HEADER
ELIGIBLITY CONFIRMATION FORM - COHORT A
Participant ID: SUBJID - A
Visit Date: VISDAT - VISIT DATE: VISDAT VI
Visit Type: M1 M2 End of TX VISIT
<u>Instructions:</u> Final Cohort A eligibility is to be confirmed for all participants within the 6-month follow-up period based on Enrollment Confirmation criteria (Refer to Protocol Section, <i>Confirmatory Inclusion Criteria</i>).
If the participant is found to be ineligible for further follow-up, end study participation and complete the Off-Study Form (F99A).
ELIGA2
1. Was eligibility confirmed in the Parent Protocol?
AINCLRO Yes No (Ineligible-STOP)
 Does the participant have culture-confirmed pulmonary TB based on expectorated or induced sputum (or, nasopharyngeal or a gastric aspirate for children ≤14 years of age)?
AINCLR1 Yes (Eligible-STOP) No
2a. At enrollment was the participant ≤14 years of age?
AINCLR1A Yes No (Ineligible-STOP)
3. At the Baseline Visit, did the child participant (≤14 years of age) have symptoms consistent with active pulmonary TB?
AINCLR2 Yes No (Ineligible-STOP)
4. Is the child participant culture-negative after two attempts at sputum collection using expectorated or induced sputum, nasopharyngeal aspirates, or gastric aspirates, or has documented reason(s) for

No (Ineligible-STOP)

No (Ineligible-STOP)

5. Does the child participant have a chest x-ray consistent with intrathoracic disease due to TB?

lack of specimen for culture?

Yes

Yes

AINCLR3

AINCLR4

Form F4A: Eligibility Confirmation Cohort A FINAL 25 JUN **201**5

PID:	A
Visit Date:	
6. Did the child participant have a pos	sitive clinical response to standard multi-drug anti-TB treatment?
AINCLR8A Yes	No
7. Did the child participant have a doc	cumented exposure to a case of active TB?
AINCLR8B Yes	No
	unological evidence of Mtb infection [e.g., reactive Tuberculin ron-Gamma Release Assay (IGRA)]?
MNOLESCO .	
AINCLR8C Yes	No
9. Is there a "yes" response to Q6, Q7	7, or Q8?
AINCLR8 Yes	No (Ineligible)