



EDC

Calyx Electronic Data Capture

CALYX™

Proven. Flexible. Easy.

Since 2002, Calyx EDC has helped global biopharmaceutical sponsors, clinical research organizations (CROs) and medical device manufacturers realize the true potential of EDC technology. Calyx EDC is synonymous with exceptional usability and rich functionality, underpinned by renowned performance, scalability, and resilience.

Uniquely focused on simplifying workflows and delivering superior user experiences, Calyx's advanced EDC features streamline the entire process starting from study design all the way to collection, management, and reporting of clinical trial data.

Delivered through the cloud and backed by the full power of our leading eClinical portfolio, Calyx EDC offers total flexibility and ease-of-use for researchers of all types and sizes.

KEY FEATURES

- Targeted Source Data Verification (SDV) focuses resources where they are most needed
- Study design comparison eliminates manual comparisons and reduces validation time required to review design changes
- Robust safety reporting provides real-time notification of critical safety events that are time-sensitive for processing

KEY BENEFITS

- Leverage Targeted SDV to reduce on-site monitoring activities and the associated costs
- Make data-driven decisions to focus site monitoring priorities
- Simple user interface enables ease of use and rapid study build
- Improve patient safety and data quality
- API web services with event-driven architecture allow you to integrate with a variety of systems or devices
- Patient profiles available on demand to facilitate cohort or safety review
- Normalized local lab values standardize results for analysis
- Identify efficiencies in study design (comparison tool)
- Increase data availability and visibility (APIs)
- Accelerate data review (patient profiles, labs)

Study Design

Effectively transforming a protocol into a comprehensive set of eCRFs is critical for EDC deployment. The Calyx design tool is an innovative study build application that provides study teams with the tools necessary to build an electronic study, all in a truly collaborative environment. Together with the expertise of our professional services group, the Calyx design tool ensures efficient and optimal study build processes.

HIGHLIGHTS

Intuitive, web-based design tool

- Simple drag-and-drop features to configure CRFs, coding dictionaries, code lists, derivations, and built-in edit checks
- Centralized repository of study design objects and metadata
- Import previous study designs using XML
- Create form libraries by reusing components from existing studies
- Visual comparison of study design changes between studies
- No advanced programming skills required. Point and click conditional fields configuration



Data Collection

Calyx EDC is designed to provide the best user experiences possible with the core features you expect, delivered in an easy-to-use interface. Built with utmost usability in mind for collection of study data, the easy-to-navigate interface and

workflow-driven display of permissible actions facilitate highly streamlined user workflows for site activities. Renowned for its ease of use, Calyx EDC's user interface empowers investigative sites to effectively utilize EDC with a minimal learning curve.

HIGHLIGHTS

Intuitive, web-enabled interface

- Built-in edit checks to ensure complete and valid entries
- Clear visibility of unscheduled visits in proper sequential order
- Robust eLearning features for site training and certification

Role- and workflow-based views and displays

- Action palette facilitating efficient user workflows
- Display of only applicable visits for individual patients

Integrate data from central labs, imaging, ePRO and other third-party systems

- Robust APIs provide complete visibility and audit trails of integrated data
- Eliminate data discrepancies, minimizing queries and reconciliations
- Store all data within a single system, eliminating the need to merge multiple databases



Study Management

Managing today's clinical trials is a complex and challenging task, involving many different people, processes, and systems. Study teams need to respond to rapidly changing situations and make timely, informed decisions throughout. Calyx EDC has a proven track record of helping organizations optimize valuable resources, gain efficiencies, and ensure quality data.

HIGHLIGHTS

Advanced suite of data management capabilities

- Extensive search and filter options using multi-criteria selections
- Flexible CRF flag options for full range of review types
- Customized event-driven notifications and alerts for collaboration across multiple users

Dynamic generation of forms and visits enable collection of targeted and relevant data

- Ability to tailor and generate specific CRFs for each individual patient
- Optimal, intuitive data entry experiences for site users

Comprehensive reporting capabilities

- Dashboard with visual displays of EDC metrics to aid strategic decision making
- Full range of standard reports and flexible ad-hoc reporting
- Drag and drop interface without the need for advanced programming

Advanced data export capabilities accelerate analysis and decision making

- Ad hoc access and review of data
- Export in SAS transport and ASCII Delimited files, available on-demand or at scheduled intervals
- Clear visibility of unscheduled visits in proper sequential order in exported data



Powered by Leading Technology Infrastructure

Calyx EDC is built to provide ultimate performance, quality, and availability through intelligent architecture and best-practice capacity provisions. The federated architecture of Calyx EDC and the resulting scalability enable us to support studies of all sizes, including extremely large-scale clinical trials.



Calyx EDC professional services

- In-depth study design and consulting services
- Development of flexible, customized training curriculum tailored to individual customer requirements
- In-person and virtual training programs
- Built-in, self-directed eLearning
- Consulting, guidance, and support to achieve alignment with client objectives

Customer care services

- Supports all leading eClinical technologies
- Quick turnaround times
- Proactive high-quality support
- Services tailored to client requirements
- 250+ local languages
- Single point of contact 24/7/365

Learn how Calyx EDC can help your trial succeed.

CALYX™

Reliably solving the complex.



calyx.ai

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