

CRF 3 - EVALUATION FORM

A1. Participant's ID number __ __ - C C C C

A2. Center __ __

D0. Research staff completing the form _____

DEMOGRAPHICS

D1. Height: C .C C m

D2. Weight: C C C .C kg

D3. In which Country were you born? _____

D4. If Country of birth is different from country of this study center, in which year did you arrive in country of this center? C C C C

D5. Immigration status: C Visa C Landed immigrant/Citizen C Refugee C Unknown C Not applicable (born in the same country of study center) C Other, D6. If Other, specify _____

MEDICAL HISTORY

RISK FACTORS

D7. HIV status: C Positive C Negative (go to D13) C Unknown (go to D13)

D8. If HIV positive, year of diagnosis C C C C (Note: if year of diagnosis is not known, write 9999)

D9. If HIV positive, CD4 count (at randomization) C C C C . C /mm³ (Note: if CD4 is not known, write 9999)

D10. If HIV positive, Viral load (at randomization) _____ (Note: if viral load is not know, write 9999 and perform viral load test)

D11. Antiretroviral therapy? C Yes C No

D12. If Yes, list the names of all antiretroviral's being taken:

- 1) _____ 2) _____ 3) _____
4) _____ 5) _____ 6) _____

D13. Contact with a person who has active pulmonary TB (choose one)

- C No known contact with a person who has active pulmonary TB (GO to D16)
C Contact, on average, for one night per week OR at least one hour per day for 5 days per week, for the past 3 months with a person with active pulmonary TB (close contact)
C Contact for 1 to 5 hours per week for at least 1 week with a person with smear positive pulmonary TB (casual contact)

If close contact or casual contact:

D14. Was a drug sensitivity test (phenotypic DST or GeneXpert) performed in patient with active TB?

- C No, sensitivity test was not performed, but patient with active TB is a new TB case with no prior treatment for TB (go to D16)
C Yes, sensitivity test was performed

If performed, D15. Result of sensitivity test is :

- C NO resistance to Rifampin C TB RESISTANT to Rifampin

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- D16. Does the study participant have any immunosuppressive conditions or therapy? No Yes
- D17-24. If Yes, which are the conditions or therapies causing immuno suppression in this participant (check all that apply)?
 - Diabetes Renal failure (dialysis) Transplant anti-rejection therapy TNF α inhibitory therapy
 - Other immusosupprevsive conditions, D22. Specify _____
 - Other immusosupprevsive therapy, D24. Specify _____
- D25. Smoking status (choose one) Never smoke Current smoker Ex- smoker
 - If current or ex-smoker D26. Age started D27. Packs/day .
 - If ex-smoker D28. Age stopped
- D29. Alcohol: How often do you have a drink containing alcohol? (choose one)
 - Never Less than once a month 1-3 times per month Once a week 2-3 times a week
 - 4 or more times a week
- D30. How many drinks containing alcohol do you have on a typical day when you are drinking? (choose one)
 - Not applicable 1 or 2 3 or 4 5 or 6 7 to 13 14 or more
- D31. How often do you have six or more drinks on one occasion? (choose one)
 - Not applicable Never < Monthly Monthly Weekly More than once a week
- D32. Do you use any recreational drug more than once a month? No Yes
 - If Yes, choose any that apply:
 - D33. Cannabis (marijuana, hashish, etc) D34-35. If other, specify _____

HISTORY OF TB

- D36. Has the participant had BCG vaccination? Yes No Unknown
- D37. Was the participant treated before for active TB? Yes No Unknown
 - D38. If Yes, year of diagnosis
 - D39. If Yes, number of months treated
- D40. Was the participant treated for latent TB in the past? Yes No Unknown
 - D41. If Yes, year of diagnosis
 - D42. If yes, number of months treated
- D43. Comments _____

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MEDICATIONS

M1. Is participant sexually active and of child bearing potential? C Yes C No (go to M12)

M2.1. If Yes to M1, is participant taking birth control pills or hormonal contraceptives? C Yes C No

M2.2. If yes to M1, is she willing to use methods of contraception alternative to hormonal contraception? C Yes C No (If NO, STOP HERE)

M3-M10. If yes, what method does she plan to use? (choose any that applies)

- C Diaphragm C Intra Uterine Device (IUD) C Condoms C Sponge/suppository C Cervical cap C Chemical method (spermicidal foam/jelly) C Abstinence C Other, M11. Specify_____

M12. Is the study participant taking any other medications prescribed by a doctor (except antiretrovirals, which are already reported in D12)? C Yes C No

M13. If yes, list the names of all the medications being taken:

- 1)_____ 2)_____ 3)_____ 4)_____ 5)_____ 6)_____ 7)_____ 8)_____ 9)_____

M14. Do any of the medications taken by participant (as antiretrovirals, or other medications) have potentially clinically important drug interactions with Rifampin? (see drug interaction list, contact pharmacist)

- C Yes C No C N/A (participant does not take any other medication)

M15. If yes, does the treating team believe interactions are manageable and therefore study participant is still eligible for the study? C Yes C No (If NO, STOP HERE)

ALLERGIES AND COMORBIDITY

M16. Allergies to medications: C None C Any, M17. Specify_____

M18. Other medical conditions: C None C Any, M19. Specify_____

MEDICAL EVALUATION

M20. Respiratory symptoms: C None C Any, M21. Specify_____

M22. Other symptoms: C None C Any, M23. Specify_____

M24. Physical exam: C Normal C Abnormal, M25. Specify_____

M26. Comments (for all the above sections): _____

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INITIAL INVESTIGATIONS

CHEST X-RAY

L1. Date of chest x-ray C C C C C C C C C C
D D M M M Y Y Y Y Y

L2. Chest x-ray results (select one only): C Normal C Abnormal possible active TB C Abnormal not TB

L3. If abnormal but not TB, Specify: _____

(NOTE: If possible active TB, complete section on microbiology: L8 to L18)

L4. Other radiological tests: C None C Any, L5. Specify _____

L6. If any, date C C C C C C C C C C
D D M M M Y Y Y Y Y

L7. If any, Results _____

MICROBIOLOGY

L8. Microbiology: C Not required C Done

L9. If Done, date of 1st test C C C C C C C C C C
D D M M M Y Y Y Y Y

L10. Number of spontaneous sputum samples obtained C

L11. Number of induced sputum samples obtained C

L12. Number of gastric aspirate samples obtained C

L13. Number of AFB smear done C

L14. Results:

C All contaminated C All Negative C At least one positive (if at least one positive, STOP HERE)

L15. Number of cultures done C

L16. Results:

C All contaminated C All Negative C At least one positive (if at least one positive, STOP HERE)

L17. GeneXpert was done? C Yes C No

L18. Results:

C Contaminated C Negative (DNA not detected) C Positive (DNA detected) (If Positive, STOP HERE)

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LABORATORY

L19. Date test was performed C C C C C C C C C C
D D M M M Y Y Y Y Y

L20. Alanine transaminase (ALT) C C C C . C UL L20.1 Upper normal limit (ALT) C C C . C UL

L21. Aspartate aminotransferase (AST) C C C . C UL L21.1. Upper normal limit (AST) C C C . C UL

L22. Total bilirubin C C C . C umol/L; L22.1. Upper normal limit (total bilirubin) C C C . C umol/L

L23. Hemoglobin C C C . C g/L; L24. Hematocrit C . C C C L/L

L25. White blood cells C C C . C 10^9/L L26. Platelets C C C . C 10^9/L

L26.1. Is there any hematological abnormality of grade 3 or 4? C Yes C No

L26.2 if Yes, please specify which is(are) the abnormal result(s) and the normal range(s):

L27. If participant is HIV+, viral load: _____ copies/ml (If participant is NOT HIV positive, or if viral load was already reported in D10, write 9 here)

L28. HIV TESTING: Has treating team offered a new HIV testing to study participant?

C Yes C No C Not required, status is known C Not appropriate according to treating team

L29. If Yes, does study participant agree to be tested? C Yes C No

L30. If Yes, date test was performed C C C C C C C C C C
D D M M M Y Y Y Y Y

L31. HIV Test Results: C Positive C Negative C Unknown

L32. Pregnancy test : c Positive c Negative c N/A

RANDOMIZATION and STUDY DRUGS

R1. Are you ready to randomize this participant? C Yes C No

R2. Study participant is randomized to

C 4 months of Rifampin 10mg/kg/day R3. Dose should be (auto-generated using weight) _____ mg/day

C 2 months of Rifampin high dose (either 20 or 30 mg/kg/day)

R4. The code given is C C ; and (R5) Dose is C pills/day (auto-generated using weight)

R6. If randomized to 2 month high dose, number of pills of study medication dispensed today C C C

R7. If randomized to 4 month standard dose, number of daily doses of study medication dispensed today C C C

R8. For how many days should this supply of pills last? C C C days

R9. Suggested date of next visit is: ___ / ___ / ___ (auto-generated to be in 2 weeks or 4 weeks)