|  |  |
| --- | --- |
| **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 | Char |  |  | *Record the term for the adverse event.* |
| AESER | Serious Event | Char | Y; N | Y N | *Is this a serious event?* |
| AESTDTC | Start Date | Char |  |  | *Record the start date of the event.* *Format: YYYY-MM-DD* *Format: dd/mm/yyyy* |
| *Right-click -> Insert -> Insert Rows Below to add more entries.* | | | | | |

## Suggested Adverse Event Terms from OpenFDA

|  |
| --- |
| **Reaction Term** |
| Drug hypersensitivity |
| Back pain |
| Cerebrovascular accident |
| Blood pressure increased |
| Pain |
| Oedema peripheral |
| Fluid retention |
| Hypertension |
| Dehydration |
| Night sweats |
| Panic attack |
| Hyperlipidaemia |
| Insomnia |
| Cold sweat |
| Bipolar disorder |
| Hyperhidrosis |
| Dysgeusia |
| Nausea |
| Transfusion |
| Influenza |
| Pneumonia |
| Rash |
| Dyspnoea |
| Haemoglobin decreased |
| Weight increased |
| Type 2 diabetes mellitus |
| Grand mal convulsion |
| Vomiting |
| Amnesia |
| Blood count abnormal |
| Platelet count decreased |
| Platelet count decreased |
| Blood count abnormal |
| Increased appetite |
| Incontinence |
| Off label use |
| Epistaxis |
| Blindness |
| Weight increased |
| Skin cancer |
| Nasopharyngitis |
| Dizziness |
| Dry eye |
| Wrong technique in product usage process |
| Pruritus |
| Increased tendency to bruise |
| Diarrhoea |
| Constipation |
| Pain |
| Dizziness |
| Headache |
| Malaise |
| Nausea |
| Haemoglobin decreased |
| Headache |
| Lower gastrointestinal haemorrhage |
| Rash |
| Rash |
| Headache |
| Oral mucosal erythema |
| Oral pain |
| Abdominal tenderness |