|  |  |
| --- | --- |
| **SECTION A ADMINISTRATIVE** | |
| Was adverse events completed? | No (Complete protocol deviation form)  Yes |
| Date of assessment: | \_\_|\_\_|\_\_\_\_|\_\_\_\_| DD-MMM-YYYY |

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Variable** | **Label / Question** | **Type** | **Controlled Terminology** | **Data Entry** | **Instructions** |
| AETERM | Adverse Event Term | text |  |  | *Record the term* |
| AESEV | Severity | text | MILD;MODERATE;SEVERE | MILD MODERATE SEVERE | *Select severity* |
| AESTDTC | Start Date | date |  |  | *Enter date* *Format: dd/mm/yyyy* |
| *Right-click -> Insert -> Insert Rows Below to add more entries.* | | | | | |