

User Reference Guide – MORE Incident Submissions

A step-by-step guide on using the MORE Platform for Submissions of device related incidents.

The following user guide provides guidance on how to use the different functions for report submissions and to manage reports.

Version 3 August 2023



Contents

Introduction.....	5
Section 1: Background	5
MORE services	5
User Group Roles	6
Authorised Representative (NI)	6
UKRP	6
Manufacturer	6
Other – Submitter/Importer/Distributor	6
Device Registration Data – Device Registration database data	7
Access levels and permissions	7
Organisation Leads	7
Standard users	8
Dashboard & Menu Bar.....	9
Dashboard tiles & functions.....	9
Organisation Lead dashboard	10
Organisation Lead Authorised Representative account.....	10
Organisation Manufacturer account.....	10
Standard user dashboard.....	11
Standard User Authorised Representative account	11
Standard User Manufacturer account	11
My workspace dashboard	11
Section 2: Logging in to MORE	12
Section 3: Reporting forms	14
New report - Submitting an incident via web-form.....	14
MIR - Manufacturer Incident Report	16
Important information required to complete MIR form fields:	17
Submitting reports during the transition period between legacy MORE and new MORE:.....	18
FSCA - Field Safety Corrective Actions.....	19
Important information required to complete FSCA fields:	19
TREND reports.....	20

Important information required to complete Trend fields:.....	21
Submitting reports during the transition period between legacy MORE and new MORE:.....	21
PSR - Periodic Summary Reports	21
PSR Approvals	23
Status of PSR reports in MORE.....	24
PSR Rejection	25
PSR Review and PSR Closed	26
SAE - Serious Adverse Events.....	27
Important information required to complete SAE fields:.....	28
Saving draft reports.....	28
Loading draft reports/existing	29
Submitting an incident by posting XML reports	31
Submitting an incident by Application Programming Interface (API)	33
Registering on the UAT MORE portal	33
Setting up the API	35
API details.....	35
Data security and encryption.....	36
Section 4: Report Management.....	37
Downloading all reports.....	37
Reports sent to MHRA	38
Updating Reports	40
Updating/Editing Draft reports	40
Updating/Editing submitted reports	42
Exporting individual reports	44
Industry Notification of Public Reports (INPR).....	45
Visibility of reports to your users	47
Notifications.....	50
Registrations	50
INPR notification.....	51
Section 5: Resources	52
Glossary	53
Contact Details	54
Other Useful Information	55

Revision History 56

Introduction

This document will guide users through the Manufacturer's On-line Reporting Environment (MORE) portal registration process via MORE and managing record submission and receipt.

Section 1: Background

Adverse incidents involving medical devices which occur in the UK must be reported to the Medicines and Healthcare products Regulatory Agency (MHRA). When a medical device has been placed on the UK market, vigilance reports must be submitted when incidents occur. Post-market vigilance reports have previously been submitted by the legacy MORE system or by emailing a Manufacturer Incident Report (MIR) form to the MHRA.

From 05 December 2022 the MHRA is decommissioning existing MORE services and transitioning to a new MORE portal.

MORE services

You will have read-only access to the old MORE system and will be able to download existing reports until 30 April 2023. If you currently hold an account on MORE, please note that we are not migrating any data to new MORE accounts. We recommend that you download any historical reports from your old MORE account if they are needed as these will not be available in your account after 30 April 2023. Any draft reports in your old account will need to be re-created in your new MORE account for submission.

In the new MORE portal, registered users will be able to continue to submit incident reports via XML report upload, manual entry via the web forms within the MORE portal or via Application Programming Interfaces (API). The MORE web forms that are available include:

- Manufacturer Incident Report (MIR)
- Field Safety Corrective Actions (FSCAs)
- Trend Reports
- Periodic Summary Reports (PSRs)
- A new web form to enable submission of Serious Adverse Events (SAEs)

When you register on the new MORE portal, you can have multiple user groups under one account in the system. The following user groups will be available for selection during the registration process:

- Manufacturers,
- Authorised Representatives (NI),
- UKRP
- Other importers, distributors, or submitters

Every organisation will need to have an initial lead user (known as 'Organisation Lead'). The Organisation Lead will approve subsequent users (Organisation Lead or Standard Users) who will be able to submit incident reports via the portal.

User Group Roles

Authorised Representative (NI)

Authorised representatives can be based in Northern Ireland or the EU for placing goods on the market in Northern Ireland and the EU. A manufacturer can delegate some of the duties to an authorised representative, however, they will need to check the specific regulations that apply to confirm what can and cannot be delegated.

UKRP

The UK Responsible Person acts on behalf of the non-UK manufacturer to carry out specified tasks in relation to the manufacturer's obligations. The responsibilities of the UK Responsible Person are set out in the UK Medical Device Regulations 2002.

Manufacturer

The person with responsibility for the design, manufacture, packaging and labelling of a device before placing it on the market under its own name. This can be a company or an individual.

Other – Submitter/Importer/Distributor

In some situations, registration will be required from distributors, importers or other types of submitters when they assume the obligations belonging to manufacturers.

Device Registration Data – Device Registration database data

The MHRA will use organisation data from the Device Registration database, including the associated addresses, account numbers and the relationships of those that are authorised to carry out vigilance activities on the organisations behalf. The information from the Device Registration database will be used at the point of registration, when logging into associated accounts and for auto population in MORE forms. Changes to information within the Device Registration database will be reflected in the MORE platform. It is important that Organisation Leads only provide access to individuals who have permission to view and submit vigilance reports. It is particularly important where this applies to approving UK RP and Authorised Representative (NI) as relationships to manufacturers are inherited based on the Device Registration Database. Detailed descriptions are provided in the section '[Visibility of reports to users](#)'.

The names and addresses of organisations available to select within MORE will only include Device Registration data if the status of the registration is 'registered', 'suspended', 'not registered' or 'unregistered'. If the organisation you are looking for is not available from MORE, please review the details in Device Registration database and update, as necessary. Unregistered accounts and associated information are available in MORE to allow reporting on devices which may still be in circulation.

If the Device Registration database data is updated, these will automatically update in MORE in line with nightly feeds.

For more information on Device Registration and guidance, please see [Register medical devices to place on the market - GOV.UK \(www.gov.uk\)](#)

Access levels and permissions

Organisation Leads

This is an account type for the lead user(s) of the organisation. This user is responsible for the initial registration request to MORE and for managing the organisations users, which includes validating and approving/rejecting/deactivating users for that organisation, including other Organisation Leads. An Organisation Lead can send and receive MORE forms.

Assigning an Organisation Lead is a local decision based on who is best placed to perform these activities. Multiple Organisation Leads may exist per organisation. All Organisation Leads linked to an organisation will have the same access levels and permissions when set up. An Organisation Lead is responsible for deactivating user accounts when a user is no

longer associated to the organisation and so local processes should be in place to support these activities.

It is the responsibility of the first Organisation Lead to ensure that any additions to their organisation, as well as the access level of each individual user suffice their company needs. For example, Authorised Representative (NI) and UKRP Organisation Leads can create accounts for new Organisation Leads under the user group 'Manufacturer' that are associated to their company – this means that they can create an account for a user who has access to a greater level of information than they do i.e. a user who will be able to see all the reports submitted by that Manufacturer alongside reports submitted by other Representatives on behalf of that Manufacturer.

It is also the responsibility of the Organisation Leads to only provide access to individuals who have permission to view and submit vigilance reports. It is particularly important where this applies to approving UK RP and Authorised Representative (NI) as relationships to manufacturers are inherited based on the Device Registration Database. Detailed descriptions are provided in the section '[Visibility of reports to users](#)'. If the sole Organisation Lead leaves an organisation, it is their responsibility to set up an alternate Organisation Lead user to manage reports for the organisation. This can be carried out by inviting a new user or upgrading an existing Standard User account to Organisation Lead. If reports need to be downloaded, it is the responsibility of the user to do so before deactivation of accounts takes place.

Organisation Leads can be a person(s) from any of the manufacturer's organisations and their selection does not depend on the location of the organisation. The decision for who should be assigned an Organisation Lead status should be made at a local level.

It will be the organisation's responsibility to manage user permissions, who is assigned as an Organisation Lead with permissions to approve others and who would be more appropriately set up as Standard Users where they do not need to approve user requests. It is important to bear in mind that Organisation Leads who approve new registration requests will be able to set permission levels to Organisation Lead or Standard User for new users/registrations.

Standard users

This is an account type for the majority of users and is a default type for all new registrations. At the point of approval, the MHRA, or an existing Organisation Lead, can upgrade accounts from standard user to Organisation Lead. A standard user can send and receive reports in MORE and will have access to the associated organisations reports and notifications.

Please note: A MORE user account can only have one access role type (Organisation Lead or Standard User). For example, if a user is an Organisation Lead for 'Organisation A' and then they are invited to join 'Organisation B', they will automatically be an Organisation Lead

for 'Organisation B'. If mixed access roles are required, then different email addresses should be used.

We recommend that registrations are made using individual email addresses and not with shared mailboxes to ensure access to MORE is secure and that individual users and other users within their organisation have an audit trail of activity.





There is no limit on the number of individual accounts an organisation can have, however, it is important to deactivate accounts when a user no longer needs, or has authority, to access MORE for your organisation.

Dashboard & Menu Bar

Dashboard tiles & functions

When you register to the MORE portal your approval will initially be pending and you will have access only to your personal workspace whilst your registration request is being reviewed. When you sign in you will be presented with a Dashboard containing tiles with various functions, your role type defines which tiles you can access. All tiles are available via the burger bar of the account screen.

Please note that some tiles, including 'Reports' are disabled until report submission via MORE is opened.

Tile Icon	Tile Name	Description
	Resources	Access to help and guidance documents for the system
	User Management	The Organisation Lead (s) (lead administrator) will be able to manage user access within the organisation.
	Notifications	Area for receipt of notifications relating to registrations (if an Organisation Lead), general updates, receipt of Industry Notifications of Public Reports (INPRs) and follow up for submitted reports.
	Reports Submission	Submit reports using the manual MORE forms or xml upload function

	Report Management	Access reports that have been submitted for the organisation. Report management can be used to view the status of the report and to view the acknowledgement. If you log into your workspace, you will only see the reports that you have submitted
	Change Management	Provides an overview of all user requests to join the organisation including, pending, approved, and rejected requests.

The 'Developer' menu option found in the left-hand side menu bar will contain information on Application Programming Interface (API) setup and documentation for integration between organisation IT systems and MORE. This option is only available for Manufacturer Organisation Leads.

Organisation Lead dashboard

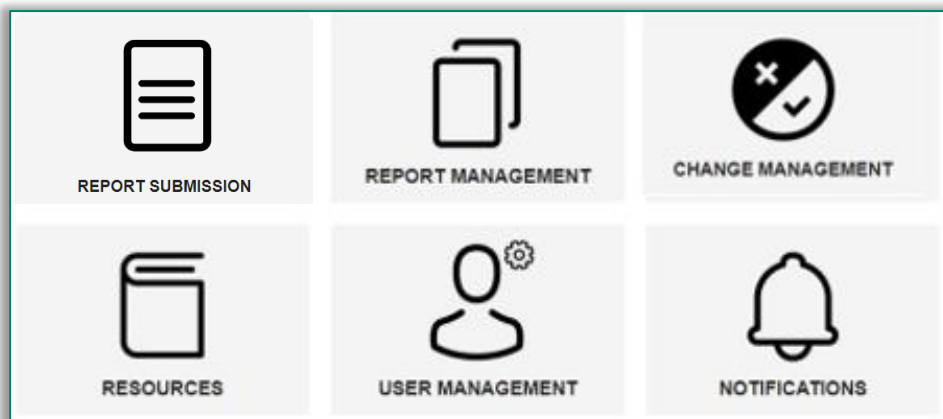
An Organisation Lead will see the following tiles on their dashboard when they log into their account as a:

Organisation Lead Authorised Representative account



Note that when logging in to an organisation which acts as a representative only, the reports tile and report management tile will not be available as all incident submissions will be submitted against the manufacturer account.

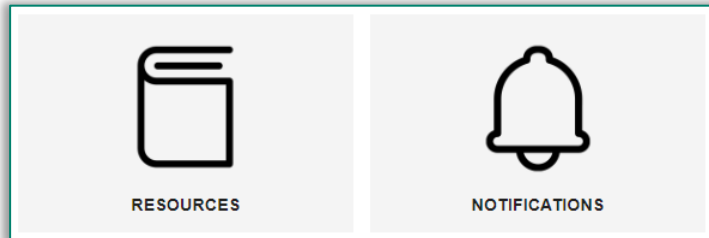
Organisation Manufacturer account



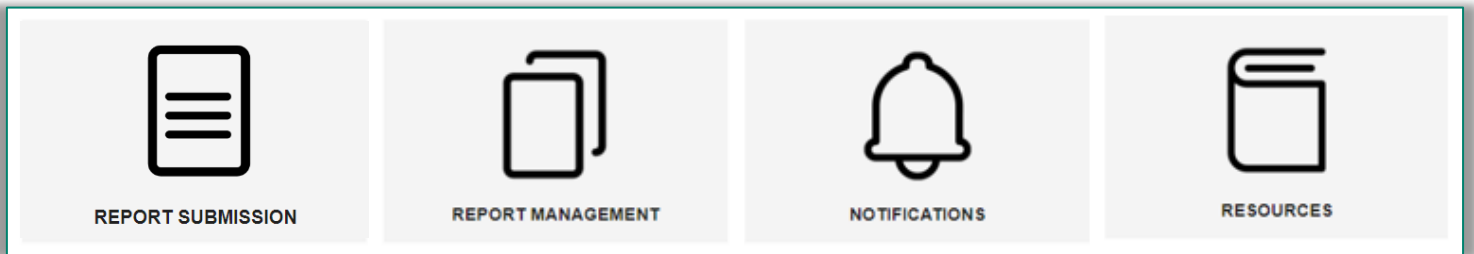
Standard user dashboard

A Standard User will see the following tiles on their dashboard when they log into their account as a:

Standard User Authorised Representative account

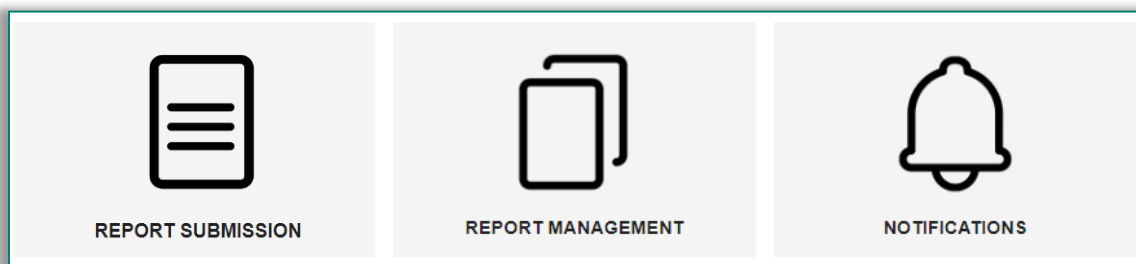


Standard User Manufacturer account



My workspace dashboard

For accounts created with 'Other' as the user group, users will have access to the workspace dashboard which will have the below tiles.



Section 2: Logging in to MORE

- From the login page, enter your registered email and password
- Select the organisation from the drop-down list and enter. You will only be able to view organisations for which you have been approved. If you have created a personal workspace, you will be directed to your dashboard after entering your log in details.
- You will then have access to your manufacturer organisation dashboard/workspace dashboard and menu options.
- You will also have access to your personal details which you can edit and update at any stage.

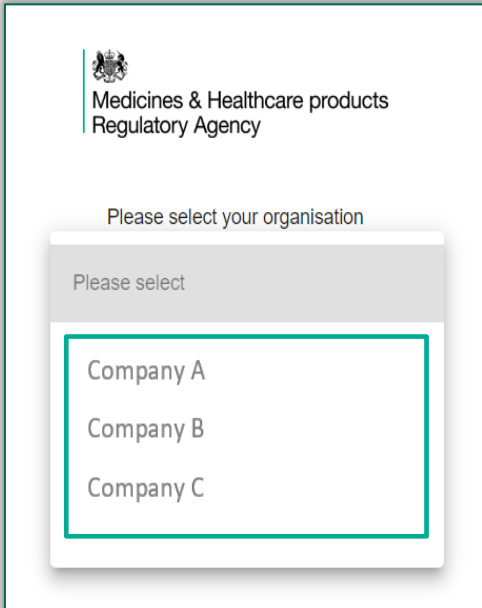
If you are a Manufacturer, you will have access to reports submitted by all representatives associated to the manufacturer organisation, based on the associations as registered in the Device Registration database.

If you are a UKRP or an Authorised Representative (NI), you will have access to reports that you have submitted for as long as you have an active account. If you leave the organisation or change roles, it will be your responsibility to download your reports if they are required. Once you are removed from an organisation you may no longer have rights to reports you submitted on behalf of the organisation.

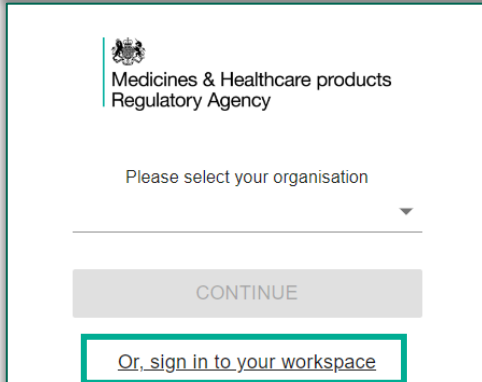
If you have been set up with a multi-role account for more than one organisation you will need to select the organisation for which you need access. You will not see reports in report management for the other organisations. You can only view the reports for one organisation at a time. To view reports for a different organisation you would need to select that organisation when you login.

You will not be able to report against devices for an organisation unless you are correctly logged in for that account.

Your 'Workspace' will be your personal space and will not be linked to the account of your wider organisation. If you submit a report in your personal workspace and later log in under an organisation for which your registration has been approved, you will not be able to see your personal submitted reports. If you would like to submit a report for an organisation other than your own, please use your personal 'Workspace'.



The screenshot shows the top part of the login page. At the top left is the Medicines & Healthcare products Regulatory Agency logo. Below it, the text "Medicines & Healthcare products Regulatory Agency" is displayed. A prompt "Please select your organisation" is followed by a dropdown menu. The dropdown menu is open, showing a grey header "Please select" and three options: "Company A", "Company B", and "Company C". The "Company A" option is highlighted with a green border.



The screenshot shows the bottom part of the login page. It features the same Medicines & Healthcare products Regulatory Agency logo and text as the previous screenshot. Below the "Please select your organisation" prompt is a dropdown menu with a downward arrow. Below the dropdown menu is a grey button labeled "CONTINUE". At the bottom, there is a link "Or, sign in to your workspace" enclosed in a green-bordered box.

'Workspaces' are local areas associated to a single user only and are not associated with any manufacturer or their representatives. All users have access to a personal workspace to allow them to report on a device which is not registered to their organisation(s). If a manufacturer would like to report an incident for a device registered to a different organisation, they can select their 'Workspace' instead of an organisation they are associated to at login. Note: Reports submitted via the 'Workspace' will not be viewable under the 'Report Management' tile for any organisation they are registered to and can be accessed by the user that reported it via their workspace only.

'Workspaces' have two intended uses:

1. To allow manufacturer or representative users to access the portal and submit reports immediately after registering, while awaiting approval, if necessary.
2. For submission of reports regarding medical devices which are not registered in the device registration database.

Section 3: Reporting forms

MORE account holders who have registered with several Organisations, must ensure that they have logged into the correct Organisation account prior to submitting a report and performing vigilance related activities.

Account holders can use any of the three options below to report an incident via the MORE submissions portal:

1. New report – This method of submission requires the MORE user to manually enter the incident details into a web-form. You can also use this option to load existing valid xml into the web-form for MIR and FSCA for preview and to edit pre-submission.
2. Post xml reports – This option allows the user to send a valid xml directly via the MORE portal.

Application Programming Interface (API) – Submission of reports via an API requires an organisation to integrate directly from their own system with the MORE portal. A valid xml which will only be ingested by MORE if it conforms to validation rules of the relevant MIR 7.2 schema or FSCA 2.6 schema. The schema for MIR and FSCA forms can be found under section 2.12 at https://health.ec.europa.eu/system/files/2022-01/md_guidance_meddevs_0.pdf

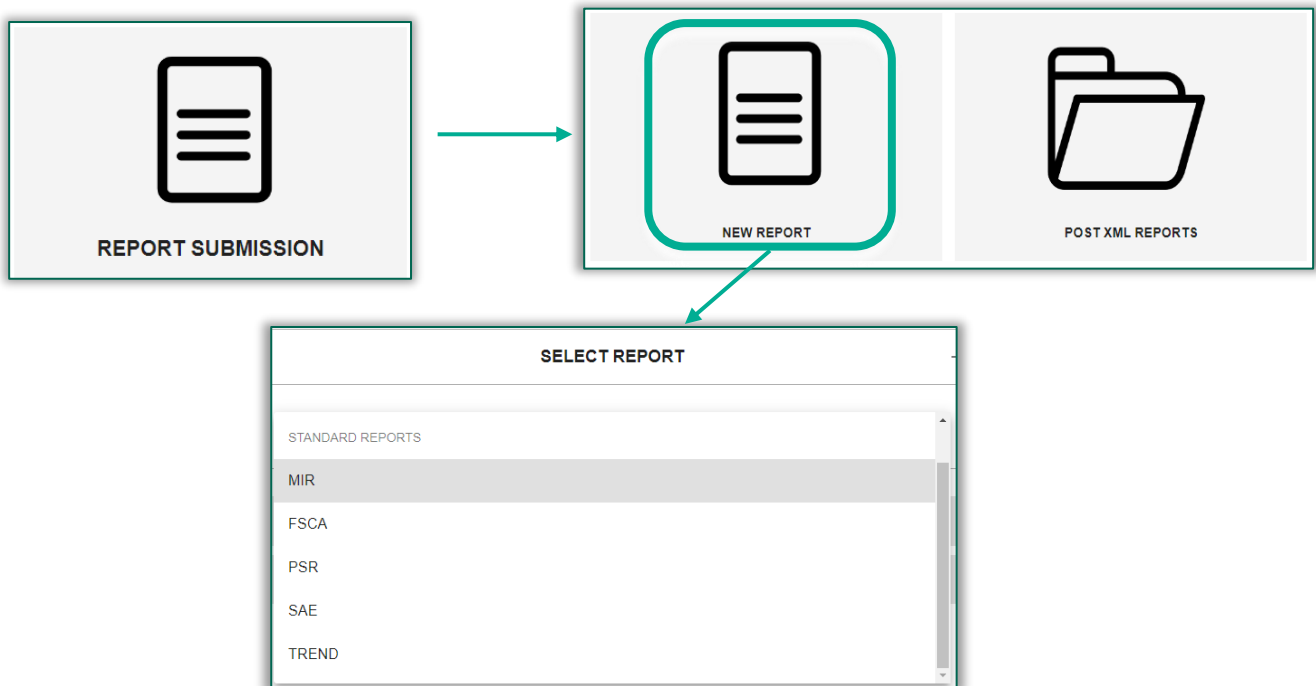
We recommend that individual incident reports are submitted using the same reporting method, for instance if your incident report was submitted via web-form, we recommend any updates are completed using the web-form also.

New report - Submitting an incident via web-form

To enter a new incident via a web-form you must log in to the reporting organisation.

From the dashboard, select the 'Reports' tile, and then select 'New Report'. A drop-down list will display the following five report options for selection:

- MIR
- FSCA
- Trend Reports
- PSR
- SAE



It is important to note that if you are an authorised representative or UKRP (either Organisation Lead or Standard user), you will not be able to submit reports from your representative organisation. Authorised Representative and UKRP dashboards will not contain the 'Reports' tile seen above and will only contain tiles and functionality relating to the tiles indicated in the following sections: [Organisation Lead Authorised Representative account](#) and [Standard User Authorised Representative account](#).

The five web-forms available for incident reporting in MORE share common features and have been designed based on existing paper reporting forms fields and schemas.

- Unless labelled '(Optional)', the field is mandatory and users will not be able to submit the report unless all mandatory fields are completed as per validation rules. Incomplete mandatory fields will be highlighted with an error message - this will be indicated with a red box and/or a red vertical line besides the mandatory field when the user selects the 'next step' or 'submit' button.

This screenshot shows a date selection form. At the top, it says 'Date of incident from' followed by a red error message: 'Error - Field Is Required'. Below this is the format 'YYYY/MM/DD'. The form consists of three input fields: 'Year' (containing 'YYYY'), 'Month' (containing 'MM'), and 'Day' (containing 'DD'). Each field has a dropdown arrow on its right side. To the right of the 'Day' field is a calendar icon. A red vertical line is positioned to the left of the 'Year' field.

This screenshot shows a text input field. At the top, it contains the instruction: 'Provide a comprehensive description of the incident, including (1) what went wrong with the device (if applicable) and (2) a description of the health effects (if applicable), ie clinical signs, symptoms, conditions as well as the overall health impact'. Below this is a red error message: 'Error - Field Is Required'. The input field itself is a large empty rectangular box with a red border. A red vertical line is positioned to the left of the input field.

- Identification of the type of report: Mandatory fields will differ between form types and will be dependent on the type of report that is selected by the user (e.g. Initial, Follow-up or Final Report).
- The reporting forms are separated into data form/report blocks. Users can select the + sign on the right-hand side of each report block to enter the details within the form.
- Incident report forms can be saved as drafts at any point and completed at a later time/date, as required.
- The date format presented in each of the incident reports is YYYY-MM-DD. Dates can be selected manually using drop-down options or using calendar pickers placed on the right-hand side of all date fields.
- Data forms will contain fields which can be completed by free text, check boxes, drop-down menus or look up functions.
- When using the web-form, some submitter fields will be auto-populated in the forms to reflect the organisations details as per the Device Registration Data e.g. postal address, contact name and email. The sections which are auto-populated include 1.3.2 'Manufacturer information', 1.3.3 'Authorised representative information' (where applicable) and 1.34 'Submitters details' (these will be copied across, based on answers to 1.3.1.a (submitter of the report). If this information is incorrect or needs to be updated, this will need to be amended first by the organisation in the Device Registration database.
- Users can load existing (valid) xml incident forms into the report page and will be able to view the data fields which will be ingested and displayed in the MORE form. The user can then amend or add to the form as required prior to submitting.

If the 'Other' reporter option is selected, the 'Submitters Information' section becomes mandatory and is **not** auto populated with any information. 'Submitter Information' will need to be completed with the details of the manufacturer, representative or other details. The incident report forms within MORE will have attachment functionality and for some of these forms this is a mandatory section. When a user includes an attachment, it is important to ensure that the file is appropriately titled to describe the document and that an appropriate name is added to the corresponding file name field.

If the type of attachment is limited to certain file types, e.g. .doc, then your file explorer will only allow you to select that file type

MIR - Manufacturer Incident Report

When a user selects the MIR reporting form, this displays all corresponding MIR data fields which can be completed in line with the MIR 7.2 schema. The schema for MIR forms can be

found under section 2.12 at https://health.ec.europa.eu/system/files/2022-01/md_guidance_meddevs_0.pdf

The MIR form consists of a 6-step reporting form which displays all fields that need to be completed.

The screenshot shows the 'Step 1 of 6' interface of the Medicines Incident Reporting (MIR) form. The header includes a 'BACK' button, a 'MIR' title, and a 'LOAD EXISTING' button. The Medicines & Healthcare products Regulatory Agency logo is in the top right. The main content area is titled 'Step 1 of 6' and includes a 'Save draft' button. Below the title, there is an 'Admin' label and a 'Next step' link. The form contains several input fields: 'Name of receiving national competent authority (NCA)' with 'MHRA' entered; 'EUDAMED Number of NCA (Optional)'; 'Reference number assigned by NCA (Optional)'; and 'Reference number assigned by EUDAMED for this incident (Optional)'. At the bottom, there is a date selection section for 'Date of incident from' in 'YYYY/MM/DD' format, with separate boxes for 'Year', 'Month', and 'Day'.

The MIR form contains an attachments page, which allows the user to attach any corresponding documents. When a user includes an attachment, it is important to ensure that the file is appropriately titled to describe the document and that an appropriate name is added to the corresponding file name field.

Once all mandatory fields are completed as per validation rules, the incident can be sent to the MHRA by selecting 'Validate & Send' at the end of the report form.

Important information required to complete MIR form fields:

- Reference number assigned by NCA – for **initial** and combined reports only, this field will be read only and un-editable, a reference number will be generated by MORE upon submission. You can view this reference number in the 'Report Management' tile please refer to [Section 7: Report Management](#)).

- The automatically generated reference number will persist for each following report related to this incident.
- Manufacturer Organisation name - this must be completed with the name of the Organisation for which you have logged in and are completing an incident report.
- 'Reference number assigned by NCA' when submitting via a MORE xml or directly via the API - for this incident' field please select an appropriate **unique reference number** which should persist across all versions of the report. For example, you may format the reference number as MHRA-XXX-ZZZZ, where XXX represents the three letters of your company name or abbreviation and ZZZZ is the sequential number of the reported incident. Note: The reference number can be any number of digits and must be unique.

Please populate the same number for Initial, and subsequent Follow up and Final reports to ensure correct linkage.

- If you are submitting a MIR form following receipt of an incident from the MHRA (Industry Notification of a Public report – INPR), please see the following section for more information on how to complete the 'Manufacturer's reference number for this incident' field which must link to the report you receive in MORE: [INPR](#)

Submitting reports during the transition period between legacy MORE and new MORE:

You will be able to submit a follow-up or final MIR in MORE if you have submitted an initial report in the legacy MORE system or via the AICxml mailbox until 31 August 2023. You can start a new report, select the 'Type of Report' as either 'Follow up', 'Final (reportable incident)' or 'Final (Non-reportable incident)'.

To link these reports to the initial report, it is essential that the field 'Reference number assigned by NCA' is completed with the reference number of the Initial report sent from the legacy MORE system. If you do not include the existing initial report reference number, the report will not be linked to your pre-existing report and will be assessed as a new and separate incident.

For users submitting reports via AICxml during the interim period (which will end on 31 August 2023), you will receive a seven-digit MHRA reference number for every submission irrespective of what version is being submitted. Please use the first MHRA reference number as the reference for record and ignore subsequent reference numbers sent when follow-up or final reports are submitted.

FSCA - Field Safety Corrective Actions

When a user selects the FSCA report form, this displays all corresponding FSCA fields for completion.

The FSCA form contains the below reporting blocks which can be expanded to display all fields that need to be completed

The screenshot shows a mobile application interface for the FSCA report form. At the top, there is a navigation bar with a 'BACK' button on the left, 'FSCA' in the center, and 'LOAD EXISTING' on the right. The top right corner features the Medicines & Healthcare products Regulatory Agency logo. Below the navigation bar, there are two options: 'Show all sections' and 'Hide all sections'. The main content area lists eight sections, each with a title and a downward arrow indicating it can be expanded:

- Section 1/8: **Administrative information**
- Section 2/8: **Information on the submitter of the report**
- Section 3/8: **Manufacturer information**
- Section 4/8: **Authorized representative information**
- Section 5/8: **National Contact Point Information**
- Section 6/8: **Medical Device Information**
- Section 7/8: **Description of FSCA**
- Section 8/8: **Comments**

At the bottom right of the form, there are two buttons: 'Save draft' and 'Submit'.

The FSCA report contains an attachments section within the 'Description of FSCA reporting block', which allows the user to attach any corresponding documents. When a user includes an attachment, it is important to ensure that the file is appropriately titled to describe the document and that an appropriate name is added to the corresponding file name field.

Once all mandatory fields are completed as per validation rules, the incident can be sent to the MHRA by selecting 'Validate & Send' at the end of the report form.

Important information required to complete FSCA fields:

FSCA reference number assigned by NCA - this will be a read only field and a reference number will be auto-generated upon report submission. You can view this reference number

in report management status (please refer to [Section 7: Report Management](#)). The automatically generated reference number will persist for the following reports related to this FSCA report

- Manufacturer Organisation name - this must be completed with the name of the Organisation for which you have logged in and are completing an incident report.

TREND reports

When a user selects the Trend report form, this displays the Trend form for completion. Users will be able to submit key information (administrative fields) and add the Trend report as an attachment i.e a word document with the Trend report for that submission.

The screenshot shows the 'TREND' report form interface. At the top, there is a navigation bar with a 'BACK' button on the left, a 'TREND' title in the center, and a 'MORE' button on the right. The Medicines & Healthcare products Regulatory Agency logo is in the top right corner. Below the navigation bar, there are two links: 'Show all sections' and 'Hide all sections'. The main content area is titled 'Section 1/2' and 'Administrative Information'. It contains several form fields: a text input for 'Reference number assigned by NCA (Optional)', a dropdown menu for 'Type of Trend report' with 'Please select' as the current value, and two date range selection sections. Each date range section has 'Reporting period from' and 'Reporting period to' labels, followed by 'Date range the report covers'. Each date selection is broken down into 'Year', 'Month', and 'Day' dropdowns, with a calendar icon to the right. At the bottom of the form, there is a label for 'Manufacturer's reference number for this incident'. The footer of the page contains the Medicines & Healthcare products Regulatory Agency logo and name.

The Trend form contains only the two reporting blocks below which can be expanded to display all fields that need to be completed.

The attachment fields within the Trend report are mandatory. When a user includes an attachment, it is important to ensure that the file is appropriately titled to describe the document and that an appropriate name is added to the corresponding file name field.

Once all mandatory fields are completed, the incident can be sent to the MHRA by selecting 'Validate & Send' at the end of the report form.

Important information required to complete Trend fields:

- Reference number assigned by NCA – for all **initial** reports this will be read only, and a reference number will be auto-generated upon report submission. You can view this reference number in report management tile (please refer to [Section 7: Report Management](#)). The automatically generated reference number will persist for all following reports related to this Trend report.
- Manufacturer Organisation name - this must be completed with the name of the Organisation for which you have logged in and are completing an incident report.

Submitting reports during the transition period between legacy MORE and new MORE:

You will be able to submit a follow-up Trend report in MORE if you have submitted an initial report in the legacy system. To do this you can start a new report, select the 'Type of Report' as either 'Follow up' or 'Final'.

To link these reports to the initial report, it is essential that the field 'Reference number assigned by NCA' is completed with the reference number of the Initial report provided by the MHRA. If you do not include the existing initial report reference number, the report will not be linked to your pre-existing report and will be assessed as a new and separate report.

PSR - Periodic Summary Reports

When a user selects the PSR report form, this displays the PSR form with a number of fields required for completion. Users will be able to submit key information (administrative fields) in the form and add a spreadsheet with incidents as an attachment.

Note: To submit summary reports for Clinical Investigations please use SAE report type.

The screenshot displays the 'PSR' (Periodic Summary Report) form interface. At the top right, there is a logo for 'Medicines & Healthcare products Regulatory Agency'. The page title is 'PSR'. Below the title, there are links for 'Show all sections' and 'Hide all sections'. The main section is titled 'Section 1/2 Administrative Information'. It contains the following fields:

- Type of PSR (periodic summary report):** A dropdown menu with 'Application for PSR' selected.
- Date of incident from (Optional):** A label 'Date range the report covers' followed by three dropdown menus for Year (YYYY), Month (MM), and Day (DD), and a calendar icon.
- Date of incident to (Optional):** A label 'Date range the report covers' followed by three dropdown menus for Year (YYYY), Month (MM), and Day (DD), and a calendar icon.
- Periodic Summary Report (PSR) ID (Optional):** A text input field.
- Manufacturer Organisation name:** A text input field.

At the bottom left, there is a logo for 'Medicines & Healthcare products Regulatory Agency'.

The PSR form contains only the two reporting blocks below which can be expanded to display all fields that need to be completed.

The PSR form contains an attachments block, which allows the user to attach any corresponding documents. When a user includes an attachment, it is important to ensure that the file is appropriately titled to describe the document and that an appropriate name is added to the corresponding file name field. For Update and Closure reporting options, the first attachment should include the application form and the second attachment should be the spreadsheet with incidents.

Once all mandatory fields are completed, the incident can be sent to the MHRA by selecting 'Validate & Send' at the end of the report form.

PSRs that have already been submitted to the MHRA will be processed and closed. When users select the PSR report, the Type of PSR will automatically be set to 'Application for PSR' and cannot be changed (i.e read only). Other types of PSR report will be disabled

until your PSR application is approved by the MHRA.

Type of PSR (periodic summary report)

Application for PSR

When a user submits a PSR Application the status will be 'Submitted - Pending' and will change to 'Ack Success' once successfully received by the MHRA.

Status	Report Form	Type of Report	Report Source
Please select	PSR	Please select	
Date From	Date To	<input type="checkbox"/> Display Latest Versions Only	
08/06/2023	dd/mm/yyyy		

DATE	SENDER	USER	REPORT FORM	TYPE OF REPORT	REFERENCE NUMBER	STATUS	SOURCE	LATEST VERSION
20/06/2023 ...	59301	Jane Doe	PSR	Application for PSR	2023/006/020/601/005	Ack Success	Vigilance Hu...	

PSR Approvals

You will receive a message via the notifications tile informing you that your PSR application has been approved.

When the PSR application is approved by the MHRA, users will be able to see a second row with the same reference number in the 'Report Management' tile status (please refer to [Section 7: Report Management](#)). This report will have a status which remains as 'Submitted - Pending'. You can select this entry, to display Additional options such as 'View/Update Report'.

To submit a follow up PSR click on the update button and select the appropriate option under 'Type of PSR' which will now be editable.

2023/006/020/601/005

Report Details

Creation Time	20/06/2023 09:28
Updated Time	20/06/2023 09:28
Reporter	Jane Doe
System Reference	16978848-f59b-45c6-a825-18a73cb1512e
Report Form	PSR Report
Report Type	Application for PSR
Report Status	Ack Success
Report Submission Route	Other
Source	Vigilance Hub Forms

Export As...

- PDF
- JSON

View/Update Report

- View/Update Report

Acknowledgement

- View Acknowledgement

Status Details

Receiver Name	Receiver Status	Validation Status	Created At
HALO Devices Batch (All)	SUCCESS	VALID	20/06/2023 09:28
HALO Devices Batch (Dev)	SUCCESS	VALID	20/06/2023 09:28
HALO Devices Batch (Val)	SUCCESS	VALID	20/06/2023 09:28

Attachments

- test case please invalidate docx

When users send a 'Periodic Analysis Update' or a 'Closure PSR' after PSR approval has been received via MORE, they will be able to view this in the 'Report Management' tile as a third row with the same reference number status (please refer to [Section 7: Report Management](#)). This will have a status of 'Ack Success' when successfully received by the MHRA.

Type of PSR (periodic summary report) *

- Please select
- Periodic analysis update
- Closure PSR

Status of PSR reports in MORE

- PSR Application – This outgoing submission will change to 'Ack Success' when successfully transmitted and received by the MHRA. If this first submission remains at 'Submitted - Pending' status, you must notify the MHRA via aic@mhra.gov.uk
- PSR approval – This incoming approval submission will be submitted with the same reference number as the PSR application, and its status will remain at 'Submitted - Pending'. The MHRA should not be notified of inbound PSR approval where the status does not change to 'Ack Success'.

- Periodic Analysis Update/Closure PSR- This outgoing submission will change to 'Ack Success' when successfully received by the MHRA. If this third submission remains at 'Submitted - Pending' status, you must notify the MHRA via aic@mhra.gov.uk. This submission will also have the same reference number as the PSR application and the subsequent incoming submission.

DATE	SENDER	USER	REPORT TYPE	REFERENCE NUMBER	STATUS
14/11/2022 16:44	39851	MHRAADMIN	PSR	2022/011/014/601/014	ACK SUCCESS
14/11/2022 16:40	39851		PSR	2022/011/014/601/014	SUBMITTED
14/11/2022 16:29	39851	MHRAADMIN	PSR	2022/011/014/601/014	ACK SUCCESS

PSR Rejection

You will receive a message via the notifications tile informing you that your PSR application has been rejected and further details as necessary.

When the PSR application is rejected by the MHRA, users will be able to see a second row with the same reference number in the 'Report Management' tile status (please refer to [Section 7: Report Management](#)). This report will have a status which remains as 'Submitted - Pending'. You can select this row, to display Additional options such as 'Update'.

2022/011/011/601/007

Created At: 11/11/2022 13:11

Report ID: d9ea0479-6a90-4949-b62d-7c7fd6793616

Report Type: PSR

Report Configuration: None

Report Configuration Version:

Report Configuration Type:

Status: ACK SUCCESS

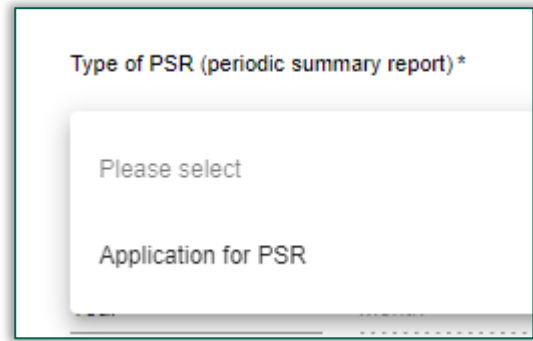
Attachments

FILE	EXT
test	docx

VIEW ACK EXPORT PDF EXPORT JSON **UPDATE**

If the PSR application has been rejected by the MHRA, the field for '**Type of PSR**' will only display the option '**Application for PSR**', which would allow you to update and resubmit as required.

You will need to make sure that any relevant attachments are included in the resubmission if required.



The image shows a screenshot of a web form. At the top, there is a label 'Type of PSR (periodic summary report) *'. Below this label is a dropdown menu. The dropdown menu is currently open, showing the text 'Please select' at the top and a single option 'Application for PSR' below it. The dropdown menu has a light grey background and a thin border.

PSR Review and PSR Closed

You may also receive messages via the notifications tile informing you that your PSR application has been reviewed or closed with further information.

SAE - Serious Adverse Events

The new MORE portal now has a new option for users to submit SAE reports for Clinical Investigations. All type of reports related to a clinical investigation should be submitted using SAE report form. When a user selects the SAE report form, this displays all corresponding SAE fields for completion.

The screenshot shows the SAE report form interface. At the top, there is a header with a menu icon, the word 'MORE', and the 'Medicines & Healthcare products Regulatory Agency' logo. Below the header, there is a 'BACK' button and the title 'SAE'. The form is divided into three sections: 'Section 1/3 Administrative Information', 'Section 2/3 Device Details', and 'Section 3/3 Attachments'. Each section has a dropdown arrow. At the bottom right, there are two buttons: 'Save draft' and 'Submit'. The footer contains the 'Medicines & Healthcare products Regulatory Agency' logo and name.

The SAE form contains the below reporting blocks which can be expanded to display all fields that need to be completed

The attachment fields within the SAE report are mandatory. When a user includes an attachment, it is important to ensure that the file is appropriately titled to describe the document and that an appropriate name is added to the corresponding file name field. The spreadsheet templates to submit incidents can be found in the Resources tile.

There are two template excel sheets which can be used when submitting SAE reports with multiple incidents. It is important to note that the columns and titles should not be amended

to ensure correct ingestion on the MHRA system and should only have details added to the relevant blank fields.

Please refer to the excel tab within the templates titled 'structured terms' or hover over the column title (if there is a red triangle) for guidance on how to populate the fields.

The SAE fields will be displayed and can then be completed. Once all fields are completed, including all mandatory fields, the incident can be sent by selecting 'Validate & Send'. If this button is disabled (grey) then there are mandatory fields that have not been completed. For SAE reporting where the sponsor has an obligation to report within a 2-10 day timeframe, selecting 'Other' will not affect MHRA processing times and prioritisation. Please continue to submit as 'Other' if appropriate.

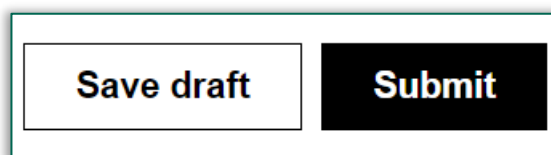
Reporting period fields are mandatory for Quarterly and Annual reports, these fields are not mandatory for 'Other' report types and should not be filled in if not applicable.

Important information required to complete SAE fields:

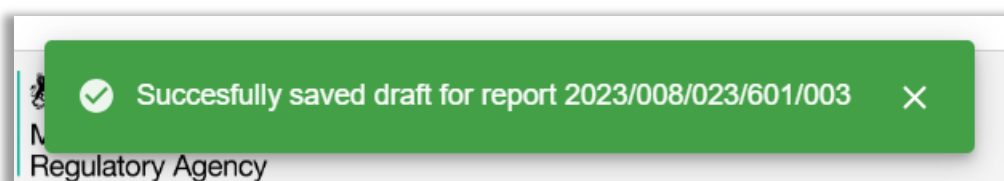
When a user opens a SAE report, the fields for contact's first name, last name and email are prepopulated based on the user's login details. If this needs to be updated, please delete the details, and replace with an appropriate contact's details. Please add your CIP number together with your Clinical study title.

Saving draft reports

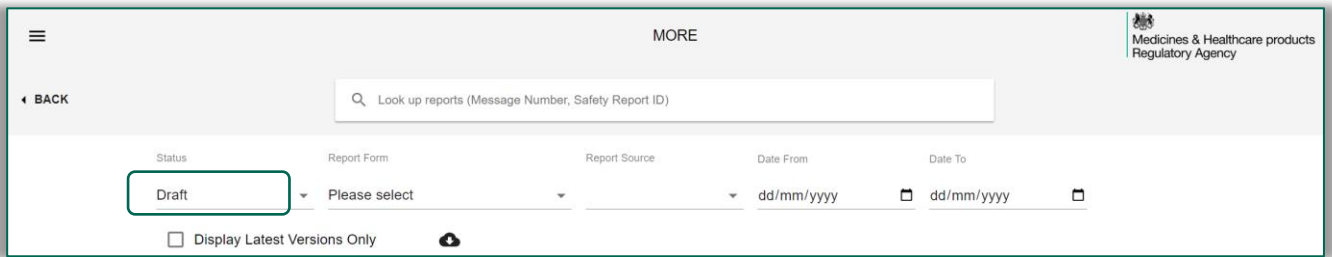
When you create a new report (MIR, FSCA, TREND, PSR, SAE), you can save a draft at any point during the completion process by selecting the 'Save Draft' option which will be in either the in the top right-hand corner of the form or at the bottom right of the form.



After doing this, you will be directed to the "Report Management" tile. A green pop-up will appear at the bottom left with the report reference number. Please note this reference number will remain the same when the report is submitted.



Saved drafts can be accessed via the 'Report Management' screen by selecting the status as 'Draft' (please refer to [Section 7: Report Management](#)).



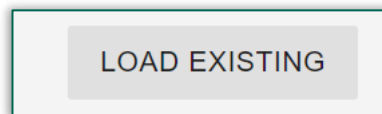
The screenshot shows the 'MORE' interface for report management. At the top right is the logo for 'Medicines & Healthcare products Regulatory Agency'. Below the logo is a search bar with the text 'Look up reports (Message Number, Safety Report ID)'. Below the search bar are five filter fields: 'Status' (set to 'Draft'), 'Report Form' (set to 'Please select'), 'Report Source' (empty), 'Date From' (set to 'dd/mm/yyyy'), and 'Date To' (set to 'dd/mm/yyyy'). At the bottom left, there is a checkbox labeled 'Display Latest Versions Only' which is currently unchecked.

To continue working on a draft at a later date please see Section: [Updating Reports](#)

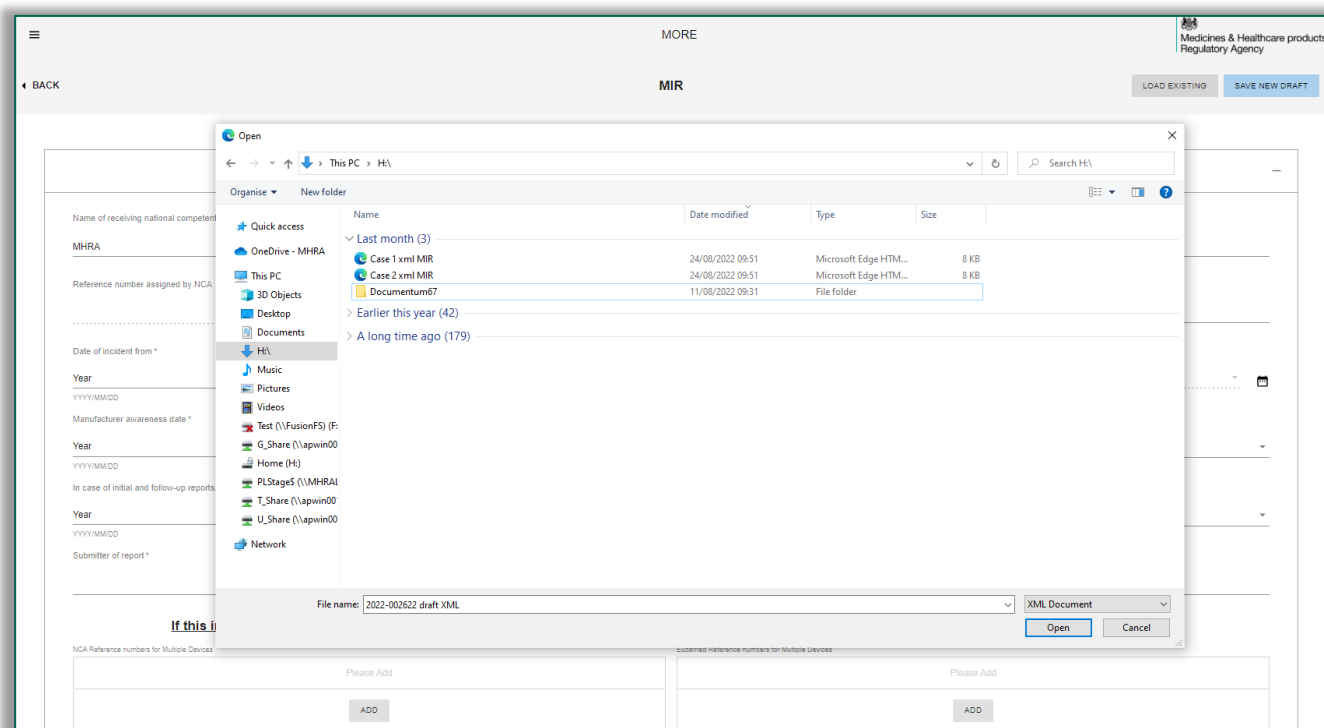
Note: Due to MORE being a submissions platform, draft reports are unable to be deleted and will remain in draft status unless submitted.

Loading draft reports/existing

If you wish to create a report based on an existing MORE form XML, you can export this xml and then import this into the form using the 'Load Existing' option in the top right-hand corner of the specified form. This function will only work with valid MIR or FSCA xml files.

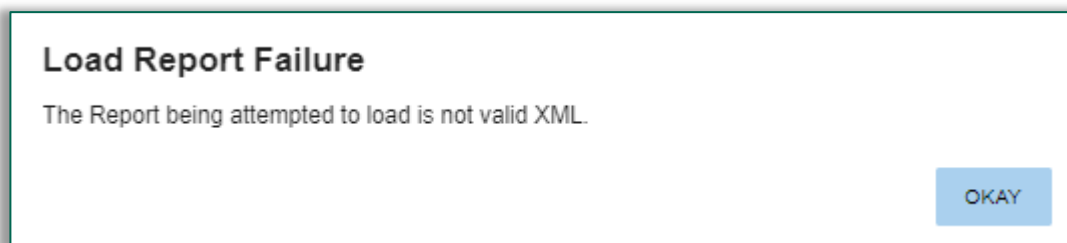


On selecting this option, you will be able to select a file from your file browser.



Loading a report will clear the form and repopulate fields.

If you attempt to upload a file that is not a valid xml file, an error message will be displayed, and the report will not be loaded.



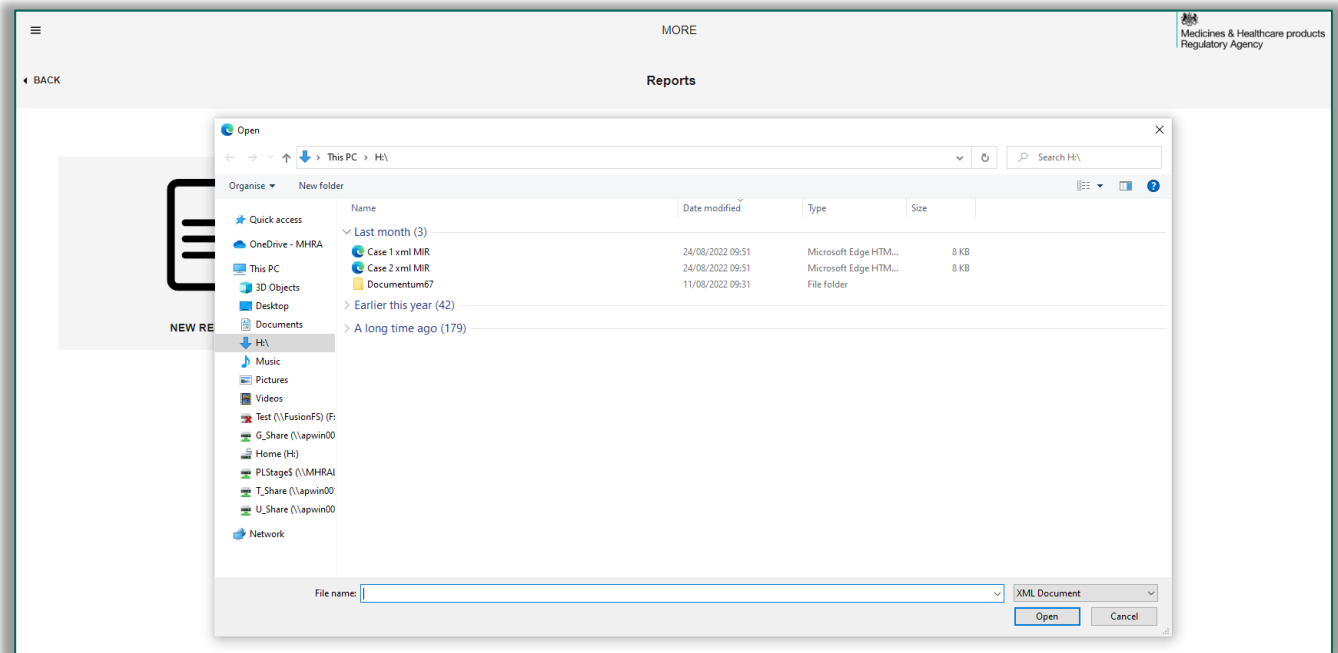
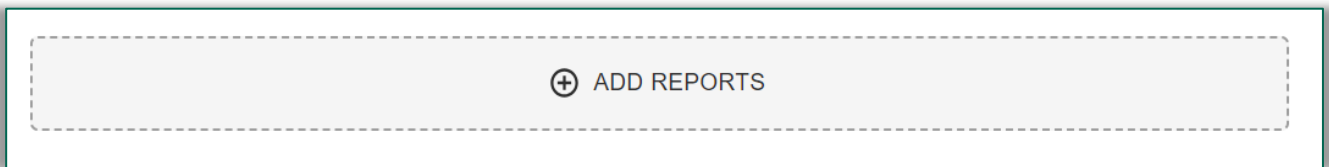
NOTE: It is the responsibility of the organisation to ensure their xmls are valid and compliant. The MHRA will not routinely advise on correcting errors within xml files. A valid xml must conform to validation rules of the relevant MIR 7.2 schema or FSCA 2.6 schema. The schema for MIR and FSCA forms can be found under section 2.12 at https://health.ec.europa.eu/system/files/2022-01/md_guidance_meddevs_0.pdf

Submitting an incident by posting XML reports

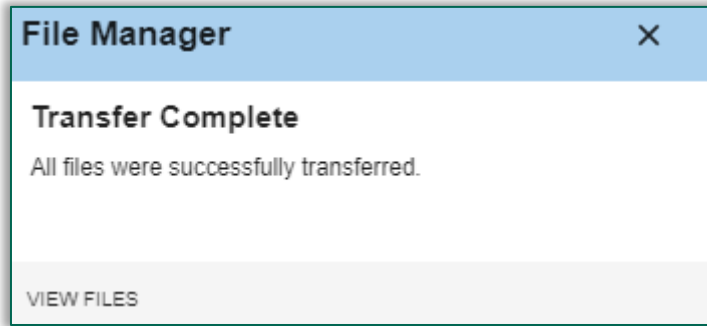
If you have an existing XML that you would like to send to the MHRA, you should select the 'Post XML Reports' tile from the Reports tile on the main dashboard.



On selecting this option, you will be able to select a file or multiple files from your file browser by selecting 'Add Reports'.



Once you select the file you wish to post, a success message will be displayed to confirm it has been sent. You can select 'View files' to verify the submission status of each file within the xml individually.

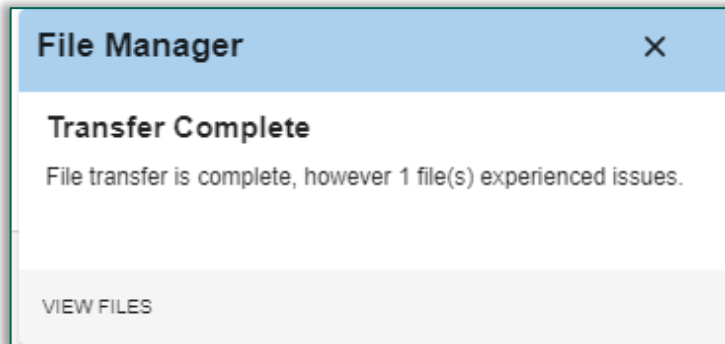


XML files submitted via MORE post xml can also be viewed from the 'Report Management' tile. This will include submission and acknowledgement status (please refer to [Section 7: Report Management](#)).

FILE	DETAILS	STATUS
2022-009-009-601-001.xml		SUCCESS

A screenshot of a "File Manager" window showing a table with three columns: FILE, DETAILS, and STATUS. The first row contains the file name "2022-009-009-601-001.xml" and a green "SUCCESS" button in the status column.

If your file does not follow formatting guidelines, the file will fail to send, and an error message will be generated.



FILE	DETAILS	STATUS
Case 1 xml MIR.xml	Report with incorrect sender ...	ERROR

A screenshot of a "File Manager" window showing a table with three columns: FILE, DETAILS, and STATUS. The first row contains the file name "Case 1 xml MIR.xml", the detail "Report with incorrect sender ...", and a red "ERROR" button in the status column.

It is important to be sure that you have logged into the correct organisation account before posting any xml files as these will then appear in report management for the organisation you have logged into and will be available to all MORE with access to that organisation.

For a failed XML please check the error message and compare the xml against the schema to help with the troubleshooting process. The schema for MIR and FSCA forms can be found under section 2.12 at https://health.ec.europa.eu/system/files/2022-01/md_guidance_meddevs_0.pdf

The 'Post XML Reports' functionality works only for MIR and FSCA reports, which are validated against respective schemas' upon submission. Any xml files that do not conform either to MIR 7.2.1 or FSCA 2.6 schemas will not be accepted by the system. If an SAE report in .xlsx format (Excel) is converted to xml format and submitted via MORE, the system will not accept it and the submission will fail. All reports relating to Clinical Investigations should be submitted via the 'New Report' tile and 'SAE' report option. Excel files can then be added in the attachment section within the report form.

Submitting an incident by Application Programming Interface (API)

If you would like to set up direct integration via the API, please get in touch with MHRA by emailing aic@mhra.gov.uk to initiate set up. Please use the following subject heading in the email 'API set up request for MANUFACTURER NAME (Account number)'.

Once the MHRA have communicated back to you with updated resources, you may continue to set up the API.

To set up an API for submission of incident reports from your system directly into the MORE portal you must first ensure that you have registered and then set up the reporting API.

Registering on the UAT MORE portal

If you have already registered via MORE and your account has been approved, please go to section: [Setting up an API](#).

If you have not registered to the MORE portal, please follow the steps below or access the guidance here for more details: <https://www.gov.uk/government/publications/more-registrations-user-reference-guide>

- Click on the following link [https://mhra-more-
uat.redant.cloud/login](https://mhra-more-uat.redant.cloud/login) to access the MORE portal in the UAT environment
- On the MORE UAT login page, select create account
- In the create account page, select 'Manufacturer' from the 'user group' dropdown list.
- Select your organisation from the 'manufacturer

association' field using the look up function.

- You will need to begin typing to display and select your organisation from the drop-down field.
- The organisation(s) that you select will be pinned below this field as confirmation of selection – **please ensure the account ID is correct.**
- Add your details within the personal detail's fields, ensuring all mandatory fields marked with an asterisk (*) are completed.
- Select your communication preference using the check box.
- Create a password using the specified criteria.
- Tick the Terms and Conditions check box.
- If all required fields are completed the 'create user' button at the bottom of the screen will change from grey to blue. Select 'create user' to submit your registration request. When successfully created a pop-up confirming account creation will appear.

- Initial account registration will be approved/rejected by the MHRA, and you will receive an email confirming this within 24 hours.
- Once your account is approved you will be able to select your organisation when you log in with your email and password.
- Select the organisation from the drop-down list and enter. You will only be able to view organisations for which you have been approved.
- You will then have access to your manufacturer organisation dashboard and menu options.


Setting up the API

API details

Once your registration has been approved by the MHRA, you will be able to set up the API.

Note that the below guidance can be used to review and look at API set up however we request that you contact MHRA before building any API to ensure the latest requirements are made available to you as the below steps may change as we continue to improve the MORE submissions platform.

An App ID and API Key are required before making requests to the MORE Incident API. To set up a reporting API, please follow the below steps:

- View your App ID and create an API Key within the 'Developer' area in the MORE portal - click on burger menu  in the top left-hand corner of the main dashboard.
- Click on the 'Developer' area located near the bottom of the drop-down menu list.
- Click Generate API Key (blue button), then enter a name of your choice into the pop-up and press Generate. An API Key will be automatically created for you.
- Copy the X-App-ID and API Key values to your internal system.
- Once logged in and configured, you can start securely submitting reports.

To complete the integration, your IT/technical team should use the following API documentation to create system-interface. Full API documentation is available at <https://more-developer-api.redant.cloud/>

The full API documentation can be found in the Resources tile in the MORE dashboard. This provides information on how to submit and validate an XML report via the API.

Data security and encryption

The system conforms to ISO 27001 and UK General Data Protection Regulation (GDPR) requirements. All communication is encrypted via HTTPS (TLS V1.2).

Section 4: Report Management

Manufacturers will have access to all reports submitted by their own manufacturer users as well as all representative users associated to the manufacturer organisation, as well as reports received from the MHRA. In MORE this relationship is based on the Device Registration database Appian relationships.

If you are a UKRP or an Authorised Representative (NI), you will have access to reports that have been submitted for the organisations you have access to, for as long as you have an active MORE account, as well as reports received from the MHRA for that organisation (s). If a representative leaves the organisation, or change roles, it is the Manufacturer's responsibility to remove the previous representative from the Device Registration Database (Appian data) to ensure they no longer have access to new reports for that organisation. In the instance of a change in representative the manufacturer will need to register for a new MORE organisation account which will be associated to the new representative. Further details are provided in section XXXXX.

Downloading all reports

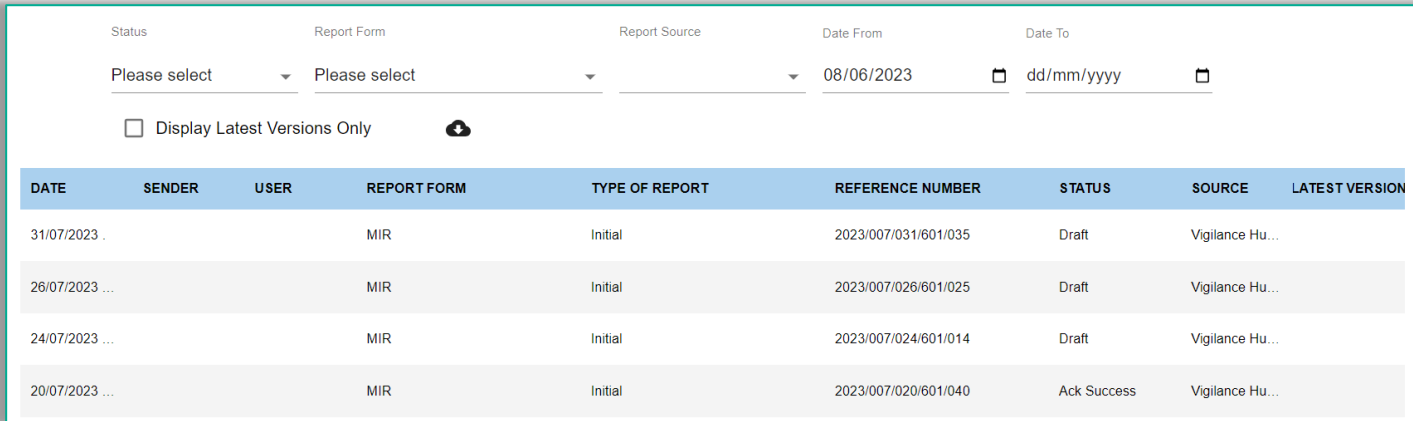
If you need to download all your reports for your Organisation you can bulk download reports via report management.

Select the reports that are required by filtering on status, report type, source and date and then click the download cloud button. This will download a zip file of report to your device. Please note that the download will be for all reports visible in the interface, this means you may need to scroll down to load more reports if you are downloading many reports.

The screenshot shows the MORE interface for report management. At the top right, there is a logo for the Medicines & Healthcare products Regulatory Agency. The main header area contains a search bar with the placeholder text "Look up reports (Message Number, Safety Report ID)". Below the search bar, there are four filter sections: "Status" with a dropdown menu set to "Please select"; "Report Form" with a dropdown menu set to "PSR"; "Type of Report" with a dropdown menu set to "Please select"; and "Report Source" with a dropdown menu. Below these filters, there are date filters: "Date From" set to "08/06/2023" and "Date To" with a calendar icon and the format "dd/mm/yyyy". There is also a checkbox labeled "Display Latest Versions Only" which is currently unchecked. A prominent blue download button with a cloud icon is located on the right side of the filter area.

Reports sent to MHRA

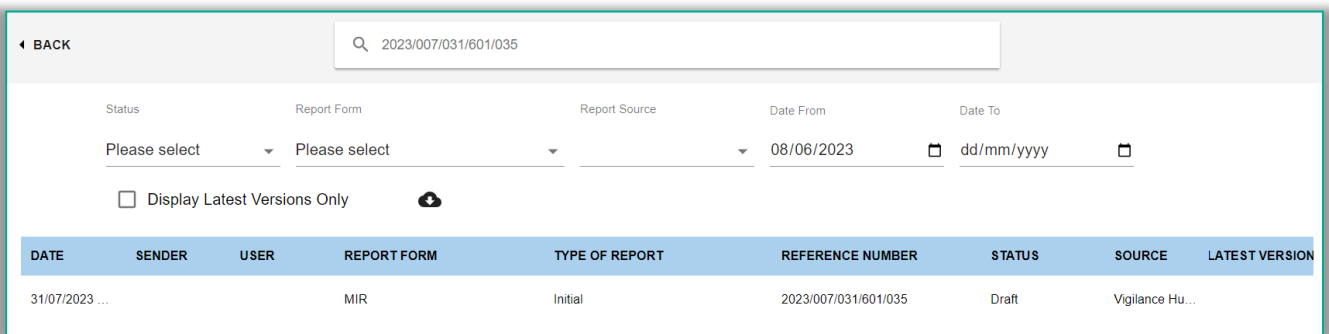
Reports sent to the MHRA, and draft reports can be tracked in the 'Report Management' screen.



The screenshot shows the 'Report Management' interface. At the top, there are filters for Status, Report Form, Report Source, Date From (08/06/2023), and Date To (dd/mm/yyyy). Below the filters is a checkbox for 'Display Latest Versions Only'. The main content is a table with the following columns: DATE, SENDER, USER, REPORT FORM, TYPE OF REPORT, REFERENCE NUMBER, STATUS, SOURCE, and LATEST VERSION. The table contains four rows of data.

DATE	SENDER	USER	REPORT FORM	TYPE OF REPORT	REFERENCE NUMBER	STATUS	SOURCE	LATEST VERSION
31/07/2023			MIR	Initial	2023/007/031/601/035	Draft	Vigilance Hu...	
26/07/2023			MIR	Initial	2023/007/026/601/025	Draft	Vigilance Hu...	
24/07/2023			MIR	Initial	2023/007/024/601/014	Draft	Vigilance Hu...	
20/07/2023			MIR	Initial	2023/007/020/601/040	Ack Success	Vigilance Hu...	

You can look up specific reports by searching for the required reference number using the search function.



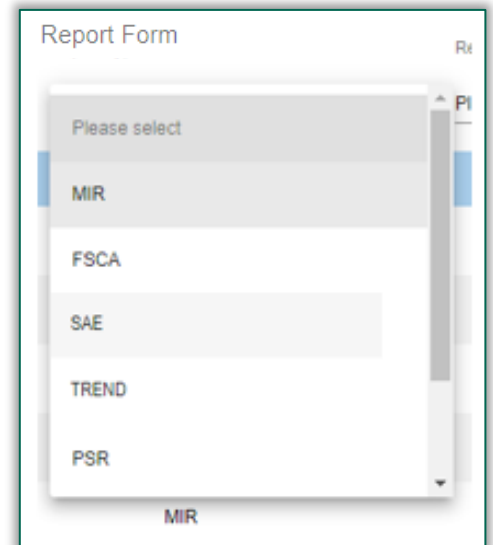
The screenshot shows the 'Report Management' interface with a search bar at the top containing the reference number '2023/007/031/601/035'. The filters and table are the same as in the previous screenshot, but only one row is displayed, corresponding to the search criteria.

DATE	SENDER	USER	REPORT FORM	TYPE OF REPORT	REFERENCE NUMBER	STATUS	SOURCE	LATEST VERSION
31/07/2023			MIR	Initial	2023/007/031/601/035	Draft	Vigilance Hu...	

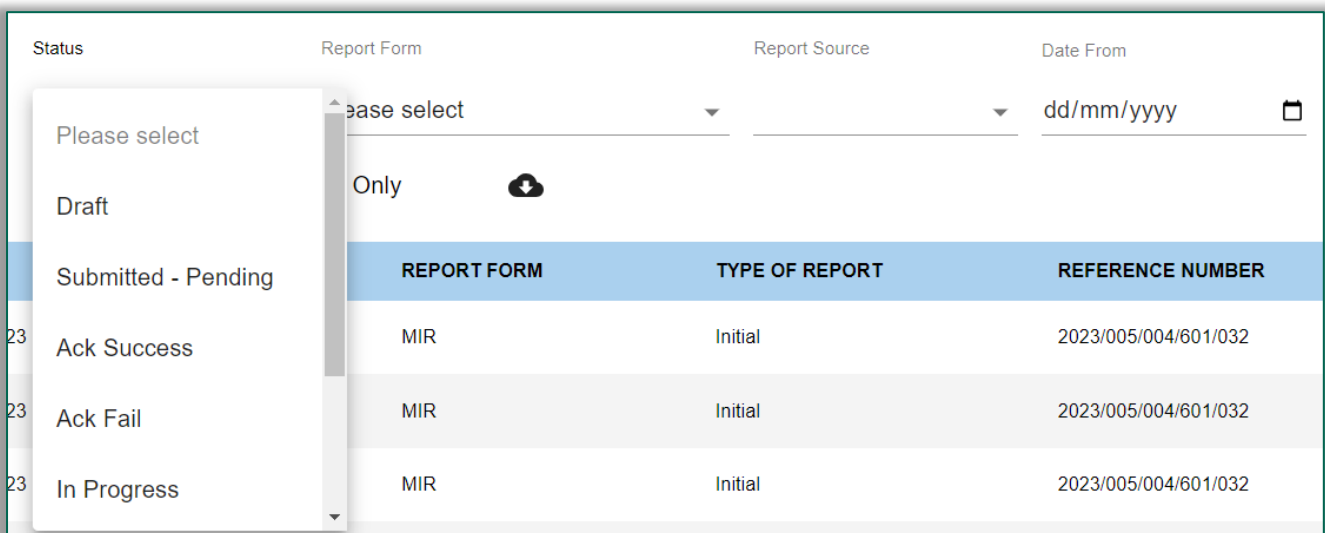
To search for your report, please ensure that the 'Date From' has been set to a date prior to the date for which the report was submitted.

The search field within the 'Report Management' tile will display reports where the value has been populated in the field 'Reference number assigned by NCA'.

You can filter reports on 'status', 'report type', 'report source', 'date from' and 'date to'. As a standard the 'date from' filter will automatically have one week prior selected. Please remove or edit this if searching for cases outside of this time frame.



The acknowledgement status of a report can be seen in the 'Status' column.



See the table below for information on the four different options found in the 'status' column:

Status	Explanation
Submitted - Pending	Report submitted to the MHRA. No acknowledgement received yet
Ack Success	Report submitted to the MHRA. Positive acknowledgement (01 ack) received
Draft	Draft report saved from the new report form

If you have not received an 'Ack Success' status within 72 hours of submitting a MORE report then contact please review your submission for validation errors or contact AIC@mhra.gov.uk, including the report reference number (seen from the 'Report Management' tile).

It is the responsibility of the user to notify the MHRA if a report remains on status 'Submitted - Pending' or 'in progress' 72 hours after submission.

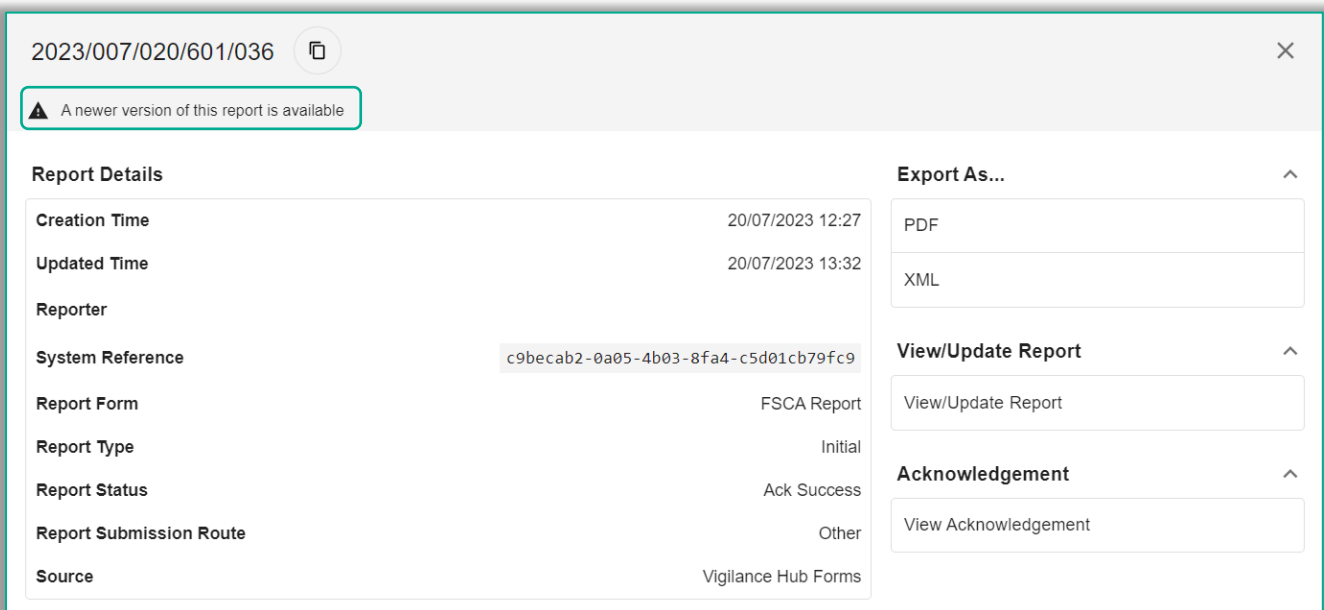
Updating Reports

If follow up information is received, or the incident needs to be updated, the 'Report management' tile can be used to create an update for the initial case report.

Use the search bar to find the initial incident report by entering your Reference Number and 'enter'. Select the incident report you want to update. This could be a report you already submitted or a draft report that you are now ready to submit. This would be the method to use if you are ready to update a previously submitted report with new or amended information for example in the case of a Field Corrective Action (FCA)

Updating/Editing Draft reports

You will not be able to update older versions of reports if it has already been updated. MORE will alert you that a newer version of the report is available.



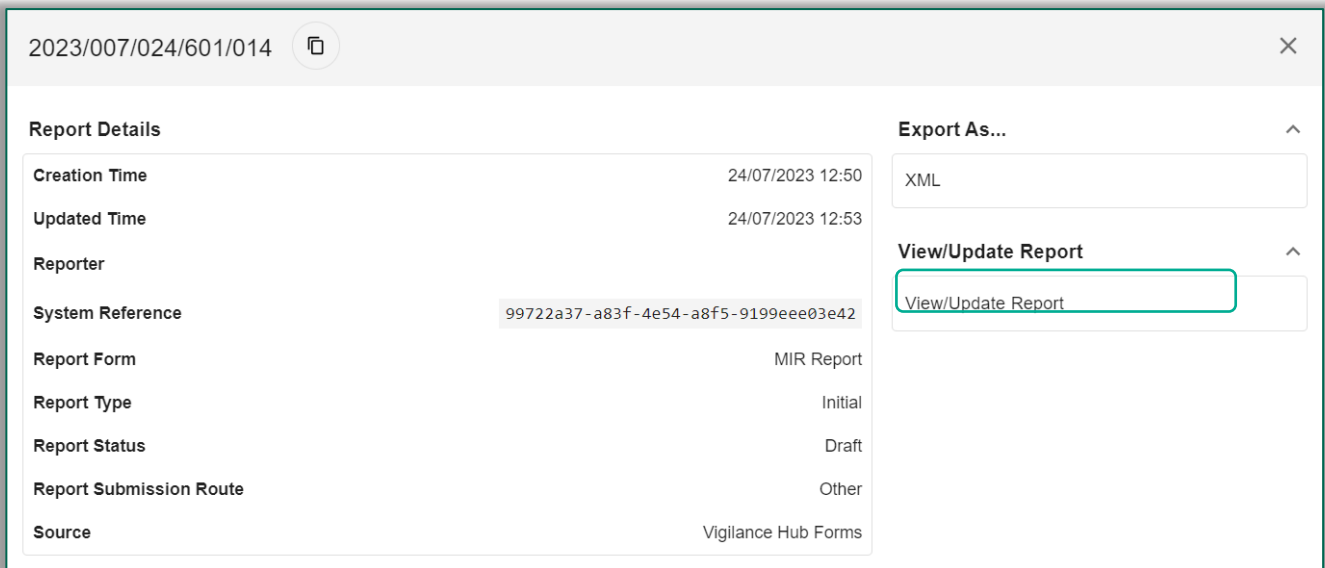
The screenshot shows a report management interface. At the top, there is a header with the report ID '2023/007/020/601/036' and a close button. Below the header, a notification box with a warning icon states 'A newer version of this report is available'. The main content area is divided into two columns. The left column, titled 'Report Details', contains a table with the following information:

Creation Time	20/07/2023 12:27
Updated Time	20/07/2023 13:32
Reporter	
System Reference	c9becab2-0a05-4b03-8fa4-c5d01cb79fc9
Report Form	FSCA Report
Report Type	Initial
Report Status	Ack Success
Report Submission Route	Other
Source	Vigilance Hub Forms

The right column contains three sections: 'Export As...' with options for PDF and XML; 'View/Update Report' with a 'View/Update Report' button; and 'Acknowledgement' with a 'View Acknowledgement' button.

Only the most current version of a report can be updated.

You can also view saved draft reports by filtering report status to 'Draft'. If you want to continue editing a draft report, select the report and select 'View/Update Report' to view the editable draft form.



2023/007/024/601/014

Report Details

Creation Time	24/07/2023 12:50
Updated Time	24/07/2023 12:53
Reporter	
System Reference	99722a37 - a83f - 4e54 - a8f5 - 9199eee03e42
Report Form	MIR Report
Report Type	Initial
Report Status	Draft
Report Submission Route	Other
Source	Vigilance Hub Forms

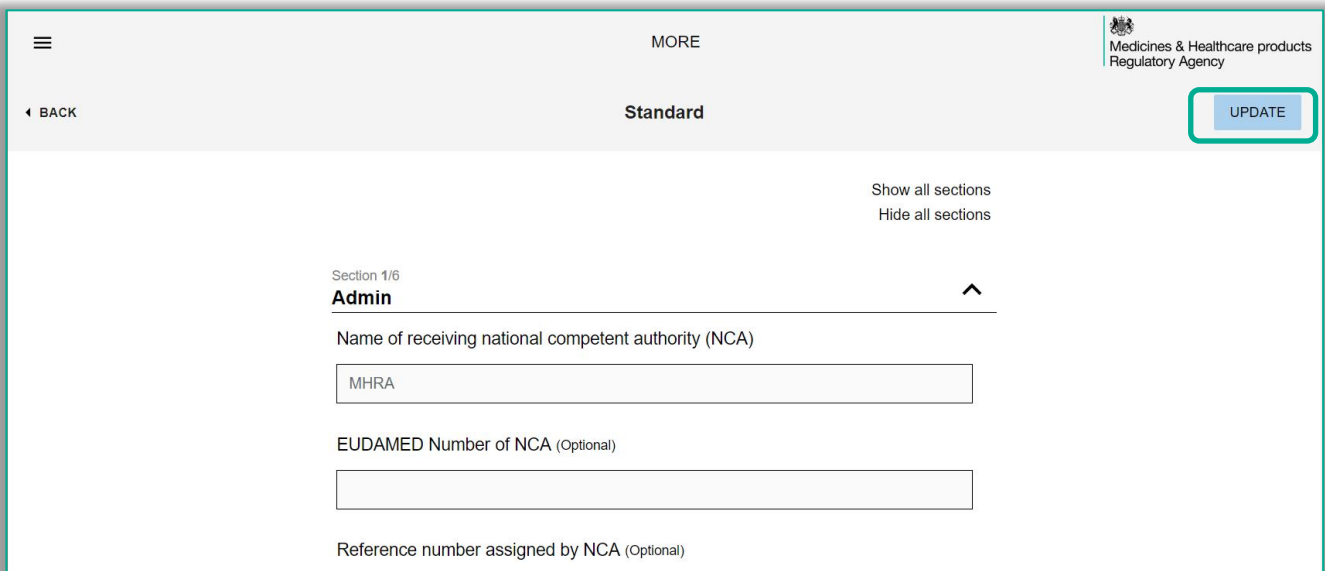
Export As...

XML

View/Update Report

View/Update Report

You will then need to select 'Update' in the top right-hand corner of the report form.



Medicines & Healthcare products Regulatory Agency

Standard

UPDATE

Show all sections
Hide all sections

Section 1/6
Admin

Name of receiving national competent authority (NCA)

MHRA

EUDAMED Number of NCA (Optional)

Reference number assigned by NCA (Optional)

Add additional information using the report form that is available.

Once the report has been completed, click 'Validate & Send' at the bottom of the page. Note, you can still save a draft at any stage of completing updates.

You will see a 'Ack Success' submission status when successfully received by the MHRA.

The status of the report will change from 'Draft' to 'Ack Success'. You will be able to view the date and time stamps for all reports.

If you have not received an 'Ack Success' status within 72 hours of submitting MORE report AIC@mhra.gov.uk, including the report reference number (seen from the 'Report Management' tile).

It is the responsibility of the user to notify the MHRA is a report remains on status 'Submitted - Pending' or 'in progress' 72 hours after submission

Updating/Editing submitted reports

You will not be able to update older versions of reports if it has already been updated. MORE will alert you that a newer version of the report is available.

Only the most current version of a report can be updated.

The screenshot shows a web interface for report management. At the top, there is a header with the report ID '2023/007/020/601/036' and a close button. Below the header, a notification box with a warning icon states 'A newer version of this report is available'. The main content is divided into two columns. The left column, titled 'Report Details', contains a table with the following information:

Creation Time	20/07/2023 12:27
Updated Time	20/07/2023 13:32
Reporter	
System Reference	c9becab2-0a05-4b03-8fa4-c5d01cb79fc9
Report Form	FSCA Report
Report Type	Initial
Report Status	Ack Success
Report Submission Route	Other
Source	Vigilance Hub Forms

The right column contains three sections: 'Export As...' with options for PDF and XML; 'View/Update Report' with a 'View/Update Report' button; and 'Acknowledgement' with a 'View Acknowledgement' button.

To update any reports you have submitted, select the report from report management and then select update from the pop up.

Report Details	
Creation Time	20/07/2023 12:57
Updated Time	20/07/2023 13:33
Reporter	
System Reference	b52aa99d-9103-4c77-8709-1315348c5163
Report Form	MIR Report
Report Type	Initial
Report Status	Ack Success
Report Submission Route	Other
Source	Vigilance Hub Forms

Export As...

- PDF
- XML
- View/Update Report**
- Acknowledgement

You will then need to select 'Update' in the top right-hand corner of the report form.

Medicines & Healthcare products Regulatory Agency

Standard

UPDATE

Show all sections
Hide all sections

Section 1/6
Admin

Name of receiving national competent authority (NCA)
MHRA

EUDAMED Number of NCA (Optional)

Reference number assigned by NCA (Optional)

Add additional/follow up information using the report form that is available.

Once the report has been updated, click 'Validate & Send' at the bottom of the page. Note, you can still save a draft at any stage of completing follow up/updates.

You will see a 'Ack Success' submission status when successfully received by the MHRA..

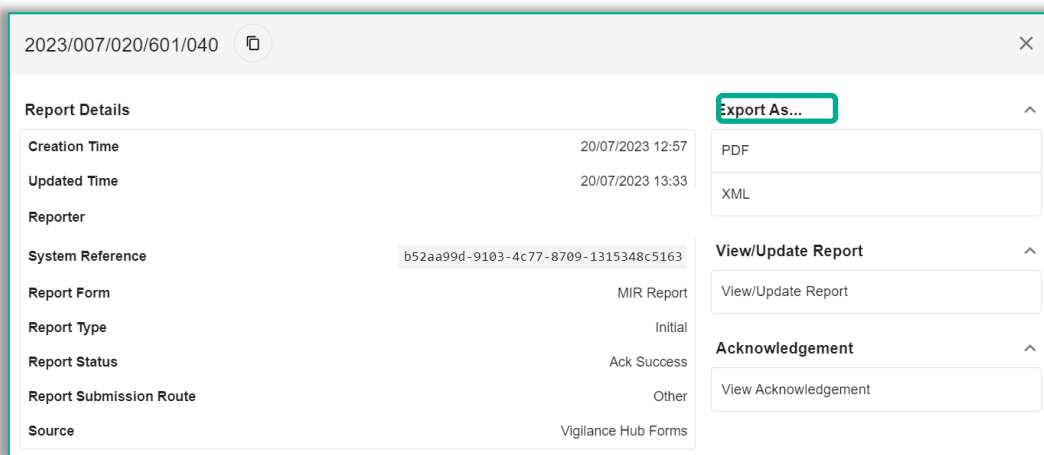
A new report row will be available, and the earlier case will become inactive to prevent version control issues. You will be able to view the date and time stamps for all reports.

If you have not received an 'Ack Success' status within 72 hours of submitting MORE report AIC@mhra.gov.uk, including the report reference number (seen from the 'Report Management' tile.

It is the responsibility of the user to notify the MHRA is a report remains on status 'Submitted - Pending' or 'in progress' 72 hours after submission

Exporting individual reports

To export a copy of a report you have submitted, select the report from report management and then select export xml or pdf from the pop up.



A XML or PDF copy of the report will then be downloaded to your device/computer.

Reports sent from MHRA

Reports sent by the MHRA, such as Industry Notification of Public Reports (INPR) can be identified by a blank user column. We will look to enhance this in future to make it clearer to users.

You will only receive an INPR on your MORE account in relation to a device if you are associated with a manufacturer organisation through registration as a Manufacturer, UKRP or Authorised Representative (NI). INPRs will only be sent to an Organisation if the Manufacturer details are provided on the original report or can be identified by the product reported.

INPRs will not be received when MORE registration first launches. In the interim, the MHRA will continue to send INPRs via email and will begin to send INPRs electronically via MORE to account holders . Please refer to the.gov site for the latest information on when this will go live.

Industry Notification of Public Reports (INPR)

Incident reports received directly by the MHRA from members of the public (patients and healthcare professionals) will automatically be sent to MORE if Manufacturer details have been included by the reporter. INPRs from the MHRA will relate to reports received via the Yellow Card scheme or reports received directly via email or telephone.

If a member of the public updates their report and sends it to MHRA, then an updated INPR will be sent to the manufacturer organisation which is identified in the current version of the Device Registration Database. This will contain the same Reference number.

These reports were previously sent via email and will now be automated to be received by Manufacturers via MORE. These INPR reports received from the MHRA can also be tracked in the 'Report Management' screen. INPRs received via MORE will be similar to previously sent user reports/complaints and will contain the same information in a different format.

When INPRs are sent electronically via MORE, users will be able to access these reports from the 'Report Management' tile and will receive an email confirmation. Emails will be sent to the email address linked to the organisation in the Device Registration Database. If the emails need to be received via an alternate email address, this will need to be updated via the Device Registration Database.

INPRs received from the MHRA can be identified in the 'Report Management' tile by their Reference Numbers which will always include '501' within it. If you receive a INPR with a reference number that has a different structure, this should still be treated in the same way as an INPR. In either situation an INPR reference number will also be followed with information stating it is a read only record and will remain at the 'Submitted - Pending' status.

DATE	SENDER	USER	REPORT TYPE	REFERENCE NUMBER	STATUS
14/11/2022 15:27	39851		MIR	2022/011/014/501/008 (Read-only)	SUBMITTED
14/11/2022 15:19	39851		MIR	2022/011/014/501/008 (Read-only)	SUBMITTED
14/11/2022 15:17	39851		MIR	2022/011/014/501/008 (Read-only)	SUBMITTED
14/11/2022 15:11	39851		MIR	2022/011/014/501/008 (Read-only)	SUBMITTED
12/11/2022 12:20	39851		MIR	2022/011/008/501/002 (Read-only)	SUBMITTED
11/11/2022 14:17	39851		MIR	2022/004/025/501/005 (Read-only)	SUBMITTED

The user column in report management will be empty, and the status will remain as submitted. You should not notify the MHRA that the status of these INPR (501 reports) do not have an 'Ack Success' status. The MHRA will aim to update the display in 'Report Management' for the 'Report Type' to read 'INPR'.

The INPR can be downloaded as a PDF to view the contents of the report.

A new MIR report should be submitted in relation to this INPR, which includes additional information that you as a manufacturer will add. An INPR cannot be updated. The two records will be linked within the MHRA system. When submitting a MIR report from an INPR, please retain the INPR reference number (NCA reference number) to ensure that these records are correctly linked.

When completing the MIR, please enter the Reference number assigned by MHRA into the 'Healthcare facility report number' field in the MIR form. This Reference number assigned by the MHRA will in most cases have 501 within it and will be structured as YYYY/0MM/0DD/501/ZZZ, where YYYY is the year, MM is the month and DD is the day.

The MHRA may receive Yellow Card reports from devolved administrations or directly by reporters via paper/email. In these situations, the reference number for these reports will not follow the structure YYYY/0MM/0DD/501/ZZZ. If you receive a INPR with a reference number that has a different structure, please enter this into the 'Healthcare facility report number'.

An INPR report will not include the 'Date of incident to' date when received by the MHRA. When submitting a MIR report after receiving an INPR report, you will need to enter the same date for 'Date of incident from' and 'Date of incident to' fields.

The report type should be selected as either 'Initial' or 'Combined initial final'.

When an INPR is updated by the original reporter, the MHRA will send this as an update. This will be displayed in 'Report Management' as an INPR with the same reference number but under an additional row (i.e two rows with the same reference number).

Visibility of reports to your users

All individual users who have access to an organisation (based on the MHRA Device Registration Database Account number) will be able to see all reports within that organisation, this includes reports sent from that organisation and received by that organisation.

Representatives of a non-UK manufacturer will automatically inherit access to manufacturer organisations as set up in the Device Registration Database.

The rules around who has access to which manufacturer organisations is outlined below.

User role:

Manufacturer: Users of this user role will be able to log in to a manufacturer organisation which they have been approved for.

Authorised Representative (Northern Ireland): Users with this user role type will automatically inherit access to manufacturer organisations that they represent. Representation of a manufacturer organisation is defined by:

- Representative relationship to a manufacturer organisation must be Authorised Representative (Northern Ireland), that is that the user role must match the representative relationship
- The manufacturer organisation status must be registered, unregistered, suspended or not registered

UK Responsible Person

- Representative relationship to a manufacturer organisation must be UK Responsible Person, that is that the user role must match the representative relationship. Users with this role will inherit access to their manufacturer organisation.

- The manufacturer organisation status must be registered, unregistered, suspended or not registered

If a single user has multiple user roles, they will see all manufacturer organisations their user roles inherit.

If a user has a representative role and manufacturer role for the same organisation, then they can report as a manufacturer as the log in for representative will be superseded by the log in for the manufacturer.

Device Registration Data is regularly refreshed. If access to a manufacturer organisation is not provided in the latest dataset, then access to a manufacturer organisation will be removed from the user group. If access to a manufacturer organisation is added to the latest dataset, then access to a manufacturer organisation will be provided to users within that user group.

Table 1. Matrix of the reports which are visible for different user roles.

User Role	MIR	FSCA	Trend	PSR	SAE	INPR
Manufacturer	Yes	Yes	Yes	Yes	Yes	Yes
Authorised Representative (NI)	Yes	Yes	Yes	Yes	Yes	Yes
UK Responsible Person	Yes	Yes	Yes	Yes	Yes	Yes
Other (Distributor, Importer, Submitter)	Yes	Yes	Yes	Yes	Yes	No

Table 2 Matrix showing which organisations are available to different user roles

User Role	Organisations available which they can log in to
Manufacturer	All organisations that the individual user has had approval from their Organisation Lead to access
Authorised Representative (NI)	All organisations which are represented by the individual users Authorised Representative (NI) organisation and have a status of registered, unregistered, suspended or not registered
UK Responsible Person	All organisations which are represented by the individual users UK Responsible Person organisation

	and have a status of registered, unregistered, suspended or not registered
--	--

Table 3 Example of the inherited relationships provided to representatives

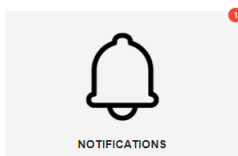
Manufacturer Name	Manufacturer account number	Representative name	Relationship	Manufacturer registration status	Which representative user groups would have access to the manufacturer organisation in MORE
MAN-1	123/987	REP-A	UKRP	Registered	REP-A will have access to MAN-1 organisation in MORE
MAN-2	234/876	REP-B	Authorised Representative (Northern Ireland)	Unregistered	REP-B will have access to MAN-2 organisation in MORE
MAN-3	234/876	REP-C	Authorised Representative (Northern Ireland)	Rejected	REP-C will not have access to MAN-3 organisation in MORE (because their status is rejected)

If you are a manufacturer and you change your representative, then you will need to create a new MORE account and continue vigilance activities in the new account. You will then need to update manufacturer users accounts to have access to this new account.

If you have any questions around this, please ensure your records in the Device Registration Database are up to date or contact the AIC@mhra.gov.uk mailbox.

Notifications

As an Organisation Lead you will receive a notification request indicated by a red circle in the top right-hand corner of the notifications tile for any notifications sent from the MHRA or for new registrations.



Selecting the notification tile will display all notifications received for the organisation as well as new user requests (completed and pending registration requests). These will be listed by date. All notifications that you have received via the MORE portal will also be available via email.

Notification emails will be sent to the email address linked to the organisation in the Device Registration Database. If the emails need to be received via an alternate email address, this will need to be updated via the Device Registration Database.

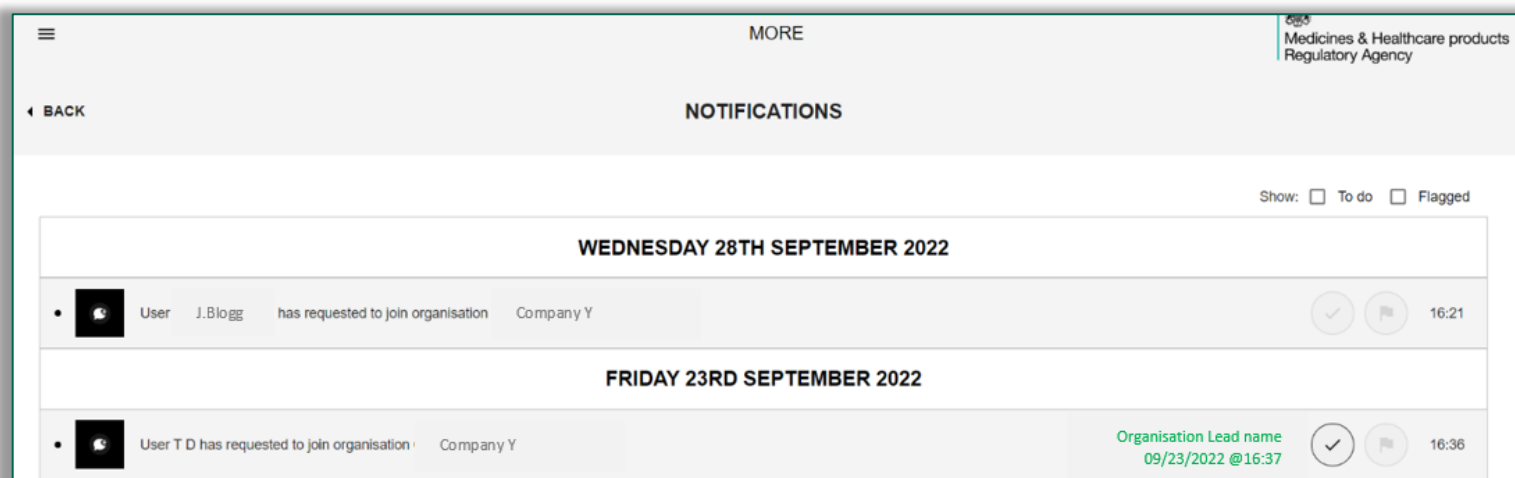
If your account is associated to multiple organisations, you will be able to view all notifications for all organisations for which you have access, however you will only be able to process notifications for the organisation you have logged in for. Please ensure you have logged in using the correct organisation details before processing any notifications.

Notifications will remain within the account once read and users will be able to view all notifications including recent and retrospective notifications.

Registrations

For registration notifications, you will also be able to view which Organisation Lead actioned the account request process with a date and time stamp. At the top right-hand side of the page, you can use the filters to select registrations which are yet to be completed ('to do') or those that have been manually flagged. Please note that selecting flags will be specific for your own account and will not be viewable for other Organisation Leads working for the organisation.

Please only approve requests within the organisation the request is for.



INPR notification

When an INPR is sent by the MHRA to MORE you will be able to view these in Report Management where the reference number is 'YYYY/0MM/0DD/501/ZZZ'. In some cases, this reference number will not be available, but you will be able to view these reports based on their 'Submitted - Pending' status and blank username. It is the Manufacturer's responsibility to check notifications and Report Management routinely to action any incoming INPRs with appropriate investigation, review and reporting. Requests for information – from MHRA

You may also receive alerts for incoming communications linked to reports submitted by your organisation via the notifications tile. These notifications will reference your submitted incident and provide access to the latest version, as well as details of the request which can include any of the below:

- Acknowledgement
- Advice
- Closure
- Reminder
- Duplicate
- Follow-up
- Referral
- Template
- Form
- Submission
- Update

Section 5: Resources

You can access resources relating to MORE submissions via the 'Resources' tile on the dashboard or left-hand side burger menu.

Resources will host documents, such as guidance materials to support using MORE registrations and Submissions. Select 'View' to download the document of interest.

It is important to note that content for guidance documents may be updated and an up-to-date copy should be downloaded when required by the organisation.

Details of the lawful basis for processing data in incident reports, how the data is handled, and the user's rights can be found on the MORE terms and conditions which can be found in the resources section.

The resources section will also contain essential templates which must be used when submitting reports via MORE. This will include the following:

- Template spreadsheet to submit a new PSR
- Two template spreadsheets to submit a SAE
- Trend report template

Glossary

Acronym	
MORE	Manufacturers Online Reporting Environment
AIC	Adverse Incident Centre
MFR	Manufacturer
AR	Authorised Representative
UKRP	UK Representative
MIR	Manufacturers Incident Report
PSR	Periodic Safety Report
TREND	Trend report
SAE	Serious Adverse Event
INPR	Industry Notification of a Public Report
MHRA	Medicines and Healthcare Products Regulatory Agency

Contact Details

If you are experiencing issues with MORE registrations and submissions, or have any questions, please email details of your questions to AIC@mhra.gov.uk.

If for any reason functionality in MORE is not working as described or displayed in this guidance document, please send an email to AIC@mhra.gov.uk detailing the error with any screenshots to display the issue. It would be helpful if you also provide the below information where available:

- Organisation:
- Report ID (WWRN):
- Issue details:
- Date issue occurred approximately:
- Steps to Recreate:
- Screen shots or recording to support:
- User Name:
- User Type:
- Device/Browser details:

Other Useful Information

Health Authority Information requests

When replying to health authority requests, please ensure that you reply via email and provide the necessary information to link the response to the request.

Test Cases

If you would like to test case submission or use the platform for training, please contact AIC@mhra.gov.uk for access to the MORE User Acceptance Testing (UAT) environment. Please do not submit test cases via the production link as these may be considered as genuine cases.

Revision History

This table sets out the revision history for the last three versions.

Version No.	Effective date	Change
1.0	11/2022	First version
2.0	04/2023	Updates to guidance for form downloads, SAE submission, INPRs, notifications and MIR/FSCA schemas.
3.0	08/2023	Update to screenshots, guidance for draft reports and auto-population of submitter fields.