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E-TMF Management

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Version	Date	Reason for Change
Version 1.0	12 Nov 2024	New Document

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1. PURPOSE

This SOP describes the requirements for management of an e-TMF system

The primary focus of the SOP is clinical trials of investigational medicinal products (CTIMPs) that fall under the remit of the Medicines for Human Use (Clinical Trials) Regulations 2004 (called "Clinical Trials Regulations") or equivalent international regulations. However, it is also relevant for any project conducted within the NHS, which has to meet the UK Policy Framework for Health and Social Care Research, and other clinical investigations that may have an impact on the safety and well-being of human participants.

2. INTRODUCTION.

A e-TMF is an electronic version of the TMF standard filing system which allows the effective storage and location of essential documents – the large volume of regulatory and approvals documents needed for clinical research. For further details on the documentation and overall requirements for a TMF please see RGIT_SOP_005

If after reading the guide anything is unclear or you would like to discuss study documentation in greater detail, please contact a member of the Research Governance and Integrity Team.

3. PROCEDURE

3.1. E-TMF use

An e-TMF can be used for non-CTIMP studies without prior permissions from RGIT but should meet the requirements below. For CTIMP studies e-TMF permission is in place for ICTU and the validated e-TMF system that they currently hold. In certain circumstances RGIT can permit the use of eTMFs outside of ICTU portfolio studies. However the CI would be responsible for providing extensive validation checks and assurances that the system meets all necessary regulatory requirements. An audit of the system will also likely be required and the CI will be responsible for any costs associated with this.
An e-TMF must contain accurate documents and ensure that all study information is recorded, handled and stored in a way that allows accurate reporting, interpretation and verification of all study data and meet the requirements and standards set out in SOP 005. Considerations should be given to the order of documents, version control, how amendments will be stored and recorded and how any deletion of documentation will be managed. E-TMFs should have an accurate audit trail

A e-TMF should be established as soon as possible after an outline protocol/proposal is available and/or first contact is made with a research sponsor. The Chief Investigator is responsible for setting up, maintaining, storing and archiving the e-TMF. This duty may be delegated to another member of staff on the Delegation and Signature Log.

E-TMF set up and management

Any e-TMF should be appropriately validated, both as an overall system and for each individual e-TMF. This should include UAT where applicable.

E-TMF and e-ISF users should be provided with appropriate training prior to access and this training should be kept on record.

Use of e-signatures and signing of documentation should be compliant with appropriate countries regulations with consideration given to international standards as applicable for CTIMP and non-CTIMP studies. Please refer to RGIT SOP 043 Electronic signature for further information. MHRA GxP guidance on how the signature is attributable to the individual, how signing is recorded within the system, how the signature is verified and the security of the signature to the owner should all be in place.

It is the responsibility of the CI to ensure that the e-TMF is set up and managed as per the regulations

3.2. Storage and access

As some documents within a e-TMF will be originals and/or contain confidential data, it is important that they are retained in a secure place, with restricted access. All members of the research team should have access to the e-TMF and those at site should have appropriate access to an e-ISF if being used. E-TMFs should have appropriate security arrangements in place. These should include overall system security alongside user access rights and there should be processes in place for providing and deletion of user access. Appropriate access will be required for sponsors, auditors and regulators in case of inspection. There should be an appropriate quality management system for the e-TMF to dictate access levels and their capabilities.

Documents should be maintained in a legible condition, with prompt retrieval possible and arrangements or backup of documentation. Documents should not normally sit outside of the e-TMF, but if there is a requirement for this then a document list should be in place to ensure that all documents are traceable. Access arrangements should be in place for monitors, auditors and regulators.

If documents are to be uploaded to the e-TMF from paper or wet ink copies (for example consent forms) then QC checks should be in place to ensure that all data is accurate. Documents should follow GxP guidance to ensure that they are ‘True Copies’

3.3. Archiving

Appropriate archiving arrangements need to be in place for the e-TMF and any associated e-ISFs. This will include not only all documentation but also any associated data and metadata such as audit trials and electronic signatures. Access will be required as per sponsor retention times and any regulatory requirements. If archiving is done via the a company who provide an e-TMF service then it should be ensured that access will be granted when required for the duration of the archive period. Any archived data needs to held securely and comply with RGIT SOP 019 Archiving

4. REFERENCES

ICH E6 (R2) Good clinical practice (cited 23 Sep 2024)

Medicines - The Medicines for Human Use (Clinical Trials) Regulations (cited 23 Sept 2024

UK Policy Framework for Health and Social Care Research (cited 23 Sept 2024)

MHRA GxP (cited 23 Sep 2024)

RGIT website:

RGIT - About Us (cited23 Sep 2024)
Imperial College London - Retention Schedule (cited 23 Sept 2024)

Clinical Trials Toolkit - TMF (cited 23 Sep 2024)

Guideline on the content, management and archiving of the clinical trial master file (paper and/or electronic) (cited 23 Sep 2024))

RGIT_SOP_005 (cited 23 Sep 2024)

RGIT SOP 043 (cited 09 Oct 2024)

RGIT SOP 019 (cited 09/10/2024)

5. APPENDICES

The following Appendices list the following Templates associated to this SOP which can be found on the SOP, Associated Documents & Templates page.

Appendix 1: Essential Documents to be maintained with a TMF – RGIT_TEMP_012
Appendix 2: Example Checklist for Inclusion with Research Project Files – RGIT_TEMP_013
Appendix 3: RGIT & Site Contact Details – RGIT_TEMP_014