# Annexure 12B Cohort Event Monitoring (CEM) - Treatment Review Form

**To be filled at per schedule and when any adverse event reported by the patient on newer drug containing regimen and for the other DR-TB patients when serious adverse event (DAIDS grade 3 or 4) is reported**

<table>
<tr><td colspan="5">PATIENT DETAILS Interview Date: _____(DD/MM/YYYY)</td></tr>
<tr><td colspan="2">Patient Name .....</td><td>Age: .....</td><td>PMDT No./ File No:_____</td><td>Nikshay ID:</td></tr>
<tr><td colspan="3" rowspan="2">Patient Address:</td><td>Weight (kg):.....<br>Height (cm):.....</td><td rowspan="2">Sex: ☐ Male<br>☐ Female<br>☐ Others</td></tr>
<tr><td colspan="5">MEDICAL DETAILS</td></tr>
<tr><td colspan="3">Type of TB<br>☐ Pulmonary TB<br>☐ Extra-pulmonary TB site/s: _____</td><td>Type of drug resistance<br>☐ H mono/ poly<br>☐ RR/MDR-TB</td><td>☐ RR/MDR-TB + any FQ/SLI<br>☐ XDR-TB</td></tr>
<tr><td colspan="5">Prior exposure to anti-TB medicines ☐ Yes ☐ No ☐ Unknown</td></tr>
<tr><td rowspan="2">Pregnancy status (UPT)</td><td colspan="2" rowspan="2">☐ Yes ☐ No ☐ Unknown</td><td>Date of LMP: DD/MM/YYYY</td><td>or estimated current gestation (weeks):</td></tr>
<tr><td colspan="2">If PREGNANT record patient details</td></tr>
<tr><td>Breastfeeding an infant</td><td colspan="4">☐ Yes ☐ No ☐ Unknown</td></tr>
<tr><td colspan="5">ADR description: Reporter's Narrative (Describe the course of events, timing and suspected causes of ADR):</td></tr>
<tr><td colspan="5"></td></tr>
<tr><td colspan="5">ADR Terminology/Adverse event</td></tr>
<tr><td colspan="5">For patient under CAP during follow up visit (Fill the details of any event happened since the last follow up visit)<br>(eg. Minor ADR, Accident, Travel, other medication etc)</td></tr>
<tr><td colspan="5"></td></tr>
<tr><td colspan="5">DAIDS grading (Tick appropriate checkbox)<br>☐ GRADE 1: Mild symptoms causing no or minimal interference with usual social & functional activities with intervention not indicated<br>☐ GRADE 2: Moderate symptoms causing greater than minimal interference with usual social & functional activities with intervention indicated<br>☐ GRADE 3: Severe symptoms causing inability to perform usual social and functional activities with intervention or hospitalization indicated<br>☐ GRADE 4: Potentially life threatening symptoms causing inability to perform basic self-care functions with interventions indicated to prevent permanent impairment, persistent disability or death</td></tr>
</table>

| | | | | | | |
|---|---|---|---|---|---|---|
| **Date of Onset** | DD/MM/YY | | | | | |
| **Date Resolved** | DD/MM/YY | | | | | |
| **ADR/SAE Seriousness** | ☐ Death<br>☐ Life threatening<br>☐ Hospitalization required<br>☐ Permanent disability<br>☐ Congenital anomaly/ birth defect<br>☐ Other medically important condition<br>☐ Required intervention to prevent permanent impairment/ damage | | | | | |
| **Outcome** | ☐ Recovered/ resolved<br>☐ Recovered/resolved with sequel<br>**Recovery date……**<br>☐ Fatal<br>☐ Recovering/resolving<br>☐ Not recovering/ not resolved<br>☐ Unknown | | | | | |
| **For Death/SAE** | Date of Death…….<br>Primary cause of death (if known): ……<br>Was autopsy performed?<br>☐ No<br>☐ Yes (If yes, attach copy of report if available)<br>Hospital Admission Date ……<br>Hospital Discharge Date…… | | | | | |
| **Causality /Relation to medicine** | Assign Causality with following grading for suspected drug | | | | | |

| | Certain | Probable | Possible | Doubtful or Unlikely | Conditional or Unclassified | Unassessable |
|---|---|---|---|---|---|---|
| H | | | | | | |
| R | | | | | | |
| E | | | | | | |
| Z | | | | | | |
| Km | | | | | | |
| Am | | | | | | |
| Cm | | | | | | |
| Lfx | | | | | | |
| Mfx | | | | | | |
| Cs | | | | | | |
| Eto | | | | | | |
| PAS | | | | | | |
| Lzd | | | | | | |
| Cfz | | | | | | |
| Amx-Clv | | | | | | |
| Clr | | | | | | |
| Bdq | | | | | | |
| Dlm | | | | | | |
| | | | | | | |

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|---|---|---|---|---|
| **Suspected drugs name** | | | | |
| **Dechallenge** | ☐ No Dechallenge<br>☐ Reaction Abated<br>☐ Dose Reduced<br>☐ Result unknown | ☐ No Dechallenge<br>☐ Reaction Abated<br>☐ Dose Reduced<br>☐ Result unknown | ☐ No Dechallenge<br>☐ Reaction Abated<br>☐ Dose Reduced<br>☐ Result unknown | ☐ No Dechallenge<br>☐ Reaction Abated<br>☐ Dose Reduced<br>☐ Result unknown |
| **Rechallenge** | ☐ No Rechallenge<br>☐ Recurrence of event<br>☐ No recurrence<br>☐ Result unknown | ☐ No Rechallenge<br>☐ Recurrence of event<br>☐ No recurrence<br>☐ Result unknown | ☐ No Rechallenge<br>☐ Recurrence of event<br>☐ No recurrence<br>☐ Result unknown | ☐ No Rechallenge<br>☐ Recurrence of event<br>☐ No recurrence<br>☐ Result unknown |
| **Expectedness** | ☐ Expected<br>☐ Unexpected | ☐ Expected<br>☐ Unexpected | ☐ Expected<br>☐ Unexpected | ☐ Expected<br>☐ Unexpected |

| | |
|---|---|
| **If newer drugs (Bdq or Dlm) is suspected**<br><br>☐ Bdq ☐ Dlm | Start Date of newer drug…… Stop Date of newer drug ……<br>Action taken for suspected drug<br>☐ No adjustment<br>☐ Dose Adjusted<br>☐ Temporary Stop<br>☐ Permanent Stop<br>If permanent stop,<br>it was provider decision ☐ please specify reason _____ or<br>it was patient decision ☐ please specify reason _____)<br>Batch/Lot No/ Expiry…… Dose……Frequency…… Route…… |

| **LABORATORY & OTHER TESTS** | | | | | |
|---|---|---|---|---|---|
| **Test** | **Date** | **Result (units)** | **Test** | **Date** | **Result (units)** |
| Sputum smear | | | ALT (SGPT) | | |
| Sputum Culture | | | AST (SGOT) | | |
| Line probe assay | | | Lactic acid | | |
| Nucleic acid testing | | | Lipase | | |
| Tuberculin Test | | | Chest X-Ray | | Cavities (Y/N) Pl specify Xray findings_____ |
| HIV Antibody | | | ECG | | QTc<br>Any other changes |
| CD4 Count | | | Audiometry | | |
| ESR | | | Visual acuity | | |
| Total WBC | | | Bilirubin- Direct<br>-Indirect | | |
| Haemoglobin | | | Hepatitis markers | | |
| Creatinine | | | TSH | | |
| Creatinine Clearance | | | Other | | |
| Glucose | | | | | |
| Drug susceptibility | | | | | |

| **Medicines** | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| Anti-TB medicines taken since last interview | Dosage (µg/mg/ g/ml) | Frequency (OD/BD/ TID) | Route (Oral/IV/IM /Topical/ other) | Start Date | Continues | If No. Stop date | Reason (s) for stopping # | Action** |
| | | | | | Yes/ No | | | |
| | | | | | Yes/ No | | | |
| | | | | | Yes/ No | | | |
| | | | | | Yes/ No | | | |
| | | | | | Yes/ No | | | |
| | | | | | Yes/ No | | | |
| | | | | | Yes/ No | | | |
| | | | | | Yes/ No | | | |
| | | | | | Yes/ No | | | |

| Other medicines & traditional medicines taken since last interview | Indication | Dosage (µg/mg/ g/ml) | Frequency (OD/BD/ TID) | Route (Oral/IV/IM /Topical/ other) | Start Date | Continues | Stop date | Reason (s) for stopping# | Action** |
|---|---|---|---|---|---|---|---|---|---|
| | | | | | | Yes/ No | | | |
| | | | | | | Yes/ No | | | |
| | | | | | | Yes/ No | | | |
| | | | | | | Yes/ No | | | |
| | | | | | | Yes/ No | | | |

| All NEW medicines (anti-TB & other) prescribed at this interview | Indication | Dosage (µg/mg/ g/ml) | Frequency (OD/BD/ TID) | Route (Oral/IV/IM /Topical/ other) | Start Date | Expected Stop date | Indication |
|---|---|---|---|---|---|---|---|
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**Any other relevant clinical information**

**REPORTERS INFORMATION**

Name of the Reporter:

Signature:

Date:

** Action taken by clinician in case of suspected adverse event linked to a drug

Dose not changed
Drug withdrawn
Not applicable
Dose reduced
Drug interrupted