**Form 4: Clinical Evaluation Form**

Study site:  Participant ID**:** -

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| 1. **Visit Information** |

* 1. Reason for reporting evaluation result(s) *(check one)*:

Baseline

Treatment evaluation

Follow up after treatment completion

* 1. Date of evaluation: --

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| 1. **Symptoms** Not done *(proceed to the next section)* |

1. Date of symptoms evaluation: --

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| **Symptoms** | |
| **Pain** | |
| Muscle pain (myalgia) | Yes  No  Unknown |
| Joint pain (arthralgia) | Yes  No  Unknown |
| Headache | Yes  No  Unknown |
| **Skin** | |
| Rash – generalized | Yes  No  Unknown |
| Rash – localized | Yes  No  Unknown |
| Itching (pruritus) – generalized | Yes  No  Unknown |
| Itching (pruritus) – localized | Yes  No  Unknown |
| Jaundice (including scleral icterus) | Yes  No  Unknown |
| Pink to brownish-black discoloration of skin | Yes  No  Unknown |
| Ichthyosis | Yes  No  Unknown |
| **Abdominal** | |
| Nausea | Yes  No  Unknown |
| Vomiting | Yes  No  Unknown |
| Diarrhea | Yes  No  Unknown |
| Abdominal pain | Yes  No  Unknown |
| **Respiratory** | |
| Cough | Yes  No  Unknown |
| Productive cough | Yes  No  Unknown |

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| **Symptoms** |  |
| **Systemic / Other** | |
| Dizziness | Yes  No  Unknown |
| Fatigue/malaise | Yes  No  Unknown |
| Insomnia | Yes  No  Unknown |
| Numbness in extremities | Yes  No  Unknown |
| Excessive sweating (diaphoresis) | Yes  No  Unknown |
| Loss of appetite (anorexia) | Yes  No  Unknown |
| Subjective fever | Yes  No  Unknown |

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| 1. **Vital Signs** Not done *(proceed to the next section)* |

Date of vital signs evaluation: --

* + - 1. Respiratory Rate: /minute
      2. Pulse Rate: /minute
      3. Systolic Blood Pressure:  mmHg
      4. Diastolic Blood Pressure: mmHg
      5. Temperature: . degrees celsius

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| 1. **Height and Weight** Not done *(proceed to the next section)* |

1. Height: . cm
2. Date of weight: --

* 1. Weight: . kg

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| 1. **Chemistry** Not done *(proceed to the next section)* |

1. Date of chemistry: --

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| **Test** | **Value** | **Lower Normal Limit** | **Upper Normal Limit** | **Unit** | **Not done** |
| ALT/SGPT |  |  |  | U/L | Not done |
| AST/SGOT |  |  |  | U/L | Not done |
| Alkaline phosphatase |  |  |  | U/L | Not done |
| Total bilirubin | . | . | . | mg/dL  μmol/L | Not done |
| Creatinine | . | . | . | mg/dL OR  μmol/L | Not done |
| Sodium | . | . | . | mEq/L (mmol/L) | Not done |
| Magnesium | . | . | . | mEq/L (mmol/L) | Not done |
| Calcium | . | . | . | mEq/L (mmol/L) | Not done |
| Potassium | . | . | . | mEq/L (mmol/L) | Not done |
| Glucose  Condition:  Fasting  Non-fasting  Unknown | . | . | . | mg/dL OR  [μmol/L] | Not done |
| Other test *(spesify):* | Result: |  |  | Units \_\_\_\_\_\_\_\_\_\_\_\_    N/A | Not done |
| Other test *(spesify):* | Result: |  |  | Units \_\_\_\_\_\_\_\_\_\_\_\_    N/A | Not done |
| Other test *(spesify):* | Result: |  |  | Units \_\_\_\_\_\_\_\_\_\_\_\_    N/A | Not done |

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| 1. **CBC and Coagulation** Not done *(proceed to the next section)* |

1. Date of CBC: --

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| **Test** | **Value** | **Unit** | **Not done** |
| Hemoglobin | . | g/dL OR g/L | Not done |
| Hematocrit | . | % OR L/L | Not done |
| Platelets |  | x103/mm3 (109/L) | Not done |
| WBC | . | x103/mm3 (109/L) | Not done |
| Other test *(spesify):* | Result: | Units \_\_\_\_\_\_\_\_\_\_\_\_    N/A | Not done |
| Other test *(spesify):* | Result: | Units \_\_\_\_\_\_\_\_\_\_\_\_    N/A | Not done |
| Other test *(spesify):* | Result: | Units \_\_\_\_\_\_\_\_\_\_\_\_    N/A | Not done |

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| 1. **Other tests/consultations** |

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| **Test** | **Date** | **Result** | **Not Done** |
| Visual acuity (Snellen test) | -- | Left Eye (OS) -  OR  No light perception  Right Eye (OD) -  OR  No light perception | Not done |
| Color vision | -- | Color vision:  Normal  Abnormal  Color vision test method:  Ishihara  Snellen chart  Other, specify: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  If abnormal Ishihara, specify number of plates missed out of 1-11 in 14 plate book:  Left  Right | Not done |
| Simple Hearing Test | -- | Normal  Abnormal | Not done |
| Audiogram | -- | Audiogram result:  Normal  Abnormal  Left Ear \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Rigth Ear \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | Not done |
| ECG (12-lead) | -- | Was this ECG done 2 hours after initiation of treatment?  Yes  No  QT interval (Fridericia): msec  QT interval (uncorrected):msec  Heart rate: bpm | Not done |
| Other clinical evaluations *(specify* *test):* | **--** | Result:  Units: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ N/A  LLN: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ N/A  ULN: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ N/A | Not done |
| Other clinical evaluations *(specify* *test):* | **--** | Result:  Units: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ N/A  LLN: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ N/A  ULN: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ N/A | Not done |

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| **Test** | **Date** | **Result** | **Not Done** |
| Chest X-ray | -- | Interpretation:  Abnormal  Normal in both lungs  Cavities:  Yes No Unknown  Aggregate cavity size:  1 (Absent)  2 (< 4 cm)  3 (> 4 cm) Unknown  Extent of disease:  A (< 25%)  B (25%-49%)  C (> 50%) Unknown | Not done |
| HBsAg | -- | seropositive  seronegative | Not done |
| HBc IgM | -- | seropositive  seronegative | Not done |
| HCV Ab | -- | seropositive  seronegative | Not done |
| Pregnancy Test | -- | Negative  Positive **(If “Positive”,**  **complete Adverse Event Form)** | Male or not done |
| Thyroid Stimulating Hormone (TSH) | -- | .  mIU/L OR U/mL  LLN \_\_\_\_\_\_\_\_\_\_  ULN \_\_\_\_\_\_\_\_\_\_ | Not done |
| Other clinical evaluations *(specify* *test):* | **--** | Result:  Units: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ N/A  LLN: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ N/A  ULN: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ N/A | Not done |
| Other clinical evaluations *(specify* *test):* | -- | Result:  Units: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ N/A  LLN: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ N/A  ULN: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ N/A | Not done |
| Other clinical evaluations *(specify* *test):* | -- | Result:  Units: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ N/A  LLN: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ N/A  ULN: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ N/A | Not done |

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| 1. **Mycobacteriology Results**  Sputum not obtained *(proceed to the next section)* |

Please fill in Mycobacteriology Results PER SPECIMEN. If >1 specimens were obtained, record results for each specimen on a separate form.

1. Specimen type:  Sputum  Other specimen, specify:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_
2. Date of specimen collection**:** --
3. Were there more than 1 specimen collected on this date?  Yes  No

If “Yes”, number of specimen recorded here:  Specimen 1  Specimen 2  Specimen 3

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| **Test** | **Date** | **Result** | **Not done** |
| AFB Smear | Date AFB smear examination  -- | Smear method:  Light microscopy  Fluorescence  Smear result:  Positive  Negative  Quantification (for positive smears):  Scanty  1+  2+  3+ | Not done |
| Primary Solid Culture | Date final culture results released  -- | Medium type:  LJ  Ogawa  Other, specify: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Solid culture results:  With growth  No growth  If growth, indicate type of growth below (check all that apply):  Mtb complex  Other acid-fast bacilli (e.g., NTM)  Contamination | Not done |
| Liquid Culture | Date final culture results released  -- | Medium type:  Bactec MGIT 320/960  Manual MGIT  Other, specify: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Liquid culture results:  With growth  No growth  If growth, indicate type of growth below **(check all that apply)**:  Mtb complex  Other acid-fast bacilli **(e.g., NTM)**  Contamination | Not done |

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| **Test** | **Date** | **Result** | **Not Done** |
| Xpert MTB/RIF Test | Specimen type:  Expectorated sputum Induced sputum  Other specimen, specify:\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Date of sputum collection:  -- | Result:  Valid Invalid  No result  If valid result:  *M. tuberculosis* (Mtb) complex:  Detected  Not detected  If MTBC detected:  Rifampicin resistance:  Detected  Not detected  Indeterminate | Not done |
| Line-probe Assay (HAIN MTBDRsI) | Specimen type:  Expectorated sputum Induced sputum  Other specimen, specify:\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Date of sputum collection:  -- | Mtb complex:  Detected  Not detected  If “detected”, provide the following drug susceptibility testing results:  Fluoroquinolones:  Susceptible  Resistant  Indeterminate  Aminoglycosides:  Susceptible  Resistant  Indeterminate  Ethambutol:  Susceptible  Resistant  Indeterminate | Not done |

1. Drug Susceptibility Testing (DST) Results:

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| **Drug** | **Concentration (mcg/mL)** | **Result** | **Method\*** | **Not done** |
| 1. Isoniazid | 0.2 | Susceptible  Resistant  Indeterminate |  |  |
| 1. Rifampicin | 40.0 | Susceptible  Resistant  Indeterminate |  |  |
| 1. Ethambutol | 2.0 | Susceptible  Resistant  Indeterminate |  |  |
| 1. Streptomycin | 4.0 | Susceptible  Resistant  Indeterminate |  |  |
| 1. Pyrazinamide | 100.0 | Susceptible  Resistant  Indeterminate |  |  |
| 1. Ofloxacin | 2.0 | Susceptible  Resistant  Indeterminate |  |  |
| 1. Levofloxacin | 1.0 | Susceptible  Resistant  Indeterminate |  |  |
| 1. Prothionamide | 40.0 | Susceptible  Resistant  Indeterminate |  |  |
| 1. Amikacin | 40.0 | Susceptible  Resistant  Indeterminate |  |  |
| 1. Clofazimine | - | Susceptible  Resistant  Indeterminate |  |  |
| Other, Specify – If other drugs were tested, specify below: | | | |  |
|  | . | Susceptible  Resistant  Indeterminate |  |  |
|  | . | Susceptible  Resistant  Indeterminate |  |  |

\*Method: A=7H10 Agar B=BACTEC MGIT C=LJ O=Other, specify\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

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| 1. **Form Completion** |

PRINT name of person completing form:

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Date Evaluation Form completed: --