



Medicines & Healthcare products Regulatory Agency

Frequently asked questions – ICSR Submissions

1. How do I create an Individual Case Safety Report (ICSR)?

To create a new R2 Individual Case Safety Report (ICSR), select the 'New R2 Report' tile which will load the new report form. Then you will be able to progress through the form to complete details about the ICSR. The form uses E2B R2 fields and generates an R2 ICSR that is sent directly to the MHRA.

2. How do I create a Suspected Unexpected Serious Adverse Reaction (SUSAR)?

You can create a Suspected Unexpected Serious Adverse Reaction (SUSAR) by selecting the 'New R2 Report' tile and entering the following values into the 'report type' and 'study type' fields (report type – 'report from study'; study type – 'clinical trial'). Then you will be able to progress through the form to complete details about the SUSAR. The form uses E2B R2 fields and generates an R2 SUSAR that is sent directly to the MHRA.

3. I need to report ICSRs on behalf of multiple organisations, can I do this?

Yes. If you are an organisation lead then when you register you can let the MHRA know, by email to ICSRtesting@mhra.gov.uk, that you need to be associated to multiple organisations. If you are a standard user then your organisation lead can associate you to any organisation that they are associated to. Each time you log in you will be asked which organisation you are logging in to and

will only be able to send ICSRs from that organisation. To send from a different organisation you will need to log out and re-sign in for a different organisation.

4. What do I do if I can't load a case into a new report form?

If you wish to create a report based on an existing E2B R2 XML, you can import this into the form using the 'Load Existing' option in the top right-hand corner of the form.

If you attempt to upload a file that is not a valid E2B R2 XML file (e.g. an E2B R3 xml), an error message will be displayed, and the report will not be loaded. If you are unable to load the case into the new report form, check the XML to confirm that it is a valid E2B R2 XML file.

5. I have a file that I want to send, how can I do this?

You can send ICSRs and SUSARs directly to the MHRA by posting R2 or R3 files through ICSR Submissions.

If you have an existing E2B R2 or E2B R3 XML that you would like to send to the MHRA, select the 'Post R2/R3 XML Report' tile. Once you select this option, you will be able to select a file or multiple files from your file browser to post.

Once you select the file(s) you wish to post, a 'success' message will be displayed to confirm it has been sent. You can track these reports via the 'Report Management' screen including the acknowledgement status.

6. What should I do if I am unable to send a case?

If you attempt to send a file that does not follow E2B formatting guidelines, the file will fail to send, and an error message will be generated. If you receive this error, you should check the validity of your XML file.

You also cannot upload a report for an organisation that you do not belong to, so the sender ID in the XML must match the sender ID associated with your organisation on ICSR Submissions. If you attempt to upload a report where the Sender ID does not match, an error message will be displayed. If you receive this error message, you should update your file to ensure that the sender ID in the XML matches that of your organisation.

7. Can I send an R3 file?

Yes. E2B R3 XMLs can be posted through ICSR Submissions.

8. How do I know if an acknowledgement has been received?

Reports sent to the MHRA and draft reports can be tracked in the 'Report Management' screen. The acknowledgement status of a report can be seen in the 'Status' column. If no acknowledgement has been received, this column will have the value 'submitted', and once an acknowledgement is received this will change to either 'ack success' or 'ack fail'. Acknowledgements can be viewed by selecting the submitted case from the report management screen and selecting 'view ack'.

9. How do I see reports that I have sent?

Reports sent to the MHRA and draft reports can be tracked in the 'Report Management' screen.

10. How do I see reports that I have received?

Reports received from the MHRA can be tracked in the 'Report Management' screen. Reports from the MHRA will have the sender 'MHRAUK'.

11. How do I generate acknowledgements for cases I have received?

Acknowledgements should be generated for all cases received from the MHRA. Acknowledgements can be generated by selecting the file received from the MHRA and selecting the 'create ack' option.

12. I have forgotten my password and can't access my account, what should I do?

You can click 'Forgot your password?' on the ICSR Submissions login page to reset your password. Please refer to 'Section 1 of the ICSR Submissions user reference guide for steps to complete this process.

13. How can I create new users?

If you are an organisation lead, you are responsible for creating user accounts for others in your organisation who require access to ICSR Submissions. Users associated with your organisation/s can be added and viewed by selecting the 'Organisation Management' tile from the ICSR Submissions dashboard or burger menu. You can create new users by selecting 'Add new user' and then enter their details. Personal details are required including their email address which they will use to log in to the system. New users should be encouraged to update their password when logging in for security purposes.

13. Can I add new users for multiple organisations?

If you are an organisation lead, you can add new users and associate them with any organisations that you are associated to.

14. How can I change my details?

To change your details, you will need to contact your organisation lead, or you will need to contact the MHRA at E2B.Support@mhra.gov.uk if the organisation lead cannot change the details

15. A user has left my company, how do I remove them from the system?

If you wish to deactivate users who have left your organisation, you can do this by choosing the desired user and selecting 'De-activate' within the 'user management' section of the ICSR Submissions dashboard.