Standard Operating Procedure			***51.037***
Storage and Transfer of Laboratory Data for Clinical Trials and Investigations Sponsored by NHS Greater Glasgow & Clyde (NHS GG&C) or Co-Sponsored by NHS GG&C & University of Glasgow*.*			
Version	**1.0**		
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1. SOP Category
NHS GG&C Sponsor R&I

2. Staff Category
R&I Lead Pharmacist
Pharmacovigilance and Safety Manager
R&I Coordinators (Sponsor Representative)
Project Managers
Clinical Trials Monitors
R&I Governance
Chief Investigators (CIs)

3. Scope
This procedure applies to all NHS GG&C staff with Sponsor responsibilities as listed above.

4. Purpose
The purpose of this SOP is to outline the Sponsor requirements to ensure that laboratory data collected within a clinical trial is stored, transferred and validated in a suitable manner in line with regulatory guidance ([1])

The SOP acts in concert with standard data storage and transfer procedures carried out by the laboratory responsible for sample analysis and all data centres contracted for storage and statistical analysis of trial data and is not intended to replace internal processes utilised by these parties.

This SOP is applicable to all data relating to laboratory tests that meet the following criteria:

- Determining patient eligibility
- Assessment of patient safety
- Informing the primary and secondary outcomes

AND are either:

a) a standard test carried out with specific additional requirements (Category 2, as per SOP 51.028[2])

OR

b) nonstandard research tests (Category 3 tests, as per SOP 51.028[2])

5. Purpose

5.1. Storage of laboratory data

Laboratory data must be pseudanonymised (unless specifically stated within the protocol and PIS) and stored on secure NHS servers where possible. If data is held outside the NHS **or registered CTU** the method of electronic storage should be compliant with ISO 27001 or equivalent at a minimum. **Compliance with the Cyber Essentials and Cyber Essential +** ([3]) **schemes are desirable.** It is preferable for laboratory data to be entered directly into a trial database (eCRF) hosted on servers provided by a registered CTU or a third party compliant with the NHS data security and protection toolkit ([4])

5.2. Transfer of laboratory data

Where laboratory data is not directly entered into the eCRF by participating site staff, procedures must be in place for the transfer of data from the laboratory to the party responsible for holding the trial dataset. The data to be transferred must be pseudoanonymised prior to any transfer of data between parties (unless explicitly stated otherwise in the protocol and PIS).

The mechanism of transfer by electronic means such as FTPS, HTTPS, or direct upload to a secure server is acceptable providing the data is fully encrypted at all points during the transfer process. Data should be password protected with a strong password and must be able to be checked for integrity from sending to receipt (see section 5.5). As per the requirements for storage the method of transfer should be compliant with ISO 27001 or equivalent at a minimum. Compliance with the Cyber Essentials and Cyber Essential + schemes are desirable ([3])

Where data is transferred via physical media the encryption standards stated above apply and the media must be sent via courier or equivalent to ensure that the chain of custody is fully tracked from sending to receipt.

The procedures for the transfer of data between the laboratory and data centre must be fully documented within a study-specific SOP and/or the laboratory manual (SOP 51.029 [5]).

5.3. Functional testing of data transfer process

Prior to any transfer of data between the laboratory and the data centre the data transfer mechanism must be tested using a dummy data set. The testing process must be fully documented within an SOP or the laboratory manual (SOP 51.029 [5]). The results of the test must be stored in the TMF.

5.4. Checking of data integrity

There must be a documented and validated method in place to ensuring that any data transferred between laboratories undertaking analyses for a trial and the data centre is identical.

The methods used to transfer this data into the trial database must also be fully documented and quality control procedures should be described within a study-specific SOP or the laboratory manual (SOP 51.029 [5]).

Where these process are not documented within a SOP then at a minimum data integrity should be monitored via the use of a validated solution designed to assess datasets to ensure consistency, for example the use of checksum algorithm. Where data is transferred between a laboratory and a data centre, processes to check file integrity must be agreed upon and detailed within the laboratory manual (SOP 51.029 [5]).

5.5. Audit trails

The data transfer process must be fully tracked and the method for documenting this process must be fully described within an SOP.

5.6. Escalation process

Any issues relating to the transfer of laboratory data throughout the trial must initially be notified to the Project Manager and discussed at study management groups. Where an issue cannot be resolved via discussion with the study management group it must be escalated to the Sponsor Oversight Committee. If a non-compliance with GCP is suspected SOP 51.008 must be followed.

6. Referenced documents

(1). EMA/INS/GCP/532137/2010: Reflection paper for laboratories that perform the analysis or evaluation of clinical trial samples
(2). SOP 51.028 NHS Laboratory Samples for Trials Involving an Investigative Medicinal Compound (CTIMP) Sponsored by NHS GG&C or Co-sponsored by NHS GG&C and the University of Glasgow
(3). https://www.dsptoolkit.nhs.uk/
(4). **https://www.ncsc.gov.uk/cyberessentials/overview**
(5). SOP 51.029 Writing Study Specific Laboratory Manuals for Trials Involving Investigational Medicinal Products Sponsored by NHS GG&C or Co-sponsored by NHS GG&C and the University of Glasgow
(6). SOP 51.008 Handling Non-compliance with Good Clinical Practice (GCP) and/or the Trial Protocol in Clinical Research sponsored, co-sponsored or hosted by NHS Greater Glasgow and Clyde

7. Related documents

None

8. Document History

Version	Date	Description
1.0	03/03/2022	First Release