



OFF STUDY FORM FOR COHORT A

*This questionnaire should be completed for all Index Cases enrolled in the study.
The purpose is to determine their final status.*

Index case ID Number: **SUBJID**

1 **0** **2** - **0** - **A**

Family ID Number:

FID

Date of evaluation:

/ /

Day

Month

Year

FA_VISDAT

Visit Type: **FA_VISIT**

☐ Month 12 (6-MO Post-Treatment)

☐ Month 5 (TB Relapse/Failure/Withdrawal)

1. Did the participant complete follow up through the 6-MO Post-Treatment Visit? **FA_FUCOMPA**

☐ Yes → *Skip to the end of the form. Sign, date and initial.*

☐ No → *Go to Q2.*

2. Reason for NOT completing follow-up through the 6-MO Post-Treatment Visit (check ONE reason only): **FA_FUCOMPADC**

☐ Participant was provisionally enrolled but not confirmed to have active pulmonary TB → *Go to Q3.*

☐ Death → *Go to Q4.*

☐ TB Relapse (declared cured or treatment completed at the end of most recent course of treatment, followed by culture confirmed or clinically diagnosed TB) → *Go to Q5.*

☐ Treatment failure (declared sputum culture positive at month 5)

☐ Inadvertent enrollment

☐ Withdrawal by participant

☐ Withdrawal by parent/guardian

☐ Lost to follow up

☐ Study terminated by sponsor

☐ Physician decision (Investigator determines that further participation would be detrimental to the health or well-being of the subject)

☐ Moved out of area

☐ Other, specify: **FA_FUCOMPADCSP**

→ *Skip to the end of the form.
Sign, date and initial.*



19600

Index case ID number: SUBJID2

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Only respond to Q3 if the participant was provisionally enrolled but not confirmed to have active pulmonary TB.

3. Provide an alternative diagnosis for participants who were not confirmed to have active TB: FA_TBALTDIAG

- ☐ Pneumonia, not otherwise specified
- ☐ Non-tuberculosis mycobacteria (NTM)
- ☐ Lung cancer
- ☐ Viral upper respiratory infection
- ☐ Malaria
- ☐ Asthma
- ☐ Chronic Obstructive Pulmonary Disease (COPD)
- ☐ Unknown
- ☐ Other, specify: FA_TBALTDIAGSP

Only respond to Q4 if the participant died while on study.

4a. Primary cause of death: FA_DTHCAUSSP

FA_DTHDAT

4b. Date of death:

[] [] / [] [] / [] [] [] []

Day Month Year

4c. Death information obtained from (Multiple responses possible): FA_DTHSRC

- ☐ Death certificate
- ☐ Autopsy report
- ☐ Medical record
- ☐ Contact with participant's family or friends
- ☐ Contact with physician/social worker
- ☐ Other, specify: FA_DTHSRCSP

Only respond to Q5 if, while on study, the participant relapsed with culture confirmed or clinically diagnosed TB after successful completion of treatment.

FA_RLPSPDAT

5. Date of TB relapse:

[] [] / [] [] / [] [] [] []

Day Month Year

Signature of Data Collector: FA_SIGN

FA_INIT
Initials of Data Collector:

[] [] []

Date Completed:

[] [] / [] [] / [] [] [] []

Day Month Year

FA_COMPDAT