

ELECTRONIC DATA CAPTURE

Proven. Flexible. Easy.

KEY FEATURES

- Electronic data capture and paper data management in one powerful system
- 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 monitoring 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

Part of the Perceptive MyTrials[®] framework, enabling integration with clinical trial software applications to help users plan, design and conduct clinical trial programs in a single place.

Since 2002, the DataLabs[®] EDC solution has been helping many biopharmaceutical sponsors, clinical research organizations (CROs) and medical device manufacturers realize the true potential of the EDC technology. DataLabs[®] EDC is synonymous with exceptional usability and rich functionality, underpinned by the renowned performance, scalability and resilience inherent in the Perceptive MyTrials[®] platform. Uniquely focused on simplifying workflows and delivering superior user experiences, the DataLabs solution's advanced EDC features help 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, the DataLabs EDC solution means total flexibility and ease-of-use for customers of all types and sizes.

Study Design

Effectively transforming a protocol into a comprehensive set of eCRFs is critical for EDC deployment. The DataLabs[®] Designer 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 DataLabs Designer tool ensures efficient and optimal study build processes.

HIGHLIGHTS

Intuitive web-based DataLabs Designer 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
- Reuse components from existing studies

DATALABS EDC

DATALABS EDC PROFESSIONAL SERVICES

- In-depth study design and consulting services
- Development of flexible, customized training curriculum tailored to individual customer requirements
- In-person 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
- Single point of contact 24/7/365

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Data Collection

The DataLabs EDC solution is designed to provide the best user experiences possible through cutting-edge features delivered by an exceptionally intuitive 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, the DataLabs EDC solution'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 based on specific patient statuses

True hybrid capability to support PDE and EDC

- Collect EDC and paper data in a single data management system
- Data capture method can switch at any point during the study
- Convenient CRF tracking/reporting tools and printable DCFs
- Review real-time dispensation activities within the EDC system

Collect and integrate data from central lab, medical imaging, ePRO and other third-party systems

- Robust middleware providing 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 database

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.

The DataLabs EDC solution has a proven track record of helping client 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 to 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
- Full range of standard and customized reports

Advanced data export capabilities to 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

The DataLabs EDC solution has been built to provide ultimate performance, quality and availability through intelligent architecture and best-practice capacity provisions. Our hosting services are backed by the full security and resilience of the Perceptive MyTrials platform and its state-of-the-art facilities. The federated architecture of the DataLabs EDC solution and the resulting scalability enable us to support studies of all sizes, including extremely large-scale clinical trials.

To learn more about how our solutions can help you, please contact us at info@PAREXEL.com.

