infonetica
Powering the Research of Tomorrow

ReDA - Clinical Trial Management System

G-Cloud 15 Service Definition Document

www.infonetica.net
enquiries@infonetica.net
+44 (0) 208 334 6900

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Contents

Introduction

At Infonetica, we empower the world's leading researchers with an ecosystem of software products that make their lives easier, so they can focus on delivering the groundbreaking research of tomorrow.

Supporting over 2 million research projects across 14 countries, Infonetica's products support clinical trial management, research governance, research ethics review, tissue tracking and compliance training for researchers.

ReDA is Infonetica's **Cloud-based Clinical Trial Management System** used by research hospitals, research-intensive universities and government bodies.

It currently supports over 225,000 research studies across the UK, Europe, North America and Australia.

In the UK, ReDA is one of the Local Portfolio Management Systems (LPMS) listed on the NIHR CRN LPMS Systems of Choice Framework and supports research delivery for multiple LCRNs (Local Clinical Research Networks) and NHS Trusts.

Summary of Functionalities

Organisation Type

ReDA supports a variety of organisation types such as:

- Single-site organisations, such as a research hospitals, research-intensive universities or research sites
- Multi-site entities, such as an NHS Trust
- Network organisations, such as a Local Clinical Research Networks (LCRN) or multi-organisation set-ups

Interfaces

- Send and receive data, reference data and terminology data from the NIHR Central Portfolio Management System, compliant with interface standards set by NIHR
- Integrate with UK HRA systems such as IRAS
- Import XML forms from other systems
- Integrate with identity management solutions to support single sign on
- Interface with other existing software and applications through APIs

Study Management

- Centrally manage studies in a network organisation
- Create local studies
- Create local data sets for network studies
- Carry out project feasibility and expression of interests (EOI)
- Manage study access across organisational levels
- Search or filter studies using multiple filters
- Search using portfolio ID, study ID, IRAS ID, study titles and acronyms
- Manage study amendments
- Bulk upload corrections

Participant Management

- Track participant-identifiable patient recruitment data
- Record participant level research activity data
- Collect aggregated research activity data
- Batch import patient data
- Apply workflows to participant pathways including study arms
- Record participant appointments
- Manage staff calendars

Site Management

- Add new sites and locations
- Edit existing site and location information
- Remap geographic or organisational relationships
- Link multiple sites, locations and people to studies
- Record study information for sites outside of organisation

Document Creation & Management

- Store documents at:
    - Study level
    - Site level
    - Location level
    - Contact level
    - Participant level
- Use document access control and restrictions
- Access all documents via links in the document repository
- Ensure documents are up to date with version control
- Generate letters using templates

SOP Store & Contracts

- Manage Standard Operating Procedures (SOP) using SOP store
- Manage and search contracts

Governance

- Build a standard list of governance events
- Record governance events
- Record clocks at all levels
- Set governance reminders
- Store governance history

Stakeholders

- Manage investigators, sponsors and funders
- Manage investigator details, projects and details of research passport or courses and their expiry dates

- Manage funder / sponsor details, associated projects and finance

Dashboard

- View project reminders
- Check contract / course expiry alerts
- Flag post-approval adverse events and amendments against studies
- Consult the calendar view to see:
    - Study dates
    - Recruitment dates
    - Reminders
    - Visit dates
    - Target dates

Reporting

- Easily access reports with dashboard functionality
- Run bespoke reports with report builder tools
- Report on any data in the system, including:
    - Recruitment
    - Portfolio status
    - Study status
    - Finance
    - Other
- Allow users to define their own reports
- Report on research activity, based on multiple criteria
- Control report access
- Share report structure
- Output in multiple formats, such as xlsx, pdf, doc and xml
- Pre-build standard reports to produce when required
- Run data quality and completeness checks

Export & Import

- Export and import in several standard formats, such as .xlsx, pdf, .doc, and .xml
- Import CRN datasets directly on to the system
- Bulk import recruitment data across multiple studies
- Configure and schedule data exports

Alerts & Reminders

- Set alerts and reminders based on core- or user-defined data items
- Use internal system messages on studies that are visible to named users
- Generate external messages via email
- Manage the staff calendar

Finance

- Add research, support and treatment costs per participant and at various levels
- Track cost savings
- Track recruitment- and research activity-based income
- Upload costing templates, such as the NIHR costing template at organisational level
- Use reports to facilitate invoicing
- Share costing templates

Security

- Closed system
- Role-based permissions
- Simple creation and deactivation of users
- Single sign-on
- Configure user accounts to allow or block access at:
    - Location level
    - Organisation level
    - Study level
    - Other sections
- User account configuration to account flexibility and access control

Audit

- Audit trails including time, date and user details on:
    - User logins
    - Changes to user accounts
    - Study records
    - Page access records
    - Data definitions
    - Reports
    - Exports

Data Protection

- GDPR compliant

Support

Training

- Periodic face-to-face and web-based training for administrators and users
- Train the trainer sessions
- Training environment to allow data manipulation without affecting the live system

Helpdesk

- Support via email, telephone and Jira online ticketing system
- 9 am – 5 pm Monday to Friday excluding bank holidays
- Defined escalation and response routes
- Appointed point of contact

Data Migration

- Data migration tools to facilitate easy migration of research database from other systems

Infrastructure

- Built on a Microsoft platform
- Hosting at an ISO 9001 / ISO 27001 certified datacentre
- Redundancy in-built at every part of infrastructure
- Cyber Essentials Plus certified