HEADER

OFF STUDY FORM - COHORT A

Participant ID: SUBJID - A

Visit Date: VISDAT (D D M O N - Y Y Y Y)

Visit Type: ☐ 6-MO Post-TX ☐ TX F/R/W VISIT

Instructions: Document the outcome status at the participant's final visit.

OFFSTUDYA

1. Did the participant complete follow-up through the 6-Month Post-Treatment visit?

   ☐ Yes ***(End of form)*** ☐ No FUCOMPA

2. Reason for NOT completing follow-up through the 6-Month Post-Treatment Visit ***(Check ONE reason only):*** FUCOMPADC

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

   ☐ Participant was provisionally enrolled but was confirmed by a culture that was conducted on respiratory secretions obtained by bronchoalveolar lavage or bronchial wash ***(Go to Q3)***

   ☐ More than 1 week of anti-TB therapy was received before the required baseline specimens for storage were collected ***(End of form)***

   ☐ HIV test was not completed within the Month 1 Visit window ***(End of form)***

   ☐ Met one of the following TB outcomes: Treatment Failure, TB Relapse, Emerging Resistance ***(Go to Q4)***

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

   ☐ Inadvertent enrollment ***(End of form)***

   ☐ Withdrawal by participant ***(End of form)***

   ☐ Withdrawal by parent/guardian ***(End of form)***

   ☐ Lost to follow-up ***(End of form)***

   ☐ Moved out of area ***(End of form)***

   ☐ Discontinued from the parent protocol ***(End of form)***

PID: ☐☐☐-☐☐☐☐☐☐☐☐☐☐-A

Visit Date: ☐☐-☐☐☐-☐☐☐☐

☐ Study terminated by funding organization or other government agency ***(End of form)***

☐ Death ***(Go to Q4)***

☐ Other, specify _____ FUCOMPADSP ***(End of form)***

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

☐ Pneumonia, not otherwise specified

☐ Non-Tuberculous Mycobacteria (NTM)

☐ Lung cancer TBALTDIAG

☐ Viral upper respiratory infection

☐ Malaria

☐ Asthma

☐ Chronic obstructive pulmonary disease (COPD)

☐ Unknown

☐ Other, specify TBALTDIASP _____

DEATH

4. Did the participant die while on study? DEATH

☐ Yes ☐ No ***(End of form)***

4a. Primary cause of death DTHCAUSSP _____

4b. Death information obtained from ***(Check all that apply)***:

☐ Death certificate DTHSRC

☐ Autopsy report DTHSRCAU

☐ Medical record DTHSRCMR

☐ Contact with participant's family or friends DTHSRCCF

☐ Contact with physician/social worker DTHSRCCP

☐ Other, specify DTHSRCOTSP _____ DTHSRCOT

4c. Date of death: DTHDAT ☐☐-☐☐☐☐

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