

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

Form F99A



This questionnaire should be completed for all Index Cases enrolled in the study.

The purpose is to determine their final status.

Visit Type: FA_VISIT    Month 12 (6-MO Post-Treatment)   Month 5 (TB Relapse/Failure/Withdrawal)  1. Did the participant complete follow up through the 6-MO Post-Treatment Visit? FA_FUCOMPA   Yes	Index case ID Number: SUBJID	Family ID Number:	Date of evaluation:
Visit Type: FA_VISIT    Month 12 (6-MO Post-Treatment)   Month 5 (TB Relapse/Failure/Withdrawal)  1. Did the participant complete follow up through the 6-MO Post-Treatment Visit? FA_FUCOMPA   Yes	102-0 - A		
Visit Type: FA_VISIT    Month 12 (6-MO Post-Treatment)     Month 5 (TB Relapse/Failure/Withdrawal)    1. Did the participant complete follow up through the 6-MO Post-Treatment Visit? FA_FUCOMPA     Yes		FID	
Month 12 (G-MO Post-Treatment)   Month 12 (G-MO Post-Treatment)   Month 5 (TB Relapse/Failure/Withdrawal)  1. Did the participant complete follow up through the 6-MO Post-Treatment Visit? FA_FUCOMPA   Yes	Visit Type: FA VISIT		
Month 5 (TB Relapse/Failure/Withdrawal)  1. Did the participant complete follow up through the 6-MO Post-Treatment Visit? FA_FUCOMPA   Yes	_		
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yes → Skip to the end of the form. Sign, date and initial.  No → Go to Q2.  2. Reason for NOT completing follow-up through the 6-MO Post-Treatment Visit (check ONE reason only): FA_FUCOMFADO Participant was provisionally enrolled but not confirmed to have active pulmonary TB → Go to Q3.  Death → Go to Q4.  TB Relapse (declared cured or treatment completed at the end of most recent course of treatment, followed by culture confirmed or clinically diagnosed TB)  Treatment failure (declared sputum culture postive at month 5) Inadvertent enrollment Withdrawal by participant Withdrawal by parent/guardian Skip to the end of the form. Sign, date and initial.  Skip to the end of the form. Sign, date and initial.  Moved out of area	Month 5 (TB Relapse/Failure/Withdrawal)		
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<ul> <li>No → Go to Q2.</li> <li>2. Reason for NOT completing follow-up through the 6-MO Post-Treatment Visit (check ONE reason only): FA_FUCOMPADE</li> <li>□ Participant was provisionally enrolled but not confirmed to have active pulmonary TB → Go to Q3.</li> <li>□ Death → Go to Q4.</li> <li>□ TB Relapse (declared cured or treatment completed at the end of most recent course of treatment, followed by culture confirmed or clinically diagnosed TB)</li> <li>□ Treatment failure (declared sputum culture postive at month 5)</li> <li>□ Inadvertent enrollment</li> <li>□ Withdrawal by participant</li> <li>□ Withdrawal by parent/guardian</li> <li>□ Study terminated by sponsor</li> <li>□ Physician decision (Investigator determines that further participation would be detrimental to the health or well-being of the subject)</li> <li>□ Moved out of area</li> </ul>			
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□ Participant was provisionally enrolled but not confirmed to have active pulmonary TB → Go to Q3.   □ Death → Go to Q4. □ TB Relapse (declared cured or treatment completed at the end of most recent course of treatment, followed by culture confirmed or clinically diagnosed TB) ☐ Go to Q5.   □ Treatment failure (declared sputum culture postive at month 5) □ Inadvertent enrollment □ Withdrawal by participant □ Withdrawal by parent/guardian → Skip to the end of the form. Sign, date and initial.   □ Study terminated by sponsor □ Physician decision (Investigator determines that further participation would be detrimental to the health or well-being of the subject) □ Moved out of area	$\square$ No $\longrightarrow$ Go to Q2.		
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□ Inadvertent enrollment   □ Withdrawal by participant   □ Withdrawal by parent/guardian   □ Lost to follow up   □ Study terminated by sponsor   □ Physician decision (Investigator determines that further participation would be detrimental to the health or well-being of the subject)   □ Moved out of area	course of treatment, followed by culture confirmed	d or clinically diagnosed	$\xrightarrow{CO} GO TO QS.$
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would be detrimental to the health or well-being of the subject)  Moved out of area	Study terminated by sponsor		
Other, specify: FA_FUCOMPADCSP	<u></u>	•	
	Other, specify: FA_FUCOMPADO	CSP	



Index case ID number: SUBJID2

Only respond to Q3 if the participant was provisionally enrolled but not confirmed to have active pulmonary TB.		
3. Provide an alternative diagnosis for participants who were not confirmed to have active TB: FA_TBALTDIAG		
Pneumonia, not otherwise specified		
Non-tuberculosis mycobacteria (NTM)		
Lung cancer		
☐ Viral upper respiratory infection		
☐ Malaria		
Asthma		
Chronic Obstructive Pulmonary Disease (COPD)		
Unknown		
Other, specify: FA_TBALTDIAGSP		
Only respond to Q4 if the participant died while on study.		
4a. Primary cause of death:		
FA_DTHDAT,,		
4b. Date of death: Day Month Year		
4c. Death information obtained from (Multiple responses possible): FA_DTHSRC		
☐ Death certificate		
Autopsy report		
Medical record		
Contact with participant's family or friends		
Contact wtih physician/social worker		
Other, specify: FA_DTHSRCSP		
Only respond to Q5 if, while on study, the participant relapsed with culture confirmed or clinically diagnosed TB after successful completion of treatment .		
FA_RLPSDAT , , , , , , , , , , , , , , , , , , ,		
5. Date of TB relapse: Day Month Year		
Signature of Data Collector: EA SIGN FA_INIT		
Signature of Data Collector: FA_SIGN Initials of Data Collector:		
Date Completed: Day / Month / Year FA_COMPDAT		