

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

## TMF/ISF File Note

**Study Title /**

TYPHOON

**Acronym****R&I Ref:**

GN24EN290

**Date Prepared:**

12.11.25

**Description of Issue:***Give a brief description of the issue(s) including the reason(s) for it happening*

Protocol version 4, PIS version 2 and ICF version 2 was not submitted during Amendment 1 (SA1). We noted this when doing Amendment 2.

**Corrective Actions Taken:***List all actions taken to address the issue(s)*

Spoke to Research Team and confirmed what had happened, informed them that all documents that are changed need to be submitted.

Protocol version 5 PIS version 2.1 and ICF version 2.1 has been submitted and approved for use.

No patient safety issues arose.

**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*

Spoke to research team so they are aware about this in future.

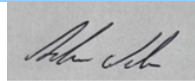
**Prepared by:**

Adam Wade

**Position:**

Research  
Facilitator

**Signature:**



**Date:**

12.11.25

---

**Reviewed by:**

Liz-Anne Lewsley

**Position:**

Research Co-  
ordinator

**Signature:**



**Date:**

12.11.25

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.