HEADER

FOLLOW-UP EVALUATION - COHORT A

Participant ID: SUBJID ☐☐☐☐☐☐☐☐☐☐-A

Visit Date: VISDAT ☐☐-☐☐☐☐
D D M O N Y Y Y Y

VISIT

Visit Type: ☐ M1 ☐ M2 ☐ End of TX ☐ 6-Mo Post-TX ☐ TX F/R/W

Instructions: Complete this form at each protocol-scheduled visit. Every effort should be made to contact the participant (or participant's contact if participant cannot be reached). Minimally the following information should be collected and documented in the participant's study file.

IDS

A. CLINIC IDENTIFICATION

IDCHGNA ☐ Not applicable ***(Go to Section B)***

1. Indicate the participant's DMC or TU if changed since the last visit:

   Designated Microscopy Centre (DMC): ☐☐☐ DMCIDCHG

   Tuberculosis Unit (TU): ☐☐ TUIDCHG

CONTACT

B. FOLLOW-UP

1. Was contact and evaluation of participant possible? CNTC

   ☐ Yes

   ☐ No, specify reason CNTCNDSP _____ ***(End of form)***

2. This visit was conducted:

   ☐ In person CNTCHOW

   ☐ By phone

   ☐ By email

   ☐ Other, specify: CONOTHSP _____

PID: ☐☐☐-☐☐☐☐☐☐☐☐☐-A

Visit Date: ☐☐-☐☐☐-☐☐☐☐

PREGNANCY

3. Is the participant pregnant?

PREGNANT

- ☐ Yes
- ☐ No ***(Go to Q4)***
- ☐ Unknown ***(Go to Q4)***
- ☐ Not assessed ***(Go to Q5)***
- ☐ Not applicable, participant is male ***(Go to Q5)***
- ☐ Participant declines to answer ***(Go to Q4)***

GESTAGE

3a. If the participant is pregnant, indicate gestational age (best estimate): ☐☐ weeks

4. Since the last visit, has the participant had any of the following pregnancy outcomes?

PREGOUT

- ☐ Live birth
- ☐ Still birth (Intrauterine fetal demise >20 weeks)
- ☐ Miscarriage (≤ 20 weeks)
- ☐ Early termination
- ☐ No, has not been pregnant ***(Go to Q5)***
- ☐ Participant declines to answer ***(Go to Q5)***

PREGOUTDAT

4a. Date of outcome: ☐☐-☐☐☐-☐☐☐☐ (D D M O N Y Y Y Y)

FOLLUPA

5. According to the Revised National TB Control Program (RNTCP) Directly Observed Therapy (DOT) card, has the participant missed any TB treatment doses since the last visit? ***(If DOT card is not accessible, ask participant directly)***

MISSDOT

MISSDOTSRC

- ☐ Yes, verified by: ☐ DOT card ☐ Self report
- ☐ No, verified by: ☐ DOT card ☐ Self report

(Go to Q6)

- ☐ Not applicable, participant completed treatment at previous visit

(Go to Q6)

DOSNUMP

5a. How many TB treatment doses were supposed to be taken since the last visit? ☐☐ doses

(Based on the participant's prescribed regimen)

DOSNUMA

5b. How many complete TB treatment doses were actually taken? ☐☐ doses

(Based on the RNTCP DOT card. If the DOT card is not accessible, please estimate number of doses taken by asking the participant. Only count full doses. A partial dose = a missed dose.)

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Visit Date: ☐☐-☐☐☐-☐☐☐☐

HIV

6. Did the participant have an HIV test within the protocol-specified time period? HIVTSTA

☐ Yes ☐ No ***(Complete Off-Study Form F99A)*** ☐ Not applicable

SSTBACTIVE

7. Status of TB signs and symptoms since previous visit:

☐ Improved, but signs/symptoms still present SSCHG

☐ Improved, no signs/symptoms present ***(Go to Q11)***

☐ Worsened

☐ No change

Note: At Month 1 and Month 2 visits, go to Q11

8. Has the participant had any of the following signs or symptoms of active TB since the previous visit?

8a. Cough: ☐ Yes ☐ No ***(Go to Q8b)*** COUGH

8ai. Coughing up blood: ☐ Yes ☐ No COUGHBLD

8b. Fever: ☐ Yes ☐ No ☐ Unknown FEVER

8c. Unintended weight loss: ☐ Yes ☐ No ☐ Unknown WTLOSS

8d. Failure to thrive (child): ☐ Yes ☐ No ☐ Unknown ☐ Not applicable FAILTHRV

8e. Fatigue or lethargy: ☐ Yes ☐ No ☐ Unknown FATIGUE

8f. Night sweats: ☐ Yes ☐ No ☐ Unknown NIGHTSWT

8g. Pleuritic chest pain: ☐ Yes ☐ No ☐ Unknown CHSTPAIN

8h. Other, specify: SIGNSOTSP _____

Note: If participant has two or more of the above, encourage them to seek medical evaluation, per standard of care.

9. If the participant has any signs or symptoms of active TB, have they been clinically or microbiologically confirmed to have extrapulmonary TB?

☐ Yes ☐ No ***(Go to Q11)*** ☐ Unknown ***(Go to Q11)***

EXTRPULM

PID: ☐☐☐-☐☐☐☐☐☐☐☐☐☐-A

Visit Date: ☐☐-☐☐☐-☐☐☐☐

10. Indicate the extrapulmonary site and verification source ***(check all that apply)***:

☐ Pleural EXTRPLEU	☐ Medical Report	☐ Self-Report	EXTRPLEUVS
☐ Lymph node EXTRLYMP	☐ Medical Report	☐ Self-Report	EXTRLYMPVS
☐ Abdominal EXTRPERI	☐ Medical Report	☐ Self-Report	EXTRPERIVS
☐ Bone EXTRBONE	☐ Medical Report	☐ Self-Report	EXTRBONEVS
☐ Joint EXTRJNT	☐ Medical Report	☐ Self-Report	EXTRJNTVS
☐ Central nervous system EXTRCNS	☐ Medical Report	☐ Self-Report	EXTRCNSVS
☐ Other, Specify ___ EXTROTSP EXTROT	☐ Medical Report	☐ Self-Report	EXTROTVS

DEMOGVS

11. Height: ***(only if ≤21 years of age)*** HEIGHT ☐☐☐ cm **or** ☐ Not Applicable

Knee height ***(Only if unable to stand)***: KNEEHT ☐☐ cm

12. Weight: ☐☐☐.☐ kg WEIGHT ☐ Check if estimated weight ***(estimate only if unable to stand)*** WEIGHTEST