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| **A. Patient and Health Facility Information** | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Name/Patient ID number (as in DRTB Register: | | | | | | |  | | | | | | | | | | | | | | | | | | | | | | Treatment Centre: | | | | | | | | | |  | | | | | | | | | | | | | | | | |
| Date of Birth (*or* Age): | | | | | | |  | | | | | | | | | | | | | | | | | | | | | | Province: | | | | | | | | | |  | | | | | | | | | | | | | | | | |
| Sex: | | | | 🞎 Male | | | | | | | | | | | | | 🞎 Female | | | | | | | | | | | |  | | | | | | | | | |  | | | | | | | | | | | | | | | | |
| HIV status: | | | | 🞎 Non-reactive | | | | | | | | | | | | | 🞎 Reactive | | | | | | | | | | | |  | | | | | | | | | |  | | | | | | | | | | | | | | | | |
| Pregnancy: | | | | 🞎 No | | | | | | | | | | | | | 🞎 Yes | | | | | | | | | | | | Trimester: | | | | | | | | | |  | | | | | | | | | | | | | | | | |
| Weight (kg): | | | | | | |  | | | | | | | | | | | | | | | | | | | | | | Height (cm): | | | | | | | | | |  | | | | BMI: | | | | | | | | |  | | | |
| **B. Adverse events experienced by patient** (including abnormal investigations) | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Adverse event | | | | | | | | | | | | | | | | | | | Onset date | | | | | | | | | End date | | | | | | Severity grade | | | | | | | | Seriousness **\*** | | | | | | | Outcome **§** | | | | | | |
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| **\*** Please select: | | | ***D*** *died* | | | ***LT*** *life threatening* | | | | | | | | | | | | | | | ***HA*** *caused or prolonged hospital admission* | | | | | | | | | | | | | | | | | | | | | | ***PD*** *permanent disability* | | | | | | | | | | | | |
|  | | | ***OS*** *other medically serious* | | | | | | | | | | | | | | | | | | ***CA*** *congenital abnormality* | | | | | | | | | | | | | | | | | | | | | | ***NS*** *not serious* | | | | | | | | | | | | |
| **§** Please select: | | | ***A*** *recovered* | | | | | | | ***B*** *recovering* | | | | | | | | | | | ***C*** *recovered with residual effects* | | | | | | | | | | | | | | | | ***D*** *died* | | | | | | ***E*** *not recovered* | | | | | | | ***F*** *unknown* | | | | | |
| Detailed description of adverse event(s): | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Was treatment of adverse event required? | | | | | | | | | | | | 🞎 No | | | | | | | | | 🞎 Yes (please specify): | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
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| **C. Laboratory assessment:** Results of tests and procedures | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Test performed | | | | | | | | | | | | | Test date | | | | | | | | | | Result | | | | | | | | | | | | | Unit | | | | | | | | | | | Reference range | | | | | | | | |
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| **D. Medicines:** DR-TB Regimen and other concomitant medicines, vaccines, traditional / herbal medicines and dietary supplements | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| 🗹 *Tick if medicine suspected of causing adverse event* | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Medicine | | | | | | | | | Dose | | | | | Frequency | | | | | | Route | | Start date | | | | | | | | Stop date | | | | | Reason for use | | | | | | | | | | | Action taken **†** | | | | | | | Response ‡ |
| 🞎 |  | | | | | | | |  | | | | |  | | | | | |  | |  | | | | | | | |  | | | | |  | | | | | | | | | | |  | | | | | | |  |
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| **†** *Action taken in response to AE:* | | | | ***DW*** *drug withdrawn* | | | | | | | | | | | | | | ***DR*** *dose reduced* | | | | | | | | ***DI*** *dose increased* | | | | | | | ***DNC*** *dose not changed* | | | | | | | | | | | | ***UK*** *unknown* | | | | | | ***NA*** *not applicable* | | |
| **‡** *Response to action taken*: | | | | ***RA*** *recovered* | | | | | | | | | | | | | | ***NE*** *no effect on AE* | | | | | | | | ***FA*** *fatal AE* | | | | | | | ***UN*** *unknown* | | | | | | | | | | | | ***NA*** *not applicable* | | | | | | | | | |
| **E. Re-challenge information** | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| List any medicines that were restarted and indicate effect on adverse event | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Medicine | | | | | | | | adverse event recurred | | | | | | | | | | | | | | | | | | | adverse event did not recur | | | | | | | | | | | | | | unknown | | | | | | | | | | | | | |
|  | | | | | | | | 🞎 | | | | | | | | | | | | | | | | | | | 🞎 | | | | | | | | | | | | | | 🞎 | | | | | | | | | | | | | |
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| **F. Other relevant information e.g. medical history, concurrent illnesses, smoking, alcohol use and Hospital Management** | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
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| **G. Causality Assessment at Treatment Center Level** | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| 1. **Certain 2. Probable 3. Possible 4. Unlikely 5. Unassessed 6. Un-assessable**   **Comments:** | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| **H. Final AE/SAE Summary** | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Adverse Events Description:  Event Start date  Event End date  Severity Grading  Event classified: 1. Serious 2. Not – Serious (Based on Annex 2)  Narrative / Additional information (Final Result): | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| **G. Reporter Information** | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Name: | | | | | | | | | | | | | | | | | | | | | | | | | Phone number: | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Email: | |  | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Occupation: | | 🞎 Doctor | | | | | | | | | 🞎 Nurse | | | | | | | | | | | | | | 🞎 Paramedics | | | | | | | | | | | | | 🞎 Other (please specify): | | | | | | | | | | | | | | | | |
| Signature: | | | | | | | | | | | | | | | | | | | | | | | | | Date | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| **Submit form to:** | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Email to: M&E Unit, NTC: [aDSMNTC@gmail.com](mailto:aDSMNTC@gmail.com) | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| **NTC Use Only:** | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Date received by NTC: | | | | |  | | | | | | | | | | | | | | | | | | | | | | | |  | | | | | | | | | | | | | | | | | | | | | | | | | |
| Causality assessment: | | | | | 🞎 Certain | | | | | | | | | | 🞎 Probable | | | | | | | | | 🞎 Possible | | | | | | | 🞎 Unlikely | | | | | | | | | 🞎 Unassessed | | | | | | | | 🞎 Un-assessable | | | | | | |
| Comment: | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Reported to DDA: | | | | | 🞎 No | | | | | | | | | | | 🞎 Yes | | | | | | | | | | | | | | | | Date reported to DDA: | | | | | | | | | | | |  | | | | | | | | | | |