# JOINT RESEARCH AND DEVELOPMENT OFFICE

Somers Clinical Research Facility

## Clinical Trial Computer System Validation

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## 1. Scope /Background

The scope of this SOP applies to any software computer systems in use in clinical trials of investigational medicinal products sponsored by Great Ormond Street Hospitals for Children NHS Foundation Trust that impact on the quality of the trial data and subject safety. The SOP is applicable to Chief Investigators (CI), PIs, and delegated trial team members involved in Trust-sponsored CTIMPs and the Joint R&D Office Clinical Trials Team with responsibility for performing sponsor activities on behalf of the Trust.

## 2. Legal basis

The legal basis for this OP is Council Directive 2001/20/EC[1] (Article 15). This Directive (published in 2001) is also known as the Clinical Trials Directive (CTD) and relates to the implementation of Good Clinical Practice in the conduct of clinical trials on medicinal products for human use. In the UK the CTD was transposed into law by the 'The Medicines for Human use (Clinical Trials) Regulations 2004: SI 2004 No 1031[2]. The UK Regulations took effect on 1 May 2004 and then further amendments.

## 3. Purpose

The purpose of this SOP is to describe the process by which the software used within the clinical trial of investigational medical product study sponsored by the Great Ormond Street Hospital for Children NHS Foundation Trust will be validated. Computer System validation is essential to demonstrate that the system is fit for purpose.

## 4. Definitions

Computer System Validation (CSV) is the formal testing and reporting that a computerised system has been designed constructed and is capable of being operated to ensure that it is suitable for its intended purpose. Validation applies to all systems that may impact on the integrity and quality of clinical trial data.

A validation methodology identifies

- Appropriate controls of the system are in place throughout the system's life time.
- Documentation is available to support the application of the controls
- The system is fit for purpose and performs reliably and consistently as intended.

## 5. Personnel responsible

5.1. It is the responsibility of the Chief Investigator and Clinical Trials Manager to assess whether a new computer system requires validation and perform it if so.
5.2. It is the responsibility of the CI or the delegate to update existing validations when necessary and to inform the sponsor.
5.3. It is the responsibility of the CI to provide the documentation required for the change management

## 6. Procedure

All systems used for the data collection should be validated. This is applicable to the system that is developed in the Trust or procured from an external supplier. Validation must demonstrate that a computer system in use is fit for purpose.

The system that is used for the data collection should be documented in the protocol or the data management plan for the process.

Validation of a system will comprise three sections.

- Risk Assessment (Section A)
- Validation Plan (Section B)
- Validation Report (Section C)

### 6.1. Risk Assessment

The level of detail in the validation will be determined by a risk based approached dependent upon the nature of the software. The software will be assessed to determine the impact upon both trial data and patient safety. If software requires validation the risk assessment will determine whether standard or full validation is required.

#### 6.1.1. Standard Validation

The used features of the software should be tested to ensure they are producing the required result. This should be tested on one more than one PC to ensure consistency. Software should be re-validated as a minimum of every two years unless there is a system update in which case the changed or new features should be tested within one week of the upgrade. Information should also be recorded on system back up, system security, audit trails, systems interaction, continued accessibility and staff training.

#### 6.1.2. Full Validation

Full Validation will require extensive testing and documentation including but not limited to:

- User Specification
- Functional Specification
- Code-Testing Documentation
- Documentation of User Acceptance Test
- User Manual
- Training Records
- Records of Release

### 6.2. Validation Plan

A Validation Plan will be developed as deemed necessary by the initial assessment. The Validation Plan will define features of the software that if they were to not function correctly would impact upon the safety of patients and/or the validity of clinical trial data. For each of these features a description of how they will be tested to ensure they function as expected and the measure by which a test will be deemed successful will be included.

The Validation Plan will indicate the frequency of which re-testing will be required.

### 6.3. Validation Report

A validation report is produced as a result of the execution of the Validation Plan. Validation report explains how the system maintains the validity, security and integrity of the study data.

### 6.4 Change Management

The computer system that used for study data collection should have a change management system in place to manage the changes to the system during its lifecycle. It is the responsibility of the CI to provide the documentation required for the prioritising of any changes to the validated system including testing.

## 7. Associated documents and SOPs*

| Document Name | File Path | Author |
|---|---|---|
| Appendix 1: Risk Assessment for Computer System | Available upon request from the Joint R&D Office | Praseeda Thaikalloor |
| Appendix 2: Computer System Validation Plan | Available upon request from the Joint R&D Office | Praseeda Thaikalloor |
| Appendix 3: Computer System Validation Report | Available upon request from the Joint R&D Office | Praseeda Thaikalloor |

## 8. Recommendations

**NA**

## 9. References

MHRA Good Clinical Practice Guide 2012

DIRECTIVE 2001/20/EC of the European Parliament and of The Council of 4 April 2001 on the approximation of the laws, regulations and administrative provisions of the Member States relating to the implementation of good clinical practice in the conduct of clinical trials on medicinal products for human use. Official Journal of the European Communities, 1 May 2001; L121/34-44

The Medicines for Human Use (Clinical Trials) Regulations 2004 and subsequent amendment

## 10. Appendices

*all these documents are available electronically