Title: **Standard Operating Procedure (SOP): Use of Florence eTMF for MCRI-Sponsored Investigator-Initiated Clinical Trials (IITs) Trial Master File (TMF), Site Investigator File (SIF) and Investigator Site File (ISF) Electronic Records and Electronic Signatures**

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The author is signing to confirm the technical content of this document

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These signatures confirm the reviewers agree with the technical content of the document and that this document is approved for implementation at the Melbourne Children's Campus.

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This document is effective from the date of the last approval signature and will be reviewed in two years.

Document History

Revision	Modified by	Change No.	Description of Change
1.0	NA		New Issue

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1. Purpose

1.1. Clinical Trial regulations require maintenance of documentation of all study-related activities. Investigators are responsible for maintaining study documents in accordance with all applicable regulations, International Conference on Harmonization (ICH) Good Clinical Practice (GCP) Guidelines, and departmental procedures.

1.2. At all times, study documents must be readily accessible for review and/or inspection by the relevant regulatory agency (e.g., the Therapeutic Goods Administration (TGA), approving Human Research Ethics Committee (HREC), local research governance office, Monitor and/or MCRI personnel as appropriate.

1.3. This Standard Operating Procedure (SOP) describes the identification and storage of regulatory Essential Documents for clinical research studies and trials in Florence eTMF and to establish the process by which the Organisational Administrator and Team Administrator controls user access, delegates study-related responsibilities to applicable personnel, describes how electronic documents are managed, and how electronic signatures are applied to documents.

1.4. Essential documents are defined by Good Clinical Practice (GCP) as "documents which individually and collectively permit evaluation of the conduct of a study and the quality of the data produced". These documents serve to demonstrate the compliance of the Investigator, Sponsor, and Monitor with the standards of Good Clinical Practice and all applicable regulatory requirements, privacy, and health records legislation.

2. Scope

2.1. This SOP applies to Melbourne Children's campus employees who undertake the role of Sponsor-Investigator for an Investigator-Initiated Clinical Trial or a member of the research team that has been delegated the responsibility of managing essential documents by the Sponsor-Investigator, and covers all MCRI-sponsored investigator-initiated clinical trials.

2.2. This SOP refers to the Central Trial Master File, Site Information Files, and Investigator Site Files, when MCRI are acting in the role of the Sponsor for an IIT.

2.3. The Sponsor-Investigator/delegate is responsible for preparing, updating, and archiving the Trial Master File (TMF), Site Information File(s) (SIFs) and Investigator Site File(s).

2.4. The Sponsor-Investigator/delegate is responsible for ongoing maintenance of the Trial Master File (TMF) and the TMF Site Information File(s) (SIFs).

2.5. The Principal Investigator/delegate at each participating site is responsible for updating, maintaining, and archiving the Investigator Site File (ISF).

2.6. This SOP applies to all electronic records for the clinical research studies and trials where Florence eTMF is utilised by this organisation. Documents with more than one purpose or that are applicable to more than one study (e.g., site staff CVs, training certifications, investigator professional licenses, site facility information, laboratory normal ranges, NATA Accreditation certificates etc.) may be stored centrally, in a non-study specific location within Florence.

2.7. This SOP applies to personnel engaged in the collection, creation, completion, maintenance, and/or storage of Essential Documents from the planning and study startup stage through study completion, effective with studies starting on or after the Florence "Go Live Date" at MCRI.

2.8. Legacy studies are defined as studies that were activated prior to the implementation and use of the Florence Platform. Legacy documents will be maintained following MCRI's current Essential Documents SOP [SOP# MCTC013 – Management of Essential Documents], with exceptions on a case-by-case basis, and in consultation with the MCRI Florence Support Team.

2.9. Where required, legacy studies identified for migration into Florence will be migrated from existing MCRI infrastructure or scanned, verified for completeness, and signed as certified copies. Migration will be validated by the Organisational Administrator(s) or delegate and documented upon completion. Migration of studies may not occur until an SOP has been developed for this process. Post migration, legacy studies and corresponding legacy documents will comply with this SOP.

2.10. This SOP excludes participant records, which will be maintained via the Electronic Medical Record (i.e. EPIC), as well as:

- Original wet-ink signed contracts/agreements, if applicable
- Investigational Product accountability records.

3. Responsibilities

3.1. The Team Administrator(s) or other appropriate User is a representative designated by the Organisational Administrator who is responsible for maintaining eTMF documents in a timely and organized fashion.

3.2. The Team Administrator(s) or delegate assigns the relevant Binder structure template for indexing the storage of electronic study documents depending on the type of clinical trial being conducted.

3.3. The Team Administrator(s) or delegate is responsible for ensuring that the appropriate Users (including external sites, monitors and auditors), have the necessary access and permissions to conduct document management, completion, review, and archiving as detailed in the Team Access Control section below.

3.4. Site Users have sole control of site records. To ensure sole control of a site's electronic records and protect the availability of eISF documents that are created, modified, and signed in Florence, the Team Administrators or delegate will not turn off a site's access to view and download records from site designated eBinder and Folder location(s).

4. Policies and Procedures – User Account Creation and Access Control

4.1. Overall maintenance of the MCRI Florence Account, User Accounts, User Roles, and User access in the Florence eTMF system, including how to create, delete, modify, or revoke a User Account, is managed by the Organisational Administrator(s) or delegate.

4.2. Organisational Administrator(s) or delegate will approve the creation and termination of all new Teams and delegate which Users will be the Team Administrator(s). The Organisational Administrator role is intended to manage team account settings (e.g., time zone, password reset policy, imports standardised filing structures and templates, etc.), as well as create the Team Administrator role(s) that will be used to manage Role Permissions.

4.3. The Team Administrator or delegate will determine Role permissions based on designated study related tasks, and will assign Roles, manage access dates, and conduct periodic reviews to verify

the status of all Users. For Participating Site Users, access to Florence eTMF will not be disabled as long as MCRI has a contract with Florence.

4.4. The Team Administrator(s) or delegate will notify the Organisation Administrator to create, modify, and terminate User accounts.

4.5. The Organisation Administrator may submit a written request to Florence [support@florencehc.com] to assist with creating new User accounts.

4.6. All users of the Florence platform (both internal and external to MCRI) should notify the Team Administrator(s) about any change of employment status, including holds (e.g., termination of employment or leave of absence).

4.7. All users of the Florence platform (both internal and external to MCRI) should maintain a unique, secure, and private password. For users using Single Sign-On (SSO) for authentication, Florence signing PINs are used to sign documents. Passwords and signing PINs are to be periodically checked, recalled, and revised, as necessary. Florence Password and PIN reset policies are configured at the team level.

4.8. Written requests for new eBinders in Florence eTMF may be submitted via the MCRI Florence web-page by any MCRI employee/honorary. The MCRI Florence Team will review all requests and forward the request to the MCTC Business & Operations Manager or delegate for approval, documentation, and billing prior to the creation of any new eBinder.

4.9. User Account Creation:

4.9.1. The User provides the following information to the Team Administrator(s) or delegate to request initiation of his/her account:

- First Name
- Last Name
- Position Title/Role
- Organisational Email Address
- Clinical Trial Name/Acronym

4.9.2. The Team Administrator(s) or delegate will arrange for the new User to be trained on Florence eTMF.

4.9.3. Upon completion of the training, the new User shall submit acknowledgment of completed training to the Team Administrator(s) or delegate to receive access to Florence eTMF, as outlined in the organisation's policy to receive access to Florence.

Note: The Florence Training Attestation form serves as additional evidence that a user's specific electronic signature is the legally binding equivalent of the signer's handwritten signature.

4.10. User Account Initiation:

4.10.1. The Team Administrator(s) or delegate will initiate the new User's account.

4.10.2. The User's unique authorised organisation email address is added, an appropriate Role is assigned based on MCRI's approved Roles, and access dates are assigned to the new User. This will grant the User the permissions to perform delegated functions.

4.10.3. The MCRI Florence Support Team may assist in creating new Roles based on documented permission requests from the Team Administrator(s) or delegate, however they may not assign Roles or access dates to specific Users. All assignments must be completed by the delegated Team Administrator(s) or delegate.

4.10.4. For new Users not using Single Sign-On (SSO) authentication, the new User will receive an email notification from Florence with a link to the Florence eTMF URL to complete the User registration process.

4.11. User Account Modification:

4.11.1. Upon a change in status impacting the use of Florence eTMF for a User, the Team Administrator(s) or delegate modifies the User's Role(s) and Permissions and notifies the User of the change(s).

4.11.2. The MCRI Florence Support Team may assist in modifying existing Roles based on documented requests from the Team Administrator(s) or delegate. Written requests must include a list of all impacted Users as well as the modifications requested. MCRI Florence Support Team will complete the request and provide a confirmation to the Team Administrator(s) or delegate. The Team Administrator(s) or delegate are responsible for verifying that Roles created and/or modified by MCRI Florence Support are appropriate.

4.11.3. The Team Administrator(s) or delegate must conduct periodic reviews of all Users in Florence eTMF to ensure that all Users have the correct permissions and are still active. The following process should be followed:

- Periodic reviews of all Users should occur every six (6) months
- Alternatively, ongoing User reviews can occur in real-time by reviewing specific roles against the study's Signature and Delegation of Authority Log, removing Users as they cease their active participation within the study
- Documented evidence of periodic reviews must be maintained – this can be in the form of a User Access Report (generated via Florence) or the use of a User Access Sign-Off Form.

Refer to the Florence Periodic Reviews Workflow for further details and instructions on undertaking periodic User reviews.

4.12. User Account Holds and Revocation:

4.12.1. Temporarily inactive Users can have access dates turned OFF and Roles maintained without access. Examples of temporarily inactive Users includes Users on a leave of absence, with plans to return.

4.12.2. Upon a change in employment status for a User that discontinues the need for specific Team access and/or all Florence eTMF use, the Team Administrator(s) or delegate removes

all permissions for the User and removes the User from each appropriate Team in Florence eTMF.

5. Policies & Procedures – Electronic Document Management

5.1. Requirements for documentation, record keeping, and record retention apply to electronic records as they do for paper systems.

5.2. Key study documents will be managed, stored, and presented electronically. Participating sites should be notified of this SOP prior to study initiation.

5.3. User access control to electronic documents is described in the Team Creation and User Access Control section above.

5.4. Electronic security controls, secure backup schedule, and routine vulnerability testing are described in the Florence Security Overview and Florence Healthcare Disaster Recovery Plan, both provided and maintained by Florence Healthcare, Inc.

5.5. Retention and/or destruction of electronic documents in Florence eTMF at the conclusion of the study is performed in accordance with local institution/HREC policies and procedures as established in accordance with the TGA's annotation of ICH GCP E6 (R2) and the Australian Code for the Responsible Conduct of Research.

5.6. Electronic Certified Copies

5.6.1. Electronic documents may include a blend of original and certified copies. Electronic certified copies are defined as copies that have been created and verified against the original and tracked with a dated signature. Electronic signatures with an audit trail demonstrate evidence of authenticity.

5.6.2. Per ICH GCP E6(R2), the data are to include the context, content, and structure, as the original. The ICH GCP guideline requires that copies (irrespective of the media used) in the eTMF that irreversibly replace originals should be certified copies of the original.

5.6.3. The copy is to have all of the same attributes and information as the original.

5.6.4. Only the User who possesses the original copy may create the Electronic Certified Copy.

5.6.5. The User who possesses the original copy of the Document will upload an electronic copy of the Document into Florence, review and verify the uploaded Document for completeness and readability and then sign the Document as a Certified Copy.

5.6.6. The audit trail will track and record the timestamp, reason, and author for authenticity and responsibility.

5.7. Central Documents and General Files

5.7.1. Documents that will be used across studies or sites can be maintained centrally.

5.7.2. Links, or shortcuts, will allow Users to access central documents as appropriate based on the User's access controls assigned. Shortcuts are to be used for viewing purposes and not as part of the official study records needed for archiving. Note: Shortcuts reflect the document's current version and are updated with each new version.

5.7.3. Central documents may include, but are not limited to CVs, medical licenses, NATA Accreditation certificates, laboratory reference ranges, MCRI templates, SOPs, Florence training attestation, and GCP training certificates.

5.8. Monitor, Auditor, and Inspector Access

5.8.1. Monitors, Auditors, and Inspectors will be given access to Florence eTMF by following the guidelines described in the Team Creation and User Access Control section above.

5.8.2. All access is monitored via the audit trail.

5.9. Document Version Control

5.9.1. Version tracking within Florence eTMF will be utilised for final and/or approved documents only, including but not limited to completed forms, logs, and redacted documents. Draft and/or development versions of essential and/or study document will be maintained outside of the Florence eTMF, within MCRI approved network servers/infrastructure or online platforms and in accordance with the MCRI Data Protection Policy and Procedure.

5.9.2. Designated "Archive" folders can be used for version tracking of approved documents such as HREC approved Informed Consents, Protocol Versions, etc. Alternatively, per each Team's preference, designated "Archive/Superseded" folders can be used for version tracking of approved documents such as HREC approved Informed Consents, Protocol Versions, etc.

5.9.3. The version tracking tool maintains each version of the document and the audit trail logs, the action of modification by authorized Users, date of modification, as well as the time stamp of modification to verify compliance with GCP.

5.10. Personally Identifiable Information (PII)/Protected Health Information (PHI) Records

5.10.1. If a Participating Site's SOP allows the upload of PHI records (that are not pseudonymized) into the eTMF, Participating Site Users are to be trained in how to redact the source documents or to flag the document as PHI to ensure that only Users with permission to View Documents with PHI will see the records.

6.0 POLICIES & PROCEDURES – ELECTRONIC SIGNATURES

6.1. This section applies to all documents and clinical research studies and trials where Florence eTMF is utilised by MCRI and where electronic signatures and handwritten signatures executed to electronic documents are intended to be equivalent to paper records and handwritten signatures.

6.2. For clinical trials regulated by the US FDA, the Organisational Administrator, or other delegated individual will complete and submit a non-repudiation letter to the FDA prior to the use of electronic signatures on any clinical trial document attesting to the fact that their electronic signatures are legally binding equivalents of their traditional hand-written signatures.

6.3. All Florence eTMF Users will be responsible for maintaining secure passwords and updating them every six (6) months.

6.4. Users are responsible for reviewing their accounts for pending signature requests on a regular basis.

6.5. The Team Administrator(s) or delegate will verify the identity of each Florence eTMF User per the Team Creation and User Access Control section and if applicable, via the email-based User registration process for non-SSO Users. The Team Administrator(s) or delegate is also responsible for ensuring that the appropriate individuals have the necessary User permissions and access to request signatures and/or sign documents in Florence eTMF.

6.6. Electronic signatures may be used for all documents stored in Florence eBinders™, except in some instances, where documents may be provided with original wet-ink signed initials and/or signatures. Some examples include:

- Wet-Ink Signature Log
- Signature & Delegation of Authority Logs
- Training Logs
- Site Initiation Visit Attendance Logs
- Others, as required.

Refer to the Florence Workflows and eSignature Reference Guide for a full list of original wet-ink documents maintained within the eTMF.

6.7. Each electronic signature shall be unique, using the individual's organization email address as the unique identifier in Florence eTMF.

6.8. When a document is signed in Florence eTMF (via Addendum or Stamp), the details of each electronic signature is listed on the signature addendum page, which can be included when the document is downloaded. If the Stamp signature option is used, the signature is also visible on the document itself.

6.9. Signatures only apply to the version of the document signed. Any updates to a version of the document do not carry over signatures from the previous version. Any updates which require review, acknowledgment, and/or approval must be signed by the appropriate Users.

6.10. Use of the Addendum (invisible) signature option and the Stamp (visible) signature option are seen as equivalent and can be utilized on all electronic documents interchangeably as both signature types maintain the details required by US FDA 21 CFR Part 11.

6.11. Signature Requests

6.11.1. Signature requests can be made by individuals with the appropriate permission and access to do so within Florence eTMF.

6.11.2. The individual requesting an electronic signature is required to specify the:

- Document that requires the electronic signature(s)
- User(s) who need to sign the document
- Reason/meaning of each signature (i.e. Approval, Acknowledgment, Authorship, Certified Copy, Responsibility, or Review)

- Optional Signature Type, either Addendum (invisible on the document) or Stamp (visible on the document)
- Optional Sign by Date to specify the date by which the document must be signed

Refer to the eBinders Workflows and eSignature Reference Guide for further details on requesting eSignatures, the type of eSignature which should be on documents and the corresponding reason.

6.12. Signing Documents

6.12.1. The individual signing the document reviews the document and the requested reason for their signature in Florence eTMF.

6.12.2. If s/he agrees, the username (authorised organization email address) and password (or signing PIN) are entered, and the system confirms that they match the User's verified secure credentials.

6.12.3. The signature addendum page and audit trail for the document are updated to reflect the new electronic signature, its reason/meaning, and the date and time of execution.

7.0 Policies & Procedures – Email Correspondence

6.13. As set forth in organisational and sponsor guidelines, all relevant study and trial-related correspondence with ethics committees, regulatory agencies, sponsors, participating sites, and study team members should be retained for review.

6.14. A User can forward an email and related attachments to the appropriate location within Florence eTMF using the 'Import via email' function if they are granted the appropriate permissions to do so.

6.15. Once emails are received in Florence eTMF, renaming of the emails for organisational purposes is permitted by a User with permissions to do so.

8.0 Wet-Ink Signature Log

6.16. This process includes the completion and maintenance of the Signature Log for any clinical research studies and/or trials that include wet-ink handwriting for eTMF documents.

6.16.1. The purpose of the Signature Log is to have a record of the handwriting sample of every individual involved in the study-related activity.

6.16.2. An individual Signature Log should be maintained for each team member who participates on a study or trial that uses wet-ink handwriting.

6.16.3. At a minimum, the Signature Log will include:

- Printed name
- Signature
- Initials
- Numbers 0-9
- Date when the Signature Log was completed

6.16.4. The Team Administrator or delegate will initiate the Signature Log with each new User.

6.16.5. Each User should provide a complete handwritten copy of the Signature Log.

- Each completed Signature Log will be uploaded and stored in Florence eTMF.
- In case of a name change for a Team member, a new Signature Log must be created and uploaded to Florence eTMF.

9.0 Applicable Regulations and Guidelines

- E6(R2) Good Clinical Practice: Integrated Addendum to ICH E6(R1), Guidance for Industry (here)
- US FDA 21 CFR Part 11 Electronic Records; Electronic Signatures (here)
- General Principles of Software Validation; Final Guidance for Industry and FDA Staff (here)
- Part 11, Electronic Records; Electronic Signatures – Scope and Application (here)
- Use of Electronic Records and Electronic Signatures in Clinical Investigations Under 21 CFR Part 11 - Questions & Answers (here)
- US FDA 21 CFR Part 312.62(c) – Investigational New Drugs – Drugs for Human Use (here)
- US FDA 21 CFR Part 812 – Investigational Device Exemption (here)
- US FDA Industry Guidelines and Information Sheets (here)
- FDA Compliance Policy Guidance Programs (here)
- Australian Code for the Responsible Conduct of Research - here
- EMA Guideline on the content, management and archiving of the clinical trial master file (paper and/or electronic); dated: 06 December 2018. EMA/INS/GCP/856758/2018 - here

10.0 Related Resources:

- Management of Essential Documents SOP
- Florence eBinders™ User Guide
- Florence eBinders™ Dashboard User Guide
- Florence eBinder™ Icon Gide
- TMF Filing Guidance Document [MCTC014]
- ISF Filing Guidance Document [MCTC093]
- SIF Filing Guidance Document [MCTC033]
- eISF/eBinders™ Workflows and eSignature Reference Guide for Investigator-Initiated Studies [MCTC104]
- eTMF eISF/eBinders™ Workflows and eSignature Reference Guide for Investigator-Initiated Studies [MCTC105]
- Florence Periodic Reviews Reference Guide

- Florence Roles & Permissions Reference Guide
- Wet-Ink Signature Log Template [MCTC097]
- Wet-Ink Signature Page Template [MCTC099]
- MCRI Data Protection Policy and Procedure
- MCRI Research Data Storage, Retention & Disposal

11.0 GLOSSARY

Delegate
A person delegated specific tasks appropriate to their expertise and training.

eBinders:
Binders are the key organisational concept behind Florence eBinders™. The electronic Binder is meant to mirror a paper ISF binder and contains Folders, Documents and/or Placeholders.
You can manage all aspects of a clinical trial's documentation needs with Binders. Key features include:

- Add and organise Folders and Documents within it
- Standardise all your new trials by Importing a Folder Structure
- Designate Placeholders for pending Documents and set due dates for receipt
- Set expiry dates on certain Documents requiring follow-up
- Quickly assess Folder and Document status
- Access Document tools such as redaction and annotation, as well as Audit Logs
- Manage Document signature and sharing workflow

Essential Documents:
Documents which individually and collectively permit evaluation of the conduct of a study and the quality of the data produced. These documents serve to demonstrate the compliance of the Investigator, Sponsor, and monitor with the standards of Good Clinical Practice with all applicable regulatory requirements.

Good Clinical Practice (GCP)
A standard for the design, conduct, performance, monitoring, auditing, recording, analyses, and reporting of clinical trials that provides assurance that the data and reported results are credible and accurate, and that the rights, integrity, and confidentiality of trial subjects are protected.

International Conference on Harmonisation (ICH)

International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use is a joint initiative involving both regulators and research-based industry focusing on the technical requirements for medicinal products containing new drugs.

Investigator Site File (ISF):
A collection of essential documents used by the Principal Investigator for the management of the trial at the site and , auditors and inspectors to review and verify whether the Principal Investigator has conducted the trial in line with the applicable regulatory requirements and the principles and standards of GCP. Format may be paper or a combination of paper and electronic.

Melbourne Children's
This term is used to encompass all staff from The Royal Children's Hospital, Murdoch Children's Research Institute and Department of Paediatrics University of Melbourne who initiate or carry out research under one or more of these institutional affiliations.

Monitor:
A person appointed by the Sponsor to undertake the role of monitoring for the trial. Monitors should be appropriately trained and should have the scientific and/or clinical knowledge needed to monitor the trial adequately.
A monitor's qualifications should be documented. They should be thoroughly familiar with the investigational product(s), the protocol, written informed consent form and any other written information provided to participants, the Sponsor SOPs (both institutional-level and trial-specific), Good Clinical Practice (GCP), and the applicable regulatory requirements.

Organisational Administrator:
A person or person(s) appointed by MCRI to oversee and manage the entire Florence platform. The Organisational Administrator creates new Roles, Binders and Folders for studies, assigns, and controls access to newly created Binders and Folders, defines User Roles and maintains these Roles within the platform and is responsible for the ongoing overall maintenance of the platform. The Organisational Administrator role manages the MCRI team account settings (e.g., time zone, password reset policy, imports filing structures and templates etc.), as well as create the Team Administrator role(s) that will be used to manage Role Permissions.

Permissions:
Authorised Users have the option to edit Permissions for access to Binders, Folders, Documents, and Placeholders. This allows Team Owners and Team Administrators to determine which actions are available to other Users. Permissions are assigned by creating Roles, editing their Permissions, and assigning those Roles to Users. Permissions are most relevant to Roles when performing tasks such as defining the visibility of a Document and sharing Documents.

Permissions that can be enabled or disabled include:

- Binder, Folder, and Document management

    - Create
    - Destroy
    - Duplicate
    - Move
- Document editing tools
    - Annotate
    - Highlight
    - Redact
    - Stamp
- Expiration and due date management
- Signature management
    - Request Signature
    - Sign Document
- Task management
- Ability to view documents with PII

Role:
A Role is a set of permissions that you can assign to one or more users. Common Roles are: Monitors, Investigator, Sub-Investigator, Coordinator or Team Admin.

Only Users with Organisational Administrator permissions can create and edit Roles.

Roles improve Permission management by allowing Teams to "group" similar Users together and select the appropriate Permissions for all Users in the group instead of having to manage Permissions directly for each User. Updating the Role updates Permissions for ALL Users assigned to that Role.

For example, you may create a Team Administrator Role that has Permissions to manage a Team and its contents, but that cannot download or view Documents with PII.

Sponsor-Investigator/Coordinating Principal Investigator/Principal Investigator
An individual responsible for the conduct of a study at a study site, ensuring that the study complies with GCP guidelines.
If a study is conducted at more than one study site, the Principal Investigator taking overall responsibility for the study and for the coordination across all sites is known as the Coordinating Principal Investigator (CPI) or Chief Investigator; the Principal Investigator at each site will retain responsibility for the conduct of the study at their site.

If a study is conducted by a team of individuals at a study site, the investigator is the responsible leader of the team and may be called the Principal Investigator. In this instance they may delegate tasks to other team members.

Note that for investigator-initiated research, the PI or CPI leading the research takes on responsibilities of the Sponsor and the term "Sponsor-Investigator" should be adopted to highlight the dual sponsor and investigator role.

Team Administrator:
A person or person(s) delegated by the Sponsor-Investigator to oversee the management of the eTMF/eSIF/eISF. Team Administrators generally have full permissions on all current and future study Binders and Folders. They will be able to invite and remove Users, have access to centrally filed study documents, request eSignatures and all major functions the platform offers. Typically, this role pertains to a Central Trial Coordinator/Clinical Trial Manager.

Trial Master File (TMF):
A collection of essential documents used by the Sponsor/Sponsor-Investigator and Clinical Research Organisation for the management of the trial and by Monitors, Auditors and Inspectors to review and verify whether the Sponsor/Sponsor-Investigator has conducted the trial in line with the applicable regulatory requirements and the principles and standards of GCP. Format may be paper or a combination of paper and electronic.

User:
A User is an individual within Florence eBinders™ who has been assigned with a specific Role. Each individual on a Team must register in Florence eBinders™ as a unique User. Team Administrators can assign Users one or more Roles based on their participation needs on the Team.