

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

Form 1A

INDEX CASE SCREENING FORM

Index case ID number: SUBJID Family ID: FID	Date of Screening: IS_VISDA	Γ				
1 0 2 - 0 - A	Day / Month / Voc					
Was the participant previously enrolled in Cohort B?: IS_PENRB						
Yes Household Contact ID: 1 0 2 - 0	- B IS_PRIOR	BID				
No How many other people over 6 years lived in last 3 months? By "household" I mean others		IS_0	CONTA	CTS		
1. Gender at birth: Male Female 2. Municipality: S_MUNIC	Puducherry Villupuram	Cuc	ldalore			
NCLUSION CRITERIA For a candidate to be eligible, all YES/NO questions	s in this table must be answered YES.	Yes	No			
3. Has informed consent been obtained as per applicable regulations?				S_IC		
IS_ICFDT If YES, date consent signed: Day / Month / 20						
If NO, specify reason: IS_ICFREAS	STOP; do not continue with screening.					
4. Are you 6 years of age or older?	IS_AGE					
4a. What is your date of birth OR age in years? IS_BIRTHDAT	·					
Date of Birth*: Day / Month / Year OR Age: S_AGE years						
*If the day and/or month are not known, please print 99 in the Day and/or Month fields.						
Tick here if the date or age entered above is an estimate. IS_AGEEST						
5. Is there laboratory documentation of at least one AFB smear grade ≥1+? IS_SMEAR						
IS_KNOWSMEAR 5a. We understand you have a positive laboratory test for tuberculosis. Are you aware of this?						
It is estimated that you will need to be treated for 6 months for your curr	ent TB diagnosis.					
6. Do you intend to live in India for the duration of TB treatment? IS_INDIA						
7. Are you willing and able to participate in the study?						
If NO, specify reason: IS_UNWILLING	IS_WILLNG					
HIV Testing is a standard part of the Government's Revised National Tuberculosis Control Program. Everyone diagnosed with Tuberculosis is requested to get HIV testing. This will help with your treatment and overall health.						
8. Are you willing to be tested for HIV?						



Inde	x cas	e ID	num	ber:	SUB	JID2			
1	0	2	-	0				-	A

EXCLUSION CRITERIA For a candidate to be eligible, all YES/NO questions in this table must be answered NO.	Yes	No			
9. Apart from this current TB diagnosis, have you ever been partially or completely treated for TB in the past?	IS_TI	ВНХ			
10. Have you begun treatment for your current TB diagnosis? Yes No IS_TBHXTX					
10a. If yes, when did you begin your current treatment? Day					
11. In the preceding 30 days, have you received >1 week of multi-drug anti TB-therapy (3 intermittent doses OR 5 daily doses within 7 days)? IS_WEEKTX					
12. We know that not everyone remembers the names of medications they are taking. Do you know if you have received >1 week of fluoroquinolone (e.g. ofloxacin, ciprofloxin, levofloxacin, moxifloxacin, nalidixic acid, sparfloxacin and gatifloxacin) therapy or other drugs with anti-TB activity [e.g. clofazamine, aminoglycosides(amikacin, kanamycin), and capreomycin] for any reason within 30 days prior to enrollment?					
13. Have you been diagnosed with multi-drug resistant or extensively drug resistant tuberculosis? IS_MXDR					
14. Have you spent time with anyone that you know has multi-drug resistant or extensively drug resistant tuberculosis? IS_MXDRCONT					
15. Have you chosen not to start or not to complete Directly Observed Therapy? IS_DOTS					
For a candidate to be eligible, questions 3-8 must be answered YES and questions 9-15 must be answered NO.	Yes	No			
16. Is the candidate eligible?					
17. Was the candidate enrolled? IS_ENROLL					
If candidate was eligible but not enrolled, specify the reason they were not enrolled:					
IS_NOTENROLL					
COMMON PROTOCOL CRITERIA Complete this section only for those who consented to participate in the specimen repository and were enrolled in the parent procol (question 17 is answered YES). The participant should be enrolled in the parent protocol and not just be eligible. For a candidate to be eligible, question 1 must be answered YES and question 2a must be answered NO.	Yes	No			
1. Do you have a persistent cough (about two weeks or longer), cough up blood, fever, weight loss or IS_CP1 failure to thrive (child), fatigue or lethargy, night sweats, or sharp chest pain that gets worse with deep breath?					
2. Have you received multi-drug anti-TB therapy in the past? Yes No IS_CP2	CP2a				
2a. If you have been treated for TB disease in the past, has it been more than 30 days since your last dose of multi-drug anti-TB therapy?					
3. Is the candidate eligible for the specimen repository? IS_ELIGIBLECP					
4. Was the candidate enrolled in the specimen repository? IS_ENROLLCP					
IS_INIT					
Signature of Data Collector: IS_SIGN Initials of Data Collector:					
Date Completed: / / / IS_COMPDAT					