Appendix 7
e-SUSAR Guidance

Completion of e-SUSAR – an Aide Memoire

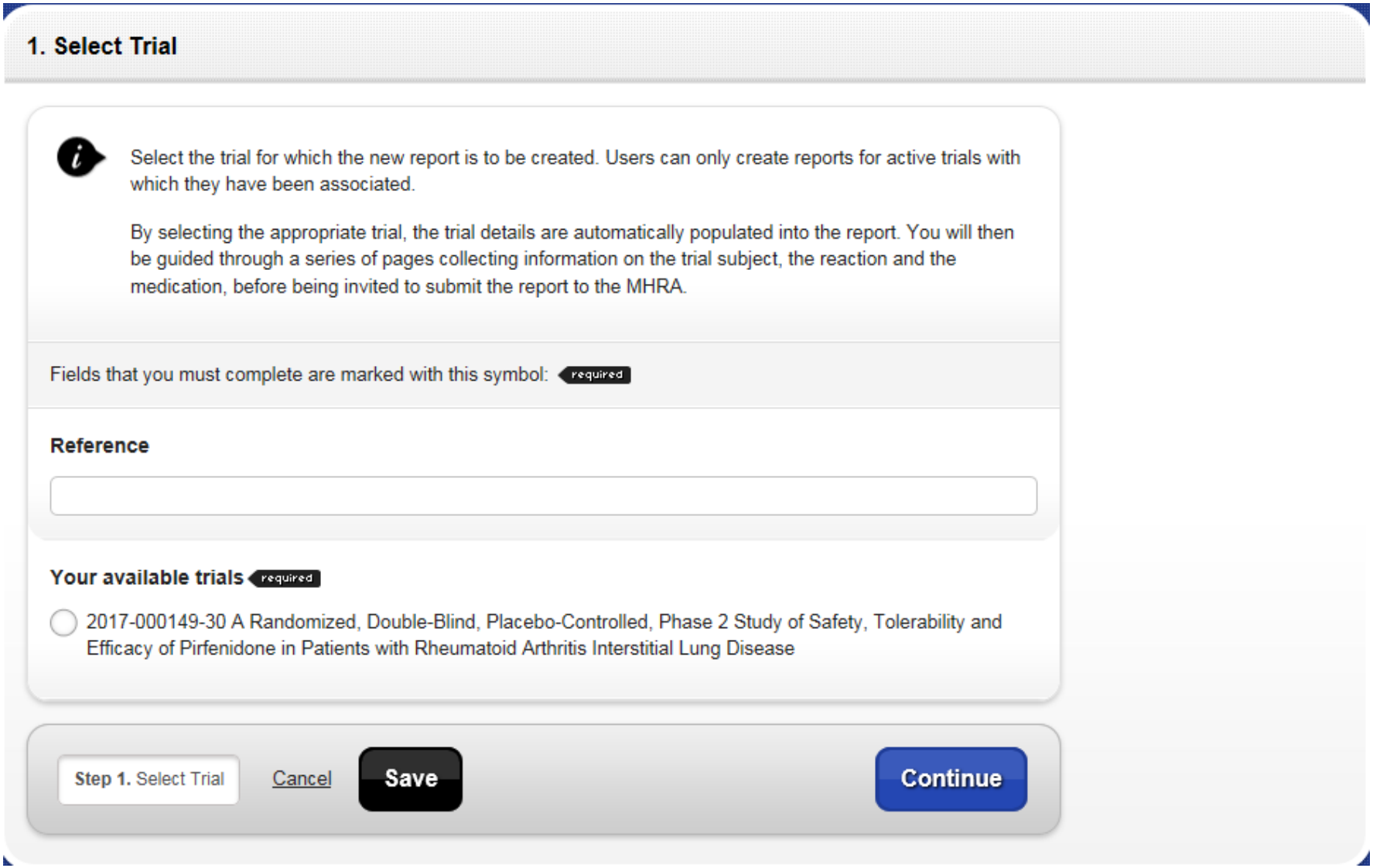
In the absence of a 'test' or 'practice' site we have accessed the e-SUSAR and provided the following. Each page is a screen shot of the tabs that can be found on the e-SUSAR report when you 'add a report' to a study.

When you initially go into the e-SUSAR site, you will only be able to see studies that have been assigned to you. In the first instance you need to check that you can see the studies that you 'should' be assigned to, so that when / if you are required to submit an e-SUSAR report you are not going to fall at the very first hurdle!

The following screen-shots have been taken directly from the site, and the 'help' text is shown next to the button. This should aid you to prepare for when you have your first report to complete.

Please don't 'practice' on the study as this will generate a report which will not be a real event.

e-SUSAR can be accessed by visiting: https://esusar.mhra.gov.uk/login


1. Select Trial
Select the trial for which the new report is to be created. Users can only create reports for active trials with which they have been associated.
By selecting the appropriate trial, the trial details are automatically populated into the report. You will then be guided through a series of pages collecting information on the trial subject, the reaction and the medication, before being invited to submit the report to the MHRA.
Fields that you must complete are marked with this symbol: required
Reference
Your available trials required
2017-000149-30 A Randomized, Double-Blind, Placebo-Controlled, Phase 2 Study of Safety, Tolerability and Efficacy of Pirfenidone in Patients with Rheumatoid Arthritis Interstitial Lung Disease
Step 1. Select Trial
Cancel
Save
Continue

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2. Subject Information

One patient identifier field (Initials, Sex, Age at time of adverse reaction or Subject ID Number) must be completed in order to proceed.

Fields that you must complete are marked with this symbol: required

Initials Help

Please enter the initials of the patient that has suffered the SUSAR

Sex Help

Male Female

Please enter the gender of the patient that has suffered the SUSAR

Age at time of adverse reaction

Units

Subject ID Number Help

Please enter the unique identification number used in the trial to identify the patient that has suffered the SUSAR

Patient weight (kg) Help

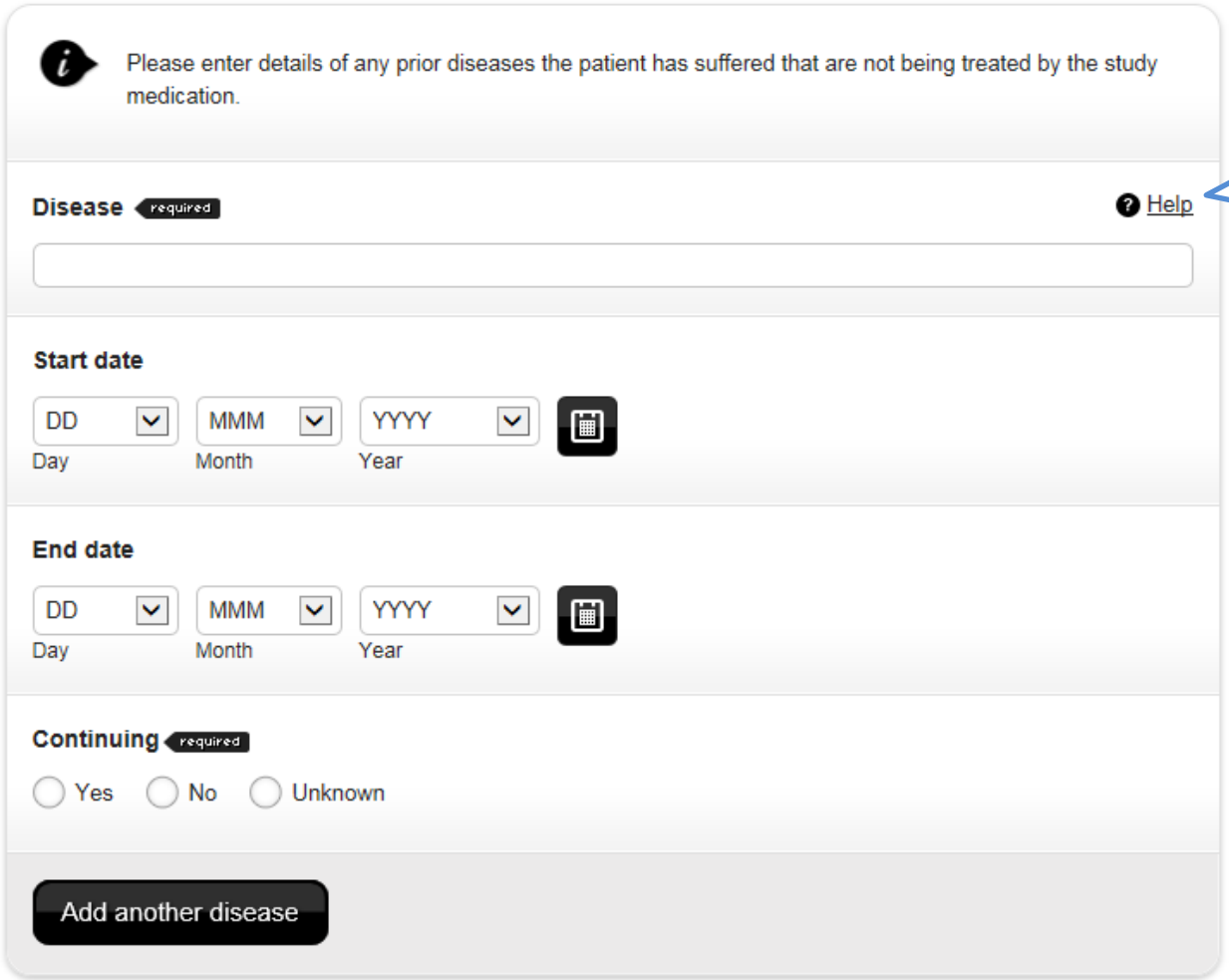
Kg Or Stone Pounds

Please use the stone and pounds fields to convert your weight to kg

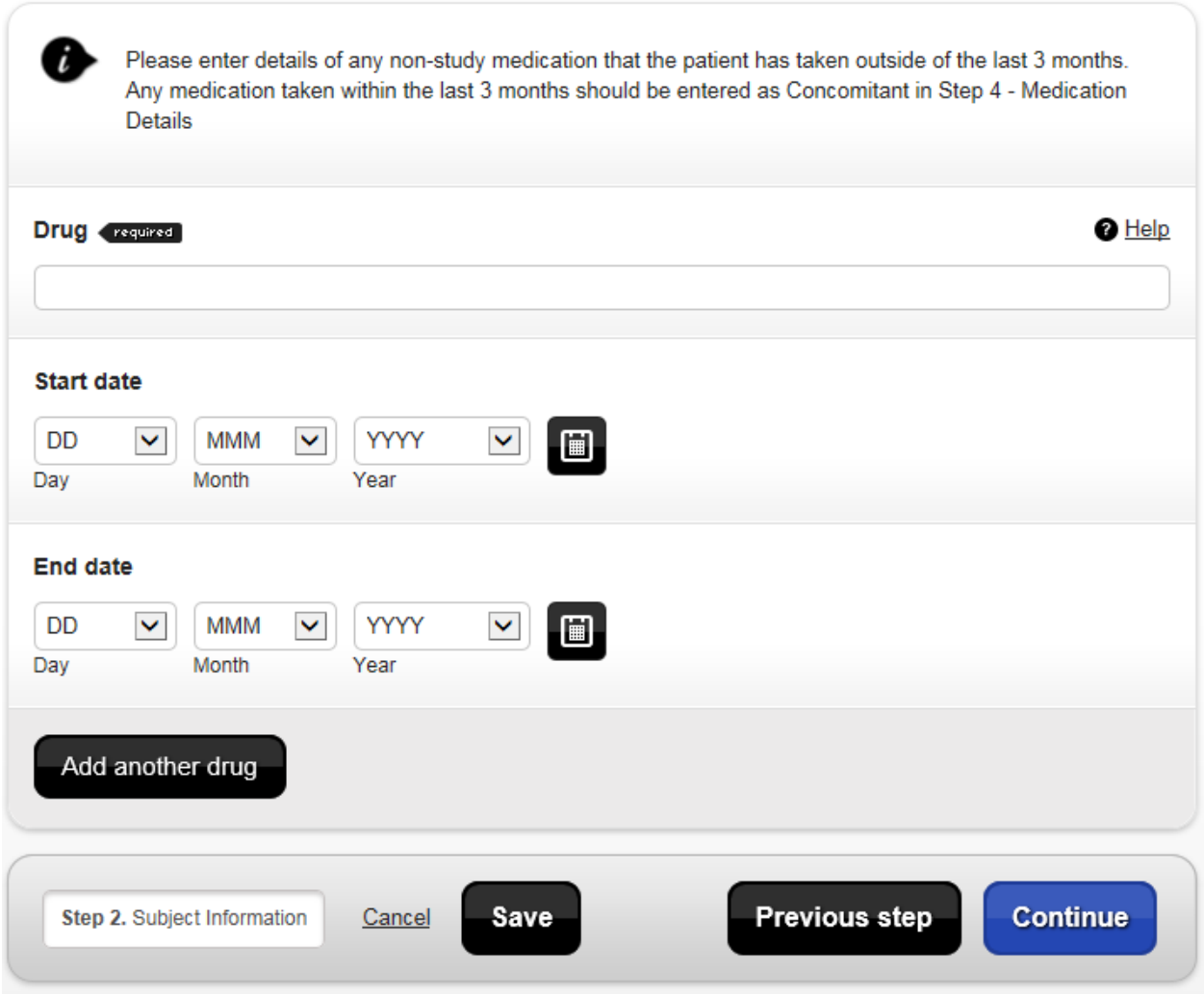
Patient height (m) Help

Metres Or Feet Inches

Please use the feet and inches fields to convert your height to metres.



This field is a predictive entry lookup against the MedDRA dictionary. Enter the first 3 characters then select a MedDRA term that matches the disease suffered by the patient.



This field is a predictive entry lookup against the MHRA's drug dictionary. Enter the first 3 characters then select the drug name from the list provided. If no match is found, enter the full drug name in the text field.

3. Reaction Details

Fields that you must complete are marked with this symbol: required

Date sponsor was made aware of the SUSAR required

DD (Day) | MMM (Month) | YYYY (Year)

Country of Origin required

Help

Please select the country the SUSAR occurred in.

Please Choose

Narrative

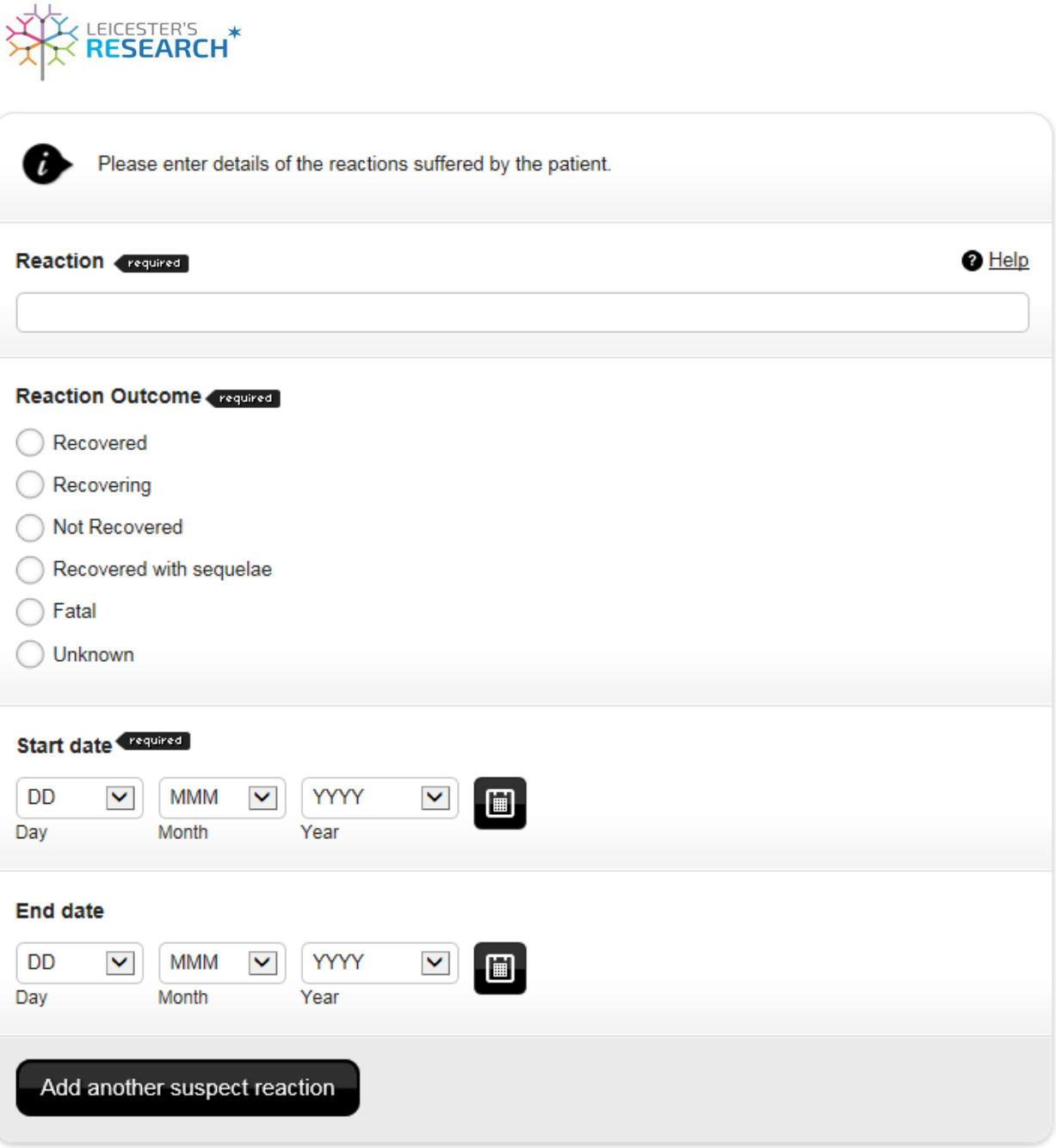
Help

Please provide a narrative of the reactions, together with any other information relevant to the SUSAR report, in no more than 20,000 characters.

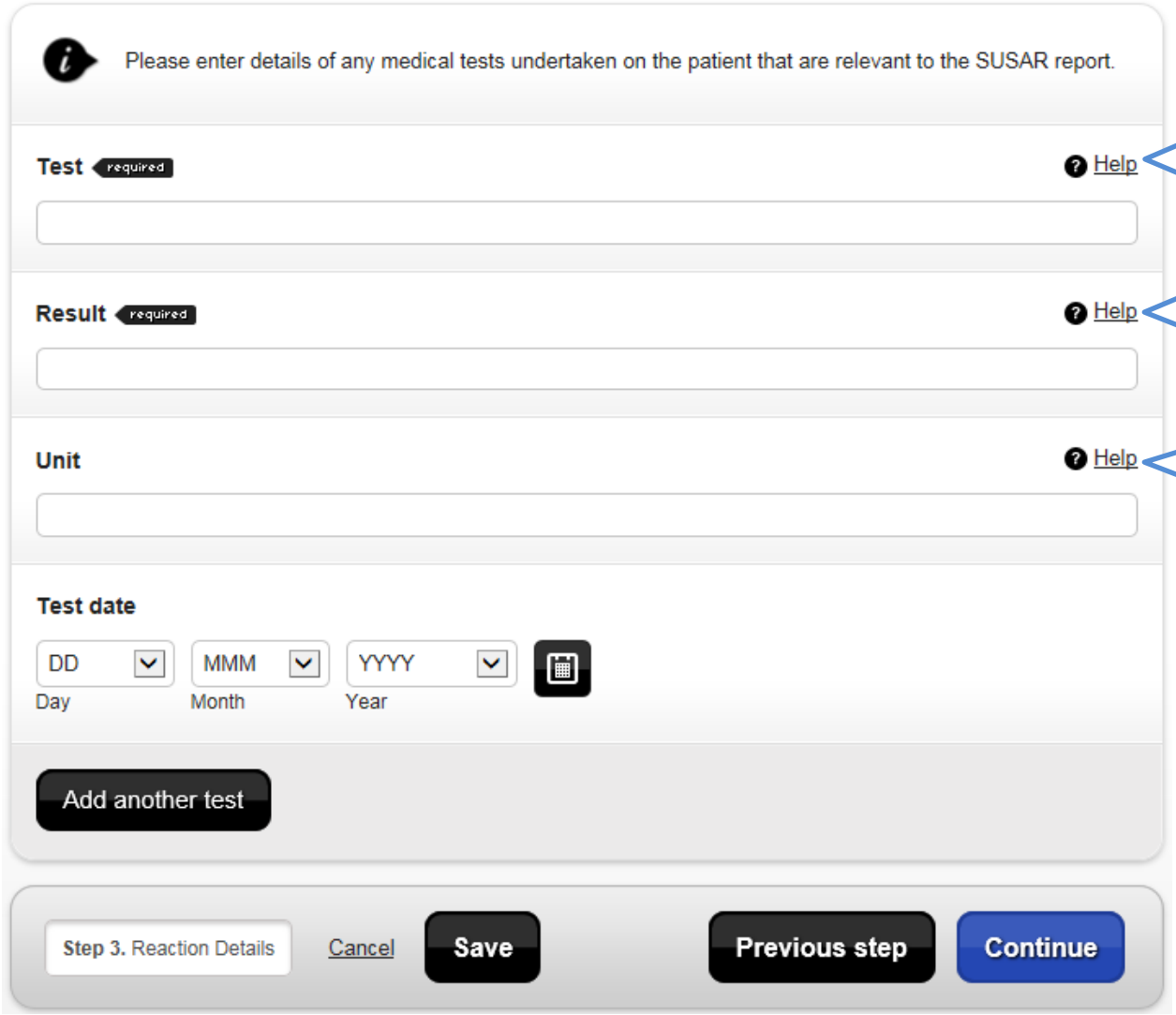
20000 characters remaining

Seriousness required

- [ ] Death
- [ ] Life threatening
- [ ] Hospitalisation
- [ ] Disabling
- [ ] Congenital anomali
- [ ] Other



This field is a predictive entry lookup against the MedDRA dictionary. Enter the first 3 characters then select a MedDRA team that matches the reaction suffered by the patient.



This field is a predictive entry lookup against the MedDRA dictionary. Enter the first 3 characters then select a MedDRA term that matches the test conducted.

Please enter the test result. This field is restricted to 50 characters; any additional information should be included in the narrative.

Please enter the result unit. Where no unit is appropriate, this field may be left blank.

4. Medication Details

Please enter details of all medication the trial subject has taken in the last 3 months, including non-study medication. Each medicine should be characterised as either 'Suspect' or 'Concomitant'.

Note regarding Drug Name entry: A dictionary of drug terms and codes is associated with the eSUSAR reporting form. This is regularly updated with new terms that have been submitted to the MHRA in CTA applications. The term entered into the Drug Name field will be matched against the drug dictionary in real time. When no match is found, the user will be prompted to check and re-enter the term. When no match is found for a second time, the user will be permitted to continue and submit the report with an unmatched name.

Fields that you must complete are marked with this symbol: required

Drug Name required — Help

Enter the drug substance term or code in the same format as in the CTA application. If the term or code matches a record in the MHRA dictionary the form will update to reflect this. Where possible please try to find a matching drug substance.

Drug Characterisation required — Help

Please Choose

Select Suspect if the drug is the suspected cause of the SUSAR

Drug Dosage required — Help

Units

Enter the dosage given to the patient.

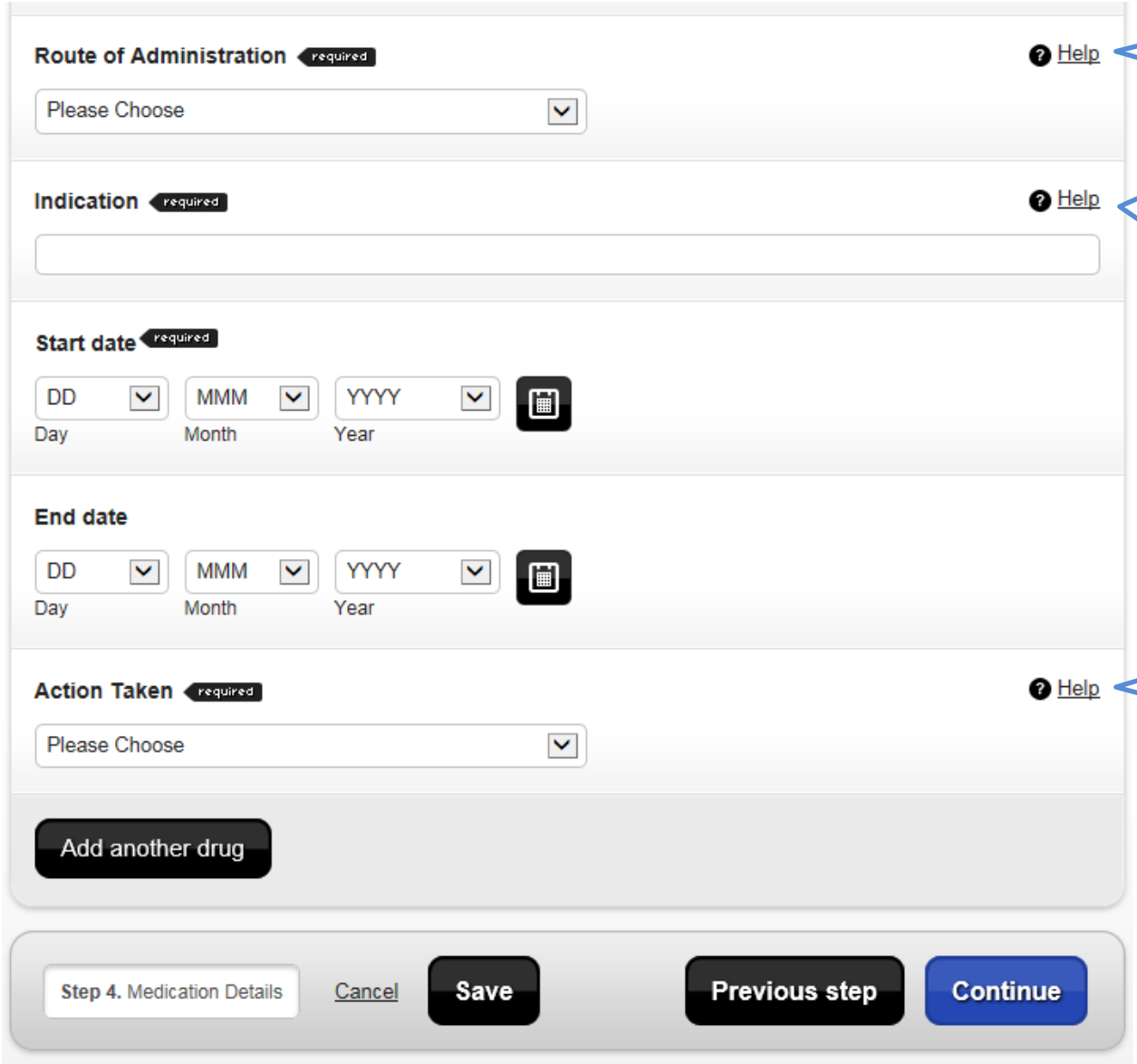
Drug Dosage Interval required — Help

Units

Enter how often the dose is, or was, administered.

Form required

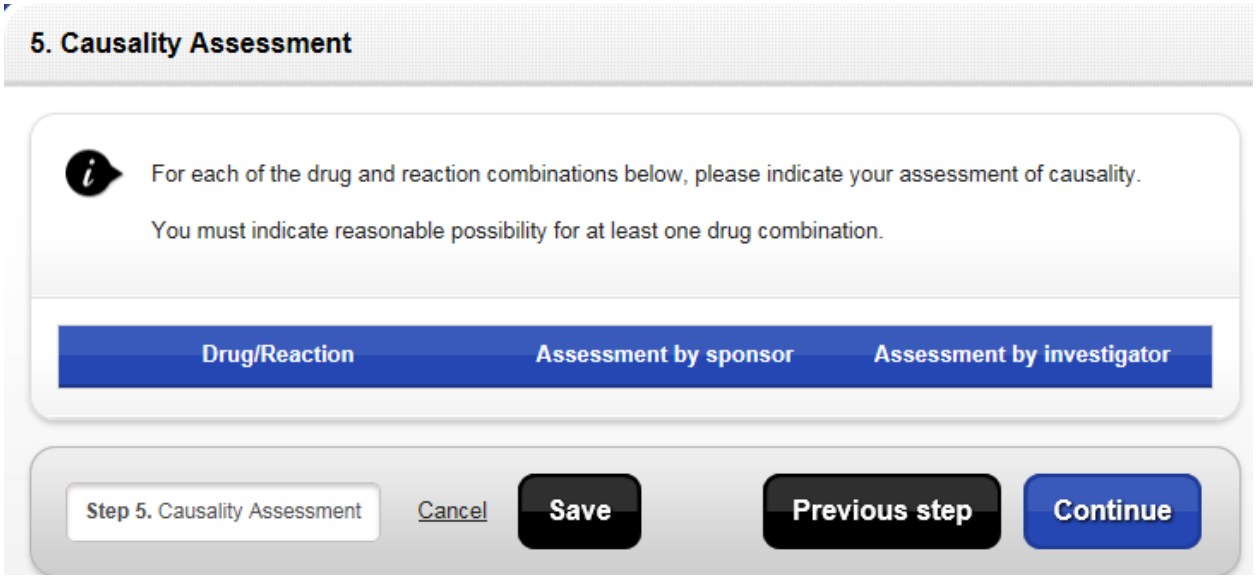
Please Choose



Select the route through which drug is, or was, administered.

This field is a predictive entry lookup against the MedDRA dictionary. Enter the first 3 characters then select a MedDRA term that matches the Indication the drug is, or was, being used to treat.

Select which action has been taken, regarding the drug, following the reaction.


5. Causality Assessment
For each of the drug and reaction combinations below, please indicate your assessment of causality.
You must indicate reasonable possibility for at least one drug combination.
Drug/Reaction
Assessment by sponsor
Assessment by investigator
Step 5. Causality Assessment
Cancel
Save
Previous step
Continue

6. Overview

This page shows a summary of the SUSAR report prior to submission. Please check and ensure that all information is correct. Changes can be made at this stage by clicking on the link for the appropriate section.

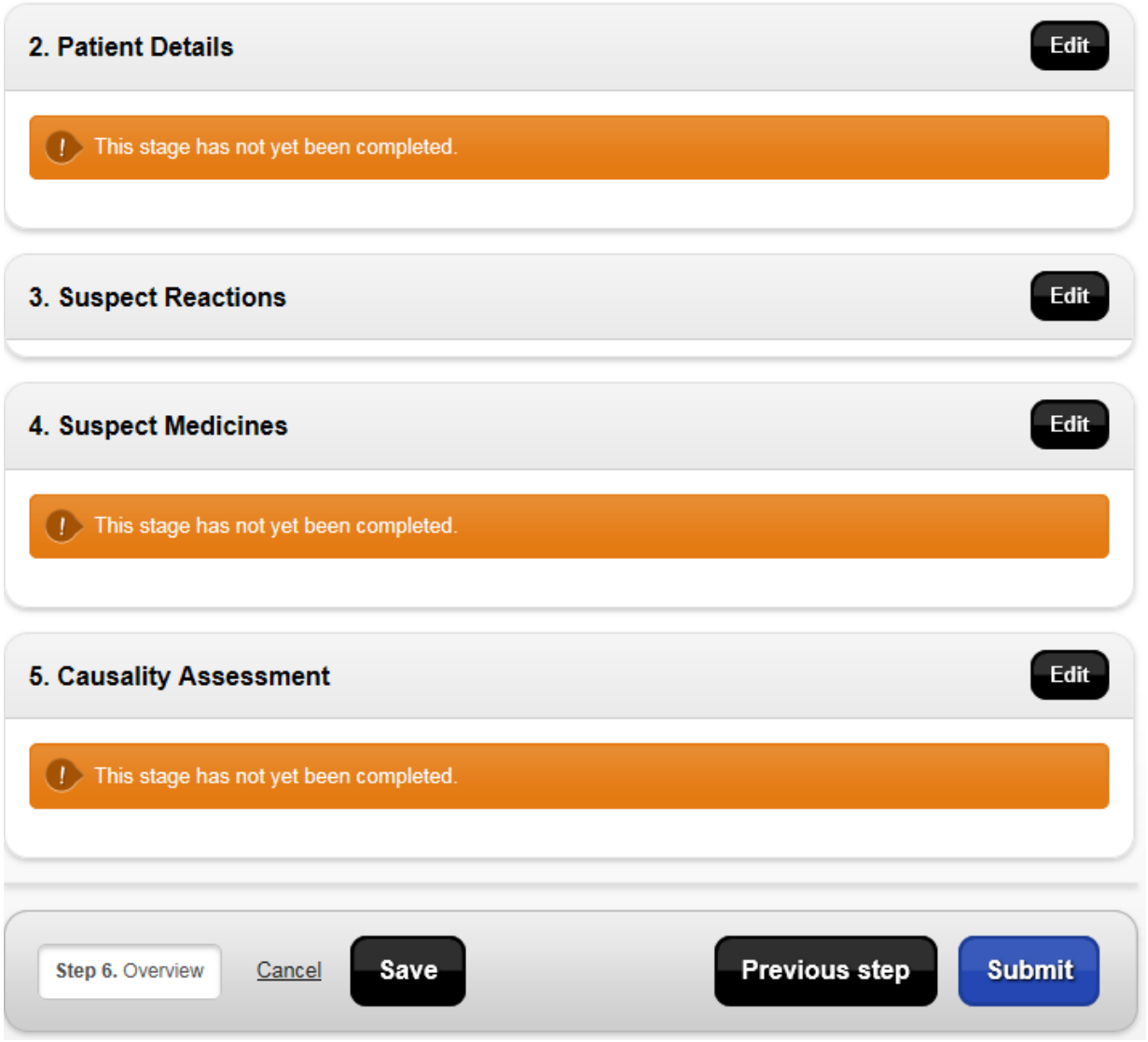
If all the information is correct, click on the 'Submit Report' button at the bottom of the page to submit the report to the MHRA. Alternatively, the report can be saved for editing and/or submission at a later date by clicking on the 'Save' button.

You may print the report summary now to check it, then you will need to submit it later.

1. Trial Information

Edit

This stage has not yet been completed.



Appendix 7 - e-SUSAR walk through – an Aide Memoire
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