

Introduction to MiDatabank Version 3

MiDatabank Version 3 is a major new release that has many new features. The following is a brief summary that introduces some of these features.

New Features for the Pharmaceutical Industry:

- Recording of Product-related MI Enquiries
- Recording of Product-related Complaints for transfer to QA Department
- Recording of Product-related Adverse Drug Reactions
 - Facility to transfer ADR data to Pharmacovigilance Department
 - Facility to electronically transmit ADR data (e.g. Yellow Card in the UK) to Regulatory Authority

New Features for Hospitals:

- Streamline the recording of enquiries
- Broadening the scope to be a core tool in Hospital Pharmacy
- Enable Clinical Pharmacists to record enquiries
- Supporting Pharmacists with their Professional Development
- Electronically transmit ADR data (e.g. Yellow Card in the UK) to Regulatory Authority

MiDatabank Document Types

MiDatabank can create, edit and manage the following types of document

- Enquiries
 - Medicines Information Enquiries
 - ADR Enquiries
 - Complaints
- FAQs - Frequently Asked Question
- Projects - Documentation of Formulary decisions, Horizon Scanning etc

Medicines Information (MI) Enquiries

MiDatabank has an established mechanism to record a MI type of enquiry. This involves documenting the process of taking data input, performing research and transfer of the answer to the enquirer.

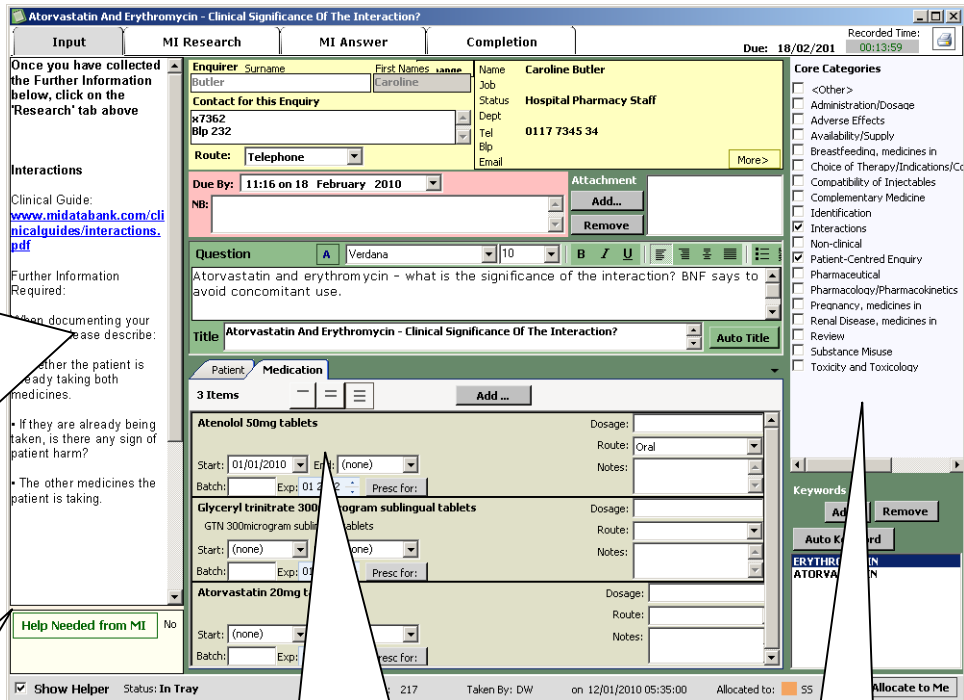
With version 3 of MiDatabank, there are a number of new facilities:

Helper Panel - a panel on the left-hand side that can be shown by clicking on the 'Show Helper' checkbox in the bottom left-hand corner. The Panel displays context sensitive information such as the Clinical Guide and requisite data that must be collected from the enquirer for the selected Category.

Facility for new users to request assistance from more experienced MI staff

The National Drugs Dictionary DM+D is available to choose the Patient's Medication

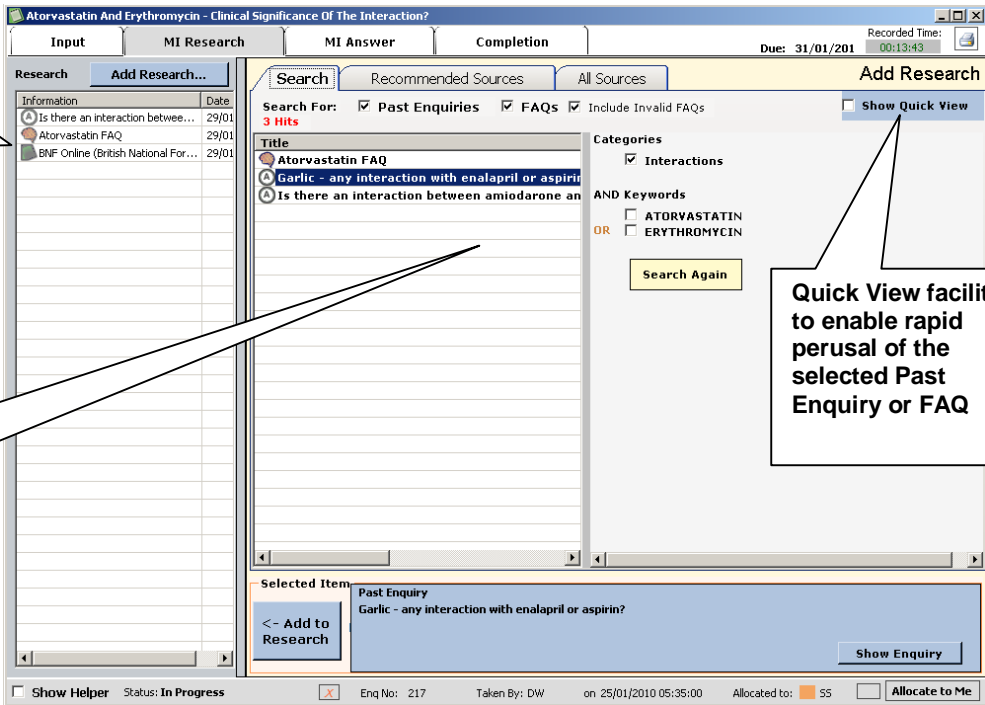
Centres can add their own categories if required



**Research Types:
Past Enquiries
FAQs
Resources**

Automatic Search of Past Enquiries and FAQs using Category and Keywords

Quick View facility to enable rapid perusal of the selected Past Enquiry or FAQ



Standard Search Pattern (SSP) that displays the recommended sources for the enquiry category.

This is a ranked list of sources that should be consulted when doing research.

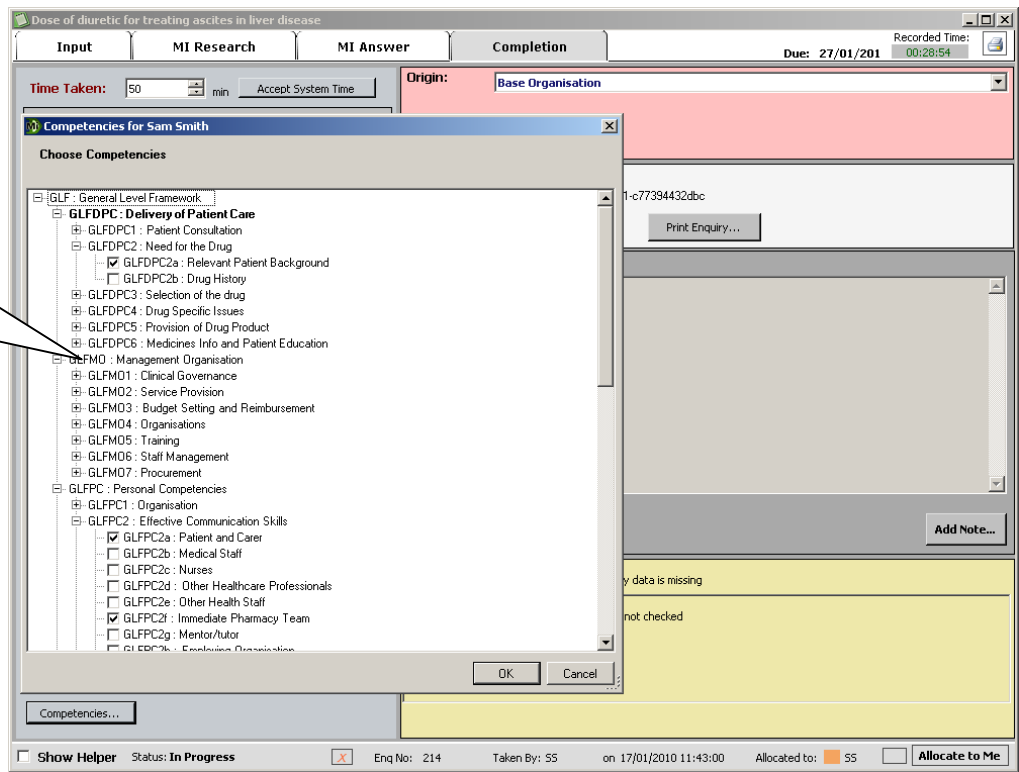
The SSP can be configured by individual centres as required

Extended Word Processing facilities for documenting the Answer

Selection of Template (ie Header and Footer) for the document

Special Fields can be inserted into the Answer. These include the Enquirer postal address, Patient Details, User's signature and pre-defined Standard Paragraphs or Standard Responses

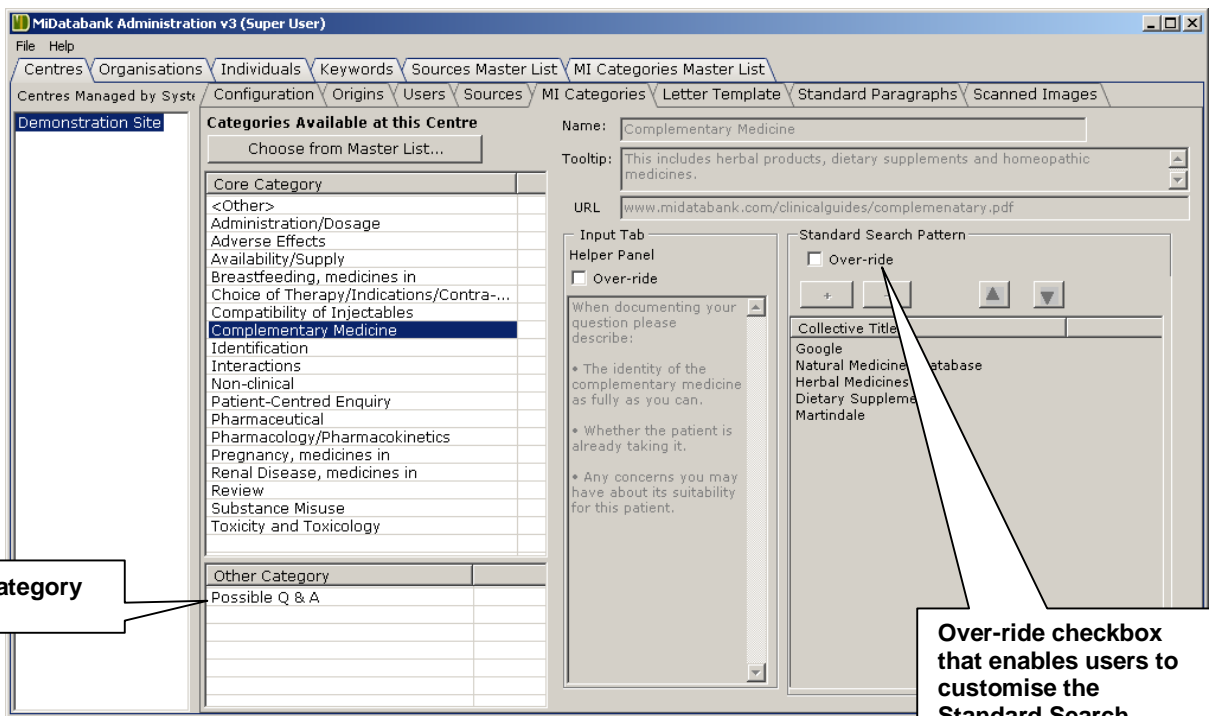
Continuing Professional Development:
Users can add their competencies to an enquiry.



The new facilities are configurable in the MiDatabank Administration module. For example, the screen-shot show below shows an additional category 'Possible Q & A' has been added to the standard set of categories.

In addition, note that there are 'Over-ride' buttons that enable the text displayed in the Helper Panel, and the Standard Search Pattern to be customised according to needs of the centre.

Custom Category



Over-ride checkbox that enables users to customise the Standard Search Pattern

Adverse Drug Reactions (ADR) Enquiries

MiDatabank version has introduced a mechanism for capturing all the required information for reporting an ADR to the Regulatory Authority. In the UK this consists of submitting a Yellow Card to the MHRA

The screenshot shows the MiDatabank ADR reporting interface. It is divided into several sections:

- Adverse Event Description:** A text area where the user describes the event. The example text reads: "The patient has reported intense migraine... sudden rash of septic spots." Callout: "List of Suspect Reactions" points to this area.
- Patient Medication:** A table listing medications. Callout: "List of Suspect Drugs" points to this section.
- Regulatory Authority:** A dropdown menu for selecting the authority. Callout: "Section for generating and submitting a standard ADR report to the Regulatory Authority" points to this area.

Suspect Drug	Dosage	Route	Notes
<input checked="" type="checkbox"/> Atorvastatin 40mg tablets Lipitor 40mg tablets (Pfizer Ltd) Start: 03/12/2009 End: (none) Batch: Exp: 01 2012 Presc for:		Oral	
<input type="checkbox"/> Aspirin 500mg / Codeine 8mg dispersible tablets sugar free			

At the bottom of the interface, there is a status bar with the following information: Show Helper, Status: In Progress, Enq No: 220, Taken By: SS, on 29/01/2010 11:31:21, Allocated to: SS, and a button labeled "Allocate to Me".

The industrial version of MiDatabank also has this facility as an alternative to passing the ADR to their Pharmacovigilance department.

The report shown below is an example report that might be submitted by MiDatabank to the MHRA in the UK. The data is electronically sent over the internet and is a direct database to database connection that makes the process quick, easy and efficient.

MiDatabank Sample ADR Report

YellowCard



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
Email: dfsf

Title:
Local ID: 220
Global ID: 3395e8d2-0f7d-4911-a600-802fb3f2c192

Adverse Event

Serious: False

Fatal: False
Life Threatening: False
Hospitalisation: False
Significant Disability: False
Congenital Anomaly: False
Other Medical Event: False

Patient Details

Local Patient ID: 3395e8d2-0f7d-4911-a600-802fb3f2c192
Age: 56 Years on 29/01/2010
Sex: Male

Patient Medication

Suspected Drug(s)

Atorvastatin 40mg tablets>Lipitor 40mg tablets
SUSPECT DRUG
Action Taken:Dose reduced
Expiry: 01/01/2012
Batch:
Dose:
Route: Oral
Start Date: 03/12/2009
End Date: <None>
Prescribed For:
Notes:

Concomitant Drug(s)

Aspirin 500mg / Codeine 8mg dispersible tablets sugar free

CONCOMITANT DRUG

Expiry: 01/01/2012

Batch:

Dose:

Start Date: <None>

End Date: <None>

Prescribed For:

Notes:

Adverse Event Details

The patient has reported intense migraine and a sudden rash of septic spots.

Reporter Comments

This is not a real ADR and is shown for demonstration purposes only.

Reactions

Reaction: Septic spots

Outcome: Recovered/Resolved

Start Date: 03/12/2009

End Date: <None>

Treatment: <none specified>

End of Adverse Event