CRF 5 - ROUTINE FOLLOW-UP VISIT DURING TREATMENT

A1.Participant's ID number C C C - C C C C **A2. Center** _____

G0. Research staff completing the form_____

GENERAL INFORMATION

G1. Date of this visit C C C C C C C C C C
D D M M M Y Y Y Y

G1.1 How was this visit conducted? (*choose one*):

- c In person visit
- c Remote visit (i.e. by phone)
- c Home visit
- c Participant sent another person to get study medication
- c Other, G.1.2. If Other, specify_____

G1.3 This visit was (*choose one*):

- c A routine follow-up visit (Go to question 1.5)
- c An additional visit, requested by research team or treating team (Go to question G1.4.)
- c An additional visit requested by participant (Go to question G1.4)

G1.4 If additional visit, please specify the reasons: _____

G1.5 If this was a routine follow-up visit, was this visit within the recommended schedule?

- c visit done within recommended schedule (go to G6)
- c visit done outside of recommended schedule for treating team or research team decision (Go to G1.6)
- c visit done outside of recommended schedule for participant decision (Go to G1.6)

G1.6 If done outside of recommended schedule, please specify reasons_____

Reminder: Schedule for follow-up visits:

In high dose arms: 1st visit: 2 weeks +/- 3 days after treatment begins; 2nd visit: 4 weeks +/- 3 days after treatment begins; 3rd visit: 8 weeks +/- 1 week after treatment begins.

In standard arm: 1st visit: 4 weeks +/- 1 week after treatment begins; 2nd visit: 8 weeks +/- 1 week after treatment begins; 3rd visit: 16 weeks +/- 2 weeks after treatment begins

G5. Comments

_____
_____
_____

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A1.Participant's ID number C C C - C C C C **A2. Center** _____

G6. This visit is:

c The FIRST visit after participant started treatment

G7. If FIRST visit, please write the date on which participant took the first dose of treatment:

C C C C C C C C C
D D M M M Y Y Y Y

c The LAST visit during treatment

G8. If LAST visit during treatment and the participant is HIV+: Viral load _____copies/ml

G8.1. Date of viral load C C C C C C C C C
D D M M M Y Y Y Y

G9. Was the antiretroviral therapy changed during LTBI therapy because of possible interactions with rifampin?

c Yes c No c N/A (participant is not on antiretroviral treatment)

c Any OTHER visit during treatment (i.e. nor FIRST after started treatment nor LAST during treatment)

G10. Has contact information changed? c No c Yes **(If YES, update information on CRF-4)**

(IMPORTANT NOTE: review contact information at each visit)

ADHERENCE TO TREATMENT

G11. The participant was randomized to: (automatically generated by the website)

G12. c **4 month** 10mg/day Rifampin, with C C C mg/day dose per day

G13. c **2 months** high dose, with randomization code C C and G14. C number of pills per day

G15. Did study participant bring their medication bottle? c YES c NO

G16. If YES, and **is randomized to 2 months high dose,** number of pills of study medication remaining in medication bottle is C C C pills

G17. **If YES**, and **is randomized to 4 months standard dose,** number of daily doses of study medication remaining in medication bottle is C C C doses (Days)

G18. **If NO**, and is **randomized to 2 months high dose**, number of pills of study medication remaining by participant's estimate is C C C pills

G19. **If NO**, and is **randomized to 4 months standard dose**, number of daily doses of study medication remaining by participant's estimate is C C C doses (Days)

G24. Comments _____

CRF 5 - ROUTINE FOLLOW-UP VISIT DURING TREATMENT

A1.Participant's ID number C C C - C C C C **A2. Center** _____

CURRENT SYMPTOMS & PHYSICAL EXAM

Does the study participant have any of the following symptoms TODAY?

Y1. Fever/Night sweats? c NO c YES, (Y2) specify _____

Y3. Weight loss without dieting? c NO c YES, (Y4) specify _____

Y5. Cough? c NO c YES, (Y6) specify _____

Y7. Sputum production? c NO c YES, (Y8) specify _____

Y9. Skin problems? c NO c YES, (Y10) specify _____
(i.e. acne, itchiness, skin rash, etc.)

Y11. Gastrointestinal problems? c NO c YES, (Y12) specify _____
(i.e. abdominal pain, loss of appetite, nausea, vomiting, etc.)

Y13. Neurological problems? c NO c YES, (Y14) specify _____
(i.e. blurred vision, numbness, paresthesis, irritability, etc)

Y15. Other? c NO c YES, (Y16) specify _____
(i.e. fatigue, joint or muscular pain, headache etc.)

Y17. Physical exam is (Reminder: Exam must be done if any symptoms reported)

c NOT NECESSARY c NORMAL c ABNORMAL

Y18. If ABNORMAL, describe_____

INVESTIGATIONS

Note: at the 4 weeks FOLLOW-UP VISIT, the following ARE REQUIRED, otherwise as clinically indicated

F1. Date tests were performed C C C C C C C C C
D D M M M Y Y Y Y

F2. Alanine transaminase (ALT) C C C C . C U/L

F3. Aspartate aminotransferase (AST) C C C C . C U/L

F4. Total bilirubin C C C . C umol/L

F5. Creatinine C C C . C mg/dL

F6. BUN (blood urea nitrogen) C C C . C mg/dL

F7. Hemoglobin C C C C . C g/L

F8. Hematocrit C . C C C L/L

F9. White blood cells C C C . C 10^9/L

F10. Platelets C C C . C 10^9/L

F11. Other investigations_____

F12. Does study participant require monitoring of other medications being taken? c Yes c NO (If NO, go to section "Treatment plan")

F13. If Yes, how was the monitoring done? (tick one) c DRUG LEVELS c BLOOD TEST c CLINICAL

F14. If Yes, was the monitoring of other medication satisfactory? c YES c NO

F15. If No to F14, comments (Report drug levels OR blood test results OR clinical effects. Describe actions taken for unsatisfactory results.) _____

F16. If this is the 4 weeks FOLLOW_UP VISIT: were sample for PK taken?

c YES c NO, because participant refuse c NO for other reason (F17), Specify _____

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A1.Participant's ID number C C C - C C C C **A2. Center** _____

TREATMENT PLAN

OTHER MEDICATIONS

N1. Is the study participant taking any NEW medications prescribed by a doctor? c YES c NO **(If NO, go to N5)**

N2. If YES, list the names of all new medications being taken _____

_____

N3. Do any of these medications have potential drug interactions with Rifampin? c YES c NO
(see drug interaction list, contact pharmacist)

N4. If YES, can treating team manage interactions & participant continues on study medication?
c YES c NO **(if NO: study medication must be stopped permanently; complete an End of Treatment form- CRF 6)**

N4.1. Comments _____
_____

ACTION REGARDING STUDY MEDICATION

N5. Plan (tick one)

c Study medication continued as per protocol at same dose

c Study medication stopped for a possible adverse event **(REPORT Initial Adverse Event – CRF 9)**

c Study medication stopped permanently **(IF STOPPED permanently, complete an End of Treatment form-CRF 6)**

Study medication dispensed today (fill one only):

N5.1. C C C **pills** of study medication were dispensed today for participant who is in **2 months** high dose arm

N5.2. C C C **daily doses** of study medication were dispensed today for participant who is in **4 months** standard treatment arm

N5.3. How many days will the pills dispensed today be for? C C C days

N6. Suggested date for next visit is C C C C C C C C C
D D M M M Y Y Y Y
(auto generated depending on date of randomization)

N7. General comments:

_____
_____
_____
_____