**TEMPLATE FOR LINE LISTING SERIOUS ADVERSE EVENTS (SAEs) AND ADVERSE EVENTS (AEs) FOR**

**MRC-APPROVED PROTOCOLS**

**PROTOCOL NUMBER:**

**PROTOCOL TITLE:**

**DATE OF INITIAL APPROVAL:**

**NAME OF PI / INVESTIGATOR:**

**SITE NUMBER/NAME:**

**STUDY PRODUCT:**

**PERIOD OF REPORTING:**

| **PID**  **NO** | **REPORT DATE** | **PI/SITE** | **AGE/DOB**  **GENDER** | **PRODUCT** | **THERAPY START DATE** | **EVENT**  **DECRIPTION/ DIAGNOSIS** | **DATE OF ONSET** | **SAE CATEGORY** | **OUTCOME** | **RELATIONSHIP TO STUDY DRUG** |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **E.g. row:**  01 | 12/08/10  Initial | Dr Day  05 | 40yrs (F) | AB | 19/05/09 | Angina | 10/08/10 | Hospitalised | Died | Not related |
|  |  |  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |  |