HEADER

ACTIVE PULMONARY TB PROVISIONAL ENROLLMENT FORM – COHORT A

Participant ID: SUBJID ☐☐☐-☐☐☐☐☐☐☐☐☐-A

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

Visit Type: Baseline VISIT

Instructions: Complete this form for all individuals who are evaluated and are eligible for enrollment into Cohort A. Assign a participant ID (PID) if provisionally enrolled.

ELIGA

PROVISIONAL ELIGIBILITY:

1. Does the participant have symptoms consistent with active pulmonary TB (e.g., persistent cough; hemoptysis; fever; unintended weight loss or failure to thrive (child); fatigue or lethargy; night sweats; or pleuritic chest pain)? AINCL01

   ☐ Yes ☐ No ***(Ineligible)***

2. Does the participant have CXR findings consistent with TB and/or is the participant sputum smear positive by microscopy or by a rapid diagnostic test such as GeneXpert?

   ☐ Yes ☐ No ***(Ineligible)*** AINCL02

3. If the participant is ≥18 years old, or is a child born to an HIV-positive mother, is the participant/participant's guardian willing to have HIV testing performed per the protocol requirements?

   ☐ Yes AINCL03

   ☐ No ***(Ineligible)***

   ☐ Not applicable (i.e. participant has documentation of positive HIV status; documentation of negative HIV status within the past 90 days; or is a child and was not born to an HIV-positive mother

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4. Has informed consent/assent been obtained as per applicable regulations?

   ☐ Yes ☐ No ***(Ineligible)*** AINCL04

5. Did the participant agree to the storage of study specimens and use of these specimens for future research?

   ☐ Yes ☐ No ***(Ineligible)*** AINCL05

6. Did the participant agree to the use of stored specimens for future human genetic research?

   ☐ Yes ☐ No STORCONS

7. Is the participant enrolled in the Parent Protocol?

   ☐ Yes ☐ No ***(Ineligible)*** AINCL07

8. Has the participant received >1 week (daily or intermittent doses) of any drugs with anti-TB activity within 30 days prior to provisional enrollment, including:
   - Any drug or combination of drugs typically used in a multidrug anti-TB therapy *(isoniazid (INH), rifampicin, pyrazinamide, ethambutol);*
   - Any *fluoroquinolone (e.g., ofloxacin, ciprofloxin, levofloxacin, moxifloxacin, nalidixic acid, sparfloxacin, and gatifloxacin);*
   - Any other drugs with anti-TB activity *(e.g., clofazamine, aminoglycosides (amikacin, kanamycin), or capreomycin).*

   ☐ Yes ***(Ineligible)*** ☐ No AEXCL01

9. Does the participant/participant's guardian have plans to move from his/her current residence, which would interfere with the participant's ability to complete all study visits (through the 6-Month Post-Treatment visit)?

   ☐ Yes ***(Ineligible)*** ☐ No AEXCL02

10. Does the participant have an active psychiatric condition, or alcohol or drug dependence that, in the opinion of the site investigator or designee, might interfere with the ability to give true informed consent and to adhere to the study requirements?

    ☐ Yes ***(Ineligible)*** ☐ No AEXCL03

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11. Is the participant currently imprisoned?

☐ Yes ***(Ineligible)*** ☐ No AEXCL04

12. Was the participant previously enrolled in Cohort B?

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

12a. If yes, Participant ID: PRIORBID ☐☐☐-☐☐☐☐☐☐☐☐☐☐-**B**