# IQVIA Clinical Insight Registry Platform

*GCloud 15 Service Definition*

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# Service Description

## IQVIA Registry Platform

IQVIA Registry platform, “Clinical Insight” provides a robust solution for collecting and managing both clinically reported and patient-reported structured data.

This comprehensive registry platform serves as a valuable resource for understanding patient experiences, diagnosis, treatment plans, and clinical outcomes.

The platform allows for the collection of disease experience, lab data, care management, adverse events, surveys, PROMs & PREMs and interventions across clinical domains, enabling research studies and longitudinal research.

The platform is a secure, GDPR-compliant disease registry software that operates as a fully managed, lightweight, cloud-based, and flexible platform.

The platform is a low code configurable to the required dataset with validation rules and business logic easily applicable.

It allows the safe storage of hundreds of data points from thousands of patient forms in clinical and other patient settings.

**There are two distinct data gathering approaches:**

1. Clinically reported, and

2. Patient reported solutions available for your registry, these can also be combined.

**Clinically Reported Data (CRD):**

The clinically reported registry is an intuitive, easy-to-use product that allows clinicians to enter, view and manage pertinent patient data longitudinally.

### Key Features:

- **Clinician Input**: Clinicians contribute an agreed set of clinical information, ensuring a comprehensive dataset that can include PREMs and PROMs. This data collection can be defined on a schedule or can be ad-hoc depending on patient interactions.

- **Patient Reported**: If configured PROMs can be input by patients through several mechanisms including patient portals, or PROM kiosks.

- **Research Ready:** The CRD product enables a research-ready, real-world dataset that combines both clinically reported and patient-reported data. This integrated approach enhances the richness and depth of information available for research and analysis.

- **Built for data quality:** Robust data quality is ensured with source data verification checks, queries and discrepancy notes, and the implementation of business logic and validation rules

### Key Benefits:

- **Comprehensive dataset with clinical input:** Clinicians actively contributes relevant clinical information, resulting in a comprehensive dataset that can include Patient-Reported Experience Measures (PREMs) and Patient-Reported Outcome Measures (PROMs).
- **Research ready real-world data:** The Clinically Reported Data (CRD) Product creates a research-ready, integrated dataset by combining clinically reported and patient-reported data. Researchers gain access to a rich and deep pool of information for in-depth analysis
- **Insights and communication:** Clinical researchers can track overall status, trends, and changes based on the collected data. Consolidated data from a group of people with a specific condition can provide valuable insights into that condition.
- **Data Quality Assurance and Integration:** Data quality is maintained through verification of source data, and the platform seamlessly integrates real-world data collection into clinical settings, enhancing efficiency and accuracy.
- **Ease of use:** The platform stands out for its intuitive ease of use, enhancing user experience and efficiency.
- **Patient Engagement:** Enables seamless collection of data from patients
- **Easy to configure and maintain:** Web based software with minimal configuration demands and simplified maintenance for hassle-free upkeep.

## Patient Reported Data (PRD):

IQVIA Patient Registry platform takes a patient-centric approach by allowing patients and caregivers to directly contribute real-world data.

### Key Features:

- **Direct Patient Input**: Patients can easily enter specific patient centric health information, providing a holistic view of their health journey.
- **Comprehensive Collection:** The registry captures a wide range of longitudinal data, including Patient-Reported Experience Measures (PREMs), Patient-Reported Outcome Measures (PROMs), surveys, or any other relevant structured dataset.
- **Curation:** Efficient curation streamlines data management in the registry.

- **Multilingual:** The platform can be available in multiple languages, ensuring accessibility for diverse user populations.

- **Longitudinal Insights:** By intuitively managing longitudinal data, researchers and clinicians gain valuable insights into disease progression, treatment effectiveness, and patient well-being.

## Key Benefits:

- **Empowering Patient Engagement:** An intuitive, easy-to-use registry allows patients and guardians to enter patient centric health information directly. By fostering trust and engagement through a professional, branded user experience, patients and carers actively participate in their own healthcare journey. The registry also enables communication with the patient community, keeping them informed about diagnoses, upcoming trials, and news. Clinicians, patients, and others can contribute valuable data, creating a collaborative environment.

- **Enhanced Communication and Education:** The registry enables communication with the patient community, keeping them informed about diagnoses, upcoming trials, and news. Clinicians, patients, and others can contribute valuable data, creating a collaborative environment. Additionally, the platform encourages long-term registry participation by communicating patient-specific information to the community.

- **Real-World Data Collection:** Patients and carers can contribute real-world data, providing insights beyond clinical settings. Convenient smartphone surveys encourage participation and facilitate data collection. The registry ensures that patients remain engaged and informed throughout their healthcare journey.

## Service Overview

The platform is designed for ease of use in data collection, applying agreed standards, providing interfacing capabilities with external systems, supporting sophisticated validation and verification.

Our service takes the dataset definition from our clients and configures the platform in a meaningful way to enable this data collection.

While the vast majority of client requirements are delivered through configuration there is also the possibility to add customisations for very specific needs.

### Technical Infrastructure

The Clinical Insight platform is hosting agnostic, and we currently have deployments hosted with various data centre vendors.

Our approach to any deployment is that the systems are deployed on a Linux operating system, using the supported firewall infrastructure, redundancy, load balancing, security, authentication and failover features.

If the client has a preferred hosting supplier, IQVIA is able to adjust this approach to various other vendors including within the NHS framework or within an academic institution as well as client specific hosting.

### System Support & Maintenance

In order to support the registry post deployment, IQVIA and the client will agree to a Service Level Agreement (SLA).

As part of this, the IQVIA Service Desk will be the single point of contact for nominated Client Super Users seeking assistance with technical incidents, connectivity issues (Incidents) and assistance with using the Software Solution (Service Requests).

All members of the service management team are trained or certified ITIL at foundation or practitioner level and include roles of service analysts, operation application engineers, information security officer and service mangers.

Escalations from our service desk are directed to our support team, which includes system administrators, infrastructure engineers, database administrators, data scientists, and software developers to provide support for applications they designed and developed. All IQVIA support is carried out by IQVIA and is not outsourced or offshored to 3rd parties.

The service management team work closely with product owners, project managers and dedicated account managers to provide lifecycle support in an agile collaborative approach with clients. IQVIA project managers are trained and certified in Prince 2 Agile methodology, both ITIL and Prince 2 were created by the UK government to promote best practices are aligned to deliver value.

## Testing & Quality Assurance

Our Quality Assurance team (QA) follows the Agile Manifesto and adheres to the testing standards outlined in the International Software Testing Qualifications Board (ISTQB) Foundation Level Certification. Our Quality Assurance team will analyse the proposed project requirements and identify functional and non-functional approaches for testing the requirements

They evaluate the Test Basis (e.g., the Requirement Specifications) and test items to identify defects of various types, such as:

- **Ambiguities**
- **Omissions**
- **Inconsistencies**
- **Inaccuracies**
- **Contradictions**

Following this the QA team define and prioritise Test Conditions for each feature, to begin gathering Test Data for the Test Conditions. On project sign off the QA team design and create Test Cases to cover these Test Conditions and Scenarios using our chosen Test Case Management Tool, TestRail. Documentation has bi-directional traceability between the test basis, test conditions and test cases, with the documentation adhering to IEEE 829-2008 - IEEE Standard for Software and System Test Documentation.

Internal penetration testing is also performed as per the requirements of ISO27001 to ensure that there are no active vulnerabilities in the software.

## Deployment

As per good industry practise IQVIA manages code in different environments depending on the stage of development of any new configurations. We deploy using a staging, UAT and production model, where staging contains the system under active development (and IQVIA QA testing), and the UAT contains the system under test by the client. The UAT and production would normally be in the target hosting environment and be configured alike, with the staging server also in the hosted environment with a simpler configuration.

## Security Systems

The security systems include regular security updates, and the security infrastructure is aligned with ISO27001 standards, incorporates encryption, firewalls, IDS, file integrity monitoring, and active response. It encompasses DMZ traffic management, VPN, and whitelisting. Disaster recovery, off-site backups, and platform security measures such as email security and containerisation are in place. At the application layer, customisable password policies, multi-factor authentication, and strict roles and permissions are enforced, along with regular security releases. IQVIA staff undergo regular GDPR and OWASP training to maintain awareness of best practices.

## Data Integrity

The security features of Clinical Insight platform target multiple levels including the data element (e.g., restricted access to fields), user (e.g., password authentication access, 2 factor authentication), application (e.g., role-based access to features, audit trails), and hosting services (e.g., firewall, HTTPS, secure sockets layer, single tenancy, system monitoring, and active security patching). Taken together, these features ensure access control, audit control, data integrity, user authentication, user authorisation, active security stance and transmission security.

## Data breaches

Data breaches are very serious, and the correct approach needs to be taken before any incident to minimise risks as much as possible. Our default security stance is for a security in depth approach. This includes:

- Minimise attack surfaces - only expose essential services to the internet – usually only the web server
- Run only necessary services - i.e., disable and remove all unnecessary software
- Apply all relevant security patches as soon as possible, usually automatically as they are released by the vendor
- Having strong internal separation between the modules i.e., application, the database, and various supporting components
- Administrative access only available from the IQVIA VPN
- Tightly controlled software development process with an emphasis on security
- Using relevant hosting providers security features where possible
- Regular secure backups of data and systems
- Active monitoring of system security alerts
- Any patient identifiable data is encrypted
- The database is encrypted at rest

If any systems are breached, we have an Incident Response Plan, which is part of our audited and certified ISO27001 stance. As part of this plan, once a breach has been confirmed we have several steps, which included:

- Assembling a major incident team, comprising of 5 senior members of staff from relevant teams
- Notifying relevant parties

- Containment if possible and where relevant, ensuring the possibility of full forensics
- Eradication - once the attach point is understood, and any changes to the system are identified, then decisions are made on the most appropriate steps to ensure that the situation cannot be repeated
- Recovery - once the system is safely brought back online and data is restored to a known point where it can be assured that the data has had no unauthorised changes
- Notification of all relevant parties of the outcome of the above steps
- Update security management logs and internal reviews on lessons learned

**Disaster Recovery**

The solution shall maintain a continuous database backup on a separate device with a geographically remote mirror. In the event of a failure (or for testing), the database can be restored on another server. The systems shall maintain full system backups, and in the event of a failure of the primary server (or for testing), the image may be restored on a new server. In the event of failure of a server or datacentre, the web address, the HL7 links, and BI integration links may need to be re-configured.

## APPENDIX 1: Clinical Reported Data (CRD) Registry

Understanding the Clinical Insight Platform and its supporting modules requires an understanding of the stages of the process it is designed to support. The stages are follows;

1. PLAN: Involves defining the key elements of the registry study, including its purpose, scope, target population, data elements, and regulatory requirements. It also involves developing a study protocol, selecting study sites, and determining data collection and management procedures.
2. BUILD: The software platform for the registry study is configured according to the study's specific requirements. This includes designing data entry forms, creating validation rules, defining workflows, reports, dashboards and setting up the initial user access and permissions.
3. EXECUTE: Involves the actual collection of data from study participants, which can include patient-reported outcomes, clinical measurements, and medical history. Data may be collected through electronic forms, surveys, or other means depending on the study design.
4. MONITOR: During data collection, ongoing monitoring and quality control are crucial to ensure data accuracy, completeness, and consistency. This involves reviewing data for quality and completeness, monitoring for adverse events and ensuring that the study is conducted in compliance with regulatory requirements.
5. EXPORT: Once the data has been collected, it can be exported from the registry platform for research and analysis. This may involve exporting data in different formats for various stakeholders, such as researchers, clinicians, and regulators.
6. REVIEW: Finally, it is important to review the performance of the registry study and identify opportunities for improvement. This may include analysing data quality, participant recruitment, and the overall effectiveness of the registry platform. Continuous improvement is essential to ensure that the registry study meets its intended purpose and provides value to stakeholders.


*Figure 1: Event stages of a registry study*

The Clinical Insight platform is designed to underpin solutions that grow with the organisation that is using the platform. An initial iteration of a project may involve getting a registry up and running, while a further iteration may involve running an observational study on a subset of the same patient cohort.

### Clinical Insight Core and its supporting Modules

### Scalability and modularity

The Clinical Insight Platform has been built with scalability and modularity in mind, this helps ensure that the system remains flexible, adaptable, and responsive to the needs of users, while also supporting the growth of the registry and the expansions of its functionalities over time.

The registry will allow users to:

- Accommodate growth: The registry will be able to accommodate a growing number of patients, healthcare providers and conditions. As the registry grows, it will be able to handle more data, more users, and more complex queries. The scalability of the registry also ensures that the system remains reliable and efficient, even as the user base grows and new conditions come on board.
- Flexibility: A modular architecture allows for flexibility and adaptability. This means that new features and functionalities can be added to the registry without disrupting the

existing system. Modularity can also help reduce the complexity of the registry, making it easier to maintain and update.

- Integration: A modular design allows for integration with other systems, such as electronic health records (EHRs) and clinical decision support systems. This can help ensure that the registry is seamlessly integrated into the clinical workflow, providing healthcare providers with access to critical patient data when they need it.
- Customisation: A modular registry can be customised to meet the specific needs of different healthcare providers and patient populations. For example, different data fields can be added or removed, depending on the type of patient being tracked or the specific research question being addressed.

## Clinical Insight (CRD) Modules

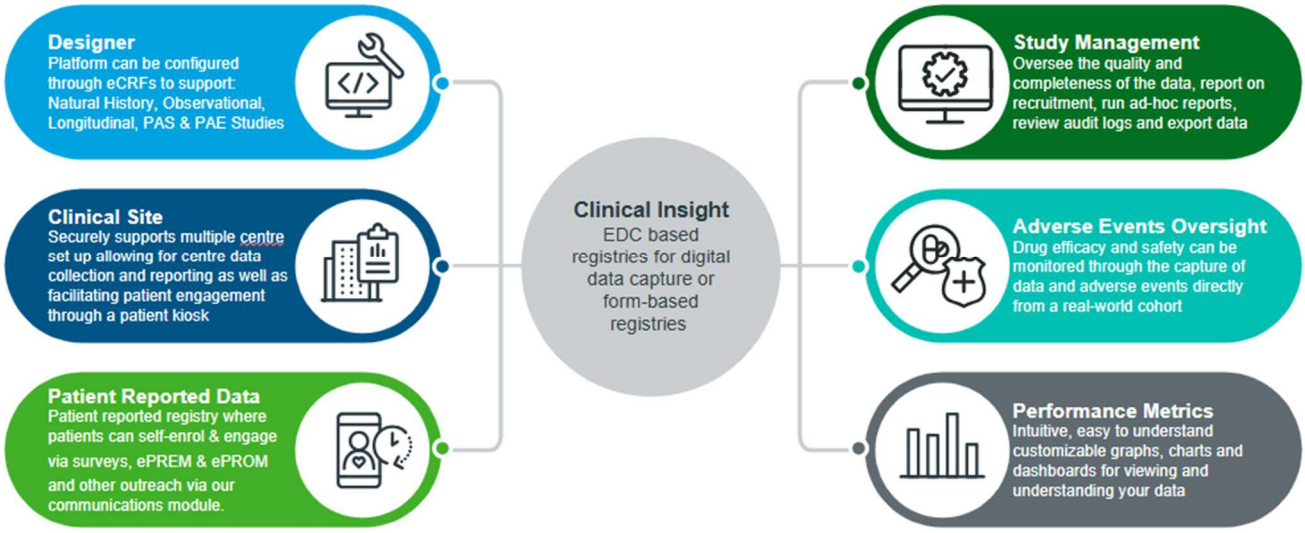



*Figure 2: Clinical Insight modules, which support the registry development process*

## Clinical Insights Core

The Clinical Insight platform is built on core characteristics that prioritise compliance with regulatory requirements, security, data privacy, scalability, modularity, and user-friendliness.

Clinical Insight has been;

- Built to adhere to regulations and standards that govern the registries, including GDPR, HIPAA, 21 CFR Part 11, and ISO 27001.
- Developed with a secure data infrastructure that ensures data is encrypted in transit and at rest, with access controls and monitoring in place to prevent unauthorised access.
- Implemented user authentication and authorisation controls to ensure that only authorised personnel can access the registry and the data it contains.
- Built to support up-to-date data retention policies and procedures that comply with relevant regulatory requirements, including the right to erasure.

- Designed to be scalable, flexible, and adaptable to changing regulatory requirements and participant needs.
- Exposed to regular security and privacy audits and assessments to identify and mitigate potential risks to the registry and its participant's data.

## System Administration Module

The Clinical Insight System Administration Module is used by the IQVIA development team to support the creation of each Registry and Study built on the Clinical Insight Platform.

The System Admin Module;

- Enables system administrators to manage and monitor the registry's data, security, and privacy settings.
- Has established user roles and permissions to ensure that system administrators can control access to sensitive data and functions.
- Is supported by a help desk to assist system administrators with troubleshooting and resolving technical issues.
- Is supported by robust data backup and recovery procedures to ensure the registry's data is protected and can be restored in the event of a system failure or data loss.
- Helps to ensure that the registry's software and hardware infrastructure are reliable, scalable, and easily maintainable and that regular updates and patches are installed in a timely manner.

## Designer Module

The Designer module provides the flexibility to customise the study to the specific requirements of the disease being studied.

The module is used to configure the parameters of the study, such as the data to be collected, how the data will be collected, the validation rules to be applied to the data, and the study schedule.

One important aspect of this configuration functionality is the ability to design and customise the forms that will be used to collect the study data. This includes defining the fields to be included in the forms, the format of the fields, and any validation rules that need to be applied to the fields.

Another important feature of the configuration functionality is the ability to set up the study schedule, if relevant including the timing and frequency of data collection events. This is particularly important for rare disease registries, where the data collection schedule may need to be tailored to the specific needs of the study participant.

The configuration module also includes tools for managing and tracking participant status throughout the study.

### Set guidelines to ensure the integrity and validity of the data collected

The Designer Module;

- Provides an interface that enables data modellers and form designers to easily create, modify, and manage the registry's data model and electronic forms.
- Provides a library of pre-defined data elements and form templates that can be easily customised to fit the unique needs of the registry.
- Implements data validation rules to ensure that data collected through the registry's forms are accurate and complete, and to minimise errors and inconsistencies.
- Enables the creation of data capture workflows that ensure that data is collected in a timely and efficient manner and that all required data elements are collected.
- Provides a mechanism for testing and validating the data model and forms prior to launch, to ensure that they are functioning as intended.

## Create Electronic Forms

Allows for the creation of specific forms (e.g., enrolment base line, visit forms) and their data elements to capture data that is specific to the registry's research goals and participant population.

### Create a ‘Study’ definition

Some studies have specific timeline that are required e.g., an assessment must be carried out at least once per year, and if the patient is on a specific treatment, then an assessment must be carried out every 3 months for the first 2 years. The Designer module enables the creation of study timelines, visit schedule, and data collection forms

## Service Desk Module

The service desk module has been developed to support registry staff with the management of user roles and permissions ensuring they can control access to functionality and clinical sites as needed in the day to day running of the registry.

## Documentation Module

The documentation module was developed to support clear documentation and training materials for registry users to ensure they understand their roles and responsibilities in maintaining compliance with regulations and security standards.

## Clinical Site Module

Enables clinical sites to enrol and manage patient data within the registry, including patient demographics, medical history, and treatment information.

- Provides a user-friendly interface for clinical sites' data collection activities.
- Supports real-time data entry and validation to reduce errors and inconsistencies.

- Provides a dashboard for clinical sites to monitor registry/study progress and patient enrolment.
- Enables the tracking of adverse events and medication data and facilitates the reporting of safety data to regulatory authorities.
- Enables the monitoring of patient compliance with study protocols and the tracking of missing or incomplete data.

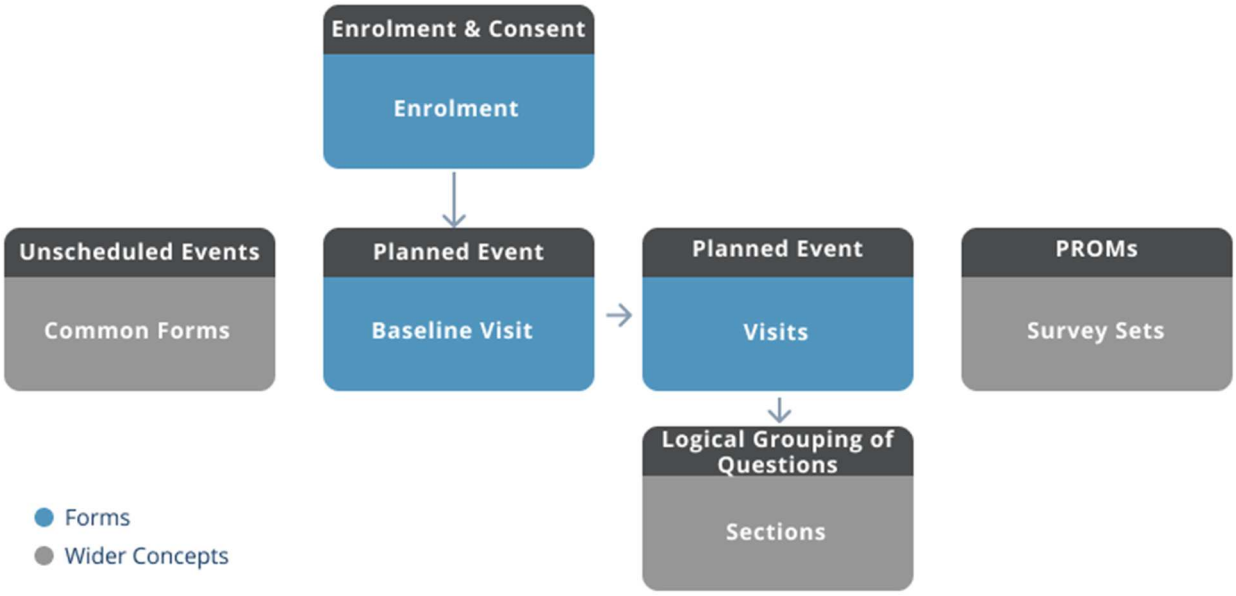



*Figure 3: Registry forms structure*

The Clinical Insight platform has separate forms for Enrolment & Consent, Baselines, Visits, Common Forms.

- The Enrolment form serves as the foundation of the patient's electronic record and typically contains key information about the patient, such as their name, age, and sex. Additionally, the enrolment form may include information related to informed consent.
- The Baseline form is typically used to record medical history at the time of enrolment, rarely changing data, as well as any required assessments or baseline measurements. This information is important for determining a patient's eligibility for the study and for tracking their progress throughout the study and serves as a reference point for subsequent forms and data collection.
- Visit forms are used to collect data from normal clinical visits and, depending on the scope of the visit, may include many optional sub-forms.
- Planned events, such as baseline visits and follow-up visits, are grouped together and typically occur over a set period.
- Common Forms cover both repeated measurements, such as blood pressure, and unscheduled adverse events.

- Common Forms have a "one-to-many" relationship with other forms, making them useful for situations where the number or frequency of measurements is unknown.
- Survey Sets are questionnaires for patients and include multiple surveys (for example PROMs) and a schedule for completion.
- Fields are known as questions, and sections group related questions together for more straightforward navigation and completion.

### Validate the data at the point of entry

Having data validation at the point of entry can improve the quality and integrity of the data collected.

By implementing validation rules, the system can detect and alert users to potential errors or inconsistencies in the data being entered. This can prevent data quality issues from occurring downstream, which can be time-consuming and expensive to address. Additionally, catching errors early on allows for more timely resolution and potentially reduces the need for manual data cleaning.

- Range checks: ensures the data falls within an acceptable range, such as minimum and maximum values.
- Format checks: verifies that data is entered in the correct format, such as dates, phone numbers, or email addresses.
- Consistency checks: checks the relationship between data fields to ensure they are consistent, such as verifying that the birthdate is earlier than the date of the first visit.
- Cross-field checks: validates that data entered in one field matches the data in another field.
- Unique checks: checks that data entered is unique, such as verifying that each participant has a unique ID.
- Logic checks: validate that the data entered makes logical sense, such as verifying that a participant cannot have a future date of birth.

## Pharmacovigilance Module

### Monitor for safety

A pharmacovigilance module enables the tracking and analysis of safety data, providing valuable information to clinicians and regulators. It also supports post-marketing surveillance of disease treatments, ensuring that patients receive safe and effective care. The value of a pharmacovigilance module lies in its ability to improve patient safety and support ongoing efforts to optimise disease treatment options. It provides a platform to identify and address safety concerns and promote safe and effective rare disease treatments.

The Pharmacovigilance Module:

- Establish a mechanism for reporting adverse events or other safety concerns to ensure prompt and effective action can be taken.

- Incorporates data fields to capture adverse event and medication data.
- Contains workflows that support the reporting of adverse events to regulatory authorities.
- Provide access to safety data and safety reports for pharmacovigilance teams and regulatory authorities.
- Implement robust data security measures to protect safety data.
- Is supported by documentation and training materials for pharmacovigilance teams using the registry for monitoring safety data.

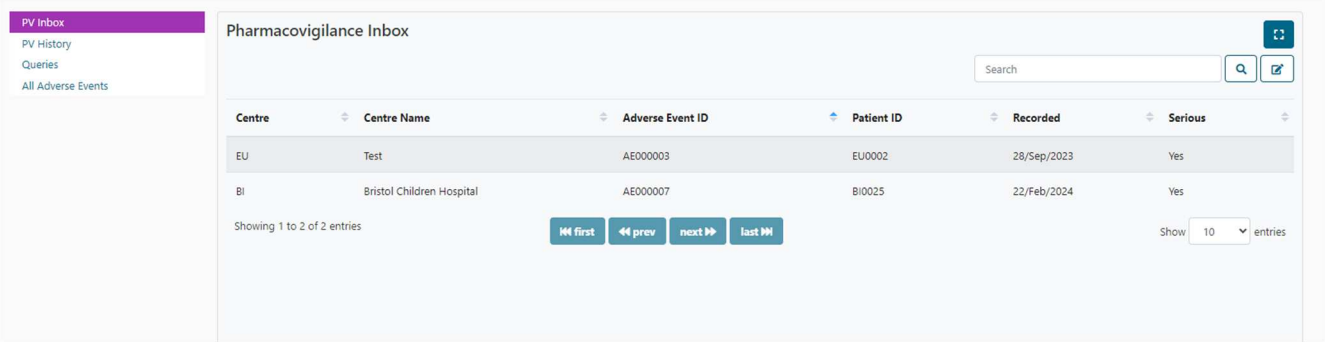



*Figure 4: Example list of adverse events in the Pharmacovigilance Module*

## Study Management Module

A study management module is crucial for the registry to efficiently collect, store, and manage patient data. It ensures that data is collected consistently and adheres to standard protocols, enabling high-quality data for research and analysis. The module also facilitates data cleaning and validation and helps ensure that data privacy and security regulations are met.

### Monitor for accuracy, completeness, and consistency

- Data Monitoring in accordance with the protocol.
- Provides automated data quality checks to identify data that is outside of expected ranges, inconsistent, or otherwise problematic.
- Develop exception reporting mechanisms to identify and address missing data, incomplete data, and outliers that need manual review.

### Generate queries to address any discrepancies or missing data

Discrepancy Query notes improve data quality by providing a mechanism for the Data Manager to identify issues, communicate these in the platform to the relevant clinical team, and for them to resolve these issues with the data. The Queries management component enables clinical site staff to address and resolve queries more quickly, reducing the time needed to complete data entry and curation activities. By facilitating communication between clinical sites and data managers, it promotes collaboration and reduces delays in the data curation process.

The Query component is used to;

- To resolve discrepancies or missing data.
- Supports automated query generation to identify any discrepancies or missing data in the patient registry, based on predefined rules or thresholds.
- Provides a user-friendly interface for managing queries and responding to them.
- Enables users to view and respond to queries easily.
- Enables multiple stakeholders, healthcare providers, and registry professionals, to collaborate in the query resolution process.
- Provides mechanisms for stakeholders to review and respond to queries, and to flag any further discrepancies or missing data for resolution.

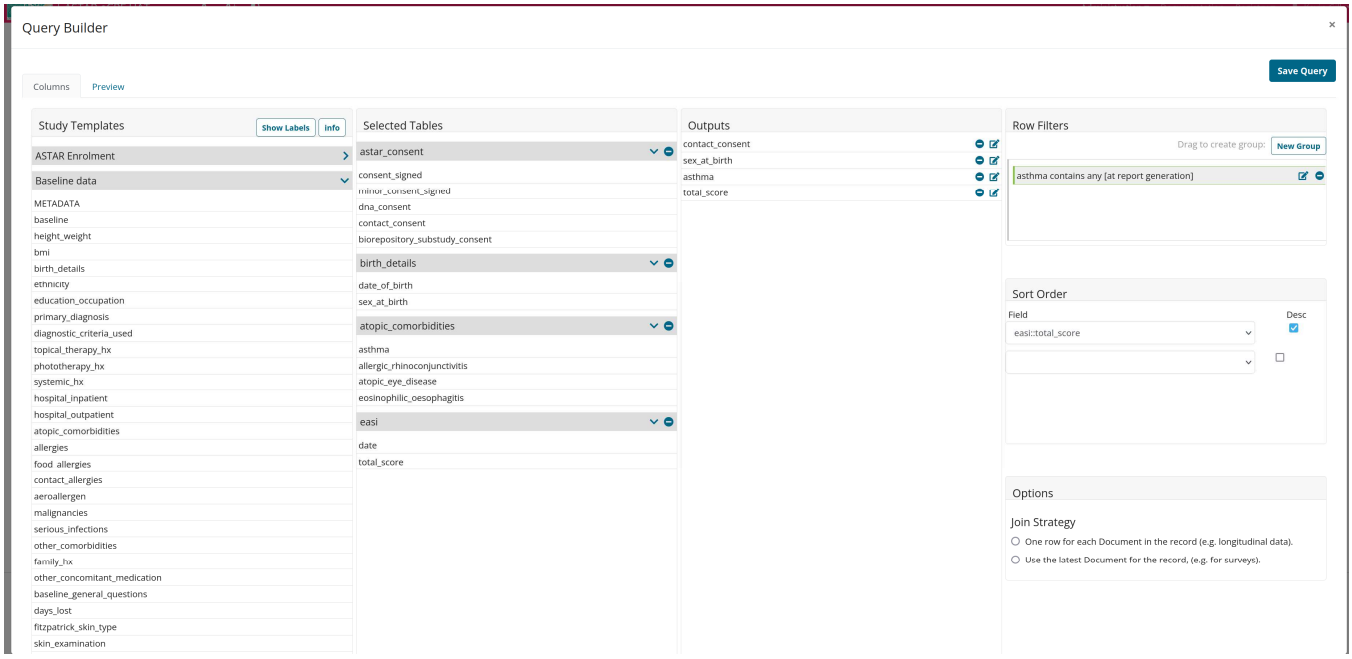



*Figure 5: User interface for generating ad hoc reports*

## Export the data for statistical analysis

Robust export functionality is an essential feature of any registry. The Data Management Module provides mechanisms to enable data to be exported from the platform as necessary for analysis and reporting. This supports researchers and clinicians, leading to new insights and potential treatments. In addition, custom reports and custom data exports can be tailored to the needs of different stakeholders to support promotion, collaboration, and performance analysis on a case-by-case basis.

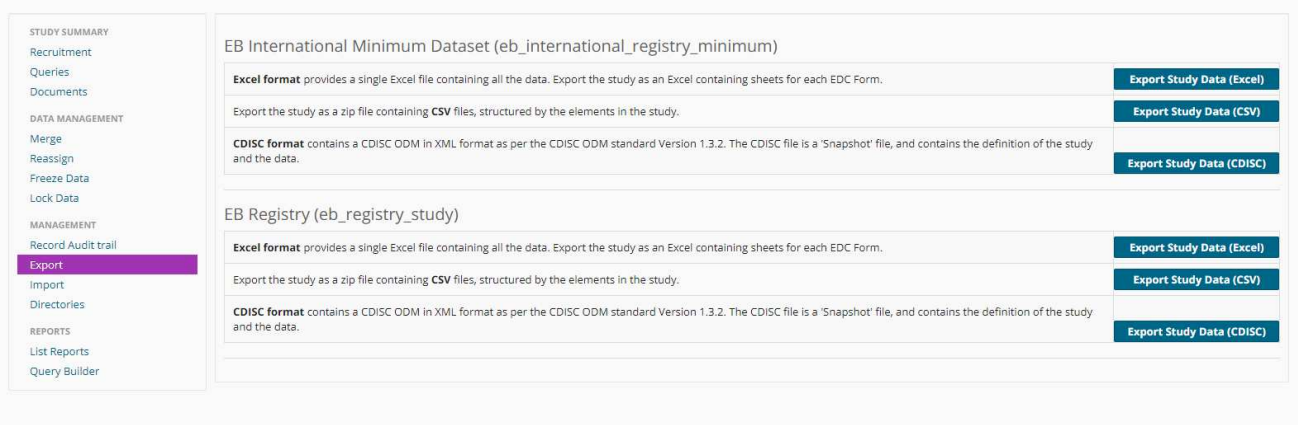



*Figure 6: Image showing data export options on the live system*

## APPENDIX 2: Patient Reported Data (PRD) Registry

The PRD Registry is best used to collect information about patients' health status and experiences as reported
directly by the patient or their proxy The data is then used by registry owners to further medical research and
clinical practice better understand patient outcomes track the effectiveness of treatments and identify areas for
improvement in healthcare delivery

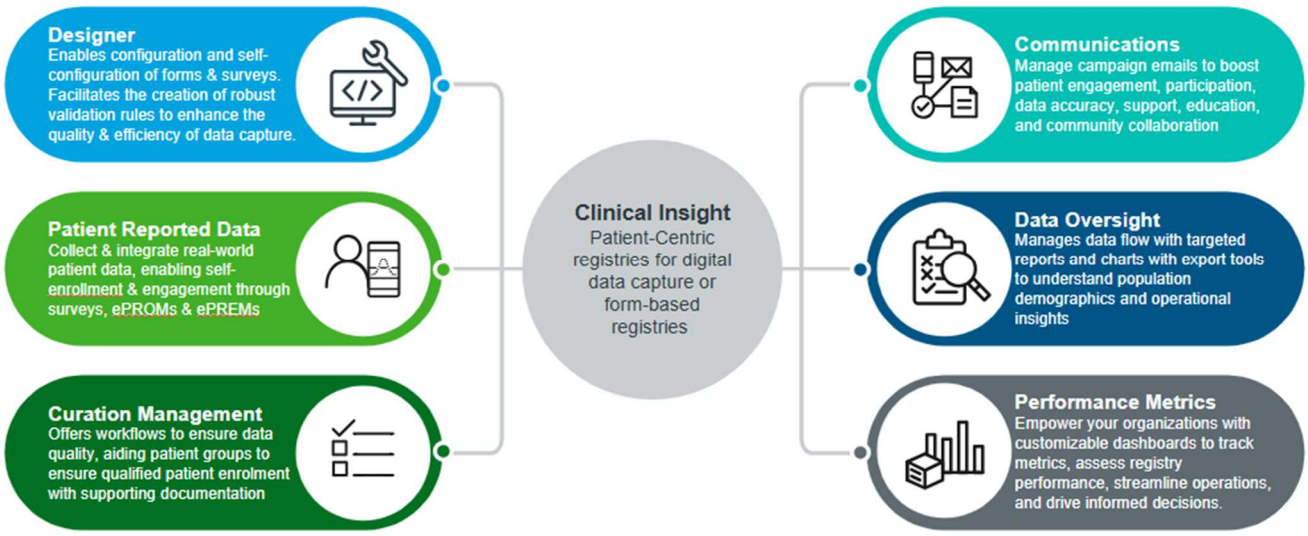



*Figure 7: Patient Reported Data Registry Modules*

The PRD registry is configured as a number of different modules, all serving various purposes:

- The Participant Reporting Data module is the module, which contains the functionality to allow a patient or carer to create an account, enrol a Participant, sign consent, enter data and complete surveys
- The Communications module is for managing the campaign emails, which encourage patient engagement with the registry, leading to increased participation and more accurate and complete data
- The Curation module provides a number of workflows to guarantee the quality of the data collected on the PRD Registry – some by the PRD Registry system itself and some by the Registry management staff
- The Data Management module provides the functionality to explore the data, manage the data in and out of the system, including the export tools, which can support the Researchers and Clinical Trials that help provide a better understanding of outcomes and treatments

The configuration of the PRD Registry Solution will address workflows) across patient access, data collection, reporting and exporting through the following stages:

- Setup of Registry & Survey forms
- Recruitment of Participants
- Creation of Accounts
- Enrolment of Participants
- Running of Campaigns
- Completion of Surveys
- Export of data for a Researcher or Clinical Trial
- Analysis of the Registry Performance

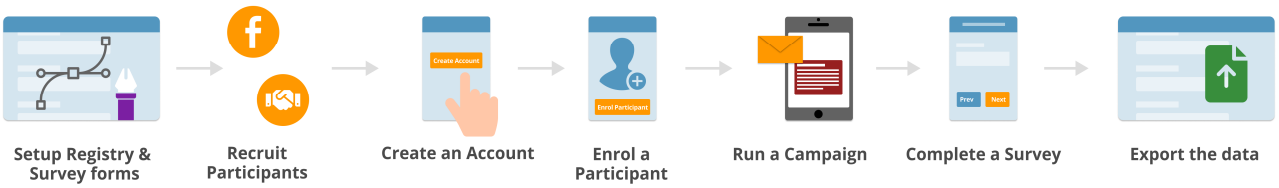



*Figure 8: Workflows of a PRD Registry*

## Configuring Registry and Survey Forms

### Set up of the Registry

PRD Registry is a web-based product that will be set up on a server of your specification. Each instance of the Registry can be configured to meet the Registry's needs including customised consent, scheduled surveys, email communications, and registry manager dashboards.

In addition, the PRD Registry can be branded to reflect the registry organisation. By branding the Registry product we can help establish a unique identity, build trust and credibility, create an emotional connection with Participants, encourage ongoing use and build a loyal user base, and make campaigns and promotions more effective.

### Field types

The PRD Registry can support all the field types one would expect to be required with a system supporting the entering of patient data, including amongst others – text inputs, radio buttons, checkboxes, drop-downs, date pickers, Likert scales and visual analogue scales (VAS) scales.

The ability to provide attachments can also be included allowing participants to upload diagnostic reports or genetic test results.

### Configuring the surveys

IQVIA will complete the initial configuration of the surveys and dataset (once received). These can be configured in the PRD system with options for multiple field types, introduction, and instruction pages.

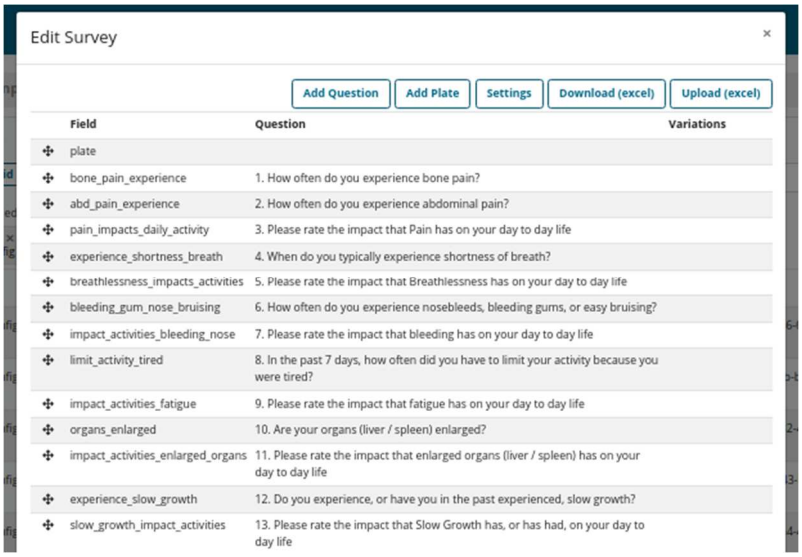



*Figure 9: Sample of survey edit tool*

## Access the Registry (Patient/Carer)

The Patient Reported Data Registry is primarily web-based and is accessed using a web browser. The latest versions of Google Chrome, Mozilla Firefox & Microsoft Edge web browsers are officially supported but the Registry will work well on a wide range of modern web browsers and the log in page for each Registry on the system can be accessed through a unique URL.

The Registry product is designed to be responsive – meaning that it can be accessed from a range of devices, including smartphones (Figure 4), tablets, and desktop computers, to accommodate different Participant preferences and needs.

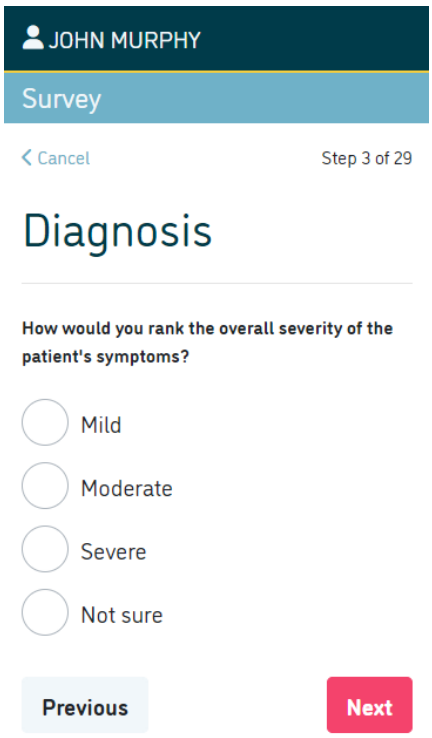



*Figure 10: Example of a survey responsive on a smartphone*

## Create an Account (Patient/Carer)

The PRD Registry user account creation and patient enrolment are done as two separate steps. This allows an individual to manage the data entry of multiple patients in the Registry, including the scenario whereby the account holder isn't a patient themselves.

The Account creation process is quite typical of what one would expect with a secure, web-based application including:

- Set up username and password
- Password strength requirements
- Password confirmation
- Email verification
- 2-factor authentication (optional)

## Login to the PRD Registry system (Patient/Carer)

Both Account holders and Registry managers can log in to the system from the Registry homepage (Figure 5). The username is the email address used when creating the account. Passwords can be reset if forgotten and if the user leaves the PRD Registry idle for more than a few minutes, they will be automatically logged out.

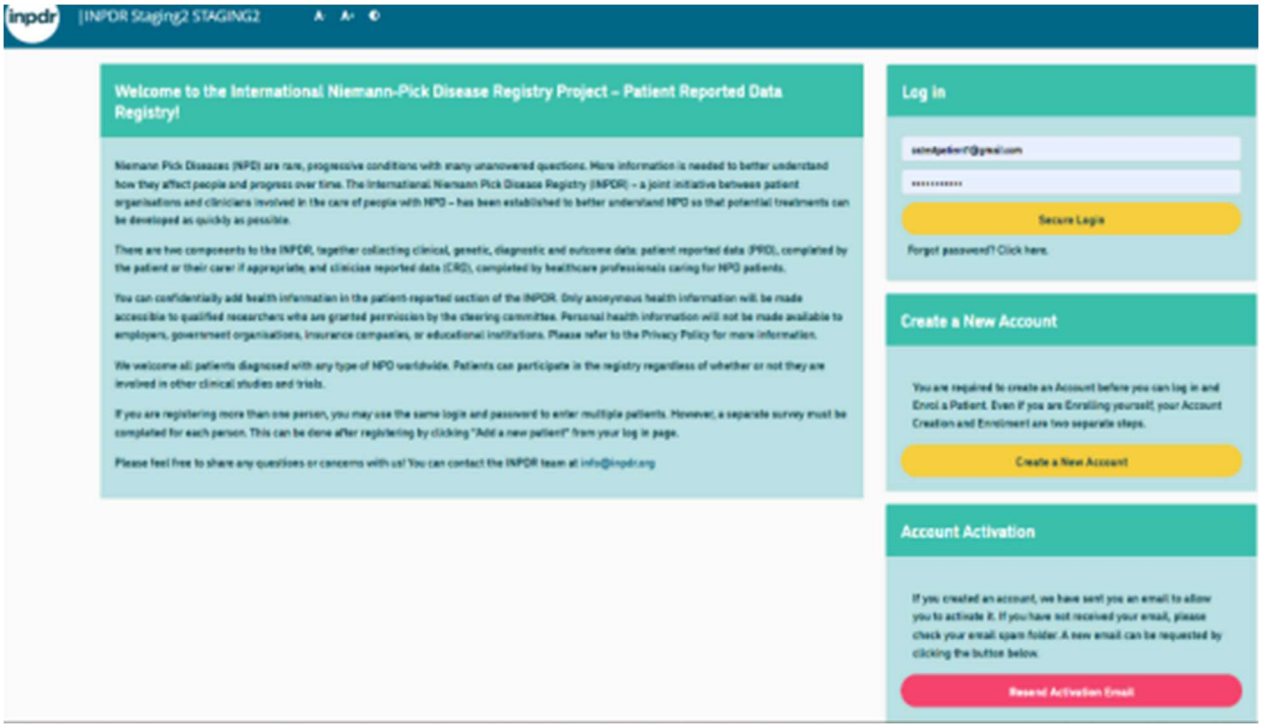



*Figure 11: Example of a log-in page*

## Enrol a Participant (Patient/Carer)

Participant enrolment may be completed by the account holder, if they are suffering from the disease being recorded by the Registry or it may be one or multiple people under the care of the account holder.

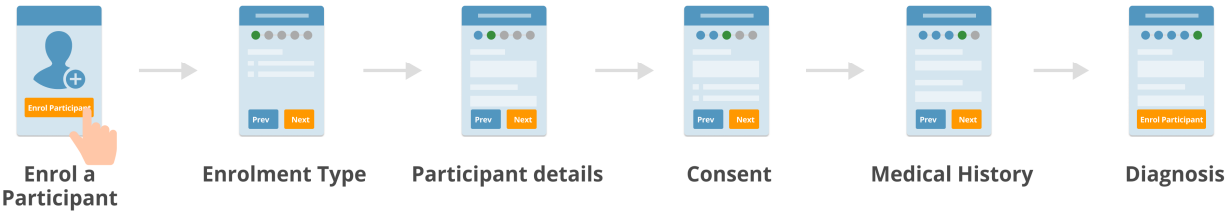



*Figure 12: Workflow for participant enrolment*

- Enrolment Type – Identify who is being enrolled – the Account holder themselves, a person younger than 18 years under their care or a person over 18 years under their care
- Participant details – name, address, contact details, sex.
- Consent – Consent for their details to be stored and shared by Registry staff, as well as additional options to Consent in future research and clinical trials

### Provide the relevant Consent to participate in the Registry, in research, and in a clinical trial

The Consent to be enrolled on the PRD Registry is required from the patient, or from their carer before they can be enrolled within the system.

However, the PRD Registry can record Consent for several other reasons. These include but are not limited to Consent for the purpose of;

- Having their data used in future research.
- Being informed of clinical trials.
- Being informed of new potential treatments.
- Being contacted about a clinical trial by a pharma or CRO (Clinical Research Organisation).

Participants have the ability of changing their various consents status throughout the time span of their contribution to the Registry.

In line with GDPR, if a Participant withdraws their Consent for contact from the PRD Registry, all requests for Survey completions will stop immediately. If a Participant withdraws their Consent for inclusion in the PRD Registry completely, then any data previously collected will be wiped.

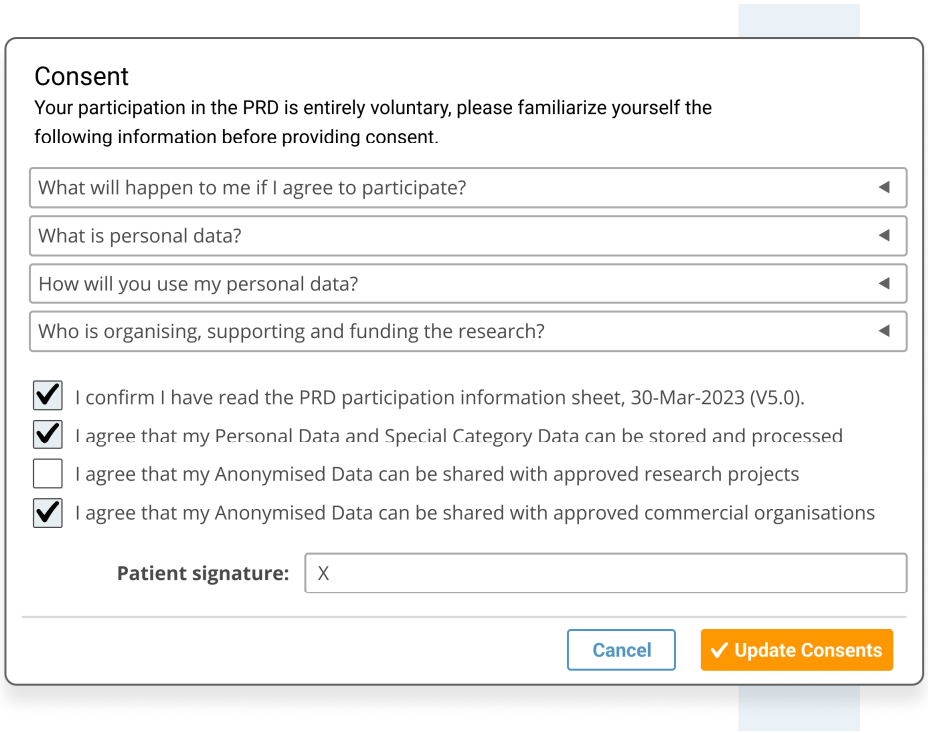



*Figure 13: Sample of consent capture*

## Curate a Participants Enrolment form (Registry Manager)

To guarantee the quality of the data collected on the PRD Registry, a certain amount of curation by both the PRD Registry system and the Registry management staff is possible.

This functionality can be provided by the Curation module (Figure 8), and a number of workflows are available to support this.

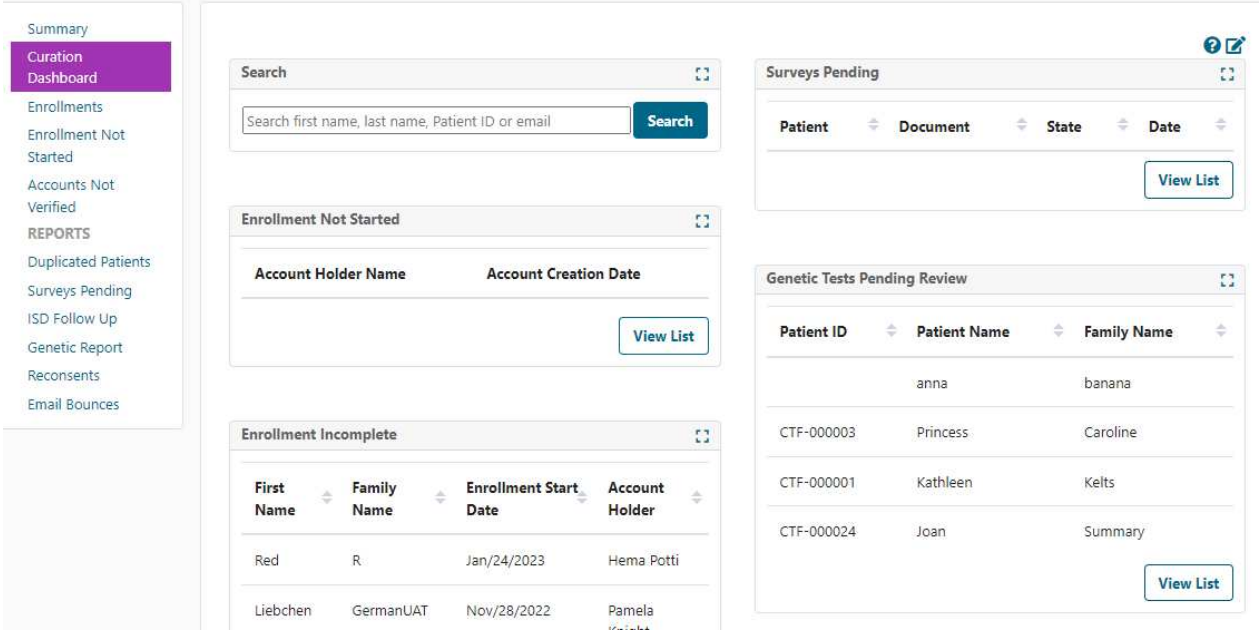



*Figure 14: Registry curation dashboard*

## Set up a Survey Campaign (Campaign Manager)

The PRD Registry contains an automated communication system, which allows system administrators to communicate with platform participants via emails (e.g., sending a notification about ongoing survey or upcoming clinical trial) and includes:

- Email template creation, editing, and selection.
- Test email functionality.
- Campaign reports – summary of email campaigns and access to log of emails.
- Custom recipient lists – filtering email communication based on collected data fields (useful for contacting a specific cohort of participants for targeted communication).
- Consent filtering – using appropriate Participant consent in email campaigns.

## Complete a Survey (Patient/Carer)

IQVIA has developed the survey interface with a strong end user focus utilising the following features:

- Progress bar – encouraging high completion levels.
- Instruction pages – guidance for completing similar types or groups of questions (Figure 9).
- Single question display – focusing the participant on each question (Figure 10).
- Survey review – allowing participants to update before final submission.
- Thank you page – used to end the survey or progress the user to the next survey.
- Automatic saving – allowing participants to return if time short.

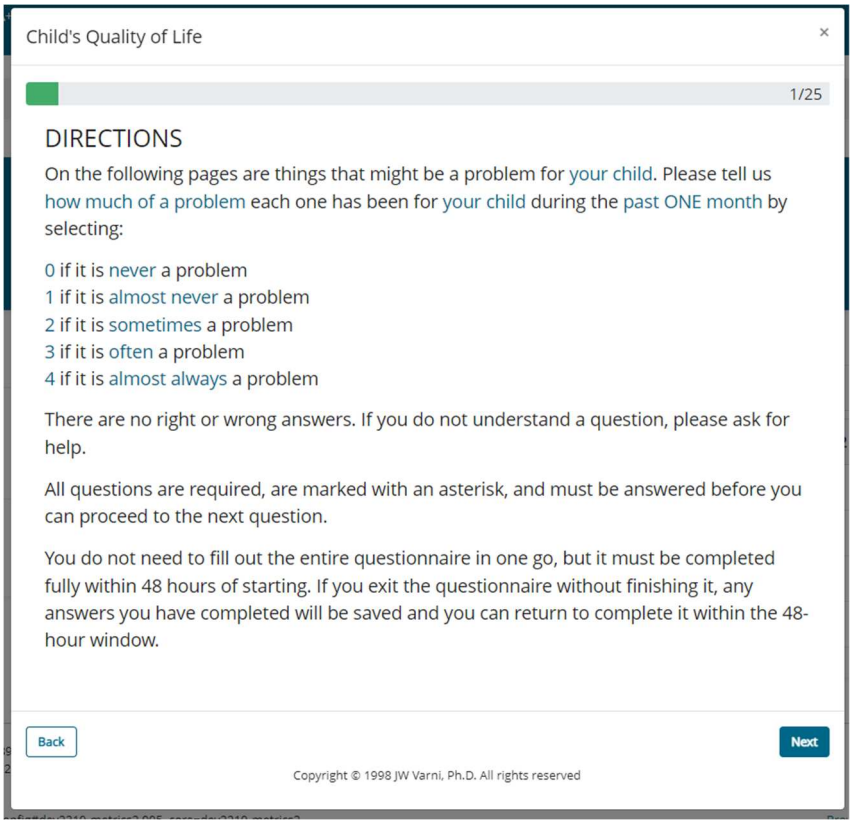



*Figure 15: Registry curation dashboard*

## See how the Participant is performing in the context of the other Registry Participants

Using data captured by Participants during survey completion, the registry may choose to display some of this information to back these users in the context of other participants.

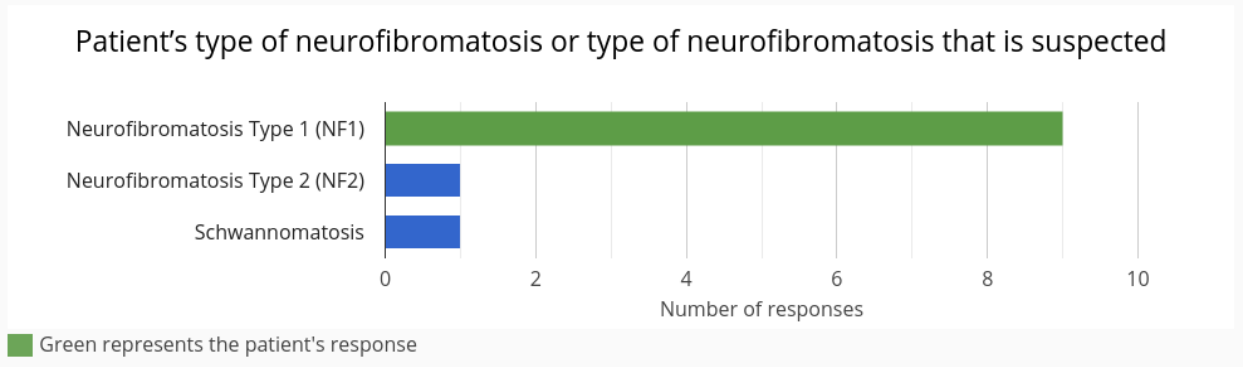



*Figure 16: Data Visualisation example*

### Create an Export (Registry Manager)

Data can be exported from the registry based on a subset of participant and survey data using specific selection criteria. Examples of selection criteria may be data points collected within a survey, a whole survey, and its responses, or based on consent provided by the participant.

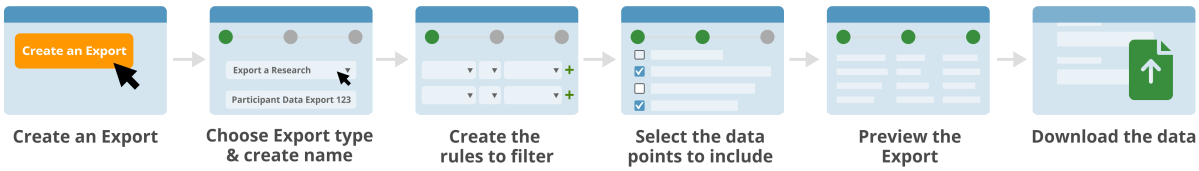



*Figure 17: Data export workflow*

Here are two use cases that may be considered, but the options are endless:

### Send survey responses to a researcher

When one survey is being used as part of a research project, the registry manager can opt to export all responses from that research survey.

### Define the Clinical trial inclusion criteria

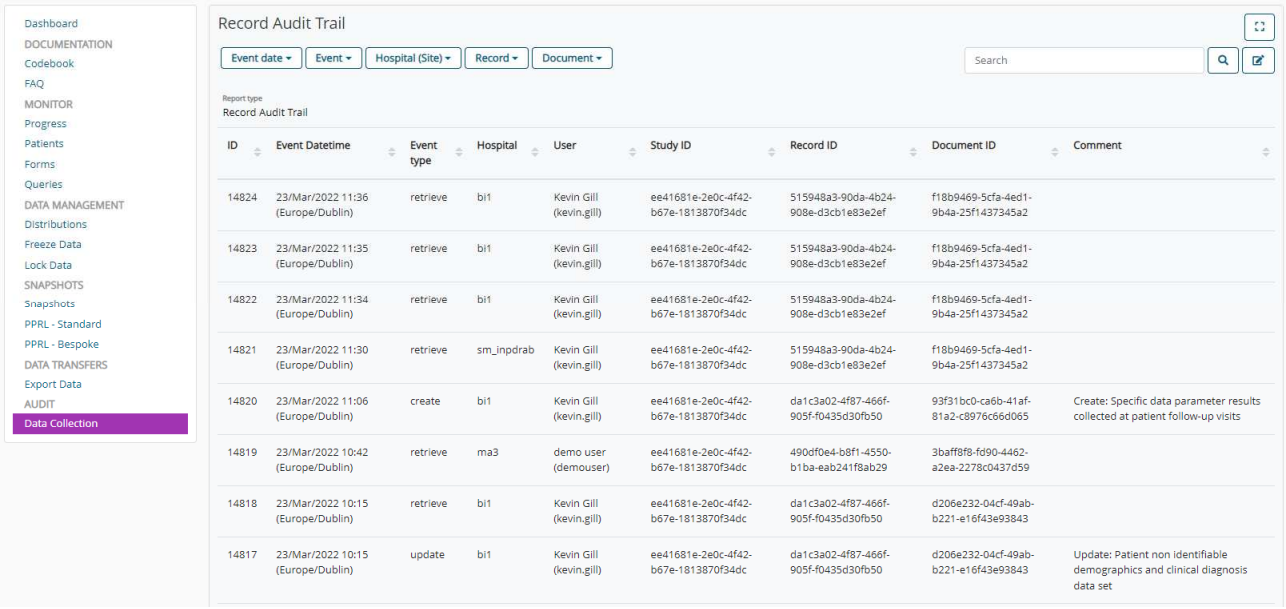
You can apply selection criteria as well as inclusion and exclusion rules, to create a list of participants meeting the defined criteria. For example, these criteria and rules can be applied to the Diagnosis and Consent, to match suitability (based on survey responses) with an acknowledged willingness to participate and permission to be contacted (consent) in the event of a suitable trial.

## APPENDIX 3: Other Core Platform Capabilities

### Audit Trails

The system is fully auditable and has complete audit trails. These include administration audit, search audit and clinical data access and alteration audit. Authorised users can view the clinical data audit trails across the system.

Data and time-stamped audit logs are available to ensure the trustworthiness, integrity and reliability of the records and database. Any change (including deletions) made to a record contain a complete time stamp and includes the user login information. Audit trails are essential in the event of a data breach or a challenge to the data protection procedures of the platform.

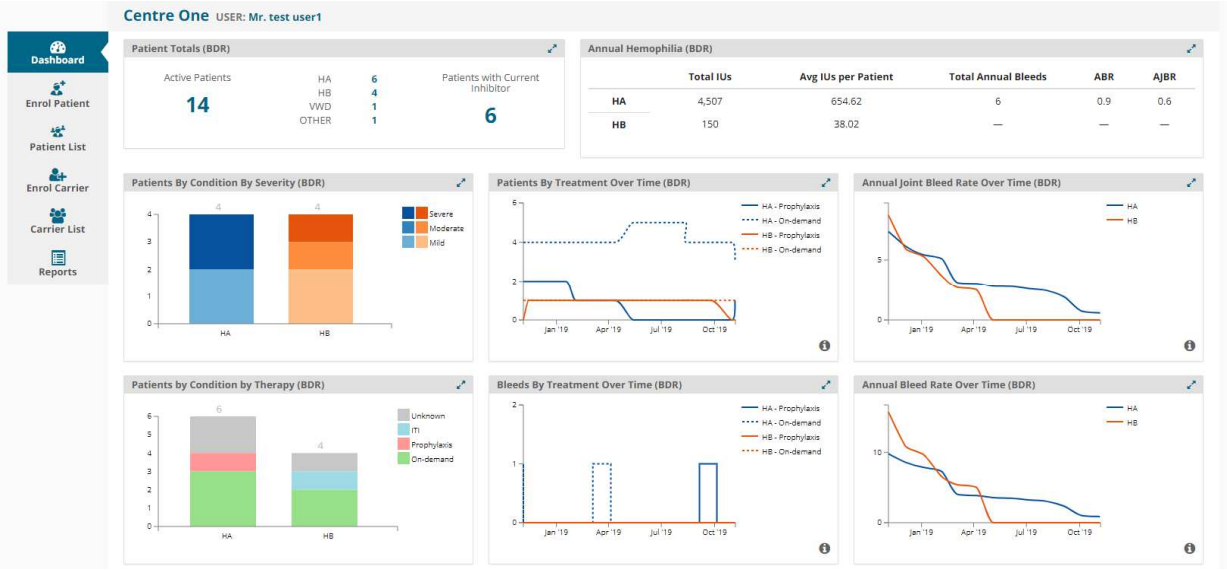



| ID | Event Datetime | Event type | Hospital | User | Study ID | Record ID | Document ID | Comment |
|---|---|---|---|---|---|---|---|---|
| 14824 | 23/Mar/2022 11:36 (Europe/Dublin) | retrieve | bi1 | Kevin Gill (kevin.gill) | ee41681e-2e0c-4f42-b67e-1813870f34dc | 515948a3-90da-4b24-908e-d3cb1e83e2ef | f18b9469-5cfa-4ed1-9b4a-25f1437345a2 | |
| 14823 | 23/Mar/2022 11:35 (Europe/Dublin) | retrieve | bi1 | Kevin Gill (kevin.gill) | ee41681e-2e0c-4f42-b67e-1813870f34dc | 515948a3-90da-4b24-908e-d3cb1e83e2ef | f18b9469-5cfa-4ed1-9b4a-25f1437345a2 | |
| 14822 | 23/Mar/2022 11:34 (Europe/Dublin) | retrieve | bi1 | Kevin Gill (kevin.gill) | ee41681e-2e0c-4f42-b67e-1813870f34dc | 515948a3-90da-4b24-908e-d3cb1e83e2ef | f18b9469-5cfa-4ed1-9b4a-25f1437345a2 | |
| 14821 | 23/Mar/2022 11:30 (Europe/Dublin) | retrieve | sm_inpdrab | Kevin Gill (kevin.gill) | ee41681e-2e0c-4f42-b67e-1813870f34dc | 515948a3-90da-4b24-908e-d3cb1e83e2ef | f18b9469-5cfa-4ed1-9b4a-25f1437345a2 | |
| 14820 | 23/Mar/2022 11:06 (Europe/Dublin) | create | bi1 | Kevin Gill (kevin.gill) | ee41681e-2e0c-4f42-b67e-1813870f34dc | da1c3a02-4f87-466f-905f-f0435d30fb50 | 93f31bc0-ca6b-41af-81a2-c8976c66d065 | Create: Specific data parameter results collected at patient follow-up visits |
| 14819 | 23/Mar/2022 10:42 (Europe/Dublin) | retrieve | ma3 | demo user (demouser) | ee41681e-2e0c-4f42-b67e-1813870f34dc | 490df0e4-b8f1-4550-b1ba-eab241f8ab29 | 3baff8f8-fd90-4462-a2ea-2278c0437d59 | |
| 14818 | 23/Mar/2022 10:15 (Europe/Dublin) | retrieve | bi1 | Kevin Gill (kevin.gill) | ee41681e-2e0c-4f42-b67e-1813870f34dc | da1c3a02-4f87-466f-905f-f0435d30fb50 | d206e232-04cf-49ab-b221-e16f43e93843 | |
| 14817 | 23/Mar/2022 10:15 (Europe/Dublin) | update | bi1 | Kevin Gill (kevin.gill) | ee41681e-2e0c-4f42-b67e-1813870f34dc | da1c3a02-4f87-466f-905f-f0435d30fb50 | d206e232-04cf-49ab-b221-e16f43e93843 | Update: Patient non identifiable demographics and clinical diagnosis data set |

### Reporting

Clinical Insight offers versatile reporting capabilities that seamlessly adapt to a wide range of requirements

The solution provides integrated reporting capabilities where data can be used on internal dashboards or exported to external dash-boarding or visualisation platforms. In addition, all data is accessible to external analytic tools for deeper analysis.



## Contact IQVIA

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