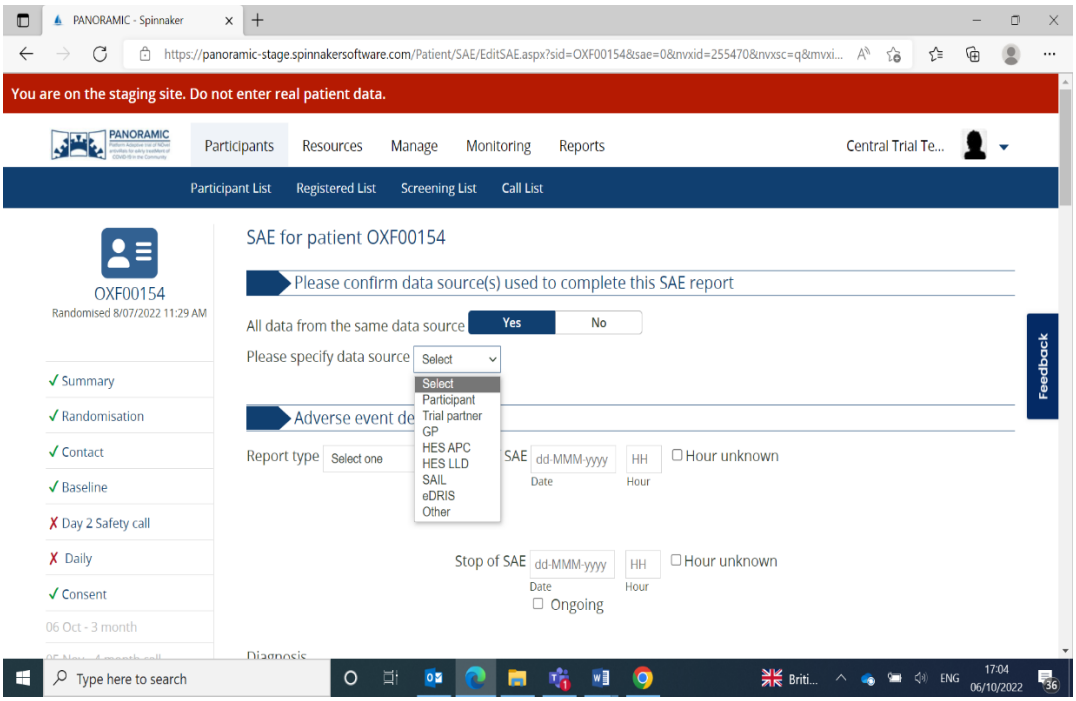
SAE CRF Completion Guidelines Updates

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



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:

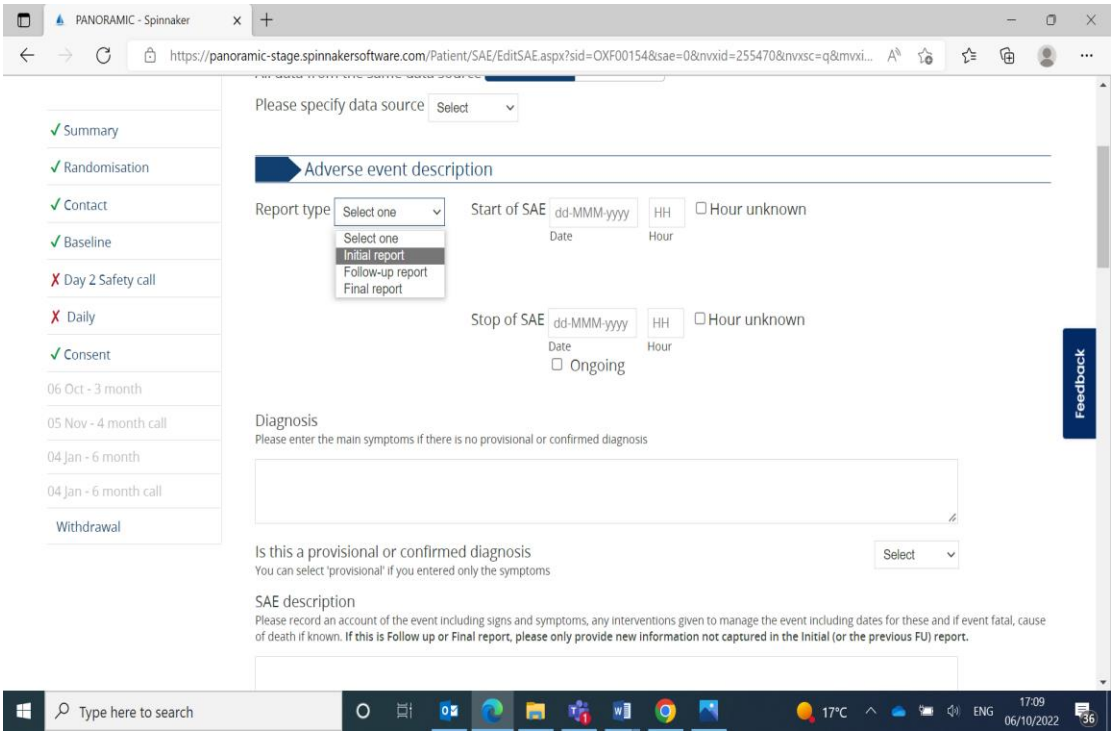
This question appears if **Yes** was selected above. Select the source from the drop- down option.

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



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

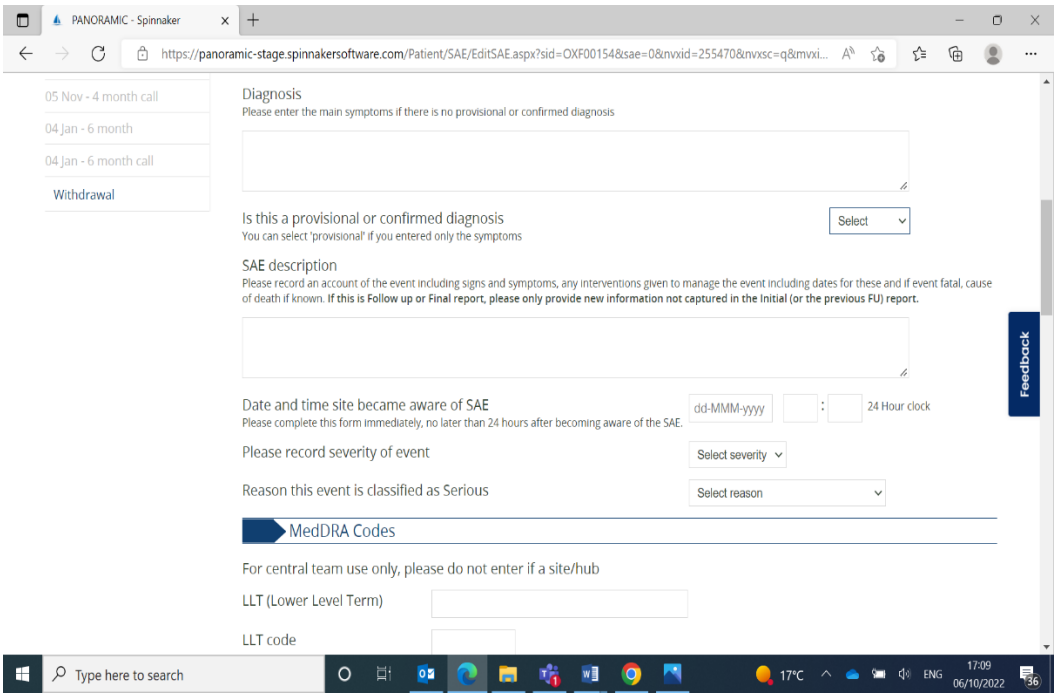
Select this option if there is an existing initial SAE report and you have new information to update regarding the existing SAE report.

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 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.