PERCEPTIVE MyTrials®

Perceptive MyTrials®

Product Overview

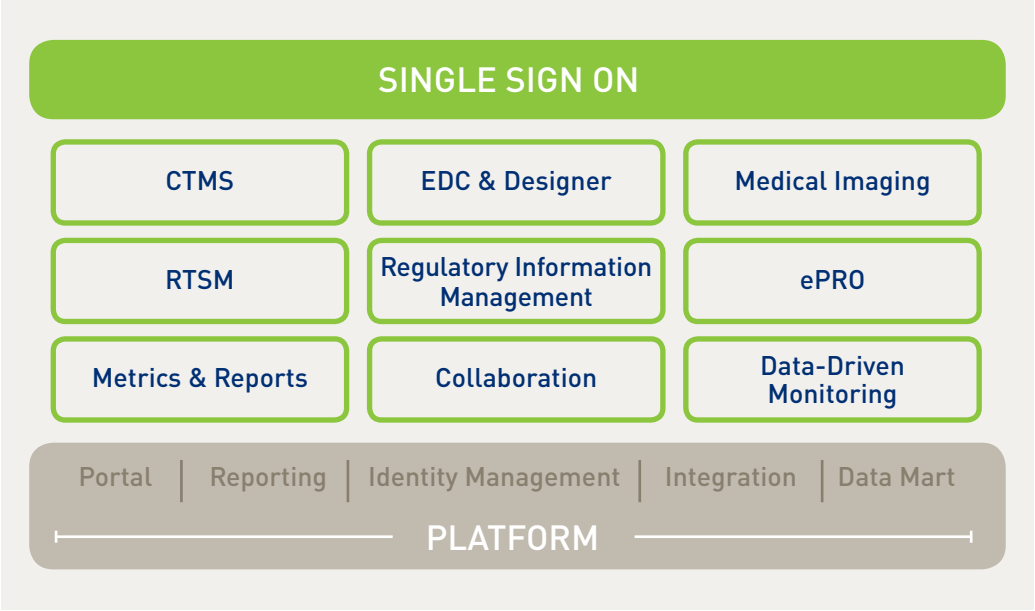
PAREXEL®

YOUR JOURNEY. OUR MISSION.™

Perceptive MyTrials®

Product Overview

The suite is greater than the sum of its parts.



At PAREXEL, we are driven by the need to make life easier for those conducting clinical trials.

Product suite, platform and design environment

Technology has always promised to accelerate the way we design, provision and conduct clinical trials. However, increased adoption of individual technology applications has brought additional challenges. While individual solutions have accelerated parts of the process, when technologies are used in combination this can disrupt efficient workflow and processes for users.

Perceptive MyTrials® provides an application framework through which we are able to converge our integrated suite of clinical trial software applications, enhancing the way our users work with our product suite.

The Perceptive MyTrials framework enables single sign on across our suite of hosted software-as-a-service (SaaS) applications. Through Perceptive MyTrials, multiple technologies, trials and programs can be accessed by a single set of credentials, providing users with efficient workflow and task continuity when using multiple applications within our product suite. Importantly, single sign on ensures strong security without the burden of remembering multiple user names and passwords.

The combination of our products yields increased value and utility because we have continually invested in each product and our platform and infrastructure with a view to delivering a more seamless user experience.

Perceptive MyTrials®

Product Overview

Access all your trial applications, data and information with a single sign on.

Our Perceptive MyTrials environment provides a framework through which PAREXEL provides access to our hosted suite of integrated applications, data and information associated with all our trials and programs including:

- ***DataLabs® EDC*** for effective data collection and management
- ***Serious Adverse Event Case Collection*** using DataLabs EDC
- ***DataLabs Designer™*** for collaborative EDC design to create studies and libraries to design and run trials on our SaaS infrastructure
- ***ClinPhone® RTSM*** for centralized randomization, drug accountability and trial supply management
- ***IMPACT® CTMS*** for all aspects of trial management including study planning and tracking, payments and budget management, monitoring visit management and reporting
- ***Medical Imaging*** for review, analysis, management and reporting of medical images
- ***ePRO*** for collection of patient-reported outcomes and clinical assessments using IVR and web
- ***RIM (Regulatory Information Management)*** enables regulatory agency submission planning, viewing, tracking, publishing and registration management
- ***Data-Driven Monitoring*** shifts the burden of site monitoring from a people-centric approach to a model that leverages the power of technology to measure and assess risk and outstanding workload
- ***Collaboration*** for document management, study news and announcements, discussion forums, study calendar, training and learning
- ***Metrics and reporting*** for consolidated industry-standard trial performance metrics and detailed reports of trial data

Each of these applications is a proven leader in its own right and their combination creates a powerful environment for effective management and operation of even the most complex clinical trials. The cutting-edge sophistication of our integration platform allows ready connectivity between the solutions. This platform, in addition to the way we continue to modify our applications, enables our suite to operate more cohesively through product convergence.

Our innovative eClinical suite helps biopharmaceutical companies and CROs maximize their technology investments by simplifying workflows and making it easy to deploy multiple technologies within a single study or program of trials. All this is enabled by our powerful technology platform and hosting infrastructure.

Access all your trial applications, data and information with a single sign on.

Perceptive MyTrials is a single sign on environment hosted by PAREXEL. With a single set of Perceptive MyTrials credentials, our users can access multiple studies and clinical programs as well as multiple applications within each study. No longer will site and sponsor users need to remember multiple sets of credentials for the many trials and technologies they use. In addition to enhanced security, this provides real task continuity for users moving between applications to complete their workflow. The end result is a superb user experience and a simplified environment that looks and feels like a single, unified application.

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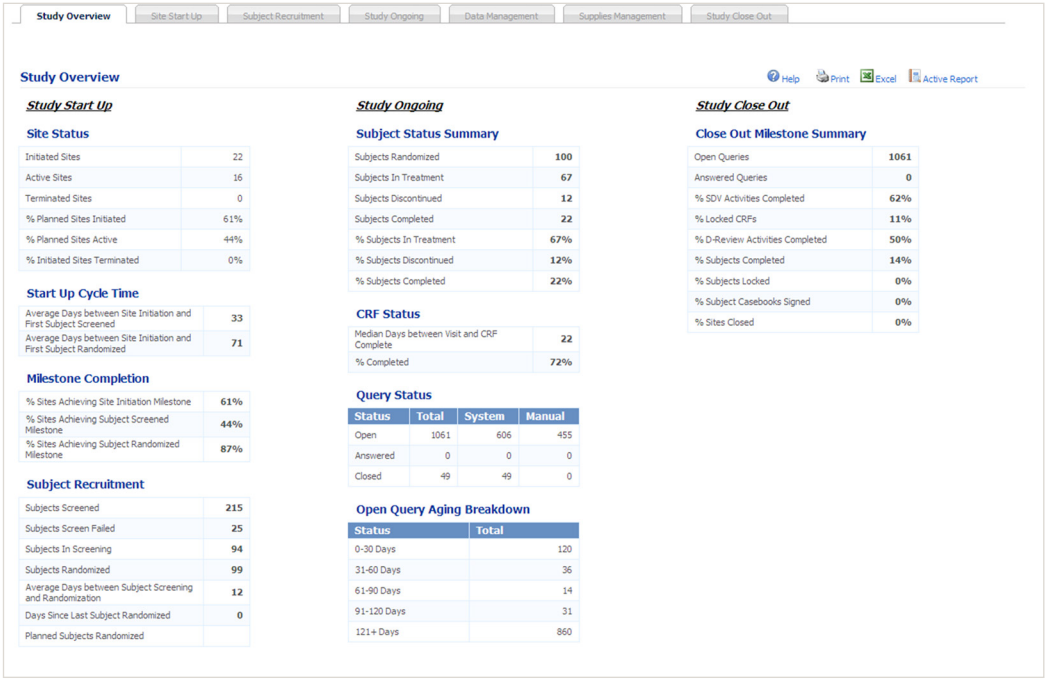
See the full picture with industry-standard metrics.



Study Overview | Site Start Up | Subject Recruitment | Study Ongoing | Data Management | Supplies Management | Study Close Out

Study Overview

Help | Print | Excel | Active Report

Study Start Up

Site Status

Initiated Sites	22
Active Sites	16
Terminated Sites	0
% Planned Sites Initiated	61%
% Planned Sites Active	44%
% Initiated Sites Terminated	0%

Start Up Cycle Time

Average Days between Site Initiation and First Subject Screened	33
Average Days between Site Initiation and First Subject Randomized	71

Milestone Completion

% Sites Achieving Site Initiation Milestone	61%
% Sites Achieving Subject Screened Milestone	44%
% Sites Achieving Subject Randomized Milestone	87%

Subject Recruitment

Subjects Screened	215
Subjects Screen Failed	25
Subjects In Screening	94
Subjects Randomized	99
Average Days between Subject Screening and Randomization	12
Days Since Last Subject Randomized	0
Planned Subjects Randomized	

Study Ongoing

Subject Status Summary

Subjects Randomized	100
Subjects In Treatment	67
Subjects Discontinued	12
Subjects Completed	22
% Subjects In Treatment	67%
% Subjects Discontinued	12%
% Subjects Completed	22%

CRF Status

Median Days between Visit and CRF Complete	22
% Completed	72%

Query Status

Status	Total	System	Manual
Open	1061	606	455
Answered	0	0	0
Closed	49	49	0

Open Query Aging Breakdown

Status	Total
0-30 Days	120
31-60 Days	36
61-90 Days	14
91-120 Days	31
121+ Days	860

Study Close Out

Close Out Milestone Summary

Open Queries	1061
Answered Queries	0
% SDV Activities Completed	62%
% Locked CRFs	11%
% D-Review Activities Completed	50%
% Subjects Completed	14%
% Subjects Locked	0%
% Subject Casebooks Signed	0%
% Sites Closed	0%

This powerful enterprise-level reporting helps answer key questions about the performance of your studies.

Study metrics overview page

See the full picture with industry-standard metrics.

Planning and managing a clinical trial involves many different people, processes and systems, making it difficult to see the full picture. Study personnel and management teams need to retrieve and combine data from multiple sources to answer key questions about their studies.

Perceptive MyTrials metrics reports present consolidated performance metrics, giving a consistent "single view" of the health and progress of trials and programs using data derived from our suite of hosted trial technologies. Standard data integrations ensure up-to-date information within our metrics database, and standard reports ensure rapid implementation of comprehensive performance metrics based on industry best practice.

This powerful enterprise-level reporting helps answer key questions about the performance of your studies including recruitment progress, country and site activation progress, data management activities and clinical supply chain health status.

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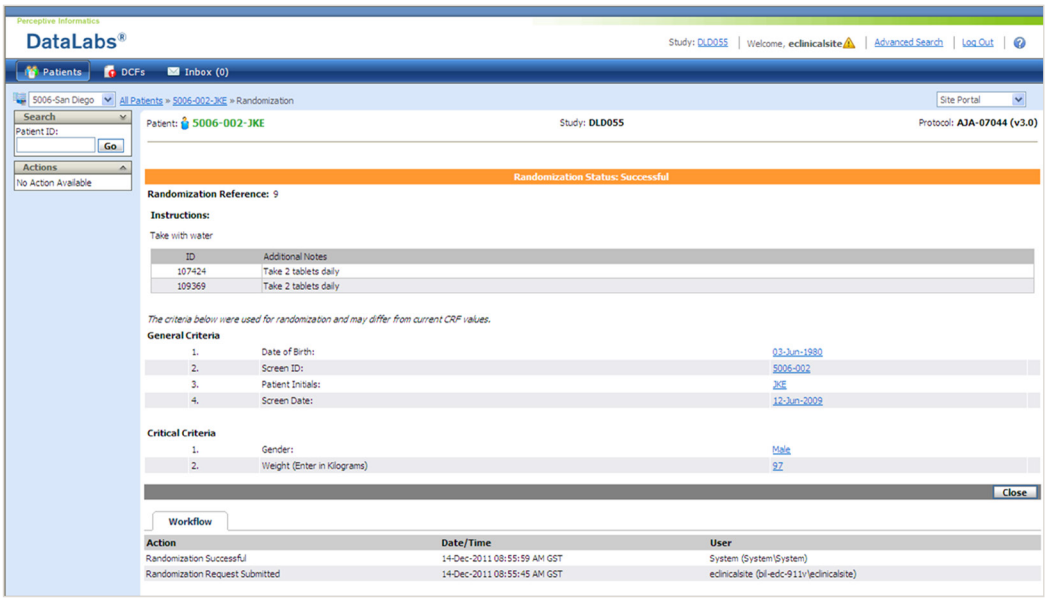
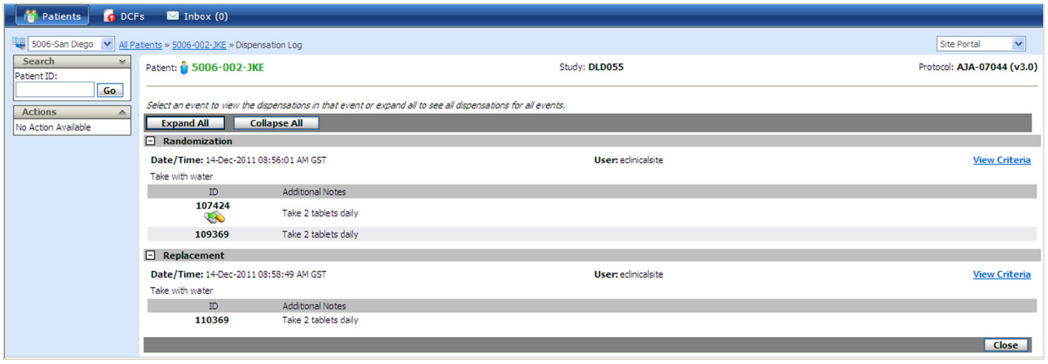
Product Overview

Optimize user experience with our EDC-RTSM convergence.





The features of the EDC-RTSM convergence include:

- Access to randomization and dispensation activities directly from DataLabs EDC
  - Use the most convenient interface — either pick up the phone (IVR) or use the web (EDC)
  - Randomize patients using functionality built into the eCRF without needing to access the RTSM application independently
  - Dispense and replace medication packs direct from within the EDC system
- Automatic data population from IVR ePRO into the eCRFs

DataLabs Randomization Page and Dispensing Log

Our eClinical Suite is blurring the boundaries between EDC and RTSM solutions. The EDC-RTSM convergence brings about a radical shift in the way technology applications can be used together in clinical trials. It enables convergence between DataLabs EDC and ClinPhone RTSM applications, resulting in significantly simplified workflows for sponsor and site users when utilizing both solutions.

Bringing together these two key solutions in clinical trial management and operation is a radical step forward in simplifying workflow and increasing utility for our site and sponsor users. It enables our customers to utilize the full functionality of our two leading solutions, but in a way that makes their combined use simpler.

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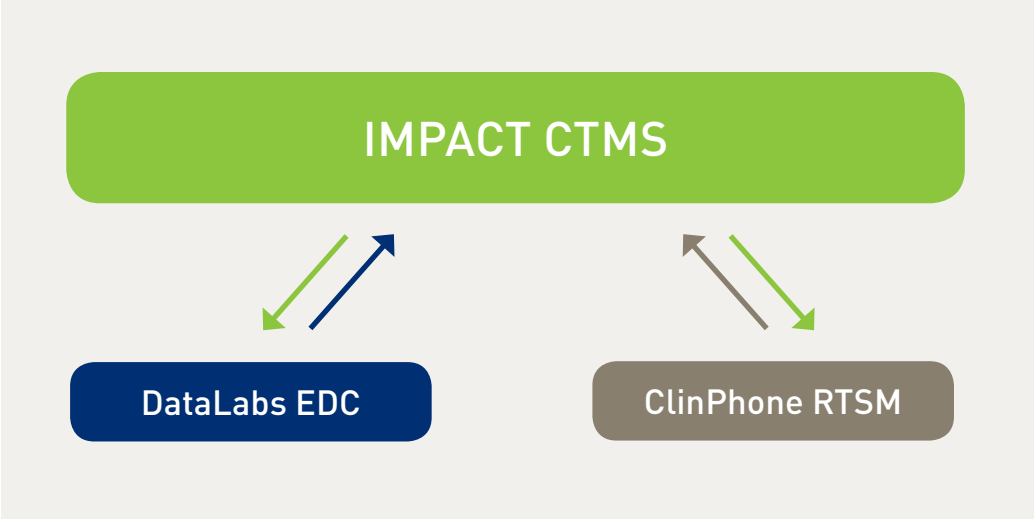
Leverage the value of data integration with IMPACT.



IMPACT data integration model

Our Perceptive MyTrials integration platform enables powerful integrations with our hosted IMPACT CTMS.

Our Perceptive MyTrials platform enables powerful integrations with our hosted IMPACT CTMS. The automated exchange of key study management information helps ensure your CTMS provides a complete up-to-date picture of study progress to keep your clinical operations personnel and senior management fully informed and equipped to make fact-based decisions.

Our solid architecture and in-house integration experts ensure that we are able not only to apply integrations with our own suite applications, but also develop integrations with sponsor on-premise systems and with other leading third-party technology applications.

Ensure your study community is up to date and informed.

When planning and managing a clinical trial, it can be challenging to ensure that everyone involved in the trial has all of the appropriate information and latest documentation to perform their activities and make timely decisions.

The Perceptive MyTrials Collaboration Toolbox provides trial communities with a secure, central place to access all of the necessary study information, documentation and training resources. Sponsors are able to collaborate and manage the creation of new study documents, publish study news and announcements and manage the trial calendar of key events and appointments. Site users are able to access up-to-date versions of all approved study documentation and training information and resources. Perceptive MyTrials provides a comprehensive resource for the entire study community making it a single place to go to access all data, information and applications for all your clinical trials.

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Perceptive MyTrials platform and framework

Our converged suite of SaaS applications is underpinned by a powerful platform of enabling technologies and framework standards, ensuring the combination of products and components interoperate seamlessly and cohesively. Our platform technologies include:

- **Clinical Technologies Integration Platform (CTIP)**, delivered using industry-standard integration and Extract Transform Load (ETL) software. Our set of standard integration services ensures easy integration across our product suite, and our ability to integrate effectively with external and third party applications.
- **Enterprise portal software** to provide the framework through which to surface our applications, data and information
- **Enterprise reporting application** to provide high-quality and feature-rich reporting solutions for all performance metrics reports and detailed application data reporting
- **Identity management software** governing the identity and access of all our users for all our hosted applications, and enabling our single sign on capability

Perceptive MyTrials provides access to business-critical applications, such as randomization and code break. As a result, our infrastructure and support models are designed to provide robust and resilient access to all of our critical systems. Using Perceptive MyTrials provides customers the ability to leverage the full power of our enabling platform. SaaS customers benefit from our ability to simply consolidate and report performance data from across our hosted product suite. They also benefit from the ability to leverage the full features of our enterprise reporting solution and our Clinical Technologies Integration Platform without investing in these platform components themselves.

Flexible models

Use Perceptive MyTrials to leverage our integrated product suite for a single study or a program of trials. Studies can utilize one or all of our suite components in a flexible, modular approach. It is also possible to use Perceptive MyTrials in combination with our CRO services as required.

Perceptive MyTrials is a framework that we use to deliver our technology services, but also an infrastructure that our clients can access to design their own clinical trials. Because our framework is extendable, some companies have selected Perceptive MyTrials to play a critical role in delivering their corporate eClinical strategy. Speak to us about gaining full access to our systems to enable your staff to design, provision and run their own clinical trials without significant in-house infrastructure investment.

SaaS customers benefit from our ability to simply consolidate and report performance data from across our hosted product suite.

PERCEPTIVE MyTrials®

A PAREXEL® eClinical Platform

For more information contact:

info@PAREXEL.com
PAREXEL.com/mytrials

Corporate Headquarters

195 West Street
Waltham, MA 02451
USA
+1 781 487 9900

Offices across Europe, Asia and the Americas

www.PAREXEL.com

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