

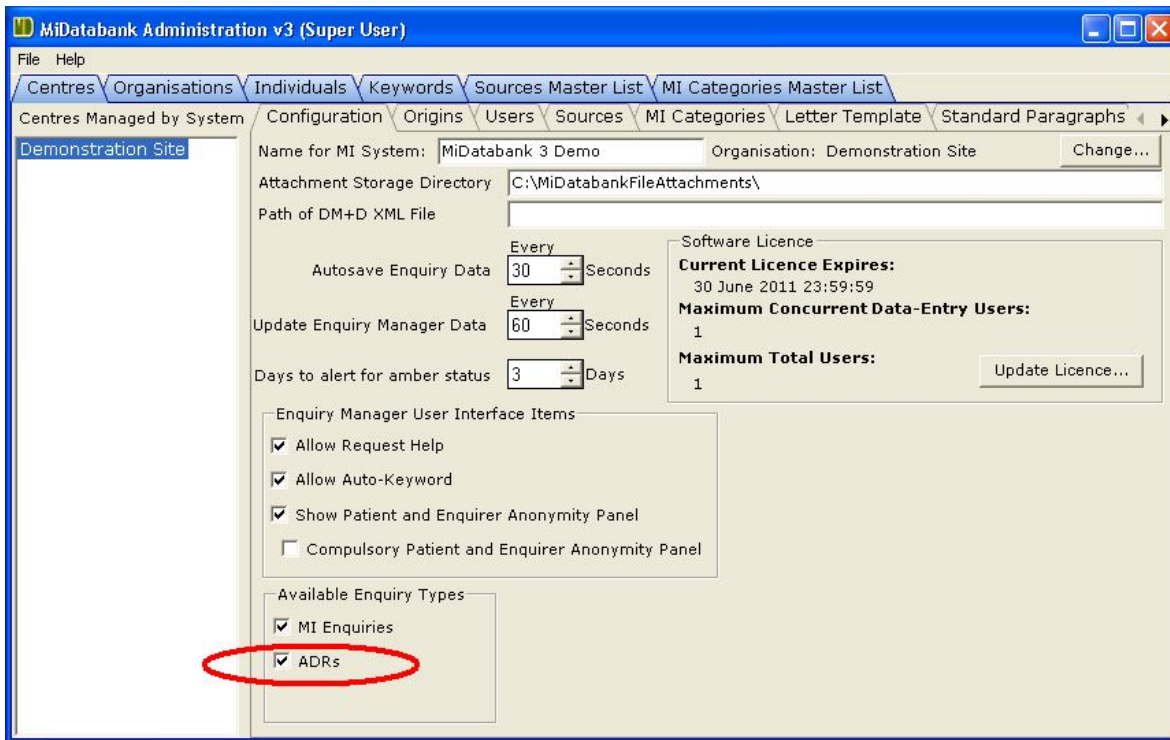
MiDatabank v3 ADR Quick Start Guide

By Keith Brown

Thanks to Sandra Hicks (Wessex MI Centre)

Enabling ADRs in MiDatabank

To enable the reporting of ADRs to the MHRA, please open the Admin application and enable ADRs for your centre:



Reporting ADRs in MiDatabank

When the Enquiry Manager is launched, it will now be possible to send ADRs to the MHRA using two methods:

1. Electronically
2. By sending an email with a pdf attachment

For the purposes of the eYC pilot, it is necessary to send each ADR by *both* methods. This is to ensure that the MHRA can reconcile the eYC data and ensure that all data has been sent correctly.

How to Report and ADR

During the course of an MI enquiry if it becomes apparent that an ADR is suspected, please click on the ADR checkbox. This results in a tab 'ADR Input', as shown below

The aim is work through the various sections of this tab and finish by submitting the ADR to the MHRA. The process has been streamlined to be as quick and easy as possible and can be summarised as follows:

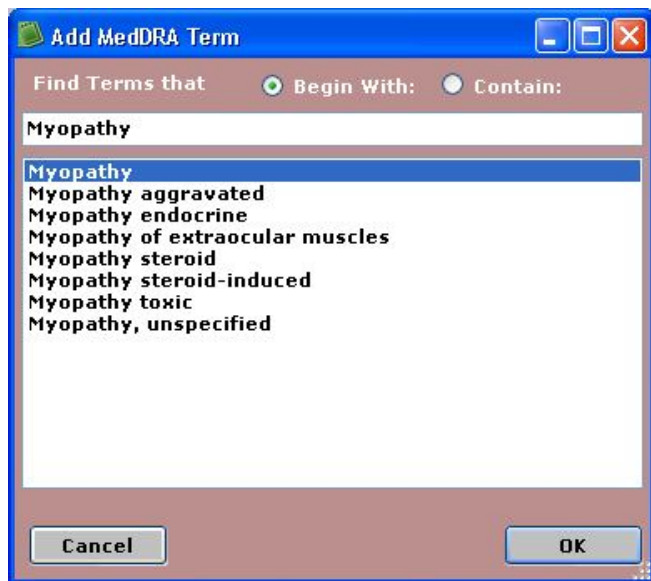
1. Enter the description of the ADR in the box in the top left:
2. Decide if this is a serious ADR, if so the check the appropriate check-boxes in the top right
3. Enter the Suspect Reactions (first tab in bottom half of screen)
4. Enter the Medication (second tab in bottom half of screen)
5. Submit to the MHRA (third tab in bottom half of screen)

In practice, this takes around 5 minutes, although it may take longer the first time you do this.

Suspect Reactions

Once you have typed the description and checked any checkboxes for seriousness, the next step is to click on the 'Add Reaction' box of the Suspect Reactions tab. This displays a dialog box:

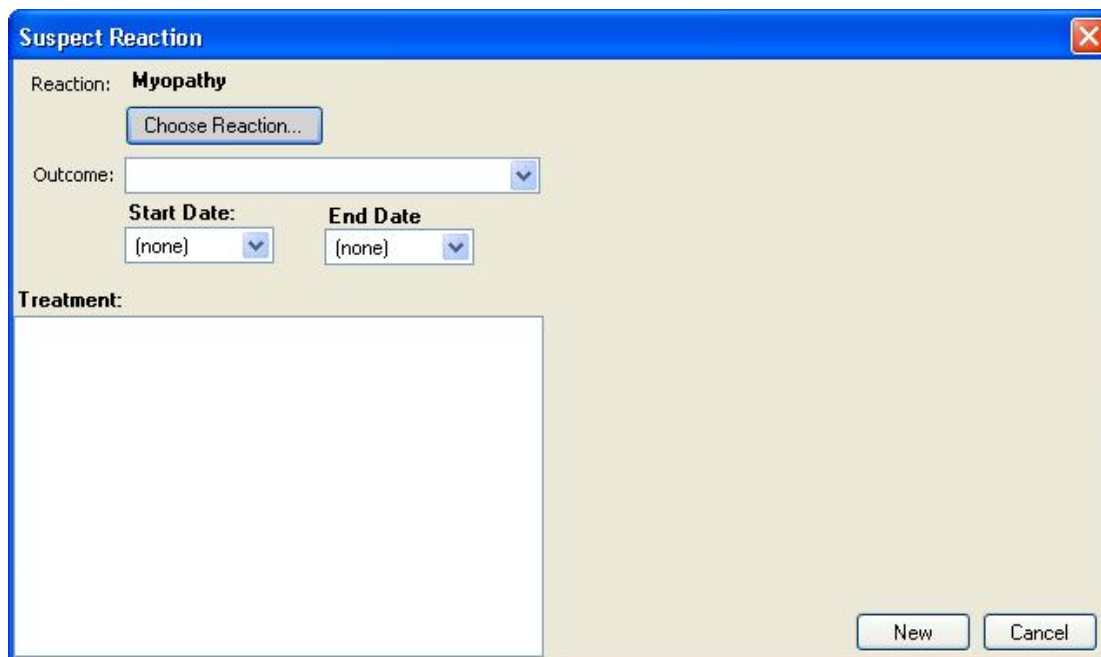
Click on 'Choose Reaction' to display another box that allows you to choose a reaction from the MedDRA dictionary which is the international standard used for reporting reactions to Regulatory Authorities:



Enter the first letters of a Reaction to be added and select a MedDRA term from the suggested list that appears.

Note: It is important to note that terms should be searched by switching around the components eg. 'suppurative lymphadenitis' and 'lymphadenitis suppurative'. The closest match for the former is 'suppurative lymphadenopathy' but there is an exact MedDRA term match for 'lymphadenitis suppurative'. If having difficulty finding a MedDRA term, use a more general term eg. 'granulocytopenia' as no MedDRA term exists for 'reversible granulocytopenia' or 'granulocytopenia reversible'.

Press OK and the reaction selected appears in the Suspect Reaction dialog box as shown below. If no exact match appears, choose the nearest and add a free text note of the exact term provided by the enquirer in the Adverse Event Description box.



The next step is to choose an Outcome from the drop-down box, and the Start and End Date, if these are known. There is also space to add any Treatment.

Note: If needed for long-term concurrent medication, add a date corresponding to 1st January for the particular year in which it was started

When all known data has been entered, click on the New button. The reaction is displayed.

ReactionText	Outcome	StartDate	EndDate
Myopathy	Recovered/Resolved		

You can continue adding any additional reactions, and remove or edit reactions using the buttons on the right-hand side.

Suspect & Concomitant Drugs

The next step is to add any medication. Click on the tab 'Suspect and Concomitant Drugs'. If you have previously added the medication as part of the Input of the MI Enquiry, this will already be available. If not, then you must add the patient medication:

The screenshot shows the MiDatabank 3 Demo software interface. The main window is titled "Atorvastatin And Erythromycin - ADR?". The interface is divided into several sections:

- Input ADR Input MI Research MI Answer Completion:** A navigation bar at the top of the form.
- Adverse Event Description:** A large text area for describing the event, with a toolbar above it. To the right, there are checkboxes for "Please Indicate if this is a serious Adverse Event:" including Fatal, Life Threatening, Hospitalisation, Significant Disability/Incapacity, Congenital anomaly/abnormality, and Other important medical event.
- Patient Medication:** A section with a tabbed interface. The "Suspect Reactions" tab is active, showing a list of medications:
 - Atorvastatin:** Atorvastatin 20mg tablets. Start: 07/05/2011, End: 09/05/2011. Includes fields for Action Taken, Dosage, Route, and Notes. A "Presc for:" button is present.
 - Aspirin:** Start: (none), End: (none). Includes fields for Action Taken, Dosage, Route, and Notes. A "Presc for:" button is present.
 - Erythromycin:** Erythromycin 250mg gastro-resistant tablets. Start: (none), End: (none). Includes fields for Action Taken, Dosage, Route, and Notes. A "Presc for:" button is present.
- Regulatory Authority:** A tab that is currently inactive.
- Status Bar:** At the bottom, it shows "Status: In Progress", "Enq No: 217", "Taken By: DW", "on 07/01/2011 05:35:00", "Allocated to: SS", and an "Allocate to Me" button.

Please enter all known data for the patient medication to provide as much information as possible. In particular, it is useful to provide details of the Indication using the button labelled 'Presc for'.

You must also indicate which drug(s) are suspect using the 'Suspect Drug' checkbox.

To remove a drug, please right-click on the item and choose 'Delete Drug'.

Regulatory Authority

The final stage is to click on the Regulatory Authority tab, and complete the ADR. It is important to note that there is a list of missing compulsory data displayed on the right-hand side.

Atorvastatin And Erythromycin - ADR?

Input | ADR Input | MI Research | MI Answer | Completion

Adverse Event Description
 You can use this box to describe the Adverse Event in your own words (sequence of events, any treatment received, final diagnosis or any other relevant information).

Verdana 10 B I U [Rich Text Editor]

The patient has reported feeling generally weak, with tenderness and muscle cramps

Please Indicate if this is a serious Adverse Event:

- Fatal
- Life Threatening
- Hospitalisation
- Significant Disability/Incapacity
- Congenital anomaly/abnormality
- Other important medical event. Specify below

Reporter: Me Other (please specify)

Reporter Comments:
 Please enter any other relevant information. For example, the history or results of any tests etc

Enquirer aware of ADR submission: Yes No

Missing compulsory data:
 Please indicate if the Enquirer is aware of this ADR report
 There is no Patient Age
 The ADR must have been Viewed to enable confirmation of the Submission

View ADR Report for Regulatory Authority...

I confirm that the Report has been Submitted Not Submitted

Reason not submitted:

Sex: Male Female Uncensored/Off Label

Is the patient pregnant? Yes No Unknown

Is the pregnancy continuing? Yes No Unknown

Drug Details: Taking all of the following prior to admission:
 Atenolol 50mg every morning, GTN spray when required, Atorvastatin 20mg daily, Aspirin 75mg every morning

Status: In Progress | Enq No: 223 | Taken By: SS | on 26/05/2011 16:16:19 | Allocated to: SS | Allocate to Me

By default, the current user is designated as the Reporter, although this can be changed if necessary.

In the example above, under 'Missing compulsory data', one of the items is 'There is no Patient Age'. To address this issue, you must go to the Input tab and add the age or date of birth, and then return to the ADR Input tab.

When the only missing data is 'The ADR must have been viewed' then you can click on the button 'View ADR Report for Regulatory Authority' to display the Yellow Card:

Adverse Drug Reaction Report

Printable Report | e2B Report | Electronically Submit ADR Report to Regulatory Authority | Close

Save Report... | Print Report...

YellowCard **MHRA**

Helping to make medicines safer

Suspected Adverse Drug Reactions In Confidence

MiDatabank User Name: Sam Smith
 User Guid:0e1bdacf-a529-40c0-99cb-7d094cd0e0ce
 MI Centre: Demonstration Site

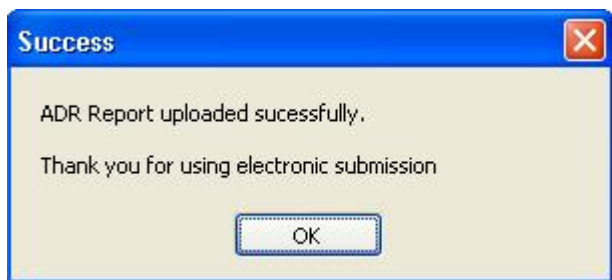
Reporter:
 Mr Sam Smith
 Manager
 Demonstration Site
 CoAcS
 Avon
 GB
 Email: sam.smith@cadeudusmicentre.com

Title: Atorvastatin And Erythromycin - ADR?
 Local ID: 217
 Global ID: 196fa37a-d13d-4d9f-9f0c-1b748c08ae71

Adverse Event

Serious: False
 Fatal: False
 Life Threatening: False

Please review the data displayed. When ready click on the button 'Electronically Submit ADR Report to Regulatory Authority'. Usually you will have to wait several seconds before a dialog box is displayed:



Or in the event of a technical problem:



In the event of a technical problem, please save the report as a PDF and email this to the Regulatory Authority using the email address on the report. Also, please email your local IT and helpdesk@coacs.com with a screen-dump of the dialog box shown above. In all cases to date, all problems have been related to web-security at the local hospital and the solution is for local IT to configure the web-proxy to allow a connection to the MHRA web-service on:

<https://ehr-services.mhra.gov.uk>