

MiDatabank *i* version 3

The replacement of paper-based, or 'home-made', systems to log medicines information enquiries can be seen as a financial and process risk. Certainly, the need to maintain and share high quality, re-usable information in a secure environment is crucial to success.

Many organisations are not realising the benefits of using a specialised computerised system. This can affect many other areas, too – typically in pharmacovigilance, regulatory and even sales and marketing. Furthermore, inspection frequency is increasing and the regulatory authorities require demonstrable excellence in competence and compliance.

Meanwhile, commercial pressures require companies to provide a professional and user-focused service. Departmental efficiency is under increasing scrutiny and reliable information retrieval is demanded. MiDatabank *i* is a cost-effective solution that can help achieve these goals in your organisation – regardless of size.

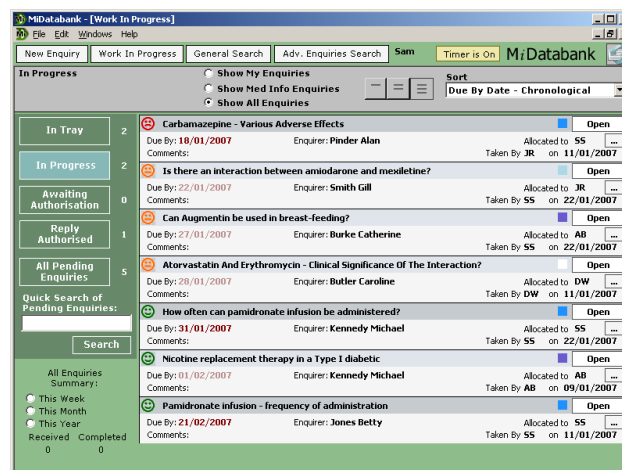
Who will benefit using MiDatabank *i* version 3?

MiDatabank *i* can be used by pharmaceutical companies involved in marketing:

- Ethical pharmaceuticals
- Generics
- Vitamins / OTC products

MiDatabank *i* enables users to record MI enquiries, complaints and adverse events. MiDatabank *i* is scaleable and may be used by individuals in small companies through to larger companies with multiple locations.

Our competitive scale of charges is based upon editor user numbers. There is an annual licence renewal - so if your organisation structure alters, MiDatabank *i* costs change accordingly.



Special features in MiDatabank *i* version 3

Organisations and their users expect a computerised medicines information enquiry handling system to provide basic logging and process functions - and MiDatabank *i* will not disappoint. Such functions include efficient enquiry logging; searching; finding past enquiries; a reference section including FAQs and wider resources; letter production facility; metrics and reports.

MiDatabank *i* also includes important special features designed to aid efficiency, compliance and professionalism:

- Processes to handle medicines enquiries, QA complaints and ADRs
- A customisable 'helper panel' to provide enquiry prompts and checklists
- Dashboard facility for easy monitoring of workload
- Extensive research facilities
- Multiple enquiry categorisation
- ADR escalation to PV with reconciliation procedure
- Projects (an auditable account of a decision-making process)
- dm+d drug directory for medicines and devices
- Standard Search Patterns (SSP) to research categories of enquiries

Configuration module

MiDatabank *i* is configurable – that is to say that many system defaults and options can be altered without expensive re-programming. Configuration settings are available for the database, user names, roles, dates / deadlines besides the maintenance of your keywords, resources, contact names and organisations.

Once these are set up, enquiries can be entered more easily into the system.

Input

Enquiries can be entered into MiDatabank *i* in a number of ways:

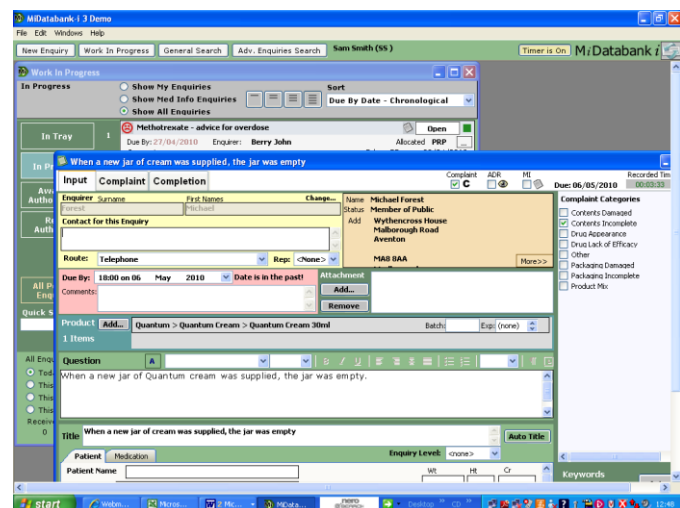
- Entering a new name and address (and organisation if appropriate)
- Re-using an existing enquirer's name, address or organisation
- Via reps / third parties / HCPs

Enquiry details may be entered 'live' or retrospectively if they have been written down originally. This can affect the time to seemingly complete an enquiry - the process is best handled under your own SOPs. MiDatabank *i* also includes a 'timer' that records how long an enquiry has actually been worked on.

Searching

It's easy to locate a past enquiry from a named person, for a product name or enquiry type – this is particularly important if an adverse event is later suspected. MiDatabank *i* uses full text searching, field and keyword searching to list enquiries and available resources.

It may be necessary to search your resources in order to select material for your individual response. Using the correct resources is important since any answer provided must be approved, accurate and up to date. A Standard Search Pattern (SSP) can help by providing additional search results based on related topics.



Processing / content

Every enquiry has an owner. Only that user can progress the enquiry but should they be unable to work on it – perhaps due to illness or holiday – ownership can be passed to, or taken over by, a colleague.

Once an enquiry is in the system it will be in one of several 'states' – In tray (awaiting action), In progress, Awaiting Authorisation, Authorised etc. An enquiry summary dashboard feature (by person and state) enables workload to be quickly assessed. Deadline dates for enquiries are set and levels of urgency may be assigned. If additional help is required to answer and enquiry, colleagues can be notified.

Each medicines information enquiry naturally passes through four stages – Input, Research, Answer and Completion – and these affect the overall enquiry status. Further information is required at each stage. The system will alert users of any omissions.

Resources / research

MiDatabank *i* enables users to list and search resources that will be required when answering an enquiry. These include:

- Books, journals and research papers
- Internet subscription services
- FAQs
- Standard letter paragraphs

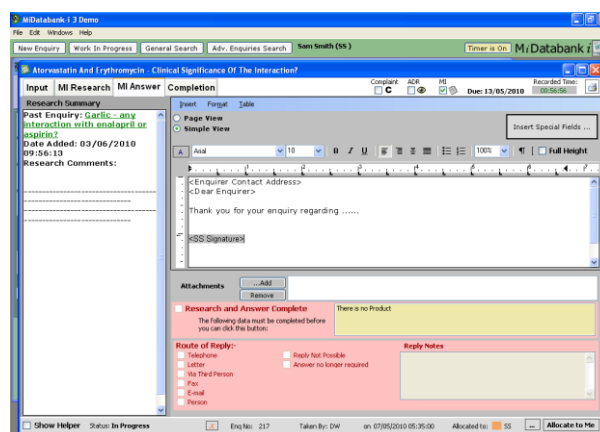
A comprehensive directory of core research resources is maintained by CoAcS on a dedicated website and is accessible from the MiDatabank *i* software. When new material becomes available, the software enables users to synchronise their resource listings.

Output and Completion

Enquiries can always be printed in a concise 'printer-friendly' format if required. Many customers need to print and store hard copies to satisfy internal SOPs. Enquiry replies can be provided via letter and fax using customisable templates maintained by users. File attachments can be used and email content created.

All enquiries go through a completion process to check that all required information has been entered. Time taken is recorded, keywords can be added and follow-up notes recorded.

Besides providing specific lists of enquiries by sorting and using selection filters, MiDatabank *i* has a comprehensive Reporter tool that provides statistics over desired time periods e.g. monthly. Reports can be saved and incorporated into several file formats.



Administration, Validation and Compliance

Regular users routinely enter the password-protected Enquiry Manager module, but MiDatabank *i* also has an Admin module for system administrators only. This provides the MI manager, IT staff, or users with administrator permissions, access to the parts of the system that maintain the virtual and physical security. Administrator responsibilities include determining available MI resources and other MI related settings.

A previous version of MiDatabank has logged hundreds of thousands of enquiries in the NHS over several years – it's very robust and in continual use. The industry version has been tested and validated in a more formalised programming environment.

Validation has many interpretations but is an organisation's assessment of risk. MiDatabank *i* has been operated using numerous test scripts and performance criteria, and this assurance level mitigates the risk component. Further documentation can be supplied as an optional deliverable.

MiDatabank *i* stores audit information - it's possible to trace the history of an enquiry field and who made any changes to it.

Training

Onsite training is provided by CoAcS charged at a daily rate. One day is usually sufficient for a typical user. Administrator training is also available.

Delivery and deliverables

MiDatabank *i* is delivered via an Internet download or from CD onto a customer server and client PCs. Installation can be performed by local IT staff or by CoAcS staff. An extensive installation and administration manual is available to explain and assist in this process.

A telephone helpdesk is available week-days during normal working hours. CoAcS also maintains a dedicated website at **www.midatabank.com** which includes help, downloads and general information about the system.

New releases of MiDatabank *i* will be provided at regular intervals and these will be entirely compatible with previous ones. Releases may include additional features that users suggest or that improved technology provides.

Technical requirements

MiDatabank *i* is built around Microsoft technologies and is a client-server application.

Server:

Requires a database hosted on Microsoft SQL Server 2005 or Microsoft SQL Server 2008 and running on Microsoft® Windows Server® 2003 or Microsoft® Windows Server® 2008.

We recommend starting with 10Gb of disk space. (A database at one of the biggest MI centres in the UK is about 8Gb and contains over 100,000 enquiries.)

Client PC:

- Windows 2000, XP or 7
- Intel® Pentium® 4, Core 2, or AMD Athlon processor
- 512Mb of RAM (1Gb recommended)
- Screen resolution of 1024 x 768 or higher
- .NET Framework 2
- 150Mb of available hard-disk space
- Network Adaptor

About CoAcS

CoAcS is a private limited company founded in 1992, with offices in the UK, Australia and the United Arab Emirates. We have an international client base of satisfied customers – including pharmaceutical companies, hospitals and universities - across the world.

The Software Division develops, publishes and markets software whilst the Services Division provides a range of commercial and academic consultancy services to the pharmaceutical industry, hospital and academia. Our strong link with academia provides an informed background that enables us to remain at the forefront of scientific and technological advances. We have a policy of long-term relationships with clients, and provide customers with post-contract support and development as required.

Contact details

For more information about CoAcS and MiDatabank *i* please contact us using one of the methods below. We will be happy to hear about your own requirements and arrange a demonstration of our software if appropriate.

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