

File Note

Short Study Title:	
Investigator / Site:	
IRAS ID:	
File Note Title:	
*FN no:	

FN Prefix Key: TMF = Trials Master File, ISF = Investigator Site File, SP = Sponsor File, DM = Data management, PH = Pharmacy, PROG = Programming;
STA = Statistics, OTHER = For use if none of the other prefix options apply

Issue:

Corrective Actions:

Ensure you are using the current version of this document. Notify any changes required to the relevant QA Manager

This document is reviewed and updated in line with emerging evidence or local requirements at least every three years CCTU/TPLO04/V3

Preventative Actions:

Name:	Study Role:	Signature and Date [yyyy.mm.dd.]:
File note author# (Person who wrote the note)		
Approved by[∞] (if applicable)		

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INSTRUCTIONS Page - remove once finalised and BEFORE PRINTING

* = Add the relevant prefix to the number to denote the origin of the file note, e.g. TMF = Trials Master File, ISF = Investigator Site File, SP = Sponsor File, DM = Data management, PH = Pharmacy, PROG = Programming; STA = Statistics, OTHER = Use if none of the other prefix options apply

= File notes should be completed by the individual or organization responsible for its content, as follows:

1. If the issue relates to site performance, the appropriate delegated individual from the site (e.g., site coordinator, research nurse) should write and sign the File Note.
2. If the issue relates to Investigator's responsibilities (e.g., human subject protection, data integrity at the site), the Investigator should write and sign the File Note.
3. If the file note has been written on behalf of the Investigator, then the author should be the writer of the File Note and the approval signed by the Investigator.
4. If the issue relates to actions taken by the Sponsor, an appropriate delegated individual from the Sponsor should write and sign the File Note.
5. If the File Note pertains to the conduct of the Sponsor, then the author should be the writer of the File Note and the approval signed by the Sponsor.
6. Keep a file note log of all file notes CCTU/FRM050
7. File the file note with the documentation it refers to

∞ = File note approval is required depending on the nature of the file note. See 3-5 above

To update a signed locked File Note (FN) perform the following steps:

Once signed, the FN will become locked and is no longer editable. If further updates are required to be made to the locked FN perform the following steps:

1. The FN author who signed must open the FN and save it as a new name
2. Once the file name is updated, go to the author signature panel and right click
3. Select 'clear signature'. *Please note*, the signature can only be cleared by the individual who signed the FN originally
4. The FN can now be updated and then re-signed, after which the FN will lock again

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