Streamline Your Clinical Development with EDETEK's R&D Cloud Ecosystem

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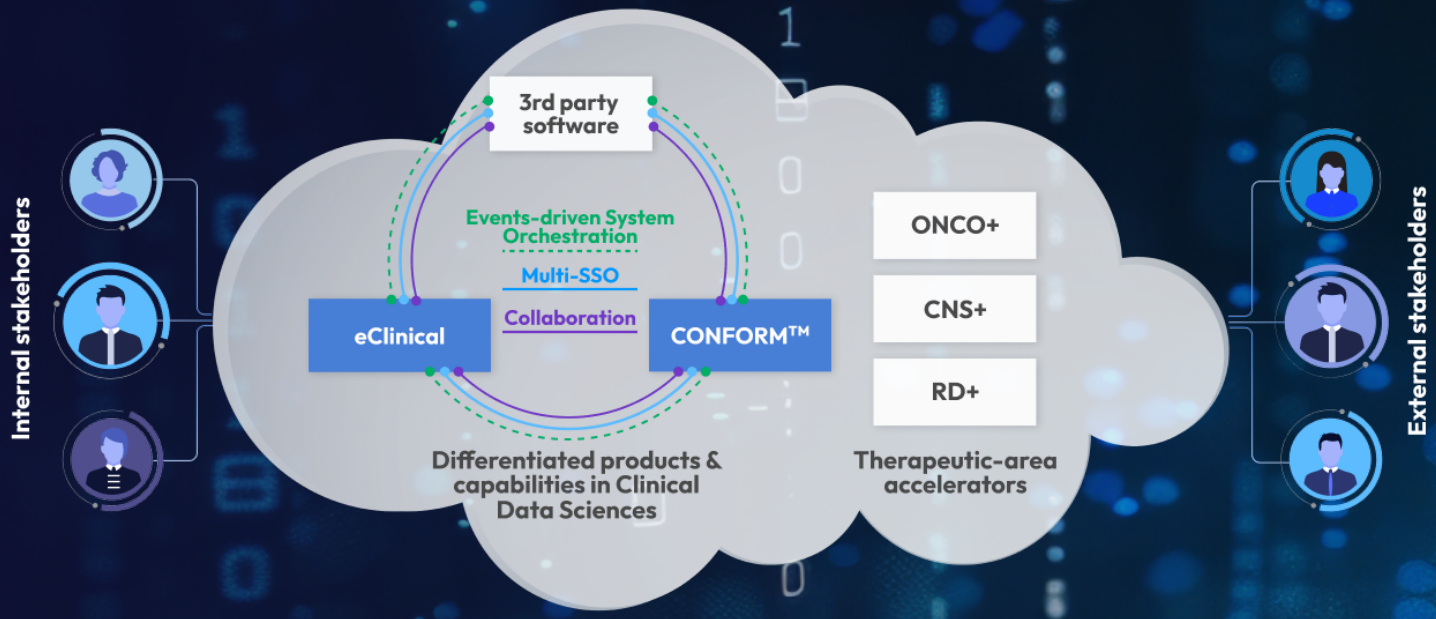
Build Your R&D Cloud

EDETEK's R&D Cloud accelerates clinical trials by integrating its CONFORM™ and eClinical platforms, along with select third-party software. This customizable ecosystem empowers Life Sciences companies with secure data integration, multi-SSO, and event-driven orchestration, fostering efficient collaboration among internal and external stakeholders.

Multi-SSO integration, collaboration, and workflow built on a state of the art cloud architecture brings together limitless capabilities and systems



Our R&D Cloud ecosystem is built for seamless integration and data flow in mind with four major design principles:

- Extensible library of ready-to-use and extensible connectors to over 80 systems such as third-party EDC, Central Labs, Safety, electronic patient reported outcomes, and clinical sources – this is facilitated through the Data Integration Gateway
- Data and human workflow in near real-time – through the Event and Collaboration Hub
- Public open API access that allows integration and extension of functionality with other software
- Semantic level standardization with the flexibility to customize data models and structures with no programming to suit specific organizational needs.

Benefits of the EDETEK R&D Cloud Ecosystem

Cost reduction

Incrementally layer our R&D Cloud without the need to rebuild or costly integrations

Business outcomes

Significantly improving the speed and efficiency of clinical trial execution. This means faster study startup, real-time data insights, and streamlined regulatory submissions.

Improved data quality and compliance

The platform's robust and reliable data integration with near real-time capabilities ensures high data quality and compliance with industry standards

EDETEK R&D Cloud Key Differentiators

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State of the art cloud architecture with scalability, security, reliability, speed of innovation, and compliance

Multi-SSO integration, collaboration, and workflow – to bring together different capabilities and systems

Breadth and depth of our capabilities including:

- Clinical Trial Design and Execution
- Data management & analytical needs
- Therapeutic area-specific accelerators

EDETEK R&D Cloud Key Differentiators

Single Sign-On Manager

Managing authentication shouldn't slow down innovation or increase risks. Our multi-SSO capability reduces friction, enabling uninterrupted access to critical systems. This technology allows collaborators to log in using their preferred systems while meeting the highest security standards.

Data Ingestion and Integration

This key capability in CONFORM™ brings all study data for further aggregation, processing, and analysis. CONFORM™ has an extensive library of ready-to-use connectors that facilitate accelerated study startup.

Data collection and Aggregation

CDL is a global, secure, and GxP-compliant information repository that stores all structured and unstructured clinical data and documents. It maintains a configurable clinical hierarchy and an information store searchable by content, attributes, metadata, and tags.

Study Analysis and Submission

CONFORM™ serves the needs of clinical programmers, biostatisticians and submission teams with a set of products designed to minimize code writing and validation, promote re-use of standards and ultimately improve the quality of regulatory submissions. It allows team members to focus on higher value activities such as data and document review, and interpretation of results.

Clinical Study Quality Management, Review and Analytics (Information Quality - IQ)

The Clinical Study Quality Management, Review and Analytics (IQ) redefines data management, medical review and quality management with an integrated platform that supports continuous data aggregation, data cleaning with advanced quality checks, scientific and operational data visualizations and monitoring and collaborative workflows.

The system continuously monitors study data, identifies and reports safety and efficacy signals and evaluates study and sites performance and compliance with the protocol. The Platform centralizes issue management automatically recording and managing issues and protocol deviations from internal and external clinical systems. Configurable workflows and timely notifications enable collaborative, role-driven resolutions and corrective actions.

Orchestration and Workflow

Orchestrate business and systems events within and outside of CONFORM™ to enable a comprehensive, integrated, and compliant clinical ecosystem.

Metadata Management

CONFORM™ metadata management consists of tools that provide enterprise-grade data governance, curation, and validation. Reusable libraries of data standards and business rules ensure accelerated trial setup, compliance with regulations, and reduced maintenance costs.

Statistical Computing and Reporting

Statistical Computing is a capability that enables the development and execution of statistical programs while offering direct integration with CONFORM™'s Clinical Data Lake (CDL) and all the Study, Analysis, and Submission tools with a comprehensive set of GxP controls.

Clinical Data Pipeline (CDP)

The Clinical Data Pipeline (CDP) is a powerful, integrated data processing engine designed to capture and process study data from any study data source, in any format or structure, transforming the data streams into consumable data models based on industry, company or TA standards, and populating the Unified Data Repository (UDR). Through advanced data validation, transformation, and aggregation processes governed by study business rules, CDP ensures data timeliness, consistency and reliability.

eClinical Suite of Applications

The eClinical Suite of applications is a comprehensive universal portal consisting of:

- Clinical Trial Management System (CTMS)
- Electronic Data Capture (EDC)
- Interactive Web Response System (IWRS)
- Trial Supply Management (TSM)
- ePayments
- Electronic Trial Master File (eTMF)

eClinical provides a complete solution for study design and conduct, data collection, safety monitoring, clinical data and documentation management, and much more!

Visit us at **https://edetek.com/edetek-rd-cloud/** to learn more