

**DATALABS<sup>®</sup> EDC**

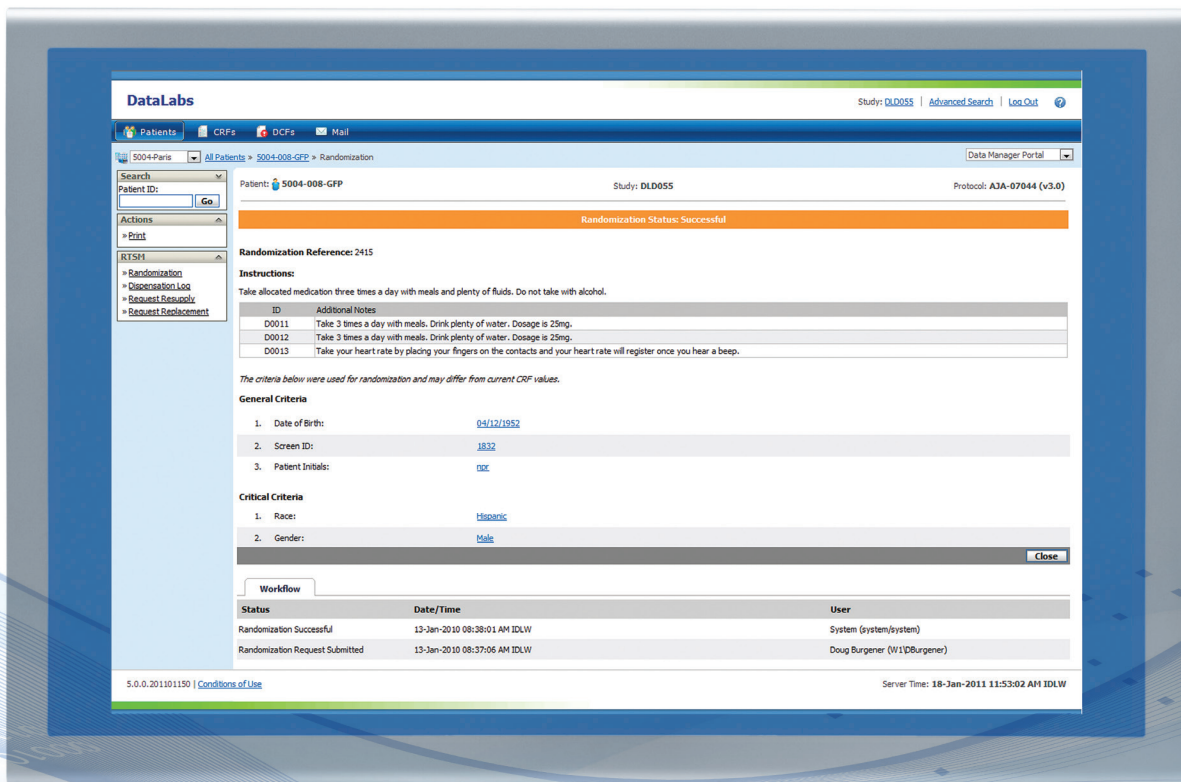
*REVOLUTIONIZING  
CLINICAL DATA  
MANAGEMENT*





**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. Available as an on-demand, software-as-a-service (SaaS) application with subscription-based pricing, 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.

# PROVEN. FLEXIBLE. EASY.



# 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.

## Innovative Web-Enabled Designer

The DataLabs® Designer tool enables users, without programming background or expertise, to easily build EDC studies through an intuitive interface. Users can create new studies by choosing components from their centralized repository of study design objects, including options to reuse pre-validated forms and components from previous or existing studies. Entirely web-enabled and accessible from anywhere in the world, the DataLabs Designer tool promotes true collaborative authoring and facilitates rapid study design, accelerating overall trial start-up timelines. A hosted solution with no software installation necessary, our approach eliminates the IT administration burden on customers. Against the backdrop of ever-growing design complexities and widely dispersed locations of study teams, the DataLabs Designer tool enables efficient and quality-assured study build processes.

## Professional Services Expertise

For customers looking for guidance on effective and practical study design, our Professional Services team provides in-depth consulting and design services. Through a flexible combination of training, consulting and professional services, we can support the full range of customer requirements. Whether you need us to build your study in its entirety or simply require targeted training on the use of the Designer tool, our Professional Services experts will guide you every step of the way.

To help clients successfully ramp up and realize the full power of EDC, our seasoned experts provide consulting founded on the extensive knowledge of EDC best practices. We offer customized training curricula tailored to individual customer requirements, combining in-person, instructor-led programs with sophisticated eLearning capabilities.

The DataLabs EDC Professional Services team consists of experienced consultants who possess not only EDC expertise, but also a deep understanding of the clinical development process. Our consultative approach and rigorous methodology help ensure that the DataLabs EDC system is implemented in a way that best supports the customer's organizational objectives.



**DataLabs® Designer** Welcome, Amy Zimmerman | [Log Out](#) ?

Home [Administration](#)

**Actions**

- [Create New Study](#)
- [Create Study from Existing](#)
- [Import Study](#)

**Studies** [Show/Hide Filter](#) [Refresh](#)

Client/Sponsor	Study Name	Study Label	Protocol	Therapeutic Area	Study Drug Name	Last Active
Client C	M3	M3	Protocol825K	Women's Health		20-Jan-2011 08:45:02 AM UTC
Client B	E110	E110	Protocol84BC	Infectious Disease		12-Jan-2011 04:06:38 PM UTC
Client B	E101	E101	ProtocolNY21234	Infectious Disease		15-Jan-2011 11:19:21 AM UTC
Client C	PA1956	PA1956	Protocol835I	Pain Management		05-Jan-2011 05:55:40 PM UTC
Client C	EE19000	EE19000	ProtocolYYY	Orthopedics		17-Dec-2010 09:27:33 AM UTC
Client A	20Y1123	20Y1123	Protocol 200-1234	Neurology	Compound851	03-Dec-2010 10:18:09 AM UTC
Client A	M2567	M2567	Protocol MM-1239	Oncology	Compound700	08-Nov-2010 12:36:17 PM UTC
Client A	PAVE	PAVE	Protocol PV-123	Neurology	Compound850	29-Sep-2010 02:15:56 PM UTC
Client A	<a href="#">ClientA Library</a>	<a href="#">ClientA Library</a>	ClientALibrary	OTHER	Library	20-Sep-2010 07:49:02 AM UTC
Client B	<a href="#">ClientB Library</a>	<a href="#">ClientB Library</a>	ClientBLibrary	OTHER	Library	11-Jun-2010 11:43:25 AM UTC

Page size: 10 18 items in 2 pages

5.0.0.201005270 | [Conditions of Use](#) 20-Jan-2011 09:43:25 PM UTC

The DataLabs Designer landing page provides options to create new or import existing studies and displays all current studies with filter selections for each column.

## Features & Benefits

### 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
- Promotes CDISC standards for eCRF design, enhancing compliance with organization-wide standards
- Rapid, accelerated study design utilizing pre-validated study components
- Global and collaborative study development through web-enabled access

### 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

# 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.

## Powerful Hybrid Capability – Single System for Both PDE and EDC

As one of the industry pioneers, we provide a single electronic clinical data management platform to unify the functionality of paper data entry (PDE) with the flexibility of EDC. This unique hybrid capability means sponsors can conduct entirely paper-based studies using the DataLabs solution. For EDC studies, sponsors can include sites using paper CRFs and support existing paper processes such as tracking CRFs and printing customized paper DCFs (Data Clarification Forms). The PDE interface includes "heads down" data entry features with conflict resolution tools and "hot key" configuration to minimize the need for a mouse. Collecting extraneous paper data such as lab normals and patient diaries through the PDE interface and natively storing with the EDC data eliminates the need for multiple databases. Sponsors have total freedom to choose their preferred method of data collection while benefiting from a single, unified system with fully integrated data. Why not enjoy the best of both worlds?

## EDC-RTSM Convergence

To optimize usability and simplify workflows, the DataLabs EDC solution provides tight interoperability with the ClinPhone® RTSM (Randomization and Trial Supply Management) solutions. It allows site users to perform real-time randomization and dispensation activities directly within the EDC application, without having to log into IVR or IWR systems. Powered by the cutting-edge integration platform and enhancements to the underlying EDC application, this functionality represents unique product convergence, making functionality of one application wholly available through another interface. Blurring the traditional boundaries between discrete applications that interrupt efficient user workflows, DataLabs EDC is bringing about a radical shift in the way technologies can be used together in clinical trials.

## The Bigger Picture – Part of our Leading eClinical Suite

Convergence between the DataLabs EDC and ClinPhone RTSM solutions is part of the Perceptive MyTrials® integrated eClinical Suite, which works together to accelerate your workflows and business processes. Our integrated Suite is powered by the cutting-edge eClinical platform, which facilitates seamless, automated exchange of data across our products as well as with third-party and customers' proprietary systems. Leveraging the built-in flexibility of our eClinical platform and robust web services, the openness of the DataLabs EDC system is consistently praised for making data interchange with other systems, such as central labs, ECG and medical imaging, extremely easy and hassle-free. This provides early visibility of holistic study data, allowing immediate reconciliations and expediting interim analyses. Backed by the full power of our eClinical Suite, the DataLabs EDC solution helps clients maximize the true value of integrated trial technologies.

Event	Date	CRFs	DCFs	Signed	Frozen	Locked
Screening	05-Jan-2010	✓	✓	✓	✗	✗
Visit 1	11-Jan-2010	✓	✓	✗	✗	✗
Visit 2	25-Jan-2010	✓	✓	✗	✗	✗
Unscheduled Visit 2.1	02-Feb-2010	✗	✓	✗	✗	✗
		12-LEAD ECG	✓	✗	✗	✗
		Central Laboratory Tests	✓	✗	✗	✗
		Physical Examination	✓	✗	✗	✗
		Vital Signs	✓	✗	✗	✗
Visit 3	08-Feb-2010	✓	✓	✗	✗	✗
Visit 4	22-Feb-2010	✓	✓	✗	✗	✗
Visit 5	08-Mar-2010	✗	✓	✗	✗	✗
Common	--	✗	✓	✗	✗	✗

Status	Date/Time	User
Enrolled	11-Jan-2010 03:47:17 PM IDLW	Doug Burgener (W11DBurgener)
Screened	05-Jan-2010 11:22:30 AM IDLW	Doug Burgener (W11DBurgener)

Patient visits can be expanded to view the workflow details for each CRF, and options in the action palette adjust depending on the status of the patient.

## Features & Benefits

### 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
- “Heads down” double data entry features
- Convenient CRF tracking/reporting tools and printable DCFs

### Access ClinPhone RTSM functionality directly from EDC

- Randomize patients using functionality built into eCRF
- Dispense medication packs directly from within the EDC system
- 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 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. The DataLabs EDC solution has a proven track record of helping client organizations optimize valuable resources, gain efficiencies and ensure quality data. Helping study teams do their jobs more effectively, DataLabs EDC makes finding, managing and analyzing data quick and easy.

## **Streamlining the Entire Workflow – Effective Review, Cleaning and Management of EDC Data**

The DataLabs EDC application helps streamline and accelerate the entire study management process. The sophisticated search function allows study teams to search for patients, CRFs or DCFs across all sites using flexible, multi-criteria selections. With the enhanced ability to find targeted information, study personnel can easily identify areas requiring further action and proactively monitor study progress. The ability to “flag” CRFs with discrete review statuses means users can track what they have done to date, and swiftly isolate and prioritize pending activities. It includes review statuses such as source document verified, data management reviewed and medical monitor reviewed, as well as additional flag statuses to indicate if data have changed after a review has been completed.

Through the robust messaging facility complete with convenient hyperlinks, users can send an eCRF to be reviewed by another user. Furthermore, investigators

are able to sign individual forms, visits or an entire casebook in a single, consolidated location upon request by data managers. These advanced features tightly control and simplify workflows for the review, cleaning and management of study data across the full spectrum of user groups including investigators, CRAs, data managers and medical monitors.

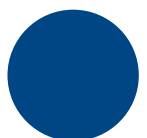
## **Powerful Reporting Engine**

Today's clinical trials require the ability to effectively utilize data to derive insights and make informed decisions. Our solution offers powerful reporting functionalities to help answer key questions through intelligent analysis and presentation of the EDC data. Through the comprehensive range of standard reports, users can monitor study progress including query management and CRF completion statuses, while the ad hoc reporting capability allows users to create customized reports for impromptu informational needs. The dashboard presents real-time, targeted EDC metrics in intuitive, graphical display formats

to aid strategic decision making by study leaders, senior management and others. Our reporting delivers highly interactive features, enabling users to drill into and interrogate data as well as download data in a variety of formats for further analysis.

## **Flexible and Convenient Data Export**

Exporting data from the DataLabs EDC solution is a simple and hassle-free process. At any time, customers can use the self-service functionality to extract data in an ODM format, available for immediate, ad hoc review and analysis. We also provide data exports in a variety of formats including SAS transport and ASCII Delimited files, allowing analysis by third-party reporting tools. These exports are entirely flexible and can be available on-demand or at specified schedules. The flexible and convenient export facilities mean customers can perform desired analyses at any time.





Patient ID	Status	Last Event	DCFs	SD-Verify	M-Review	D-Review	Signed	Frozen	Locked
5005-001-LTL	Completed	Visit 5	✓	✓	✓	✓	✓	✓	✓
5005-002-VBI	Completed	Visit 5	✓	✓	✓	✓	✓	✓	✓
5005-003-JHI	Completed	Visit 5	✓	✓	✓	✓	✓	✓	✓
5005-004-LUN	Enrolled	Visit 5	✓	✓	✓	✓	✓	✓	✓
5005-005-CBA	Enrolled	Visit 4	✓	✓	✓	✓	✓	✓	✓
5005-006-OLU	Discontinued	Visit 2	✓	✓	✓	✓	✓	✓	✓
5005-007-VBL	Enrolled	Visit 4	✗	✓	✓	✓	✗	✗	✗
5005-008-FCU	Enrolled	Visit 4	✗	✓	✓	✓	✗	✗	✗
5005-009-NGE	Discontinued	Visit 3	✗	✓	✓	✓	✓	✓	✗
5005-010-NVA	Enrolled	Visit 4	✗	✗	✗	✓	✗	✗	✗
5005-011-OEA	Enrolled	Visit 3	✓	✗	✗	✗	✗	✗	✗
5005-012-HCT	Enrolled	Visit 2	✓	✗	✗	✗	✗	✗	✗
5005-013-TNQ	Enrolled	Visit 1	✗	✗	✗	✗	✗	✗	✗
5005-014-TRC	Screened	Screening	✗	✓	✗	✗	✗	✗	✗
5005-015-OU8	Screened	Screening	✓	✓	✗	✗	✗	✗	✗

Data managers and medical monitors can flag CRFs as reviewed and track the progress of the data cleaning process through a high-level roll-up at the patient level.

## Features & Benefits

### 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
- Built-in routing and messaging capabilities to send a CRF to another user
- Full query management and dictionary coding features

### 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
- Flexible ad hoc reporting for creating customized reports

### Advanced data export capabilities to accelerate analysis and decision making

- Export in ODM format for immediate, 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. The robust infrastructure with built-in flexibility also means we can offer the application through a SaaS (software-as-a-service) model where customers benefit from rapid and efficient deployment of our leading EDC solution without high upfront costs, system investment or ongoing maintenance issues.

## Customer Support

The DataLabs customer support team is available 24/7/365 to address any inquiries that customers or users may have. Known for exceptional customer focus and can-do attitude, our support team consists of trained specialists who can directly troubleshoot and resolve customer issues.

PAREXEL is a leading eClinical solutions provider that helps customers accelerate the drug development process through innovation. Uniquely combining cutting-edge technologies with proven clinical research know-how, we enable biopharmaceutical clients to successfully drive their development programs. The comprehensive eClinical portfolio from PAREXEL includes Electronic Data Capture (EDC), Randomization and Trial Supply Management (RTSM), Clinical Trial Management Systems (CTMS), Medical Imaging and Electronic Patient-Reported Outcomes (ePRO).

Synonymous with robust infrastructure, global footprint and proven expertise, we are the industry's trusted name for the provision of technology solutions to simplify workflows and improve trial efficiency. At the forefront of research and innovation, we are committed to developing and investing in our leading solutions to ensure they continue to meet evolving customer requirements.

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PERCEPTIVE  
**MyTrials**<sup>®</sup>



A PAREXEL<sup>®</sup> eClinical Platform

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