

SAE CRF Completion Guidelines Updates

The changes to the SAE CRF are listed below. Please follow the guidelines provided to you with screenshot of the SAE CRF to complete the required questions.

1. Please confirm data source(s) used to complete this SAE report

The screenshot shows the PANORAMIC SAE CRF form for patient OXF00154. The form is titled "SAE for patient OXF00154" and includes a navigation menu with options: Participants, Resources, Manage, Monitoring, Reports, and Central Trial Te... The form is divided into several sections: a summary checklist on the left, a main form area, and a feedback button on the right. The summary checklist includes: Summary (checked), Randomisation (checked), Contact (checked), Baseline (checked), Day 2 Safety call (unchecked), Daily (unchecked), Consent (checked), and 06 Oct - 3 month. The main form area contains the following questions and options: "Please confirm data source(s) used to complete this SAE report" with "Yes" and "No" buttons; "All data from the same data source" with "Yes" and "No" buttons; "Please specify data source" with a dropdown menu showing options: Select, Participant, Trial partner, GP, HES APC, HES LLD, SAIL, eDRIS, and Other; "Adverse event de" with a dropdown menu showing options: Select one, HES APC, HES LLD, SAIL, eDRIS, and Other; "Report type" with a dropdown menu showing options: Select one, HES APC, HES LLD, SAIL, eDRIS, and Other; "SAE" with date and hour fields (dd-MMM-yyyy, HH) and a checkbox for "Hour unknown"; "Stop of SAE" with date and hour fields (dd-MMM-yyyy, HH) and a checkbox for "Hour unknown"; and "Ongoing" with a checkbox.

1.1 Initial SAE report

All data from the same data source (Q1.): Yes / No

Select **Yes** if a new SAE CRF is being completed since the initial data might come from one source, mainly the participant/contact.

Select **No** if the data comes from different sources. Then the data source question appears under each question.

Please specify data source:

This question appears if **Yes** was selected above. Select the source from the drop- down option.

1.2 Follow up /Final SAE report

All data source/s that have been entered on to the initial report will not be displayed on the FU/Final SAE report. Hence select **No** to Q1 if the Initial report data source is different to the one you are completing.

For example, if the initial report data source was ‘participant’ and the FU report source is the GP. In this case whatever data is displayed from the initial report, select ‘participant’ as the data source and select GP for the new data entered or for any participant provided data was replaced with the GP provided data.

2. Adverse event description

The screenshot shows the PANORAMIC software interface for editing an SAE report. The browser address bar shows the URL: <https://panoramic-stage.spinnakersoftware.com/Patient/SAE/EditSAE.aspx?sid=OXF00154&sae=0&nvxid=255470&nvxsc=q&mvxi...>

The interface includes a sidebar with a checklist of items: Summary, Randomisation, Contact, Baseline, Day 2 Safety call, Daily, Consent, 06 Oct - 3 month, 05 Nov - 4 month call, 04 Jan - 6 month, 04 Jan - 6 month call, and Withdrawal.

The main content area is titled "Adverse event description" and contains the following fields:

- Report type:** A dropdown menu with options: Select one, Initial report (highlighted), Follow-up report, and Final report.
- Start of SAE:** Fields for Date (dd-MMM-yyyy) and Hour (HH), with an option for Hour unknown.
- Stop of SAE:** Fields for Date (dd-MMM-yyyy) and Hour (HH), with an option for Hour unknown and a checkbox for Ongoing.
- Diagnosis:** A text area with the instruction: "Please enter the main symptoms if there is no provisional or confirmed diagnosis".
- Is this a provisional or confirmed diagnosis:** A dropdown menu with the instruction: "You can select 'provisional' if you entered only the symptoms".
- SAE description:** A text area with the instruction: "Please record an account of the event including signs and symptoms, any interventions given to manage the event including dates for these and if event fatal, cause of death if known. If this is Follow up or Final report, please only provide new information not captured in the Initial (or the previous FU) report."

A "Feedback" button is located on the right side of the interface.

2.1 Report type (Please make sure to select the correct option)

Initial report

Select this option if it is the first reported SAE.

Follow up report

Select this option if there is an existing initial SAE report and you have new information to update regarding the existing SAE report.

If you selected **Follow Up/Final** report option by mistake then the corresponding initial report data will be displayed. If you change the option to initial report, then the displayed data won't disappear. In this case you have to discard the CRF and start fresh by coming out of the CRF. You can do it by clicking on **Summary** and then adding a new SAE.

Final report

Select this option if there are no further updates required for the SAE and you are providing the answer to all the questions, such as the confirmed diagnosis, causality, stop date and the outcome. If the stop date is unknown but the outcome is resolved or resolving, then no further updates are required because the missing data can be updated on the last report.

2.2 Diagnosis:

The screenshot shows a web browser window with the URL <https://panoramic-stage.spinnakersoftware.com/Patient/SAE/EditSAE.aspx?sid=OXF00154&sae=0&nvxid=255470&nvxsc=q&tmvxi...>. The page displays the 'Diagnosis' section of an SAE report. On the left, a sidebar lists report dates: '05 Nov - 4 month call', '04 Jan - 6 month', '04 Jan - 6 month call', and 'Withdrawal'. The main content area includes a text box for 'Diagnosis' with the instruction 'Please enter the main symptoms if there is no provisional or confirmed diagnosis'. Below this is a dropdown menu for 'Is this a provisional or confirmed diagnosis' with a 'Select' button. The 'SAE description' section has a text box and the instruction 'Please record an account of the event including signs and symptoms, any interventions given to manage the event including dates for these and if event fatal, cause of death if known. If this is Follow up or Final report, please only provide new information not captured in the Initial (or the previous FU) report.' The 'Date and time site became aware of SAE' section has a date-time picker (dd-MMM-yyyy) and a '24 Hour clock' checkbox. Below are dropdown menus for 'Please record severity of event' and 'Reason this event is classified as Serious'. A 'MedDRA Codes' section is highlighted with a blue arrow, containing a note 'For central team use only, please do not enter if a site/hub' and input fields for 'LLT (Lower Level Term)' and 'LLT code'. A 'Feedback' button is visible on the right side of the form. The Windows taskbar at the bottom shows the date as 06/10/2022 and the time as 17:09.

The diagnosis should be brief with one or two words only and should be suitable for coding. If the diagnosis is not known then the significant symptoms /signs or the provisional diagnosis needs to be updated and the status of diagnosis as provisional.