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| Form number | **51.016M** | Version | **1.0** |
| Title | **TMF/ISF File Note** | | |

**TMF/ISF File Note**

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| **Study Title /**  **Acronym** |  | | |
|  |  |  |  |
| **R&I Ref:** |  | **Date Prepared:** |  |
|  |  |  |  |
| **Description of Issue:** | *Give a brief description of the issue(s) including the reason(s) for it happening* | | |
|  |  |  |  |
| **Corrective Actions Taken:** | *List all actions taken to address the issue(s)* | | |
|  |  |  |  |
| **Preventative Actions Taken:** | *Describe what measures have been put in place to ensure the issue does not happen again or explain why preventative measures are not applicable* | | |
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|  |  |  |  |
| **Prepared by:** |  | **Position:** |  |
|  |  |  |  |
| **Signature:** |  | **Date:** |  |
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|  |  |  |  |
| **Reviewed by:** |  | **Position:** |  |
|  |  |  |  |
| **Signature:** |  | **Date:** |  |

*Guidance on use of file note template*

*A file note should be used to document discrepancies in the essential documents (e.g. empty sections, missing documents) for a study or to explain an aspect of study conduct that is unclear or deviates from normal process (e.g. illogical dates). A file note should only be used if the information is not clearly documented elsewhere in the file. Reasonable efforts must be made to retrieve missing documents and file notes must document the steps taken to locate the documents. Relevant supporting documentation should be attached to the file note.*