Data Collection and Analysis Tool

**SAE REPORT**

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| **A. BASIC PATIENT INFORMATION** | | | | | | |
| Patient Name | \*PatientName\* | | | Date of Birth | | \*BirthDate\* |
| Age Group | \*AgeGroup\* | | | Age at time of onset | | \*OnsetAge\* |
| Gender | \*Gender\* | | | Facility | | \*Facility\* |
| Medical Record Number | \*MedicalNumber\* | | | Identity Number | | \*IdentityNumber\* |
| Weight (kg) | \*Weight\* | | | Height (cm) | | \*Height\* |
| Notes: |  | | | | | |
| **B. PRE-EXISITING CONDITIONS** | | | | | | |
| Condition 1 | \*Condition\_1\* | | | | | |
| Start Date | \*StartDate\_1\* | | | | | |
| End Date | \*EndDate\_1\* | | | | | |
| Condition 2 | \*Condition\_2\* | | | | | |
| Start Date | \*StartDate\_2\* | | | | | |
| End Date | \*EndDate\_2\* | | | | | |
| **B. ADVERSE EVENT INFORMATION** | | | | | | |
| Source Description1 | \*SourceDescription\* | | | MedDRA Term | | \*MeddraTerm\* |
| Onset Date | \*OnsetDate\* | | | Resolution Date | | \*ResolutionDate\* |
| Duration | \*Duration\* | | | Outcome | | \*Outcome\* |
| Seriousness | \*Seriousness\* | | | Grading Scale | | \*GradingScale\* |
| Severity Grade | \*SeverityGrade\* | | | SAE Number | | \*SAENumber\* |
| Notes: |  | | | | | |
| **C. MEDICATIONS** | | | | | | |
| Drug 1 | Start Date | End Date | Dose | | Route | Indication |
| \*Drug\_1\* | \*DStart\_1\* | \*DEnd\_1\* | \*Dose\_1\* | | \*Route\_1\* | \*Indication\_1\* |
| C.1 CLINICIAN ACTION TAKEN WITH REGARD TO MEDICINE | | | | | | |
|  | | | | | | |
| C. 2 EFFECT OF DECHALLENGE/ RECHALLENGE | | | | | | |
|  | | | | | | |
| Drug 2 | Start Date | End Date | Dose | | Route | Indication |
| \*Drug\_2\* | \*DStart\_2\* | \*DEnd\_2\* | \*Dose\_2\* | | \*Route\_2\* | \*Indication\_2\* |
| C.1 CLINICIAN ACTION TAKEN WITH REGARD TO MEDICINE | | | | | | |
|  | | | | | | |
| C. 2 EFFECT OF DECHALLENGE/ RECHALLENGE | | | | | | |
|  | | | | | | |
| C. 3 NOTES | | | | | | |
|  | | | | | | |
| **E. CLINICAL EVALUATIONS** | | | | | | |
| Test | Test Date | | | Test Result | | |
| \*Test\_1\* | \*TestDate\_1\* | | | \*TestResult\_1\* | | |
| \*Test\_2\* | \*TestDate\_2\* | | | \*TestResult\_2\* | | |
| \*Test\_3\* | \*TestDate\_3\* | | | \*TestResult\_3\* | | |
| \*Test\_4\* | \*TestDate\_4\* | | | \*TestResult\_4\* | | |
| Notes: |  | | | | | |