



4631

Indo-US VAP Biomarkers for Risk of Tuberculosis and for Tuberculosis
Treatment Failure and Relapse

Form 17

ELIGIBILITY CONFIRMATION FORM - COHORT A

Participant ID Number: - - SUBJIDVisit Type: ☐ Month 1 ☐ Month 2 ☐ End of TX ☐ Unscheduled
EC_VISIT

Instructions: Final Cohort A eligibility is to be confirmed for all participants enrolled in the common protocol within the 6-month follow-up period based on Enrollment Confirmation criteria (Refer to Common Protocol Section, *Participant Inclusion Criteria: Criteria for Enrollment Confirmation*).

If the participant is found to be ineligible for further follow-up, end study participation and complete the Off-Study Form F99A. All specimens that were previously collected from the participant will be retained in storage at the Central Repository.

1. Does the participant have culture-confirmed pulmonary TB based on expectorated, induced sputum (or nasopharyngeal or a gastric aspirate for children <14 years of age)? EC_ELIG2A1

☐ Yes (**Eligible-STOP**) ☐ No

2. At enrollment, was the participant <14 years of age? EC_ELIG2A2

☐ Yes ☐ No (**Ineligible-STOP**)

3. Is the child participant (<14 years of age) culture-negative after 2 attempts at sputum collection using sputum induction, nasopharyngeal aspirates, or gastric aspirates OR has documented reason(s) for lack of specimen for culture? EC_ELIG2A3

☐ Yes ☐ No (**Ineligible-STOP**)

4. Does the child participant have a chest x-ray consistent with intrathoracic disease due to Mycobacterium Tuberculosis (MTB)?

☐ Yes ☐ No (**Ineligible-STOP**) EC_ELIG2A4

5. Did the child participant have a positive clinical response to standard multi-drug anti-TB treatment (as defined in Common Protocol Section, *Outcome Measures for Cohort A*)? EC_ELIG2A5

☐ Yes ☐ No

6. Did the child participant have documented exposure to a case of active TB (as defined in Common Protocol Section, *Enrollment Confirmation Criteria*)? EC_ELIG2A6

☐ Yes ☐ No

7. Did the child participant have immunological evidence of MTB infection (e.g. reactive TST or positive IGRA)? EC_ELIG2A7

☐ Yes ☐ No

8. Is there a "yes" response to Q5, Q6 or Q7? EC_ELIG2A8

☐ Yes ☐ No (**Ineligible**)

Signature: EC_SIGN

Initials:

EC_INIT

Date Completed: / / EC_COMPDTE