**Appendix 2. Clinical Advisory Committee Request Form**

**endTB Clinical Trial Clinical Advisory Committee Request Form – P.1**

|  |  |  |  |
| --- | --- | --- | --- |
| **Study Suject ID** |  | **Date of request:** |  |
| **Subject’s Date of Birth (YYYY):** |  | **Subject’s Sex (Tick one):** |  Male Female  |
| **Request Form Filled by (Name and Role):** |  | **Responsible Clinician for the case (Name and Role):** |  |
| **Treatment Arm (if participant already enrolled) 1 2 3 4 5 SOC**  |
| Category |  Eligibility Clinical Management ED approval Permanent drug change Build SOC | If relevant:Weight at baseline: Weight at current date:  | If applicable:ConMeds treatment ongoing at current date: |
| Background information |  |
| **Question to the CAC:** |
|  |
| **General Subject Information** |
| **Week Number (or UNS) and** **Date (DD/MMM/YYYY)** | **Clinical Data**(Vital signs, main clinical issues) | **Treatment**(Con meds other than anti-TB drugs, hospitalization, surgery…) | **Non-TB Test Results**(Tests other than smear, culture, DST. Specify dates of results) |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |
|  |
|  |
| **Attached Documents (Please tick all applicable):** |   Blood test results ECG traces Chest X-ray AE/SAE form(s) Concomitant Medication Log |

**endTB Clinical Trial Clinical Advisory Committee Request Form – P.2**

**(Please complete only if you are submitting a clinical management query)**

|  |
| --- |
| **MDR-TB Treatment** (Please specify date treatment started and daily dosage (mg), change of dosage, and cessation of drugs) |
| Date | H | R | E | Z | Km | Am | Cm | Lfx | Mfx | Pto | Eto | Cs | PAS | Bd | Dl | Lzd | Cfz | Other | Other |
| Prior |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
|  **Bacteriology** (Please specify sample collection date and result) |  |
| Date | Smears(0, scanty, +, ++, or +++) | Culture(P=positive, N=negative, C=Contaminated) | Comments | Date | Weight | Comment |
| Prior |  |  |  |  |  |  |
|  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |
| **Drug Susceptibility Results**(Please specify test collection date and result: R = resistant, S = susceptible, C = contaminated, N = negative) |
| Date | H | R | E | Z | S | Km | Cm | Ofx2 | Ofx8 | Eto | PAS | Lzd | Cfz | Bd | Dl | Others |  |  |  |
| Prior |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |