NHS
Royal Papworth Hospital
NHS Foundation Trust

Also reference SOP011, SOP013, SOP015, SOP041, SOP060 and SOP064

TMF and eTMF Process Guidance Document

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1. Introduction

A Trial Master File (TMF) is a collection of essential documents that tell the story of your study, documented proof that it was conducted well and allow the conduct of the trial to be reconstructed. TMF is used as an umbrella term including both the Sponsor File, held by the Sponsor organisation and the Site File/s held by the Investigator/Site (one Site File for each participating site).

The TMF (the Sponsor File and Site File/s) are used by Sponsors and Investigators/Sites for the management of a study. The files are also used by Monitors, Auditors and Inspectors to review and verify whether the Sponsor and the Investigator/Site have conducted the study in line with the applicable regulatory requirements and the principles and standards of Good Clinical Practice (GCP).

In clinical research, essential documents are defined as documents which individually and collectively permit evaluation of the conduct of a trial and the quality of the data produced. GCP guidelines list a number of essential documents, but it is always expected that a TMF will contain more than just this list, as appropriate to the study and at the discretion of the study team.

The Sponsor File is held by the Sponsor organisation and the Site File/s (also sometimes referred to as the Investigator Site File) is held by the Investigator/Site. This is to segregate some documents that are generated and/or held by the Sponsor only, from those that are generated and/or held by the Investigator/Site only (e.g., master randomisation list filed in the Sponsor File only and subject identification code list filed in the Site File only).

The Sponsor File and Site File/s will be established at the beginning of the study. For a Royal Papworth sponsored study, both a Sponsor and a Site File for each participating site will be set up (unless RPH is the only site then these files can be combined). For a non-Royal Papworth sponsored study, only a Site File will be set up as the external Sponsor is responsible for maintaining their Sponsor File.

1.1. Glossary of Terms

CTIMP – for the purposes of this document means a clinical trial involving an investigational medicinal product where regulatory approval from the MHRA is required.
Device – for the purposes of this document means a clinical investigation of a non-CE/UKCA marked device or other device study, where regulatory approval from the MHRA is required.
Non-CTIMP – for the purposes of this document means a trial/study not involving an investigational drug or a non-CE/UKCA marked device, where no approval from MHRA is required (for example an Observational Study).

1.2. Selecting the correct Index

It is good practice for a TMF to follow a standardised index indicating the essential documents that must be included. This gives a clear, <u>standardised</u> structure for the Sponsor and Site File/s as well as guidance on what should be filed in each section. At RPH we have four indexes listed below.

- Sponsor File Index (FRM021)
- Site File Index (FRM068)
- Accompanying eTMF paper folder Index (FRM073)
- Pharmacy File Index (FRM070)

1.3. Selecting the correct TMF format

The TMF can be created as a paper TMF or as an electronic TMF (eTMF), the decision will depend on the type of study being conducted.

Paper TMF

All CTIMP and Device (non-CE/UKCA marked) studies must have a paper TMF. All essential documents must be printed and filed as paper. Electronic folders will be available on the N: drive but must only be used as a back-up and to organise documents for printing. They are **not** considered part of the TMF and cannot be referred to as an eTMF.

> Paper TMF = Sponsor File + Site File/s
> (Paper file + back-up electronic folders)   (Paper file + back-up electronic folders)

eTMF

Non-CTIMP studies will have an electronic TMF (eTMF), unless the external Sponsor objects. All essential documents will be kept in the electronic folders created in the N: drive. An '*accompanying eTMF paper folder*' will also be set up to complement the eTMF, as some documents will always need to be filed as paper (e.g., wet ink signed consent forms, wet ink signed contracts).

> eTMF = Sponsor File + Site File/s
> (Electronic folders + accompanying eTMF paper folder)   (Electronic folders + accompanying eTMF paper folder)

Quick TMF Format and Index reference table

Trial Type	TMF format	Index Form Reference		
		Sponsor	Site	Accompanying eTMF paper folder
CTIMP	Paper	pFRM021	pFRM068	N/A
Device	Paper	pFRM021	pFRM068	N/A
Non-CTIMP	Electronic	eFRM021	eFRM068	pFRM073

Pharmacy is responsible for setting up their own paper file for CTIMP trials using the FRM070 index. This will not be mentioned any further in this guidance.

1.4. Electronic folders on the N: drive

Regardless of whether a paper or electronic TMF is being set up, an electronic folder structure for the study will be established automatically on the N: drive by the Governance team.

The TMF will be identified by the R&D code (P0XXXX/CRFXXXX) and a brief study title.

P0XXXX Folder on the N:drive (R&D PROJECTS)

- Governance (for Gov team only)
- Site File
- Sponsor File
- Working Documents - Site
- Working Documents - Sponsor

Governance Folder

There will always be a 'Governance' folder. This will be used for document storage by the Governance team only and **should not be accessed by the study team**. Please note that the Governance team will have filed any pertinent documents/emails in the Sponsor and Site File/s when the set-up is complete, and they hand over the study.

Sponsor File and Site File (Back-up electronic folders or eTMF)

These two folders will be built in the same way whether a paper TMF or an eTMF is being set up, but their use will differ.

If the study requires a paper TMF, the electronic folders will be used only as a backup and should continue to be referred to as the '*back-up electronic folders*' (they should not be referred to as an eTMF).

If the study allows the use of an eTMF, these folders will serve as that eTMF and will be used as the repository to store all essential trial documents. In this case the electronic folders can be referred to as the eTMF.

Refer to Section 1.3 to check which TMF format your study will require.

Working Documents

For each TMF format, a Working Documents electronic folder will also be set up. However, they do not form part of the back-up electronic folders for the paper TMF and they do not form part of the eTMF.

The purpose of this folder is to serve as the day-to-day 'go to' folder for the study. The study team has full control over how this is set-up and what sub-folders are created and used. Essential documents will be drafted here and final Word copies of essential documents (i.e., that are filed as PDF in the Sponsor or Site File) will be saved here in case of the need to make amendments or corrections and re-version at a later date.

2. Setting up a paper TMF for a RPH sponsored study (Sponsor and Site file/s)

Quick TMF Format and Index reference table

Trial Type	TMF format	Index Form Reference	
		Sponsor	Site
CTIMP	Paper	pFRM021	pFRM068
Device	Paper	pFRM021	pFRM068

For a single site RPH Sponsored trial the Sponsor and Site files can be combined to avoid duplication.

2.1. Tailoring the index

The indexes should be reviewed by the study team when the TMF is set up so that they are tailored to the study. A tailored TMF means less need for multiple File Notes to explain empty sections that are not applicable to a study.

For both the Sponsor File and the Site File/s, open the electronic copy of the index. Use the 'Set-up' column to agree as a team which sections and documents are applicable to the study (refer to the example Site Index FRM068 shown below). If a section is applicable tick/check the 'Yes' box and if it is not applicable tick/check the 'N/A' box and add a comment to the 'Comments' field to explain why it is not applicable.

Do not delete any Section Numbers from the index.

NB: It is only expected that a very small handful of sections or documents will be marked N/A.

When making this decision it is important to think about whether the section or document will be needed throughout the lifetime of the study rather than just at the set-up stage (e.g., the publications section may not be applicable at the time of study set-up but may be needed during study close-out and reporting). Sections or documents that are definitely not applicable for a study will usually be very obvious (e.g., a Health Economics Analysis Plan will not be needed for a study with no health economics outcomes in the protocol).

2.2. Signposting in the index

The paper TMF may also rely on some electronic systems to facilitate trial management. Please note that these systems are different to the electronic folders used as back-up.

Any essential documents that will be stored in other electronic systems instead of directly in the paper TMF should be signposted by adding a comment to the 'Comments' field of the index. This will avoid the need to copy and duplicate documents between the systems and the paper TMF and will enable monitors and other staff to locate important trial-related documentation. For example:

- IQM for SOPS.
- R&D Samples logs (until the end of study, when the final log would be moved into the Site File).
- eForms in a database for recording file notes and protocol non-compliances (until EOT when these should be printed and field in the Sponsor/Site File as appropriate).

2.3. Adding a new section

If you need a section that is not already included in the index this must be discussed and approved by one of the eTMF project leads. Once approved the new section number and title can be added to the index as directed by the eTMF lead.

2.4. Final index

Once the index is agreed and finalized, the CI or delegate will approve the index by adding their name, Study Version Number and date of approval in the <u>header</u>. See diagram below.

The 'Study Version Number' is the index version number specific to the study, and this may change during the study if modifications are made. For example, the first index created will be V 1.0 and will become V2.0 if any changes are made during the life of the study.

Remember the <u>footer</u> states the index <u>template</u> version number, which will never change during the study and will not start from V1.0.
See below the Footer on the Site File Index and the version number available in March 2025:

FRM068: Site File Index
Version 8.0 Review Date: January 2028

2.5. Saving the index

The final indexes will be saved electronically in both Excel and PDF format and must be stored in Section 1.0 Sponsor (or Site) File Structure and QC in the back-up electronic folders of the N: drive.

The PDF version captures the 'Day 1' agreed TMF set-up as a reference and the Excel copy is available to amend if necessary, during the life of the study.

Approved indexes should then be printed and filed in Section 1.0 of the paper TMF.

2.6. Adjusting the back-up electronic folders to match the approved index

For the sections that have been marked as N/A in the index set-up column, go to the corresponding back-up electronic folder and add 'NOT IN USE' to the folder name. Do not remove or re-number back-up electronic folders as they must match the index section numbering.

Sub-folders in sections *'NOT IN USE'* can be deleted.
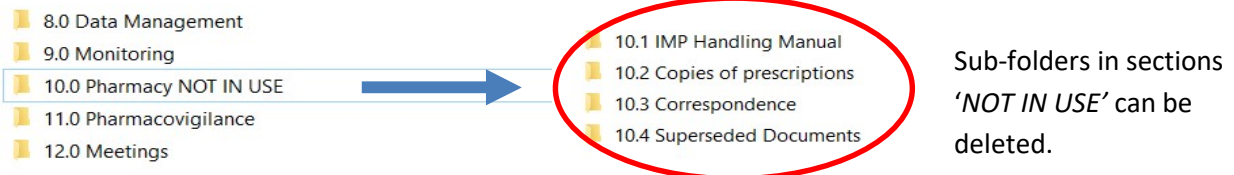
If new sections were added to the index as described in Section 2.3, the back-up electronic folders can also be updated to match the modified index.

2.7. New versions of indexes

When a new version of an index is released, an email will be sent to the TMF committee members, study teams will be notified at the next scheduled BUZZ meeting. The study teams should review the 'Version History' tab in the new version of the index to see if there are any new sections/ sub-folders that would be of benefit to organise the study documents.

To add new section/sub-folder from a newly released version of the index (issued on IQM) follow the steps outlined below.
   a. Open the saved excel file of your current in-use study index.
   b. Save a new copy of the index for editing.
   c. Insert a new row in the appropriate location and complete the section number and title.
   d. Insert 'Y' in the Set-up column and copy and paste the new guidance information.
   e. Add a comment that this section has been added from a new version of the index: Version X.0, dated XX/XX/XXXX. See example screenshot below.
   f. The edited index should then be saved with a new Study Version Number (in the header) for immediate use in the study, following the same method described previously in Section 2.4. Remember: the template number in the footer must not be changed.
   g. Add a new paper divider in the physical paper TMF for the new section and update the back-up electronic folders in the N: drive so it matches the new approved index.

		Set-up		Check		Guidance on folder and sub-folder contents	Comments (include signposting to documents stored in other systems outside the pTMF/eTMF)
		Y	N/A	Y	N		
8.6	Superseded Documents					Superseded versions of any documents pertaining to the Finance/Insurance/Indemnity of the study. Sub-folders can be added for organisational purposes.	
8.7	Insert new section here	Y				Copy guidance notes from the newly approved index	Section added from new version of index Version XX, dated XX/XXX/XXXX
9.0	Grants					Folder 9.1 can be duplicated if there is more than one grant.	

2.8. Superseding an index

Score through the superseded version of the paper index, add your initials and date as per GCP. Transfer the superseded index into the superseded documents section. Please note you may need to create this sub-section yourself.

In the back-up electronic folders on the N: drive, move the superseded index (Excel and PDF files) to the superseded section.

Start using the new version of the index.

3. Setting-up a paper TMF for a Non-RPH sponsored study (Site file only)

For studies that are not sponsored by RPH, the external Sponsor may provide their own Site File and Index for the RPH team to use. In this case, the review of the indexes as described above may not be applicable.

The back-up electronic folders on the N: drive will still be available for you to use. You are free to edit these folders to match the Non-RPH Sponsor index if you wish. You do not need to seek approval from the TMF Leads to makes these changes.

4. Setting-up an eTMF for an RPH sponsored study (Sponsor and Site file)

Quick TMF Format and Index reference table

Trial Type	TMF format	Index Form Reference		
		Sponsor	Site	Accompanying eTMF paper folder
Non-CTIMP	electronic	eFRM021	eFRM068	pFRM073

4.1. Tailoring the index

The indexes should be reviewed by the study team when the eTMF is set up so that they are tailored to the study. A tailored eTMF means less need for multiple File Notes to explain empty sections that are not applicable to a study.

For both the Sponsor File and the Site File/s, open the electronic copy of the index. Use the 'Set-up' column to agree as a team which sections and documents are applicable to the study (refer to the example Site Index FRM068 shown below). If a section is applicable tick/check the 'Yes' box and if it is not applicable tick/check the 'N/A' box and add a comment to the 'Comments' field to explain why it is not applicable.

Do not delete any Section Numbers from the index.

NB: It is only expected that a very small handful of sections or documents will be marked N/A.

When making this decision it is important to think about whether the section or document will be needed throughout the lifetime of the study rather than just at the set-up stage (e.g., the publications section may not be applicable at the time of study set-up but may be needed during study close-out and reporting). Sections or documents that are definitely not applicable for a study will usually be very obvious (e.g., a Health Economics Analysis Plan will not be needed for a study with no health economics outcomes in the protocol).

4.2. Signposting in the index

Electronic systems may be used to facilitate trial management. Please note that these systems are different than the electronic folders used the eTMF.

Any essential documents that will be stored in other electronic systems instead of directly in the eTMF should be signposted by adding a comment to the 'Comments' field of the index. This will avoid the need to duplicate documents between the systems and the eTMF and will enable monitors and other staff to locate important trial-related documentation. For example:

- IQM for SOPS, CVs and GCP Certificates.
- eForms in a database for recording file notes and protocol non-compliances.

Remember you may also need to add a comment to signpost the reader to paper documents held in the Accompanying eTMF paper folder. For example:

- Wet ink signed informed consent forms
- Wet ink signed contracts

4.3. Adding a new section

If you need a section that is not already included in the index this must be discussed and approved by one of the eTMF project leads. Once approved the new section number and title can be added to the index as directed by the eTMF lead.

4.4. Final index

Once the index is agreed and finalized, the Chief Investigator or delegate will approve the index by adding their name, Study Version Number and date of approval in the header. See diagram below.

The 'Study Version Number' is the index version number specific to the study, and this may change during the study if modifications are made. For example, the first index created will be V 1.0 and will become V2.0 if any changes are made during the life of the study.

Remember the footer states the index template version number, which will never change during the study and will not start from V1.0.

See below the Footer on the Site File Index and the version number available in March 2025:

FRM068: Site File Index
Version 8.0 Review Date: January 2028

4.5. Saving the index

The final indexes will be saved electronically in both Excel and PDF format and must be stored in Section 1.0 Sponsor (or Site) File Structure and QC.

The PDF version captures the 'Day 1' agreed TMF set-up as a reference and the Excel copy is available to amend if necessary, during the life of the study.

4.6. Adjusting the eTMF folders to match the approved index

For the sections that have been marked as N/A in the index set-up column, go to the corresponding electronic folder and add 'NOT IN USE' to the folder name. Do not remove or re-number electronic folders as they must match the index section numbering.
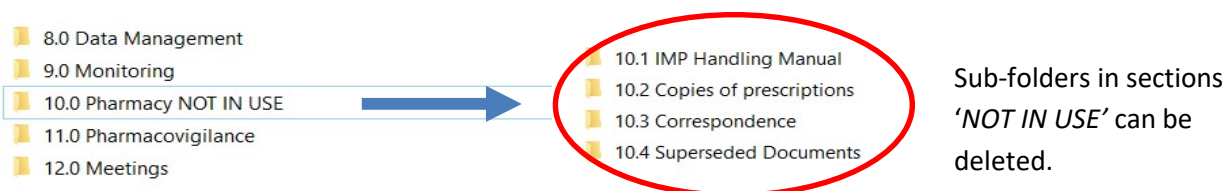
If new sections were added to the index as described in Section 4.3, the electronic folders can also be updated to match the modified index.

4.7. New versions of indexes

When a new version of an index is released, an email will be sent to the TMF committee members and study teams will be notified at the next scheduled BUZZ meeting. The study teams should review the 'Summary of Changes' tab in the new version of the index to see if there are any new sections/sub-folders that would be of benefit to organise the study documents.

To add new sections/sub-folders from a newly released version of the index (issued on IQM) follow the steps outlined below.
   a. Open the saved excel file of your current in-use study index.
   b. Save a new copy of the index for editing.
   c. Insert a new row in the appropriate location and complete the section number and title.
   d. Insert 'Y' in the Set-up column and copy and paste the guidance information.
   e. Add a comment that this section has been added from a new version of the index: Version X.0, dated XX/XX/XXXX. See example screenshot below.
   f. The edited index should then be saved with a new Study Version Number (in the header) for immediate use in the study, following the same method described previously in Section 4.4. Remember: The template number in the footer must not be changed.
   g. Update the eTMF folder structure so that it matches the new agreed index.

		Set-up		Check		Guidance on folder and sub-folder contents	Comments (include signposting to documents stored in other systems outside the pTMF/eTMF)
		Y	N/A	Y	N		
8.6	Superseded Documents					Superseded versions of any documents pertaining to the Finance/Insurance/Indemnity of the study. Sub-folders can be added for organisational purposes.	
8.7	Insert new section here	Y				Copy guidance notes from the newly approved index	Section added from new version of index Version XX, dated XX/XXX/XXXX
9.0	Grants					Folder 9.1 can be duplicated if there is more than one grant.	

4.8. Superseding an index

In the eTMF structure of the N: drive, put the superseded index (Excel and PDF files) in the superseded section. **No deletion and re-numbering of electronic folders is required.**

4.9. Accompanying eTMF paper folder

Only a limited number of documents are expected to be filed in this folder which serves as an accompaniment to the eTMF, hence the name '*Accompanying eTMF paper folder'*.
- Accompanying eTMF paper folder Index (FRM073)
- Signed Protocol Signature page (for all approved versions/amendments)
- Signed Contracts (title page and signature page only)
- Study Delegation Log
- Study Training Log
- Screening/Enrolment Log (if maintained as a paper log)
- Signed Informed Consent Forms.

5. Setting-up an eTMF for a Non-RPH sponsored study (Site file only)

For a non-CTIMP study with an external Sponsor it may be possible to use the RPH eTMF folder structure to organize study documentation. Send the external Sponsor the formal 'eTMF Invitation letter' (TPL054). If the external Sponsor agrees to use the RPH eTMF structure, follow the steps outlined in Section 4.0 of these guidelines to set up the eTMF.

If the sponsor provides their own electronic folder structure to create the study eTMF follow the guidelines provided by the external sponsor.

If the external Sponsor declines the use of an eTMF, you may be required to set up a paper TMF. In this case follow the guidance provided by the external sponsor. If no guidance is provided follow the steps outlined in Section 2.0.

NB: If the external Sponsor sends RPH any Sponsor-level essential documents these should not be filed in the Site File, they can either be discarded or filed for information and reference purposes only, in the Working Documents Folder.

6. Scanning of documents for an eTMF

Any document with a wet ink signature (other than those listed above in Section 4.9 which are to be filed as paper), must be scanned using the validated eTMF scanner.

Scanning using the eTMF scanner ensures that the scanned copy is a true representation of the original document (known as a certified copy).

Although this list is not exhaustive here are some examples of documents that could be scanned:
- Completed paper CRFs
- Paper SAE Forms
- Paper File notes
- Paper Protocol Deviation Forms (FRM038)

The process for scanning completed paper CRFs and the timing of destruction/shredding of the originals will be agreed on a per study, case-by-case basis. The decision will be documented on the study decision log.

NB: A SCANNING PROFILE WILL NEED TO BE SET UP ON THE SCANNER BEFORE YOU CAN START. Please contact Isa Hajee (Isa.hajee@nhs.net) or Beth Haines (beth.haines@nhs.net) who will set this up for you.

See details and screenshots in Appendix 2 for the scanning process.

7. **TMF Index Check**

7.1. **What is a TMF Index Check?**

This is the process of checking that all the sections ticked as present on the index have been correctly set-up for the paper TMF or eTMF (as appropriate) and contain the correct documents.

Regardless of whether it is a RPH, a Non-RPH sponsored study, a paper TMF or an eTMF, it is expected that the TMF Index Check will be performed a minimum of three times during the lifetime of a study: prior to gaining Sponsor Green Light, during the study and at close-out. It is also advisable to perform a TMF Index Check before the first monitoring visit for a study.

7.2. **Can I do the TMF Index Check?**

YES! It can be completed by any member of the study team.

7.3. **What do I need to do?**

The indexes FRM021, FRM068 and FRM073 are dual purpose and will be also used to document the TMF Index Check. Use the agreed/modified version of the indexes for the study and use the 'Check' columns to indicate whether expected documents are filed or not.

Once completed, the team member performing the TMF Index Check will add their name and the date to the footer of the appropriate index and select one of the options to indicate the time in study the check was performed i.e. Prior to Sponsor Green Light/ During the Study or at Close-out.

See diagram below of footer of site file index.
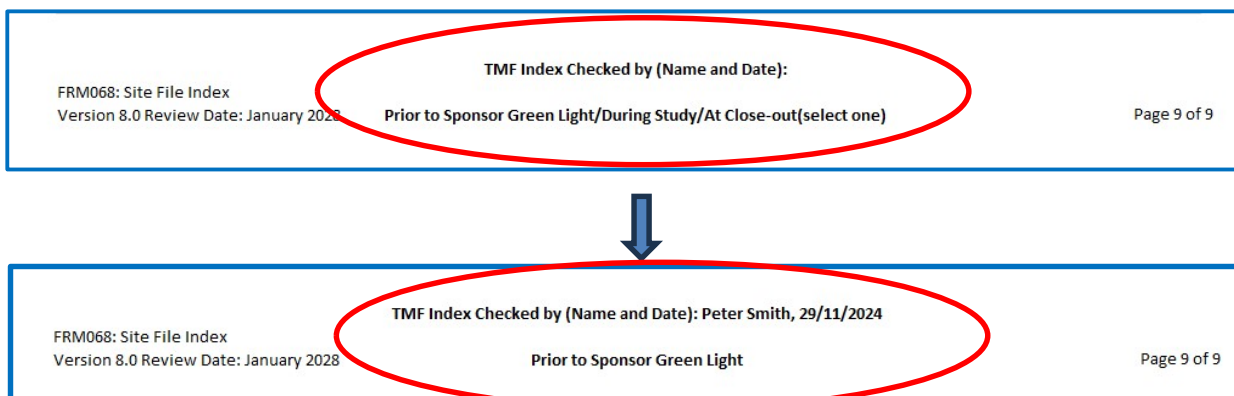
You will need to use a new copy of the index to complete each TMF Index Check.

7.4. <u>Saving the index after TMF Index Check</u>

Save each completed TMF index Check as shown below.

If Peter Smith (PS) completed the TMF Index Check prior to Sponsor Green Light (SGL) on 29th November 2024, for study P03500 the index will be saved as:

> 2024-11-29 P03500 Site_File_Index_V1.0 Check_<mark>Prior SGL</mark>_PS

Further examples for saving index checks:

> 2025-08-03 P03500 Site_File_Index_V1.0 Check_<mark>During study</mark>_PS
>
> 2026-02-25 P03500 Site_File_Index_V2.0 Check_<mark>Close-out</mark>_PS

For further guidance on naming documents for saving see Appendix 1- Good Document Filing.

Remember to print the completed TMF Index Check for filing in a paper TMF.

8. <u>Archiving of a TMF and eTMF</u>

When an eTMF study is ready to be archived, all the electronic folders must be moved from the R&D PROJECTS area to the R&D PROJECTS ARCHIVE by an authorised member of staff (eTMF lead/QA).

The paper TMF and paper documents included in the accompanying eTMF paper folder must be archived following the process for paper archiving (see SOP011 Archiving of Research Studies).

Appendix 1: FILING GOOD PRACTICE

- Documents must be filed in the electronic folders in PDF format so they cannot be edited. Word versions of all documents will be maintained in the Working Documents folder in case of the need to make amendments or corrections and re-version at a later date (e.g., file meeting minutes as PDF in the Sponsor and/or Site File but keep a Word copy in Working Documents so that they can be updated/corrected at a later date if needed and filed in the Sponsor or Site File next to the original version, clearly indicating that these are a corrected version).

- Documents will be saved using the following naming convention. For the paper TMF, the documents must be filed in reverse chronological order by date of event (newest document at the top).

    YYYY_MM_DD_P0 number_Document description_Version number
    (Eg. 2016_07_27_P01910_Protocol_Version 14.0)

- Emails containing pertinent study decisions or information that is important to document the 'story' of the study will be saved in a PDF format using the following naming convention (i.e., with the word 'email' included after the date). For the paper TMF, the documents must be filed in reverse chronological order by date of event (newest document at the top).

    YYYY_MM_DD_Email_P0 number_Document description

- Saved emails that have attachments will be grouped into sub-folders within the appropriate Correspondence folder. Attachments will be saved with the same name as the parent email chain plus 'attachment 1 of X' at the end:

    YYYY_MM_DD_Email_P0 number_Document description_Attachment 1 of X

If you are unsure where to file a document, refer to the guidance notes in the applicable index and/or ask a TMF Committee representative (each R&D team has a TMF Champion).

Do not forget that a paper TMF must have all documents printed and filed as paper. Electronic folders in the N: drive will only be used as a back-up and to organise documents for printing.

When replacing a document with a new version, move the superseded document to the **superseded sub-folder** in that section of the file.

All documents should be anonymised <u>before</u> filing. This will reduce the workload and time spent reviewing and anonymising documents at the time of archiving. Documents with unavoidable patient identifiable data should be saved to EDMC (previously called EMR), rather than in the TMF (e.g., GP Summaries as part of AE follow-up).

Appendix 2: Step-by-step eTMF scanner scanning process

Preparation

- The eTMF scanner (Fujitsu Fi-7140) is located at Royal Papworth Hospital (HLRI) on the ACE2 desk.
- The scanner is on a desk that belongs to the ACE team, meaning that other teams are not allowed to book this desk in advance. The ACE team are happy to swap desks on the day, so book your own desk in advance as usual and arrange to swap desks on the day. Please message the ACE team member in advance to arrange the swap.
- In order to scan documents to the eTMF for a given study, that study must have a 'scanning profile' set-up on the scanner software (PaperStream Capture).
- Please do not attempt to set-up a scanning profile yourself, email **Isa Hajee** (Isa.hajee@nhs.net) or **Beth Haines** (beth.haines@nhs.net) and they will to do this for you.
- A Scanning Log (in Excel format), will automatically be created each time you scan a document and this log is saved alongside your scanned document in your chosen destination folder (i.e., there will be a Scanning Log in every folder to which documents are scanned). Do not delete this document. The Scanning Log is a record of the successful scanning of your master document.
- If you scan more than one document to the same destination folder, an entry will automatically be made in the same Scanning Log (even if documents are scanned at a later date).

Scanning Process

1. Once you have confirmation from Isa or Beth that your Scanning profile is set up you can begin scanning. If this is your first time using the scanner and you would like support, please contact Beth Haines who will be happy to help.
2. Log-in to the desktop computer that is connected to the eTMF scanner with your own log-in details (this is to allow detection of who scanned each document for the scanning log). If you need help setting up the PC cables, please go to Page 24 for help.
3. Push the power button on the eTMF scanner, once on it will be green.
4. Double click on the PaperStream Capture icon from the desktop.

5. From the menu drop-down select 'Configure Profiles'.

6. Find your 'Scanning Profile' and hover over the icon. Select the 'pencil' icon to 'Edit'.
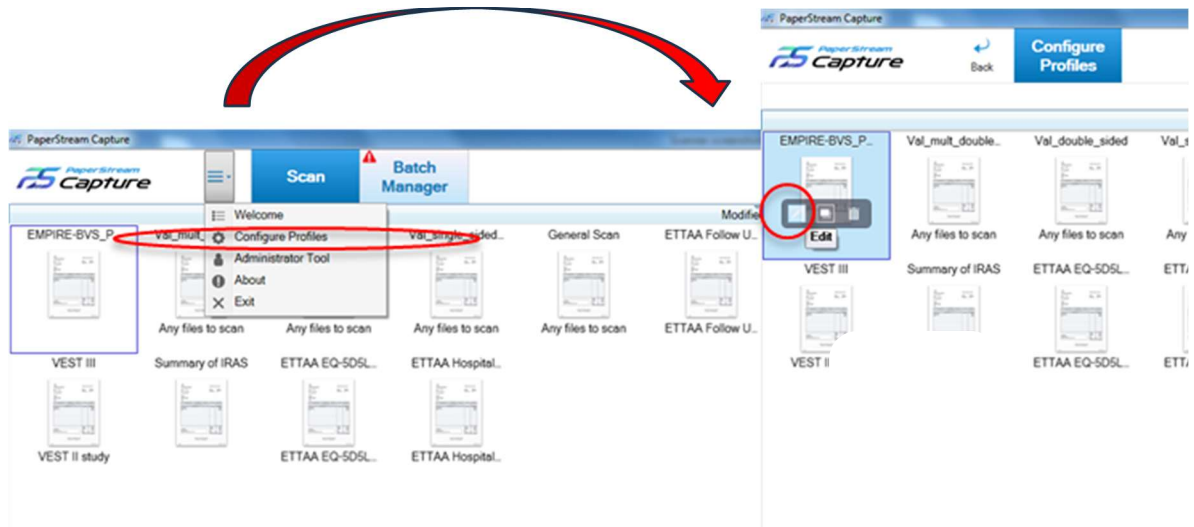

7. You will see a list of 6 options on the left side of the screen. Select the 3rd option, the 'Destination' folder.

8. In the 'Folder field' copy and paste the file path to the eTMF location where you want to save the scanned document/s.
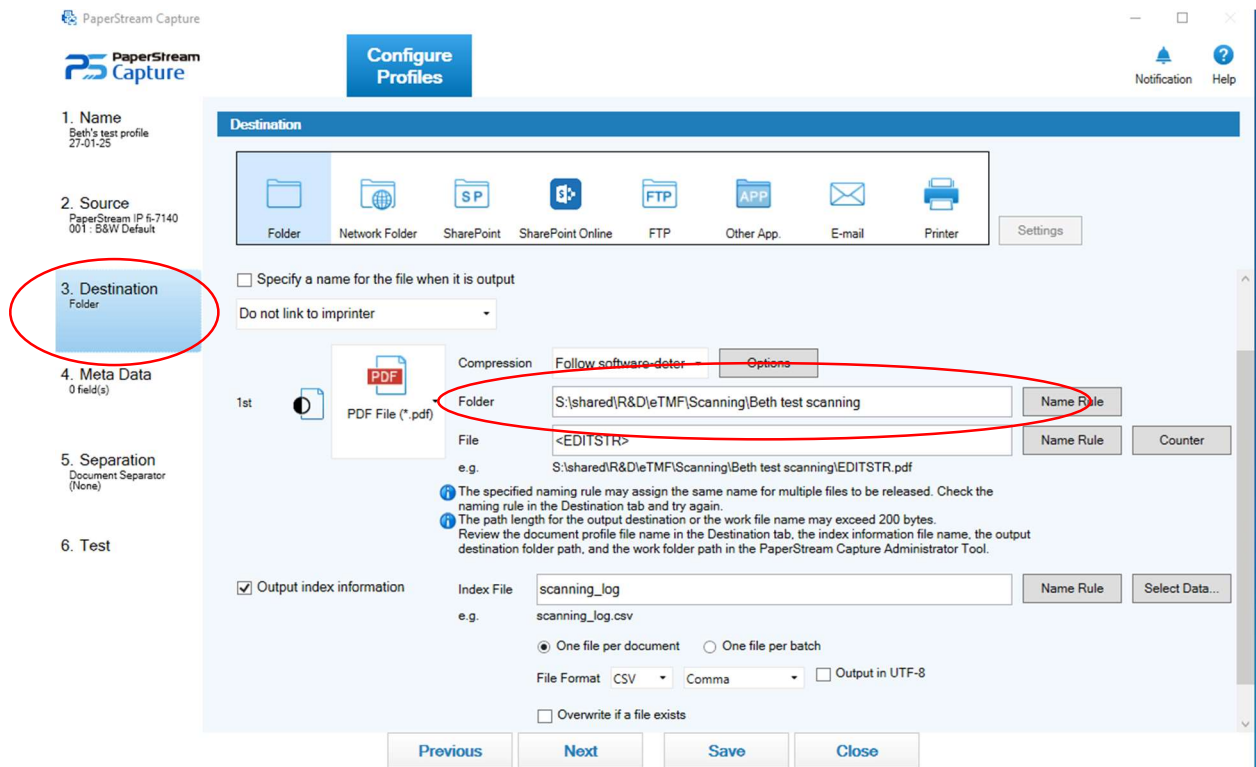
9. The 'File' field is where you add the name of the document being scanned. Alternatively, a file name of "<EDITSTR>" will prompt the user to input a new file name each time a batch is scanned

which can be useful when scanning multiple documents of the same type but different study subjects. The <EDITSTR> will remember the previously used name, so remember to edit the file name after each document if using this method otherwise you may encounter an error that the file already exists.

10. To add <EDITSTR> click 'Name Rule' at the end of the File row, scroll down to 'Optional character string' and select. This will add <EDITSTR> to the File filed. See screen shots below.
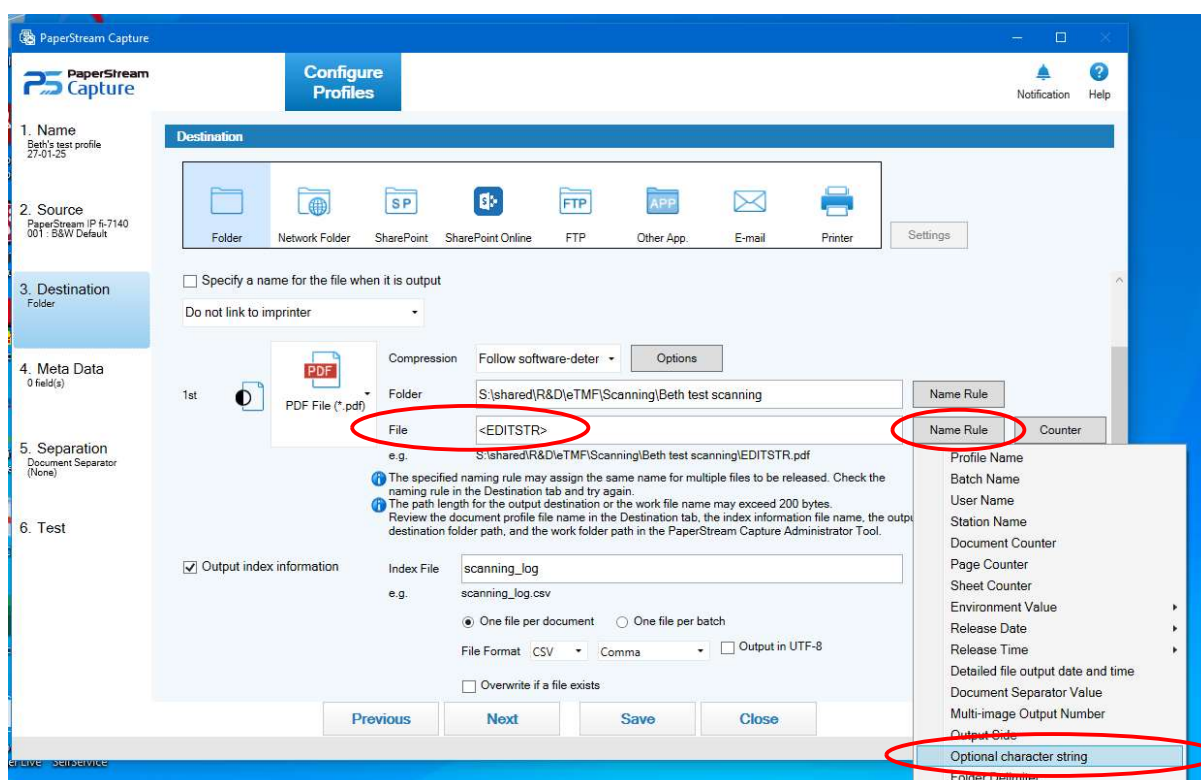
11. In the Index File box type 'scanning log' as the name, and make sure the file format shows 'CSV' and 'Comma' as shown below. The one file per document option will record each page in a document that was scanned in the scanning log, whereas the one file per batch option will only update the scanning log with one entry per document. Make sure the 'Overwrite if file exists' box is **UNCHECKED**

12. Then click 'save' followed by 'close', shown below.

13. Use the 'back' button to exit the 'Configure Profiles' area and return to the 'Scan' home page.
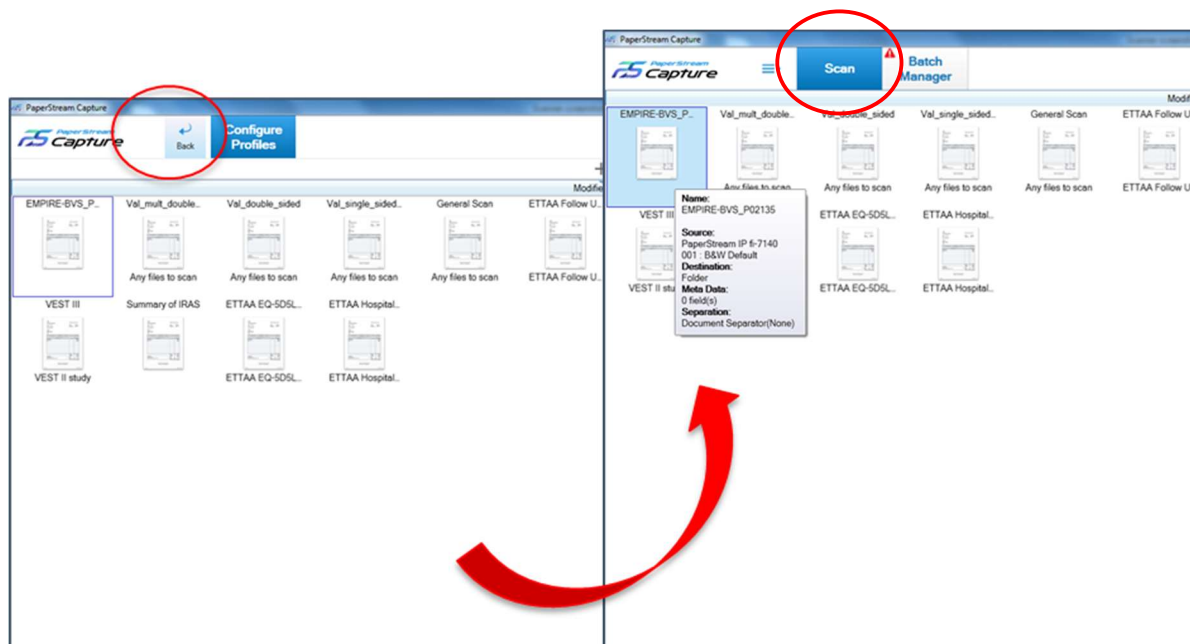

14. Navigate to: S:\R&D\PaperLight_Scanning folder and make a copy of the 'scanning_log_template(comma_seperated)' file. Paste the file into the destination folder where your scans will be saved. Change the name of the file to 'scanning log' (to match the Index file name shown in point 10. above). This file contains the column headers for the scanning log so that it is easier to interpret the data once you start scanning.

15. **You are now ready to start scanning**. Make sure the scanner is turned on; the power button should be green. Place the document to be scanned on the feeder of the scanner (face down).

16. Click on the scanning profile for the study (document will immediately be fed through the machine and scanned).

17. Use the left-hand viewing pane to review all pages of the document to confirm they are all present (including blank pages) and verify the scan is a true copy of the original. Pages can be rearranged (drag and drop) and rotated (right click) as required. After reviewing the scanned pages select 'Complete Batch'.

18. You will then be prompted to name the file, before selecting OK.
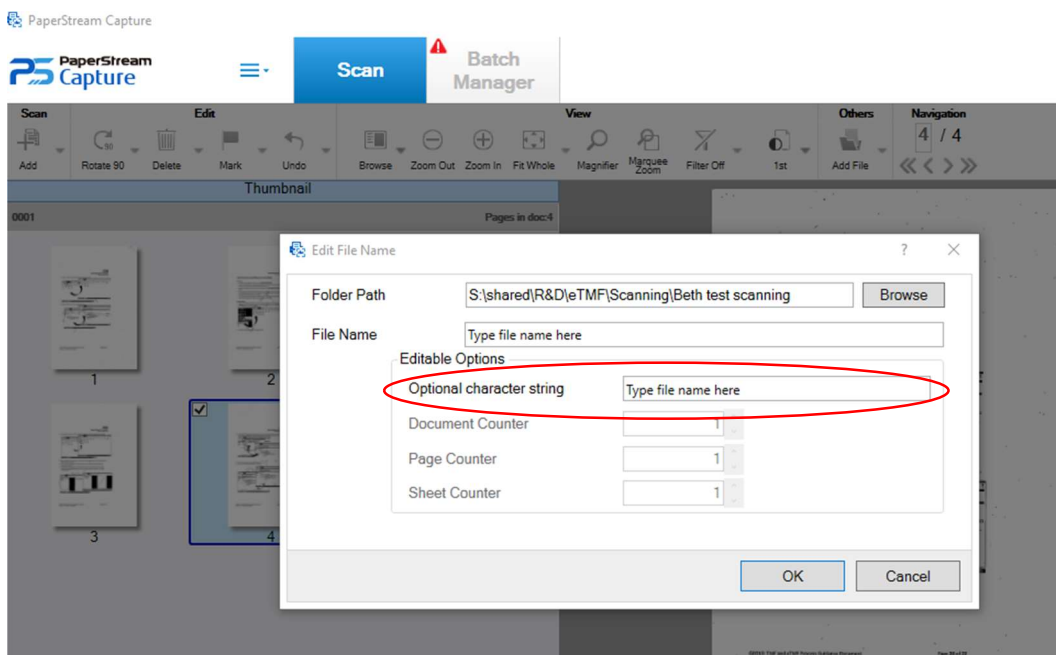

19. **Checks**
    - Navigate to the folder of the eTMF that you intended to send/save the document to and check that it is there and opens successfully.
    - The Scanning Log (Excel file), will **follow the scanned document** and appear in the destination folder to which the document has been scanned.
    - Open the Scanning Log and check that the document that has been scanned is shown at the bottom of the log (there will be a line for each page, including blank pages).
    - It is vital that you **close Excel** after looking at the Scanning Log, as keeping it open will prevent subsequent scans from being recorded in the log.

20. **General Scanning Guidance**
    - Blank pages of documents to be scanned must be marked with a diagonal line across them – this is so that the scanner detects the blank pages and they are easy to review and count.
    - If you are scanning a batch of similar documents with the same name except one variable (e.g., CRFs for a number of different patients in the same trial), use the <EDITSTR> tool for saving scanned documents described in point 9&10. If you need help, ask Isa or Beth how to do this as it will save you a lot of time!
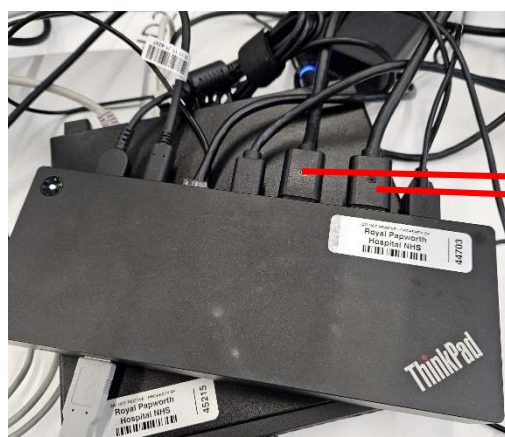
21. **Scanner/Desktop Troubleshooting**

- The scanner can only be used from the desktop, make sure the network cable from the ThinkPad hub is plugged into the front of the Dell PC box and not to a laptop.
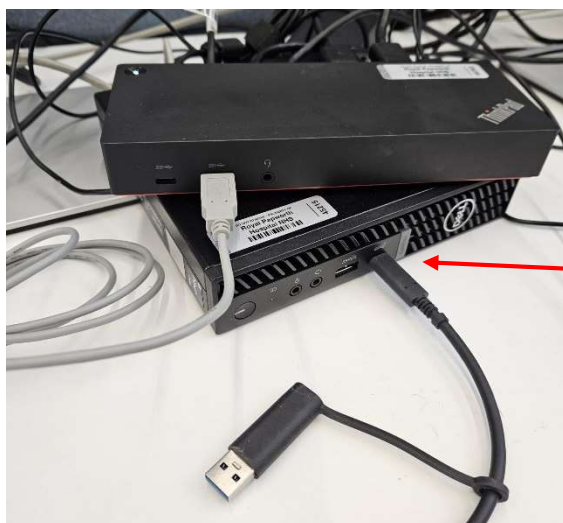
Network cable

- Make sure all the monitor cables are plugged into the ThinkPad Hub and not the Dell PC box itself.

Monitor cables

- Make sure that the Dell PC box, hub, and scanner are all turned on. The light for the desktop PC is very dim so you may need to double check it if you are not sure.