Narratives should include patient identifier, age, and sex. The drug/investigational product administered and dose (if not the same for all patients) should be included, as well as the dates/length of time of administration. This information may be provided in a tabular format and/or contained in the narrative text.

A narrative should be provided for each death, other serious adverse event, and other significant adverse event that is considered to be of special interest due clinical importance; this may include events that lead to withdrawal of study drug, dose interruption, and/or dose delay or another event or laboratory abnormality deemed of interest for monitoring. Events clearly not related to study drug may be omitted or described briefly. Key details of the events meeting narrative criteria may be displayed in a tabular format and discussed further in text.

HEADER (Patient details) **Protocol:** XXXXXXXX
Patient ID: XXX
Assigned Treatment Group: XXXX
Race/Ethnicity/Gender:
Age at Screening: xx Years
Date Study Drug First Administered: DD Month YYYY
Date Study Drug Last Administered: DD Month YYYY
REASON FOR NARRATIVE/EVENTS MEETING NARRATIVE CRITERIA

Event Term	Onset Date (Study Day)/	Total Exposure To Study	Event Outcome	Relationship to Study	Action Taken With

Disease under study, if not the same for all patients, and duration should generally be mentioned.

Event Term	Onset Date (Study Day) / Resolution Date (Study Day)	Total Exposure to Study Drug at Event Onset	Event Outcome	Relationship to Study Drug	Action Taken with Study Drug
Preferred Term (MedDRA)	DD Month YYY (Study Day XX) / DD Month YYYY (Study Day XX)	XX Days	Resolved	Related	None

EVENT SUMMARY (written text)

Subject X was a <age>-year-old <gender> with <disease> since <YYYY>. The subject received study treatment from <first dose date> to <last dose date>. The most recent dose prior to the event was received on <recent dose>.

Relevant medical history included <relevant medical history>.

Relevant concomitant medications included <relevant concomitant medications>.

The narrative should include details of relevant current and prior medical history as well as relevant concomitant and/or prior medications. This information may be included in a tabular format or in text.

Event details: On <date or study day>, the subject experienced <event >. The subject presented with <relevant details surrounding the event> and was hospitalized. Diagnostic tests included <relevant tests and results>. Laboratory test results included <relevant results in text or table form for dates throughout the event>. Treatment included <treatment details>. Action taken with the study drug was <action>. The event <event resolution details> and the subject was discharged from the hospital.

Assessments of relationship: The Investigator assessed the event as <severity/intensity> and considered the event <related; not related; possibly related, etc.> to study drug.

Disposition: The subject <continued to participate in> <withdrew from> <completed> the study.

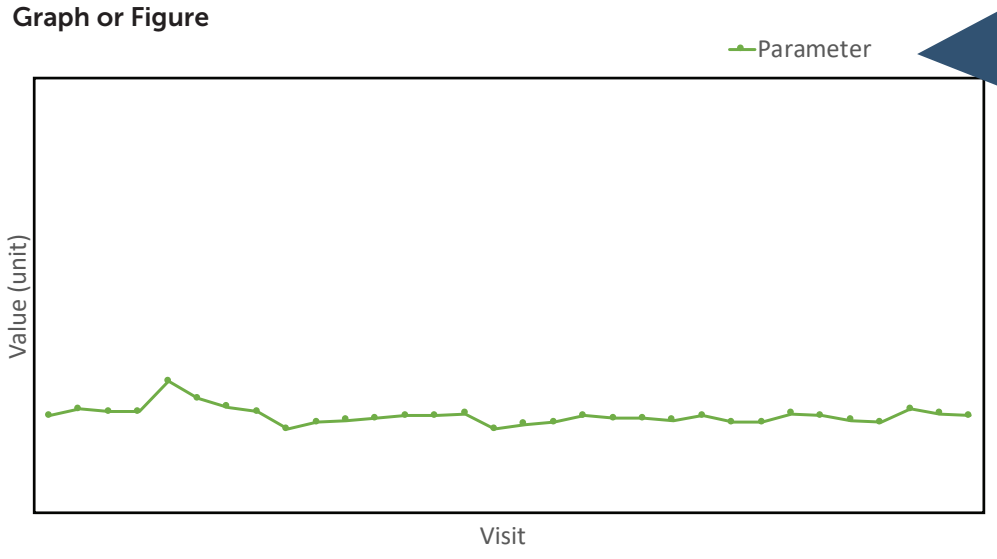
A narrative should include the assessment of causality (relationship to study) by the investigator and sponsor, if appropriate. The narrative story should support the causality assessment.
Patient disposition may also be included in the narrative as appropriate; this may be helpful to include for ongoing trials.

A narrative should chronologically describe the nature and intensity/severity of the event, as well as the clinical course, including timing related to study drug administration. Relevant laboratory findings should be mentioned as applicable. The narrative should discuss treatment for the event and outcome of the event. Any action taken with the study drug should be discussed, including details on dechallenge and rechallenge, if applicable. If the event results in death, any postmortem findings may be included, if available. This information comes from the clinical database (listings, patient profiles, case report forms [CRFs]), safety database (CIOMS forms), and other sources as applicable.

Table

Visit/Date (Study Day)	Laboratory Test (reference range XX - XX unit)	Laboratory Test (reference range XX - XX unit)	Laboratory Test (reference range XX - XX unit)
Screening / DD Month YYYY (Study Day X)	XX	XX	XX

Graph or Figure



Laboratory test results/vital signs deemed relevant or of interest may be presented in a tabular or graphic format to aid the reviewers in studying changes/trends over time for the patient.