IQVIA Trial Manager

Supporting the execution and management of clinical trials, including multiple use types and providing the tools required at every stage.

IQVIA Trial Manager provides all the capabilities needed to explore and evaluate research projects and trials, assess feasibility and costs, support patient recruitment, design study layout, facilitate electronic data capture, and provide the tools for patient contribution.

As part of the IQVIA Health Data Research Platform (HDRP), which aggregates and harmonizes available clinical data from primary source systems (e.g., Hospital Information Systems, Electronics Medical Records (EMR), etc.) it makes it available for research use. This data is then utilized for clinical research projects, and further complemented with the IQVIA Trial Manager tools.

The solution includes a Case Report Form (CRF) designer that allows building smart forms (for manual data capture) with validation checks, routing logic, commenting functionality, and approval and verification workflows. Fields can be further designed as EDC (Electronic Data Capture) fields, allowing either automated data transfer from source systems into the CRF or offers data verification processes allowing a user to choose from values from relevant data points (e.g., diagnoses, medications, etc.). Since the solution aggregates and harmonizes available clinical data, it can also be used in E2E (EMR to EDC) projects. This allows the pre-population of eCRFs with all relevant source data.

Key features of IQVIA Trial Manager

Patient Registry

The IQVIA HDRP serves as a patient registry. All data that is ingested from primary source systems in combination with the solution's data capture tools is organized in longitudinal patient-centric research records. These records are used for identification of patients matching structured inclusion and exclusion

criteria. Following identification, patient's can be consented and enrolled into the study and data capture can begin.

Interoperability

IQVIA Trial Manager supports all current interface standards (e.g., HL7, FHIR, RESTful APIs, etc.) and data export formats making it possible to support an EMR to EDC system. This provides institutions with the functionality required for their own trial management, and the ability to participate in sponsor-initiated studies.

Pseudonymization

The pseudonymization mechanism in the solution allows for patient protections without hindering research. Pseudonymization allows the connection to the patient to be maintained allowing patients to benefit from the results of any research projects they participated in.

Capabilities

Study register

- Provides a registry of all trials with configurable documentation points
- All studies can be searched and study KPIs can be evaluated
- Collaborative tool to support initial idea sharing amongst researchers

Cost planning

- Calculate cost projections for running a study
- Create invoices for specific milestones or completed events
- Track all costs against budget for the life of the study

Patient recruitment

- Structured inclusion and exclusion criteria is matched against research records for identification of suitable patients
- Randomization methods are available for appropriate study arm assignment, including with stratification

Electronic data capture

- Study layout and visit design, including eCRFs
- Manual data capture and the ability to perform source data verification for data prepopulated from an EMR system
- Includes Clinical Monitoring functions and SAE logging

Patient contribution

- Includes ePROs functionality with the Patient App or Portal access allowing patients to contribute to research with the completion of consent, questionnaires, eCRFs, and SAEs
- Enables direct communication when offsite

IQVIA Trial Manager fulfills the needs of multiple user types at institutions conducting or managing clinical research. This one solution offers oversight of multiple studies, monitoring of financials and safety reporting, and improved efficiency with integration and streamlining of various processes. This results in enhanced collaboration, both internally and with sponsors.

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