FDB OptimiseRx®

FDB OptimiseRx
Service Definition
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1. Executive Summary

- FDB OptimiseRx® is the UK's leading primary care prescribing decision support system. It processes individual patient information to present clinically relevant and uniquely patient specific messages at the point of care
- Fully integrated with the prescribing workflows within TPP SystmOne and EMIS Web, providing a seamless messaging interface that is intuitive to prescribers

1. Utilises evidence-based national guidance from multiple reference sources including NICE, MHRA, and many others. Supports clinicians to;
    - Prescribe in line with national best practice guidance e.g.,, NICE, PHE, NHS England,
    - Stay abreast of drug safety issues e.g., MHRA Drug Safety Alerts;
    - Adhere to evidence-based prescribing safety indicators: e.g.,, RCGP
- Delivers best practice and safety guidance directly at the point of care, promoting clinically effective prescribing and reducing variation in prescribing behaviour
- Combines national guidance with your local formulary and cost saving initiatives to optimise the clinical and cost effectiveness of prescribing within your ICB
- The secure web-based profile management tools are simple to use, quick to set up and give you all the power you need to instantly manage your prescribing profile
- The FDB team of clinicians, pharmacists and researchers update and maintain the national best practice, safety and cost message base and customise it to meet your local needs, freeing up medicines management resource to focus on benefits realisation

Analytics and reporting capabilities with FDB OptimiseRx

The OptimiseRx reporting module, housed within the OptimiseRx secure web-based portal, has been designed to offer easy access to the data required to manage the solution and produce operational and management reports to support and demonstrate:

- ROI and benefits to the ICB board and other stakeholders;
- Practice engagement, often used by Medicines Optimisation Teams (MOT) pharmacists/technicians for practice visits;
- Profile optimisation to review the message hit and acceptance rates to ensure the ICB maintains value through sustaining good adoption; and
- Deviation from the clinical pathway/formulary

Reports are available in real time and can be used to review compliance levels across user-defined timescales. FDB's reporting functionality offers a summary view e.g., grouped by the area of guidance, practices, or month, and includes reports focused on:

- Hit Count (number of times message is presented to users)
- Action Count (number of time messages is accepted or rejected)
- Offer Rate (percentage of consultations which resulted in a message being presented)
- Accept and Reject Rates

Users are then able to drill down to a specific message, individual practices, or a point in time. This flexibility allows the MOT to access the information they require at any given time and fine tune the profile to achieve the optimum balance between maximising potential benefits whilst managing the impact on clinicians.

2. Solution Overview

OptimiseRx is a prescribing decision support tool which provides patient specific clinical guidance to clinicians, at the point of prescribing. FDB OptimiseRx supports ICBB's in delivering their medicines optimisation strategy by providing healthcare professionals with evidence-based alerts and prompts in the form of messages relating to best practice, safety, and cost.

OptimiseRx combines national guidance, local formulary and cost-based messages, promoting clinically effective prescribing and guiding your clinicians towards formulary compliance.

One of the key factors that makes FDB unique is the expertise of our team and their processes, with over 40-years' experience of developing clinical decision support content for prescribing systems; OptimiseRx content builds and augments this expertise in a market-leading solution which sets the benchmark for point of care medicines optimisation.

FDB provides a set of 'core' national OptimiseRx messages which are authored by an in-house dedicated expert team of clinicians, clinical researchers and clinical informatics experts ensuring consistency of content to improve the end user (clinician) experience, while reducing pressure on ICB staff. The clinical authoring team reviews prescribing guidance from multiple national reference sources coupled with experience of clinical practice and applies expertise in healthcare informatics to present relevant and actionable clinical decision support in the right context and at the right time.

This core content is continually monitored and updated or withdrawn by our team, in line with national guidance and any changes to the evidence base for best practice and safety content. Where savings are included on messages that offer more cost-effective alternatives, these will be routinely updated by the FDB content team in line with Drug Tariff pricing changes. Cost switches which no longer result in a saving will be centrally retired from the core message profile to prevent prescribers from seeing negative savings when accepting cost messages. This also reduces the maintenance burden for ICBs in terms of keeping up to date with constantly changing pricing information.

Medicines Optimisation Teams
OptimiseRx messages are housed within a web-based administration portal, offering ICB Medicines Optimisation teams easy and secure access to manage their OptimiseRx profile and tailor message content that is made available to prescribers. Any changes made via the portal are immediately visible to prescribers, ensuring they have access to the latest best practice, safety, and cost guidance. The portal contains the following functionality:

- Access to over 2,000 messages of 'core' national content, including best practice and safety, national stock shortages, and cost-saving messages.
- Messages grouped by therapeutic chapter to facilitate review in line with local priorities.
- Action buttons to instantly enable/ disable individual messages.
- Ability to add or update local ICB text and links to local ICB reference sources on national messages.
- Functionality to tailor alternative products (and trigger products for cost) in line with local preferences, on certain national complex messages.
- Exclusive facility to mute messages i.e., run them silently to track and assess the number of times a message would trigger within the ICB, without displaying to the clinician.
- Content request area to submit requests for local messages with the ability to track the progress of these and view previous requests.
- Ability to create and maintain your own formulary lists via the Formulary Tool.
- Ability to display and surface differences between profile formularies using the Alignment Tool.
- Search functionality including filters for message type, categories, reference source, and drug products.
- Inbuilt audit history for actions completed via the portal to support governance
- Supporting documentation such as user guides and regular content release update bulletins
- Reminder functionalities to allow you to track messages efficiently and easily.

Best Practice & Safety messages
OptimiseRx focuses on content relating to medical conditions commonly managed in primary care, where pharmacological interventions form a large part of disease management. FDB author messages which enable you and your clinicians to: (i) Prescribe in line with national best practice guidance e.g., NICE, PHE, NHS England, (ii) Stay abreast of drug safety issues e.g., MHRA Drug Safety Alerts; and (iii) Adhere to evidence-based prescribing safety indicators: e.g., RCGP.

Simple Cost Saving Messages
Present prescribers with a single lower cost alternative product of the same drug and strength. Messages appear once prescription details have been completed, and cost savings are based on the dosing information entered by the prescriber. The latest pricing information from the Drug Tariff is used to help identify suitable substitutions of expensive products for clinically appropriate alternatives.

Complex Cost Messages
ICBs using OptimiseRx can drive up acceptance of cost messages by including additional logic to filter so that they are only presented when relevant to a specific patient context (e.g., by looking at previous medication history). Certain cost messages may also include additional textual guidance for the prescriber to consider and links to applicable reference sources.

Formulary Messages
Formulary messages can be authored as simple 'Do not Prescribe' or 'Information' messages, but they can also be provided with the full OptimiseRx functionality including patient specific logic. This can be particularly useful for filtering formulary to present (or not present) messages to the prescriber when the coded patient information matches the relevant documented indication.

OptimiseRx is fully integrated within the workflow of the GP clinical system, and is fully integrated with the patient record, considering patient specific attributes including: Age, Gender, Medication history, Historical conditions, Presenting complaint, Allergies, Measures and observations, BMI, Blood pressure, FEV1, Red blood cell count, Cardiovascular risk, Cholesterol, Ethnicity, Neutrophil count, Creatinine clearance, DEXA T-Score.

OptimiseRx has a low impact on medicine management resources. FDB OptimiseRx contains preloaded content allowing the medicines management team to select the information it deems most relevant and reducing the need for medicines management teams to originate complex content. The unique level of patient specificity means prescribers are only alerted with messages relevant to a particular patient or scenario. Additionally, ICB-specific content can be further added by our in-house dedicated team of pharmacists and clinicians, thereby further reducing the burden on local resources.

The OptimiseRx portal offers your medicines management team quick and easy access to management tools. From the portal, individual messages can easily be turned on or off as required, and built-in reports and dashboards allow users to analyse and report on prescribing patterns, the effectiveness of best practice, formulary adherence, and cost efficiency with ease. A Profile Management tool on the dashboard also allows Profile Managers to streamline and enhance their profiles, by reviewing and enabling high-performing messages, low-value messages and their actual vs missed savings.

3. Information Assurance

OptimiseRx is hosted on Microsoft Azure and meets all relevant data protection legislation, Caldicott principles and NHS Guidance regarding the handling and processing of data, including Patient Identifiable Data. This can be evidenced by FDB achieving the following:

- Certification to Cyber Essentials and Cyber Essentials Plus standard.
- FDB has published its Data Security and Protection Toolkit (DSPT) submission under Organisation Code 8HV90, with 100% compliance and a Standards Exceeded status achieved.
- Registration with MHRA as a Class I medical device under the Medical Device Directive. Registration ensures compliance with the current legislation and paves the way for future compliance as we transition to the forthcoming Medical Device Regulations.
- Code of Connection approved through NHS Digital under ODS Code 8HV90.
- Registration with ICO on the Data Protection Register under Register Number: ZA274627.
- Hosting supplier accreditation to ISO 27001. A copy of their certificate is available upon request.
- Accredited to ISO 13485:2016 with SGS since 2023.
- Replicated NHS Information Governance structure to include the appointment roles including: Caldicott Guardian, Information Governance Manager, Senior Information Risk Owner, Data Protection Officer. FDB has also established Privacy Champions across the business to ensure all processes and policies are monitored for potential information governance concerns or queries.
- All staff undertake annual Information Governance Training in line with NHS Level 1 and at the date of submission, 100% of staff and contractors have completed this training for 2025.
- Data Protection and Impact Assessment (DPIA) for OptimiseRx.
- Data Sharing Agreement in place between FDB and its customers.
- OptimiseRx is hosted on Microsoft Azure, which holds the following accreditations:
    - Certified with ISO 27001
    - Certified with ISO 27017
    - Certified with ISO 27018
    - Certified with ISO 22301
    - Certified with ISO 9001
    - Certified with ISO 20000
    - CSA STAR

FDB would be happy to produce a copy of certificates upon request.

4. Disaster Recovery Provisions

FDB has several processes within the business to manage service failure/outages which include both reactive and proactive processes.

If an outage/failure should occur, we have four main processes to manage resolution:

- Handling customer queries
- Technical support
- Managing a non-conformity
- Out of Hours support

These processes combined help FDB quickly and efficiently respond to outages/failures if they should occur.

In relation to OptimiseRx service and data stored, OptimiseRx has full business continuity/disaster recovery facilities with replication of data to multiple data centers. In the event of technical issues our Recovery Point Objective (RPO) is 15 minutes, and Recovery Time Objective (RTO) is 8 hours as per contract SLAs to avoid unacceptable consequences associated with a break in continuity.

FDB has performance and uptime SLAs that are constantly monitored and reviewed, to ensure we have adequate capacity to support our expanding customer base.

For the OptimiseRx solution, we have extensive monitoring and alerting that helps us monitor possible issues before they become significant to customers. In the rare instances that service is interrupted, FDB's monitoring system will quickly alert our IT teams, and we will carry out a full investigation in partnership with the clinical system provider, where necessary, to identify and enact a resolution.

We will work with each customer to make them aware of any potential issues and provide details of the proposed resolution (once agreed).

Although OptimiseRx is fully integrated with TPP SystmOne and EMIS Web, in the event of an OptimiseRx outage, the underlying clinical system can continue to be used for clinical decision support until such time as the system is resolved, thereby minimising impact to end users.

In addition, FDB has implemented the following security measures to proactively prevent a breach:

- The OptimiseRx solution is hosted on the Microsoft Azure Cloud Platform in the UK and there is no international transfer of data.

- By default, all storage containers and databases are encrypted. All transactions are encrypted and decrypted in real-time. All connections to the database are made using industry leading secure methods (SSL/TLS).

- Access to all environments is controlled by the creation of secure user accounts, linked to their active directory account facilitating the use of Enterprise level, Multi-factor Authentication. Log files will identify access attempts and actions and will be exported to Security Incident and Event Management systems for regular analysis and audit. Administrator account lists are reviewed through audits on a regular basis.

- The Prescribing API is not exposed on the public Internet, which dramatically reduces the likelihood of attack. All network connections to and from the OptimiseRx services are over SSL-secured connections, and cloud-based firewalls are configured to prevent access to the environment by unauthorised users. Access to the endpoint is protected by a firewall.

- The OptimiseRx Portal (which is the only Internet-facing component) is behind a WAF (Web Application Firewall).

- FDB completes annual penetration testing through a third party contracted supplier. Subject to the findings, a Security Implementation Plan is put in place and risks will be managed on an ongoing basis until resolved.

- Information risk assessments are performed at least once every six months on all information assets where they have been assigned 'ownership' following guidance from the SIRO on assessment method, format, content, and frequency. Information Asset Registers are audited, and Risk Assessed annually and will involve Information Asset Owners plus Heads of Departments, Team Leaders, and other staff, as necessary. Aspects of security will be looked at during these audits and can be utilised to help complete this review.

- All client machines are either currently supported versions of Windows or Mac. Server machines are current versions of Windows or Linux. Software is licensed through enterprise agreements with vendors. Workstations are enrolled in the Windows Update for Business Microsoft service. All Critical and High patches are applied immediately upon release from Microsoft. All third-party applications installed on workstations are set to auto-update where possible.

- The Head of IT & Software is responsible for ensuring that backup copies of all data including the network configuration are taken regularly in accordance with IT local procedures and relevant SLAs such that services and data can be restored in accordance with requirements. Backups are encrypted.

- The Information Governance Manager will ensure that reviews of security and access arrangements within each area are scheduled and undertaken on a regular basis and recorded on the report as required.

- If any detection system identifies a threat (potential or active) we revisit the risk assessment relating to our security controls.

If an issue is discovered by an end user, it can be reported to FDB using the contractual SLA and we will work together to reach a mutual resolution.

5. On-boarding Process

A dedicated Business Manager and OptimiseRx Clinical Account Manager (GPhC registered pharmacist) are assigned to ensure the ICB has the same named member of staff from the beginning of implementation and throughout the life of the contract supporting a thorough and consistent end to end process for all customers. Each Clinical Account Manager follows a comprehensive Delivery and Implementation (D&I) process following PRINCE2 and Miller-Heiman processes.

The process includes several vital steps to ensure deployment is rapid yet successful:

- Operational Readiness Assessment to confirm readiness to deploy for both parties
- Dedicated FDB team members supporting the ICB including Commercial Manager, Clinical Account Manager, nominated Content Lead, and Customer Services
- Core message content preparation including access to our database of over 2,000 national messages, allowing rapid deployment; creation of formulary message content; and any additional local message content required for ICB clinical priority areas
- Training of Medicines Optimisation team members (including OptimiseRx portal and reporting sessions - minimum of 3 hours)
- End user engagement sessions and support for practice activation
- Joint Project Initiation Document with careful execution against full deployment plan with kick off meeting and key stage gates throughout
- Post Implementation Survey of key customer stakeholders
- Project Closure Documentation including lessons learnt

Practice-level activation is straightforward as OptimiseRx is an integral component of EMIS Web and SystmOne, and therefore already available to activate within any GP practice. OptimiseRx activation takes a few minutes and only needs to be done once, on one computer using an activation code. This will turn on OptimiseRx for all users who have prescribed rights within the practice, including any locum and remote working prescribers. Activation for each practice can be monitored through the practice status report or via the Clinical Account Manager.

The total setup period is approximately 12 weeks from commitment to proceed through to switching on at the practices. This can vary subject to the volume of localisation of content required and will be fully documented in an Implementation Plan and agreed with you in the Project Initiation Document.

6. Off-boarding Process

FDB OptimiseRx is an integral modular component of prescribing systems and can be instantly de-activated by removal of the license key.

7. Service Management Details

The OptimiseRx Customer Service department are contractually available between 9.00am to 5.30pm (GMT) Monday to Friday, excluding public holidays in England ("Contracted Support Hours"). Support may be requested by email or telephone, and voicemail is available outside of Contracted Support Hours to enable support requirements to be logged.

All support queries are logged and assigned a unique reference number. Support activity is logged from the time of initial receipt through to resolution. Progress and response times can be reported on at any time within Contracted Support Hours, via our internal Customer Relationship Management (CRM) system.

The Customer Service team is the first point of contact for all technical and content queries. In addition, the OptimiseRx portal enables Medicine Optimisation teams to easily make new requests which are received directly by the OptimiseRx Content authoring team, and tracked through our system from receipt to resolution, with update notifications at key stages.

8. Training

Training on the use of the FDB OptimiseRx portal to manage the messages and use the reporting capabilities is provided to the ICB/CSU medicines optimisation teams in the set-up period, as well as discussing the need for any localised guidance.

On site demonstrations of how FDB OptimiseRx is implemented within the clinical software, and any necessary training, can be provided for GPs and practice staff.

User guides, FAQs, and associated training materials are available for download from the FDB OptimiseRx portal as well as from your dedicated Clinical Account Manager.

9. Ordering and Invoicing Process

Invoices for the License Fees and any other applicable charges shall be issued in accordance with the Call-Off Contract. All invoices shall be payable within thirty (30) days of receipt of a valid invoice. All payments shall be made in pounds sterling.

10. Termination Terms

Termination terms are set out in the Call-Off Contract.

Upon termination or expiry, each party shall, within fourteen (14) days, return or securely destroy all Confidential Information belonging to the other party. Where destruction is requested, written confirmation shall be provided within seven (7) days of completion.

11. Customer Responsibilities

The customer shall:

- promptly submit Patient Declarations in accordance with the Agreement between the parties;
- ensure that FDB OptimiseRx users are in compliance with all reasonable specifications and other reasonable instructions given by First Databank UK Ltd from time to time and notified to Licensee in writing and are otherwise in accordance with the provisions of this Agreement;
- upon reasonable notice provide First Databank UK Ltd or its authorised representative free access at any reasonable time during working hours to the premises and necessary members of staff for the purpose of implementing FDB OptimiseRx, delivering training as agreed and ensuring you are observing the obligations contained with the agreement between the parties;
- accept responsibility, through its Medicines Management Team, for Administration of the Licensed Solutions. Licensee shall indemnify FDB in respect of the Medicines Management Team's Administration of the Licensed Solutions within the Vendor System; and be required to accept and communicate the following disclaimer:

IMPORTANT NOTICE:

First Databank UK Ltd (FDB) is proud of the extensive editorial and quality control procedures which it has developed over many years. However, since every patient's history is different, and even the most exhaustive sources of information cannot cover every possible eventuality, you should be aware that all information is provided from the FDB Solutions on the basis that the healthcare professionals responsible for patient care will retain FULL and SOLE responsibility for deciding what treatment to prescribe or dispense for all patients and, in particular whether the use of any drug or other products is safe, appropriate or effective for any particular patient or in any particular circumstances. This is because (and all healthcare professionals should bear in mind):

1. The FDB Solutions are intended to supplement, not substitute for, the expertise and judgment of physicians, pharmacists or other healthcare professionals and should not be taken as an indication of suitability of a particular treatment for a particular individual.
2. The FDB Solutions and those who are responsible for their construction, operation and maintenance do not know the particular circumstances, condition or medical history of particular patients or groups of patients and so cannot advise as to particular cases.
3. While the FDB Solutions use reputable sources of information, such as published data of pharmaceutical manufacturers, it does not validate or verify the information received from third parties.
4. The information stored on the FDB Solutions is not exhaustive. It therefore cannot be relied upon as complete.

Although the information stored on the FDB Solutions is updated on a regular basis, healthcare professionals should ensure that they are satisfied that the information they have is current.

12. Technical Requirements

The ICB/CSU will require the following to use the FDB OptimiseRx portal:

- Internet connection

Each GP practice will require:

- FDB OptimiseRx compatible clinical system
- N3/HSCN connection

FDB shall outline full technical requirements as part of the onboarding process.

13. Trial Service

On request

For more information please contact:

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