Closing participant files

Title	**Closing participant files**
SOP Code	2R2 SOP17_01Sep2022
Effective Date	26 Sep 2022

VIII. **Participant file**: A participant file refers to all documents which purpose is to record specifically research-related information about a participant. These documents include case report forms (CRFs), as well as documents that are site-specific. A participant file does not include source documents that need to remain in a patient s chart after the conclusion of a study.

IX. **Participant file closure**: Participant file closure refers to the process by which a participant file is reviewed, cleaned, and archived once a participant has completed every phase of the study. Once closed, a participant file should not undergo any change.

5.0 Procedures

5.1 General information

- A participant file should be closed as soon as possible after follow-up period has been completed (i.e. when post-treatment follow-up is completed, 26 months post-randomisation);
- Study sites must develop operational and staffing plans for completion of all required procedures listed in this SOP;
- **The use of liquid corrector or correcting material is prohibited when making modifications to a participant file. Modification must be clearly visible, be dated and signed by the person doing the modification.**

5.2 Reviewing and cleaning the participant file

Once a participant s follow-up period is completed (i.e. 26 months post-randomisation), site investigator should ensure the integrity and coherence of the collected information by reviewing and cleaning the participant file:

- For each participant, an authorized person, as documented in the task delegation of responsibilities form (refer to **SOP1**), reviews the participant file by adhering to the following procedures:
  - **a)** If not already done, put all documents pertaining to a participant file into one file folder (except the participant identification form and the consent form);
  - **b)** Attach the applicable study file closure labels on the outside of the file folder. Note: all files will have **Label 1- FOR ALL FILES** (refer to **Appendix 1** for a sample of labels). Other labels (see **Appendix 1**), will be applied as needed, in particular: files of participants with Adverse events reports (CRF9, CRF10) will have also **Label 2- Adverse Events**; files of participants with active TB reports (CRF11-12) will have **Label 3-Active TB**, files of participants who died (at any point during the study), will have **Label 4-Death**; files of participants who participated in PK sampling (CRF13), will have **Label 5-PK**.
  - **c)** When a section of the participant file has been reviewed, indicate this on the appropriate area of the label (i.e. indicate YES/NO/NA);
  - **d)** For Indonesia and Vietnam sites: ensure that all necessary paper copies of Source

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APPENDIX 1

LABELS FOR CLOSING STUDY PARTICIPANT FILES

(1) FOR ALL FILES

Reviewed: Screening & randomization CRF: ____ source doc: ____
Follow-up during treatment CRF: ____ source doc: ____
End of treatment CRF: ____
Follow-up post treatment CRF: ____ source doc: ____ NA:____
Adverse Events CRF:_____ NA: ____ source doc: ____ NA:____
Active TB CRF: _____ NA: ____ source doc: ____ NA:____
Subject file FULLY anonymized: _____
Consent stored separately: _____
Identification form stored separately: _____
Subject file ready for archiving: _____
Date of file closure ___ ___ /___ ___ ___ /___ ___ ___ ___

(2) FOR ADVERSE EVENTS

ADVERSE EVENT

Date of ADVERSE EVENT ___ ___ /___ ___ ___ /___ ___ ___ ___
TYPE: _____
GRADE: 1 2 3 4 5
RELATIONSHIP: Unlikely Possible Probable

(3) FOR ACTIVE TB (ATB)

Active TB Patient

Diagnosis: ATB Clinical ATB Microbiological Not TB

If ATB, Date of DIAGNOSIS ___ ___ /___ ___ ___ /___ ___ ___ ___

If ATB, Date of tx started ___ ___ /___ ___ ___ /___ ___ ___ ___

If ATB, Date of conversion ___ ___ /___ ___ ___ /___ ___ ___ ___or N/A

(4) FOR DEATH

DEATH

Date of death ___ ___ /___ ___ ___ /___ ___ ___ ___
Death in: treatment phase post-treatment phase
If in treatment phase, relationship: Unlikely Possible Probable

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Sample shipped: Box A only **All samples**