham.ac.uk](mailto:researchgovernance@contacts.bham.ac.uk)).

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| --- | --- | --- | --- | --- | --- |
| Name of Computerised System: | | | | | |
| Description: | | | | | |
| System requirements | | **Does the computerised system meet the requirements? (Yes/No)** | | **Further Information (if required)** | |
| 1 | |  | |  | |
| 2 | |  | |  | |
| Validation Performed By: | | | | | |
| Name: |  | Date (dd-mmm-yyyy): |  | Signature: |  |
| **Computerised System Approved For Use in Trial By:** | | | | | |
| Name: |  | Date (dd-mmm-yyyy): |  | Signature: |  |