

eSUSAR Reporting Investigators Guide CCTU/GD003

SUSAR reporting by eSUSAR system is a MHRA requirement.

The Trust is registered on the system as Sponsor organisation. The responsibility of SUSAR reporting is delegated to the Chief Investigators (CI) and their teams. Each study requires access to the system. Study teams are asked to complete and return an eSUSAR registration form and return this to the Cambridge Clinical Trials Unit (CCTU).

To register as a study team member:

1. Complete the eSUSAR Registration Form available from the CCTU CCTU@addenbrookes.nhs.uk
 2. Return the form to the CCTU and await acknowledgement of receipt. Registering you can take up to a week, please allow for that time. You will receive an email with your login details, from there you are advised to log in and check that the details work and change your password.
1. Log onto <http://esusar.mhra.gov.uk/>
 2. Using your email address as a user name and the password sent to you when your details are registered by the CCTU.

To change your password:

1. Click 'Account' in the side menu
2. Select 'Change Password form the expanded side menu and follow the instructions on screen.

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Home
About
Account
 > Reports
 > Manage Members
 > Manage Trials
 > Change Password
Report
Logout

Change Password

Your password should be a minimum of 8 characters and contain at least 1 capital, 1 number and 1 special character (@, #, \$, %, ^, &, +, =).

Password

Confirm Password

Submit

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This document is reviewed and updated in line with emerging evidence or local requirements at least every two years

To Report a SUSAR

Please note: The system cannot account for Placebo reports; all the SUSARs entered must have been un-blinded before reporting. For blinded or double blinded trials specific arrangements for the un-blinding need to be put in place **before** trial starts.

1. Log in as before
2. Click 'Report' on the side menu, the following screen will be displayed:

eSUSAR MHRA

Select Trial Patient Information Reaction Details IMP Details Summary Confirmation

Step 1 - Select Trial

Click on the 'Create report' link next to the listing for 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 clicking the link for the appropriate trial, the trial details are then automatically populated into the SUSAR report. The user is then guided through a series of steps collecting information on the Trial Subject, the Reaction and the IMP, before being invited to submit the report to the MHRA.

2004-000245-38 PT1: A randomised trial to Compare Aspirin versus Hydroxyurea/Aspirin in "Intermediate Risk" Primary Thrombocythaemia and Aspirin only with observation in "Low Risk" Primary Thrombocythaemia	Create report
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3. Read the instructions on screen and then select the trial that you wish to create a report for by clicking on the trial title.
4. This will automatically move you on to the next page, 'Patient Information'

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Select Trial Patient Information Reaction Details IMP Details Summary Confirmation

Step 2 - Patient Information

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

Initials ?

Sex ?

5. Enter the patient information as prompted, you must click on the green 'Add' button where it appears to save the entry and progress through the form; also note that if you wish to enter more than one

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notable disease history or drug history you can do so by clicking on the 'Add' button.

6. Then click the continue button once you have completed the page and this will move you onto the 'Reaction Details' page. (Here you also enter the country of origin).
7. You have the option to add reactions and relevant tests that were conducted by clicking the green 'Add' button.
NB: The reaction is the Suspected Unexpected Serious Adverse Reaction that you have recorded on your paper Case Report Form pages.
8. Click continue and you will be navigated to the 'IMP Details' page.

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Select Trial > Patient Information > Reaction Details > **IMP Details** > Summary > Confirmation

Step 4 - IMP Details

Please enter details of all study medication the patient has taken in the last 3 months.

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 marked with * are mandatory.

Drug Name*

Drug Characterisation*

? If the patient is taking 200mg four times a day, this should be entered as '800' for the drug dose, 'mg' as the drug dosage unit, '1' as the drug

This page allows the entry of the IMP details. Please note the instructions about the inbuilt medical dictionary, if the term you enter is not in the medical dictionary you will be prompted to check and re-enter the term. When no match is found for a second time, you will be permitted to continue and submit the report with an unmatched name.

Again you must click on the 'Add' button to save your entry. You can add multiple IMPs using the same command.

9. Clicking on continue will now take you to the summary page, this shows all the information that you have entered and allows you to check the details.
10. The summary page allows you to edit each section, providing a quick link back to the data entry page in question.

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11. Check the summary information is correct. Then click 'Submit', this will generate a PDF confirmation page which you can review before sending.

12. Print this PDF for your records. This is the proof that the SUSAR has been reported to the MHRA.

If you send an invalid report you will receive a letter from the MHRA prompting you to amend the entry.

Viewing Reported SUSARs

1. Click 'Account' in the side menu.
2. Select 'Reports' from the expanded side menu all the reports submitted are listed under the heading 'Your Recent Reports'. You can then edit or copy the event from this page.

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Account

This page allows Administrators to view their own recent reports as well as those of other users of the Institution. Reports are listed with a unique Reference number together with the date created and the name of the author.

As well as the ability to submit SUSAR reports, Institution Administrators have a number of additional functions available to them.

Administrators are able to manage the accounts of existing Members and create profiles for new Members. This includes the ability to give Administrator rights to Members.

Administrators also have the responsibility to create and manage Trials and to assign active Members to each Trial, thus allowing them to submit reports for that Trial. It is recommended that, as soon the trial sponsor receives the Notice of Acceptance from the MHRA for a clinical trial, an Institution Administrator creates the Trial in order to avoid any unnecessary delays at the time of submission of the first SUSAR report.

Your recent reports [Add new report](#)

Date Created	Reference	Followup	Edit	Copy	Report PDF
Blanked for confidentiality					

Your members' reports

Date Created	Reference	Created By	Followup	Edit	Copy	Report PDF
Blanked for confidentiality			Followup	-	Copy	Report PDF
Blanked for confidentiality			-	Edit	Copy	-

Adding Follow-up information to a Previously Reported SUSAR

To add follow up information to a SUSAR that has already been entered onto the eSUSAR site:

1. Click 'Account' in the side menu
2. Select 'Reports' from the expanded side menu all the reports submitted are listed under the heading 'Your Recent Reports'
3. Then click on 'Follow Up' next to the relevant report

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4. The system helpfully pre-populates the form with the information from your original submission:
 - This is a new form – altering the information in it WILL NOT change your original submission
 - Delete the entries you wish to change and enter information as you did during your original report.
5. To delete information that requires update click on the red 'x' next to the fields

If you are involved in an international trial please check if the confirmation PDF holds appropriate information to be able to contact the other member state's Competent Authority.

Trouble Shooting:

If you have any difficulties with the system please consult the 'About' Page by clicking on it in the side menu.

If this information does not resolve your query please contact the MHRA via email on 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 MHRA clinical trials helpline on 020 3080 6456