

# eSUSAR Online Reporting

## A Quick Guide

## A Quick Guide to the eSUSAR Website

### Introduction

The eSUSAR website is a reporting tool that enables clinical trial sponsors and other institutions responsible for safety reporting to electronically report Suspected Unexpected Serious Adverse Reactions (SUSARs) that are relevant to ensuring the safety of the UK clinical trial population, to the MHRA.

This includes;

- SUSARs occurring in the UK
- Global SUSARs occurring where the sponsor for that trial also has a UK trial involving the same IMP.

The eSUSAR website provides a free and fast registration process without the need to complete a testing phase which is favoured by other reporting tools such as the Eudravigilance Gateway or EVWEB.

In order to prevent duplicate reporting, only UK and third country (defined as being countries outside the European Economic Area (EEA)) SUSAR reports submitted through the eSUSAR website are forwarded to the European Medicines Agency's Eudravigilance Clinical Trial Module (EMA's EVCTM).

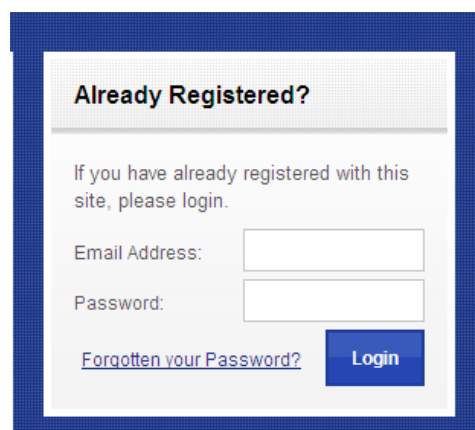
SUSARS occurring outside the UK but within the EEA can be reported to the MHRA using the eSUSAR website, but sponsors must also notify the relevant National Competent Authority (who is responsible for ensuring the report is received by the EVCTM).

The eSUSAR website consists of 4 sections:

- Home
- About
- Reports
- Accounts

### **Home**

Users are prompted to input their login details that were provided in the automated acknowledgement email following institution registration or from the activation of a user account by the Administrator. Users are required to reset their password immediately following their initial successful login.



The screenshot shows a login form titled "Already Registered?". Below the title, it says "If you have already registered with this site, please login." There are two input fields: "Email Address:" and "Password:". Below the "Password:" field, there is a blue button labeled "Login" and a blue link labeled "Forgotten your Password?".

## About

This page provides further information on the eSUSAR form.

You are here: [Home](#) > [About](#)

### About the eSUSAR Reporting Form

This page is intended to provide an overview of the eSUSAR Reporting Form functionality.

#### Institution Registration

Institutions will need to register their details with the MHRA before using the eSUSAR website for the first time. This process registers the institution and a representative of the institution as an administrator. In order to commence the registration process, the representative must complete the eSUSAR Registration Form (available on the MHRA website) and email it to [esusar@mhra.gsi.gov.uk](mailto:esusar@mhra.gsi.gov.uk) with the subject line eSUSAR Registration. The MHRA aims to process eSUSAR registration requests within two working days of receipt of a valid application form.

#### Using the form

The eSUSAR form has been designed to be intuitive, with clear instructions and an easy to use format. It is hoped that users will quickly understand the administrative aspects of registering new members and creating new trials as well as being able to navigate through the steps involved in creating and submitting a SUSAR report to the MHRA.

Help icons have been included to provide hints and advice at key stages throughout the website. To view the help information simply hold the mouse over the relevant icon and the text will be displayed.

#### Administration

**Institution Management:** Following the initial registration process, changes to Institution details can only be made by the MHRA's eSUSAR administrator. All requests to change these details should be made by sending an email to [esusar@mhra.gsi.gov.uk](mailto:esusar@mhra.gsi.gov.uk) with the subject line eSUSAR Administration. Documentary evidence may be requested by the MHRA prior to the implementation of any change.

**Member/Administrator Management:** Following completion of the registration process, new members and administrators (collectively referred to from hereon in as users) of an institution can be added, and existing member details can be edited, by any administrator of that institution. Administrators can amend their own details in the member management section. There is no limit to the number of users that can be added for each Institution.

Users can be flagged as either active or inactive; only active users have the ability to login. Changes to administrator account access (for example inactivation of an account after an employee has left an institution) can be made by the MHRA's eSUSAR Administrator. Requests should be made by sending an email to [esusar@mhra.gsi.gov.uk](mailto:esusar@mhra.gsi.gov.uk) with the subject line eSUSAR Administration. Again, documentary evidence may be requested by the MHRA prior to the implementation of any change.

When a new user is created, an email notification is sent to the new user's registered email address that will include their login details. The new user will be prompted to change their password at first login.

**Trial Management:** Administrators of an institution have the responsibility to add and edit trials. It is recommended that, as soon the sponsor receives the Notice of Acceptance from the MHRA for a clinical trial, the trial is created by each institution that has a responsibility for safety reporting in that trial to avoid any unnecessary delays at the time of submission of the first SUSAR report.

As for users, trials can also be flagged as either active or inactive; eSUSAR reports can only be submitted for active trials.

There is no limit to the number of trials that can be created for each institution and there is no restriction on the number of institutions that can submit eSUSAR reports for a particular trial. However, each institution will have to create and maintain its own record of the trial and will only be able to view reports created and submitted by its own users.

Administrators also have the responsibility to associate users with each trial; only users associated with a particular trial will have the ability to submit eSUSAR reports for that trial. There is no limit to the number of users that can be associated with each trial.

#### Creating and Submitting SUSAR Reports

Submitting SUSAR reports using the MHRA's eSUSAR form is a straight forward and logical process. The trial details are automatically populated in the report by first selecting the trial for which the report is to be made. The form then guides the user through a series of steps collecting information on the trial subject, the reaction and the medication (suspect and concomitant drugs). The reporter details are also automatically populated into the report and are defined by the account information of the logged-in user.

Having completed all relevant fields of the form, a summary of the data is presented for the user to check, giving the opportunity to amend any details prior to submission. The user also has the option to download a full report in either PDF format or as an XML file. Institutions may find these reports useful for informing Ethics Committees of SUSARs.

As well as creating and submitting new reports, users can submit follow-up reports, edit draft reports and create and submit copy reports based on previous reports.

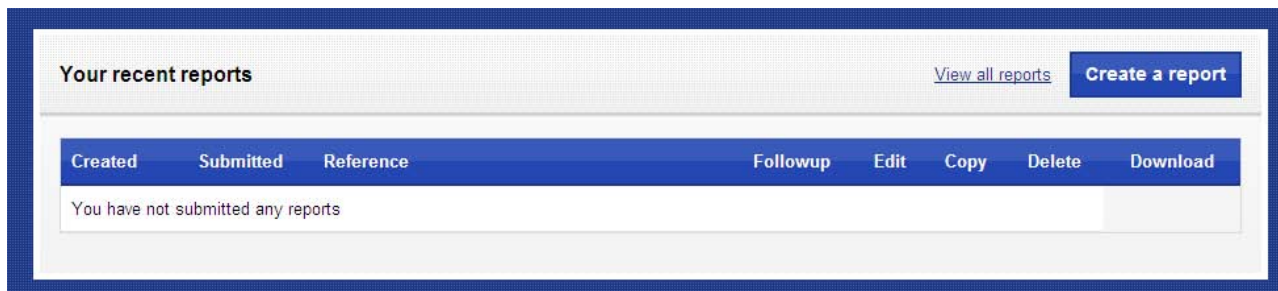
#### Comments or Question?

If you have any questions or comments regarding the eSUSAR form, please send an email to [esusar@mhra.gsi.gov.uk](mailto:esusar@mhra.gsi.gov.uk) with the subject line eSUSAR Reporting Form.

For urgent enquiries relating to problems encountered whilst submitting SUSAR reports using the eSUSAR form, please contact the clinical trials helpline on 020 3080 6456.

## Report

The report page guides the user through the process of completing the sections of the online report for active trials with which they are associated. There is also a quick link to the online report available in the Account page within the user's recent reports as well as on the home page. Please note, reports can only be entered for trials that have been created and registered as active. Likewise, reports can only be created for trials that the user is associated with.



## Account

The Account page is displayed as soon as the user logs into their account. This page lists users own reports as well as those of other users of the same Institution; these reports are only visible and accessible to the user if they are associated with that trial. Users also have the option of managing and reviewing created reports. Only Administrators can view all reports for all of their institution's trials and also have additional features to create and manage member accounts as well as create and manage trials.

Users can revisit the Accounts page at any time by clicking on the welcome link on the top right hand corner.

# Getting Started

## Managing Users

- Registering as the administrator of an institution

Sponsors can apply to have an eSUSAR account by registering their Institution using the relevant form found on the Safety Reporting pages of the MHRA website and allocating staff with administrative rights for reporting.

### eSUSAR Registration Form

---

Please note that all data fields are compulsory. If information is missing, the registration form will be returned for completion, resulting in a delay to registration.

#### 1. Institution Details

Institution Name	
Institution Address	
Type (Commercial or Non-commercial)	

#### 2. Institution Administrator Details

Title	
First Name	
Last Name	
Email*	
House Number or Name	
Address 1	
Address 2	
Town/City	
County	
Postcode	
Country	
Telephone Area Code	
Telephone Number	
Telephone Extension	
Job Title	
Qualification (tick <u>one</u> of the following):	
Physician	
Pharmacist	
Other Health Professional	
Lawyer	
Other	

This form should be emailed to [esusar@mhra.gsi.gov.uk](mailto:esusar@mhra.gsi.gov.uk) where the registration process should take 2 working days to complete. An acknowledgement email will be sent to the new user with their login details; a temporary password will be provided by the eSUSAR administrator however, the new user will be prompted to change this password upon initial login following registration.

- Registering new users

Only Administrators have the ability to create profiles for new users to the Institution Account. To create a new user profile, Administrators should go to the Members section within the Account page where all users of the Institute are listed. Administrators should then click on the *Add a member* link and fill in the member form with the relevant information. The *View all members* link takes users to the Manage Members page where all members of the institution are listed. There is also another *Add a member* link on this page. There is no limit to the number of users that can be added for each Institution.

You are here: [Home](#) > [Account](#) > [Manage Members](#)

### Add Member

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

**Title**

**First Name**

**Last Name**

**Email Address** **required**

**Job Title**

**Profession** **required**

**What type of member** **required**

Institution Admin  
 Institution Member

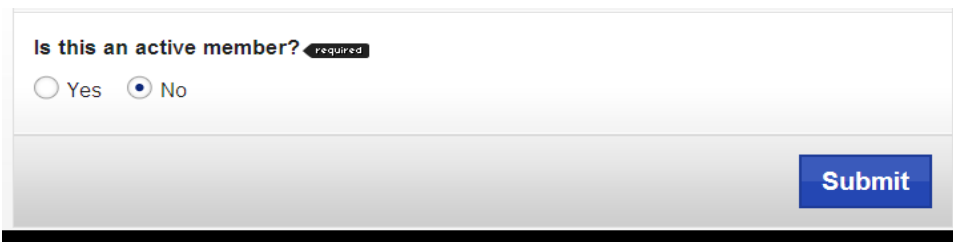
**Is this an active member?** **required**

Yes  No

It is advised that more than one user is given administrative rights to the Institution Account to avoid issues with accessing the eSUSAR website in the possible event of an existing Administrator becoming unavailable (for example sickness, annual leave). The member form allows the Administrator to mark new users as either an Institution Member or an Institution Administrator. Please note, Administrators cannot make changes to another Administrator's account unless they initially created that account.

- Unregistering users

All new and existing users are marked as *Active* in order to access the website. In the event that a user needs to be unregistered from that Institution Account (for example if the user leaves the institution), the Administrator can select the user from the list of Members on the Manage Members page and click on the *Edit* icon to change their status.



The screenshot shows a form field with the label "Is this an active member?" followed by a "required" indicator. Below the label are two radio buttons: "Yes" (unselected) and "No" (selected). A blue "Submit" button is located at the bottom right of the form.

- Editing user accounts

Administrators can edit the details of existing active users listed in the Manage Members page. Users are also free to make changes to their own profile accounts such as marital status, name changes and contact details.

## Managing Trials

- Creating and registering a trial

All clinical trials associated with the Institution are listed in the Trials section within the Accounts page. From here, Administrators can add a new active trial by clicking on the icon *Add a new trial*. This should take the Administrator to the relevant form where all fields should be filled. By clicking on the *Add Trial* icon the clinical trial is then registered with the Institution.

You are here: [Home](#) > [Account](#) > [Manage Trials](#)

### Add Trial

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

**Trial Name** **required**

**Trial phase** **required**

Please Choose

**Protocol number** **required**

**Eudra CT Number** **required**

**CTA Number** **required**

CTA

**Is this an active trial?**

Yes  No

**Select Users** **required**

john.smith@ctu.com

robert.smythe@ctu.com

**Add Trial**

It is recommended that, as soon as the sponsor receives MHRA approval for a clinical trial, the trial is created by the Institution Administrator in order to avoid delays at the time of submitting the first SUSAR report. It should be noted that trials must be flagged as active for SUSAR reports to be submitted.



- Associating users to a trial

Administrators are able to associate existing users for reporting SUSARs to each clinical trial upon registering a trial. To associate new users to a trial, administrators should click on the *Edit* icon next to the relevant active trial where the new user's name will then appear listed to be selected.

You are here: [Home](#) > [Account](#) > [Manage Trials](#)

### Edit Trial

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

**Trial Name** **required**

  
**Trial phase** **required**  
**Protocol number** **required**  
**Eudra CT Number** **required**    
**CTA Number** **required**

CTA

**Is this an active trial?**

Yes  No

**Select Users** **required**

john.smith@ctu.com  
 robert.smythe@ctu.com  
 ann.jones@ctu.com

**Save Trial**

- Unregistering a trial

A trial must be classed as active upon registering onto the Institute Account. Once a trial has ended, the administrator can edit the trial listed and change the status of the trial as not active.

**Is this an active trial?**

Yes  No

## Creating and submitting a report

Reports can only be submitted for registered active trials that the user is associated to. The trial and reporter details are automatically populated by selecting the relevant trial. The user is guided through each step of the online form:

1. Select Trial    2. Subject Information    3. Reaction Details    4. Medication Details    5. Causality Assessment    6. Overview

### 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**

1234-123456-12 Test

**Step 1. Select Trial**    [Cancel](#)    **Save**    **Continue**

1. Select Trial

2. Subject Information

3. Reaction Details

4. Medication Details

5. Causality Assessment

6. Overview

## 2. Subject Information

**i** 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

JB

**Sex**

**?** Help

Male  Female

**Age at time of adverse reaction**

30

Years

**Subject ID Number**

**?** Help

123456

**Patient weight (kg)**

**?** Help

83.81

Or

185

Kg

Stone

Pounds

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

**Patient height (m)**

**?** Help

1.90

Or

6

3

Metres

Feet

Inches

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

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

**Disease** **required**

**?** Help

Asthma

**?**  
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.

**Start date**

DD

MMM

1986

Day

Month

Year

**End date**

DD

MMM

YYYY

Day

Month

Year

**Continuing** **required**

Yes  No  Unknown

Add another disease

1. Select Trial

2. Subject Information

3. Reaction Details

4. Medication Details

5. Causality Assessment

6. Overview

## 2. Subject Information



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**

SALBUTAMOL

Help

Start date

DD

MMM

1985

Day

Month

Year

End date

DD

MMM

YYYY

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 **required**

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

5 Jan 2012

Day Month Year

Country of Origin **required**

[Help](#)

United Kingdom

Narrative [Help](#)

The E2B standard cannot accept reports where the narrative is larger than 20,000 characters.

Seriousness **required**

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

[i](#) Please enter details of the reactions suffered by the patient.

Reaction **required**

[Help](#)

Anaphylactic shock

In order for users to progress to the next step, only valid medical terminology may be submitted

Reaction Outcome **required**

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

Only one fatal reaction can be recorded per report.

Start date **required**

1 Jan 2012

Day Month Year

End date

1 Jan 2012

Day Month Year

Add another suspect reaction

1. Select Trial

2. Subject Information

3. Reaction Details

4. Medication Details

5. Causality Assessment

6. Overview

### 3. Reaction Details



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

There should be no limit to the number of reactions and tests to include in the report. However, only enter the tests most relevant to the reaction.

Step 3. Reaction Details

[Cancel](#)

[Save](#)

[Previous step](#)

[Continue](#)

## 4. Medication Details

**i** 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

Drug Characterisation **required**

Please Choose

**?** Help

Drug Dosage **required**

Units

**?** Help

Drug Dosage Interval **required**

Units

**?** Help

Form **required**

Please Choose

Route of Administration **required**

Please Choose

**?** Help

Indication **required**

**?** Help

Start date **required**

DD  / MMM  / YYYY

Day Month Year

End date

DD  / MMM  / YYYY

Day Month Year

Action Taken **required**

Please Choose

**?** Help

Add another drug

**?**

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 term.

The suspect medication is the drug that is believed to have a causal relationship to the reaction and can be either the IMP or a concomitant drug.

A maximum of 10 concomitant medications can only be entered.

Step 4. Medication Details

Cancel

Save

Previous step

Continue

## 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](#)

Drug Characterisation **required**

Please Choose [Help](#)

Drug Dosage **required**

Units [Help](#)

Drug Dosage Interval **required**

Units [Help](#)

Form **required**

Please Choose

Route of Administration **required**

Please Choose [Help](#)

Indication **required**

 [Help](#)

Start date **required**

DD  / MMM  / YYYY

Day Month Year

End date

DD  / MMM  / YYYY

Day Month Year

Action Taken **required**

Please Choose [Help](#)

Add another drug

Step 4. Medication Details

Cancel

Save

Previous step

Continue



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 term.



1. Select Trial

2. Subject Information

3. Reaction Details

4. Medication Details

5. Causality Assessment

6. Overview

## 4. Medication Details

✖ There are problems with the following fields:

• Drug Name



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

✖ No drug substance name match was found with the MIRRA drug dictionary. Please check and re-enter the drug substance name in the same format as in the initial CTA application. To proceed with an unmatched drug substance name click Add another drug or Continue.

A Medicine

Drug Characterisation

Help

Suspect

Drug Dosage

Help

500

Mg milligram(s)

Drug Dosage Interval

Help

2

Days

Form

Tablet

Route of Administration

Help

Oral

Indication

Help

Lung transplant rejection

Start date

1

Jan

2012

Day

Month

Year



End date

1

Jan

2012

Day

Month

Year



Action Taken

Help

Unknown

Add another drug

Step 4. Medication Details

Cancel

Save

Previous step

Continue

1. Select Trial

2. Subject Information

3. Reaction Details

4. Medication Details

5. Causality Assessment

6. Overview

## 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](#)

A-Med-icin

Drug Characterisation [Help](#)

Suspect

Drug Dosage [Help](#)

500 Mg milligram(s)

Drug Dosage Interval [Help](#)

2 Days

Form

Tablet

Route of Administration [Help](#)

Oral

Indication [Help](#)

Lung transplant rejection

Start date

1 Jan 2012

End date

1 Jan 2012

Action Taken [Help](#)

Unknown

Add another drug

Step 4. Medication Details

Cancel

Save

Previous step

Continue

1. Select Trial

2. Subject Information

3. Reaction Details

4. Medication Details

5. Causality Assessment

6. Overview

## 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](#)

AZITHROMYCIN

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

Suspect

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

500 Mg milligram(s)

Drug Dosage Interval **required** [Help](#)

2 Days

Form **required**

Tablet

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

Oral

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

Lung transplant rejection

Start date **required**

1 Jan 2012

Day Month Year

End date

1 Jan 2012

Day Month Year

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

Unknown

Add another drug

Step 4. Medication Details

Cancel

Save

Previous step

Continue

1. Select Trial

2. Subject Information

3. Reaction Details

4. Medication Details

5. Causality Assessment

6. Overview

## 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
AZITHROMYCIN Anaphylactic shock	Reasonable possibility <input type="button" value="v"/>	Reasonable possibility <input type="button" value="v"/>

The causality for each reaction must be listed by either or both the sponsor and investigator. This is a compulsory requirement set by the European Medicines Agency (EMA).

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 [cancel](#) the report summary now to check it, then you will need to submit it later.

## 1. Trial Information

Edit

• Trial Name: 1234-123456-12 Test

## 2. Patient Details

Edit

• Patient initials: JB  
 • Patient gender: Male  
 • Patient age at time of the side effect: 30 Years  
 • Patient Identification Number: 123456789  
 • Patient weight (kg): 83.81  
 • Patient height (m): 1.90

## Asthma

• Start date: 1986  
 • Continuing: Yes

## SALBUTAMOL

• Start date: 1996

## 3. Suspect Reactions

Edit

Date sponsor was made aware of the SUSAR:  
05/01/2012

Country of Origin:  
United Kingdom

Seriousness  
• Hospitalisation

## Anaphylactic shock

• Reaction Outcome: Recovered  
 • Start date: 01/01/2012  
 • End date: 01/01/2012

## 4. Suspect Medicines

Edit

## AZITHROMYCIN

• Drug Characterisation: Suspect  
 • Drug Dosage: 500 Mg milligram(s)  
 • Drug Dosage Interval: 2 Days  
 • Form: Tablet  
 • Route of Administration: Oral  
 • Indication: Lung transplant rejection  
 • Start date: 01/01/2012  
 • End date: 01/01/2012  
 • Action Taken: Unknown

## 5. Causality Assessment

Edit

## AZITHROMYCIN - Anaphylactic shock

• Assessment by sponsor: Reasonable possibility  
 • Assessment by investigator: Reasonable possibility

Step 6. Overview

Cancel

Save

Previous step

Submit

## Edit an existing report that has not previously been submitted to the MHRA

This reporting tool allows users to save and edit their reports at a later date for completion prior to submission to the MHRA. When saving reports, users will be prompted to provide a valid email address. A 'key' (in the form of a unique identifier) will be generated automatically and displayed on-screen. Users will be required to input both the email and key when they are retrieving the saved report.

To edit an existing report, users should go to the Reports section within the Accounts page and click on the *Edit* icon next to the saved report.

## Submit further information for a submitted report as a Follow-up

Follow-up reports are usually submitted to provide further information to that submitted in the initial SUSAR report (such as an incomplete initial report detailing a fatal SUSAR, or to notify the MHRA of upgrading a non-fatal SUSAR to a fatal).

To create and submit a follow-up report, users should go to the Accounts page where the listed reports are located, before clicking on the *Follow-up* icon next to the relevant submitted report. Upon submitting a follow-up report, all validation is removed throughout the report form so that none of the fields are pre-populated.

You are here: [Home](#) > [Account](#) > [Manage Reports](#)

### Reports

This page allows all users to manage and review eSUSAR reports that have been created for their institution. Whilst administrators are able to view all reports submitted for all trials, members can only view their own reports and reports submitted by other users for trials with which they are associated. The display can be filtered to show either 'All reports' or just the reports submitted by the logged-in user 'My reports'.

Additional functionality has been included to allow users to:

- Submit further information for a submitted report as a 'Followup'.
- 'Edit' an existing draft report that has not previously been submitted to the MHRA.
- Create a new report for a new SUSAR as a 'Copy' of a previously submitted report (the user is advised to take care when using this function to ensure that all data fields are updated correctly).

This page also includes a link to 'Add new report', which guides the user through the process of creating an eSUSAR report and submitting it to the MHRA.

### Your recent reports

[All reports](#) [My reports](#) [Create a report](#)

Created	Submitted	Reference	Created by	Followup	Edit	Copy	Delete	Download
29/11/2012	29/11/2012	UK- 567891	John Smith	<a href="#">Followup</a>	-	<a href="#">Copy</a>	-	<a href="#">PDF</a> <a href="#">XML</a>
09/11/2012	09/11/2012	123456789	Robert Smythe	<a href="#">Followup</a>	-	<a href="#">Copy</a>	-	<a href="#">PDF</a> <a href="#">XML</a>

## Create a new report for a new SUSAR as a Copy of a previously submitted report

Users can create a new report for a new SUSAR by using a copy of a submitted report as a template; for instance, when the same SUSAR occurs in the same clinical trial but to another trial patient. To do this, users should go to the Reports section within the Accounts page where the listed reports are found and click on the *Copy* icon next to the relevant submitted report to create this new SUSAR.

When submitting a report, a key will also be generated in the same way when saving a report. Users can retrieve this submitted report to use as a template copy for the new SUSAR by entering the required email and key.

Users should ensure that all data fields are correctly updated with the relevant information relating to the new SUSAR.

**Summary**

The eSUSAR website enables users to create and submit SUSAR reports as well as reports based on previous submissions. Users also have the option to edit any saved reports prior to submission and provide further information as a follow-up report.

The online eSUSAR form is a straightforward process that guides the user through each step of the report. A summary of the data collected is provided at the end of the process allowing users to make any amendments before submitting the report.

The full report can be downloaded by the user in a PDF or xml format. The latter enables the institution to inform Ethics Committees of these SUSARs.

## Frequently Asked Questions

1) *On the eSUSAR reporting page, under Step 3 – Reaction, there is a field for the Start date. Should we enter the ‘date of the first sign/symptom of the event’ or the ‘date the event became a SUSAR.’ If it is the former, please could you confirm that this date will not be used to assess the timeliness of SUSAR reporting (as it may well be some time after the first sign or symptom of the event that it then progresses to be a SUSAR and subject to expedited reporting).*

The date entered should be the date of the first sign/symptom of the SUSAR. For expedited reporting, the initial report is to be done within seven days after knowledge by the sponsor of the SUSAR.

2) *Whilst we collect various information about concomitant medications on our SUSAR form, we do not collect concomitant medication product form - is it possible to have an option for ‘unknown’ for this please? In the [Detailed guidance on the collection, verification and presentation of adverse reaction reports arising from clinical trials on medicinal products for human use - April 2006](#) product form for concomitant medications is not one of the items listed in Section 5.1.6.1 (Minimum criteria for initial expedited reporting of SUSARs) and as such we would not wish not having this information to hold up submission of a report?*

The addition of an option for ‘unknown’ may be added in the future during further development of the eSUSAR website. At the current time, the applicant is advised to submit initial reports without details of concomitant medication, so as to avoid delays in submission, and to add these later as a follow-up when further information is available. The applicant is reminded that as much information as is available should be included with the initial report.

3) *One of our options (and quite a commonly used one) for the question ‘Action taken as a result of the SUSAR’ is Treatment delayed. Would it be possible to add this as an option or confirm how you would like this response to be entered as none of the existing options seem appropriate?*

The addition of an option for ‘Treatment Delayed’ may be added in the future during further development of the eSUSAR website. At the current time, the applicant is advised to select the option of ‘Dose Reduced’ as this is considered to be the closest current match.

4) *Some of the Sponsors we work with have requested to be given access to the site for the trials which they sponsor; however, as they have registered as members under their own institutions I am unable to allow them access to our institution. Is there any way around this at all as it seems entirely appropriate that they have access to both.*

Users can be registered with more than one Institution. However, a different email address will have to be used for each registration since this is used as the part of the login identification.

5) *I am about to enter the trial details for one of our Sponsors. There is no field for the name of the Sponsor but I presume that this information can be concluded by the system due to the trial details such as EudraCT no. etc. Is this correct?*

Yes, this is correct; the trial sponsor can be concluded from the EudraCT number and CTA number.

6) *Does the field CTA number refer to the reference number issued by your Authority for the particular trial? For the Sponsor in question, we as the CRO are responsible for two trials conducted by the Sponsor with the same study drug. In case of a SUSAR, would we need to enter the SUSAR details twice, separately for each trial or is it possible to choose more than one trial when creating a report?*

Yes, the CTA number refers to the reference number issued by the MHRA for a particular trial. Each SUSAR report should only be submitted once. Therefore, if the applicant is responsible for reporting for two or more trials involving the same IMP, the report should only be submitted for one trial. Details of any other relevant trials can be included in the additional information section of the eSUSAR web form.



7) *Regarding the field CTA no: for the one of the trials which I have added the CTA number is 12345/1234/001-0001. The 3<sup>rd</sup> field of the CTA number on the website is shorter than 001-0001. This is the same for two other trials I have just added. Could you please clarify how the number should be entered?*

The CTA number field should be completed with just the first three sets of digits. In the above example '12345', '1234' and '001'. The final four digits '0001' are not required to identify the trial. For information, '-0001' refers to the initial application, '-0002' refers to the first amendment, '-0003' to the second amendment etc. etc.

8) *For an investigational (not yet marketed) product, how can we report cases from a clinical trial that is conducted outside of the EEA through the eSUSAR portal? These studies do not have a EUDRACT number or CTA.*

At the current time, SUSARs originating in trials that do not have a EudraCT number or CTA number should be reported under a trial that uses the same IMP, which is being carried out in the UK and which, therefore, does have an EudraCT number and CTA number. The report should include a note in the additional information section explaining the origin of the SUSAR and the Country of Origin field should be selected to indicate the correct origin of the report. The MHRA are currently developing a more robust method for reporting these SUSARs and it is anticipated that this will be available in the near future.

9) *Is there a mechanism for us to set up a "test" trial and report to use for staff training purposes?*

There is no 'test' function on the eSUSAR website. However, it is possible to fill in an eSUSAR report up to the point of submission in order to make screen shots for staff training purposes. Once this new report has been started, it can not be deleted or removed from the website. However, the information can be edited. Therefore, what we have suggested to other users is that you edit the 'test' SUSAR data and replace it with the data from your first 'real' SUSAR (when it occurs) in order to remove the test from your records.

10) *What are alternative procedures that sponsors should follow in the incidence of system failure i.e. the eSUSAR website or the sponsor's computer facilities including internet/e-mail access? The European Medicines Agency has very specific procedures to follow in case of EudraVigilance system failure. These procedures are also suitable for use where the sponsor's computer facilities have gone down.*

In either of these situations you must contact the MHRA before taking action. If your own IT has failed then please contact us and we will discuss options with you.

11) *We have recently tried to submit a SUSAR via the eSUSAR Reporting Form however, we have experienced difficulty when a CTA number has been requested as the SUSAR we are reporting does not have a UK site and therefore does not have a relevant number. The UK does however; have a clinical trial using the same investigational product. Please could you advise on how we can proceed with such reports and how we should be reporting them to you?*

In this instance please put in the CTA number of the trial running in the UK.

12) *When adding follow-up information to a previously reported SUSAR on eSUSAR, is a new eSUSAR reference number generated or is this number unique to the event and stay the same regardless of how many follow-ups are added?*

Yes the eSUSAR ID relates to the worldwide case ID to Eudravigilance and this number changes with each follow-up report.

13) *I would like to enquire about how you can delete a report and you have created in error?*

The eSUSAR does not currently have the functionality to delete a report. Please simply update the report when you have a new SUSAR to report.

14) *How do I inform the MHRA that an event previously submitted as a SUSAR has been reclassified and no longer fulfils the requirements for reporting to the competent authority?*

If you have a downgraded an adverse event and it is no longer considered a SUSAR then please email detail of the event including the EudraCT number of the trial involved, the

reference number of the SUSAR and reasons for the down grading of the event to this address.

15) *I need to edit a SUSAR which my colleague started entering onto eSUSAR the other day but it doesn't appear to give me the option to edit it. Can you confirm if this can be done as I know you can do a follow up report for a SUSAR which someone else has entered?*  
You will need to have administrator user rights.

## References

For further information on the eSUSAR form, please send an email with the subject line *eSUSAR Reporting Form* to [esusar@mhra.gsi.gov.uk](mailto:esusar@mhra.gsi.gov.uk).

For urgent enquiries relating to problems issued whilst submitting eSUSAR reports, please contact the Clinical Trials helpline on 020 3080 6456.

Safety reporting – SUSARs and ASRs:

▶ [www.mhra.gov.uk/Howweregulate/Medicines/Licensingofmedicines/Clinicaltrials/Safetyreporting-SUSARsandASRs/index.htm](http://www.mhra.gov.uk/Howweregulate/Medicines/Licensingofmedicines/Clinicaltrials/Safetyreporting-SUSARsandASRs/index.htm)

eSUSAR Registration Form May 2010:

▶ [www.mhra.gov.uk/home/groups/l-ctu/documents/websiteresources/con082186.doc](http://www.mhra.gov.uk/home/groups/l-ctu/documents/websiteresources/con082186.doc)

eSUSAR website:

▶ [www.esusar.mhra.gov.uk](http://www.esusar.mhra.gov.uk)