

## Completion of eSUSAR

The following document contains screenshots and guidance notes for adding a new report to the eSUSAR system.

Each page is a screen shot of the tabs that can be found on the eSUSAR report when you 'add a report' to a study.

We recommend logging into eSUSAR **prior to** needing to report an event. You will only have access to studies which have been 'assigned' to you. Please ensure you have been assigned all the studies you expect.


eSUSAR 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: 

### Reference

### Your available trials

- 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**

## 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: 

**Initials**

 [Help](#)

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

**Sex**

Male  Female

 [Help](#)

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)**

 Or    
Kg Stone Pounds

 [Help](#)


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


**Patient height (m)**

 Or    
Metres Feet Inches


 [Help](#)

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


 Please enter details of any prior diseases the patient has suffered that are not being treated by the study medication.

**Disease** required  [Help](#)

**Start date**

DD         
Day Month Year

**End date**


DD         
Day Month Year

**Continuing** required

Yes  No  Unknown

**Add another disease**


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.

 Please enter details of any non-study medication that the patient has taken outside of the last 3 months. Any medication taken within the last 3 months should be entered as Concomitant in Step 4 - Medication Details

**Drug** required [? Help](#)


**Start date**

DD

Day Month Year 

**End date**

DD


Day Month Year 


**Add another drug**

Step 2. Subject Information [Cancel](#) **Save** **Previous step** **Continue**

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: 

**Date sponsor was made aware of the SUSAR** 

DD  MMM  YYYY  

Day Month Year

**Country of Origin** 

Please Choose 

 [Help](#)


Please select the country the SUSAR occurred in.

**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** 

- Death
- Life threatening
- Hospitalisation
- Disabling
- Congenital anomaly
- Other



Please enter details of the reactions suffered by the patient.

**Reaction** required

 [Help](#)

**Reaction Outcome** required


- Recovered
- Recovering
- Not Recovered
- Recovered with sequelae
- Fatal
- Unknown

**Start date** required

DD   MMM   YYYY  

Day Month Year


**End date**


DD   MMM   YYYY  


Day Month Year


Add another suspect reaction

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.





 Please enter details of any medical tests undertaken on the patient that are relevant to the SUSAR report.

**Test** required  [Help](#)

**Result** required  [Help](#)

**Unit**  [Help](#)

**Test date**

DD  MMM  YYYY  

Day Month Year

**Add another test**

[Step 3. Reaction Details](#) [Cancel](#) **Save** **Previous step** **Continue**

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: 

**Drug Name** 


 [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** 

 [Help](#)

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


Please Choose 

**Drug Dosage** 

 [Help](#)

Enter the dosage given to the patient.

Units 


**Drug Dosage Interval** 

 [Help](#)

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

Units 

**Form** 

Please Choose 

**Route of Administration** required [? Help](#)

Please Choose

**Indication** required [? Help](#)

**Start date** required

DD  MMM  YYYY

Day Month Year

**End date**

DD  MMM  YYYY

Day Month Year

**Action Taken** required [? Help](#)

Please Choose

**Add another drug**

Step 4. Medication Details [Cancel](#) **Save** **Previous step** **Continue**

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.

## 2. Patient Details

[Edit](#)

! This stage has not yet been completed.

## 3. Suspect Reactions

[Edit](#)

## 4. Suspect Medicines

[Edit](#)

! This stage has not yet been completed.

## 5. Causality Assessment

[Edit](#)

! This stage has not yet been completed.

[Step 6. Overview](#)[Cancel](#)[Save](#)[Previous step](#)[Submit](#)