

IMPACT<sup>®</sup> CTMS

*THE INNOVATION  
YOU NEED WITH THE  
EXPERIENCE YOU TRUST*



# THE TRUE eCLINICAL SOLUTION

IMPACT® CTMS is one of the most used enterprise-wide clinical trial management systems in the world, with over 26,000 end-users in more than 85 countries. There may be no other CTMS provider that offers such a flexible yet proven approach to improving trial conduct and operational efficiencies.

## The Right Choice

Regardless of trial complexity, company size or global reach, IMPACT® CTMS is the right choice. IMPACT has provided the solution for sponsors and CROs ranging from highly sophisticated operations with experienced IT departments to young start-up companies with minimal infrastructure. Whatever your company profile, the IMPACT solution can suit your clinical operation.

## The Standardization Breakthrough

IMPACT CTMS means that all clinical research across the globe will be speaking the same language, using the same terms, tracking in similar ways—allowing a common view company-wide, but with a great deal of local flexibility when the need arises. IMPACT CTMS is able to integrate all sources of information involved in the clinical trial process providing a single source of truth throughout the entire lifecycle.

## Built With Flexibility In Mind

Whether your organization is a start-up biotech or an enterprise-leading company, IMPACT CTMS has the flexibility and scalability to support your unique needs. Delivered as either a hosted or on-premise solution, our experts provide the proven processes to get your team up and running quickly, so you can focus on what really matters—getting life changing medications to market quickly and safely into the hands of those who need it most.



**26,000+**  
**USERS**  
**IN 85+**  
**COUNTRIES**

### Better Resource & Activity Tracking

IMPACT® CTMS has sophisticated data tracking capabilities including:

- Multiple study viewing
- Comprehensive investigator and center information, with configurable performance metrics and sophisticated data mining
- Patient recruitment tracking with figures fed in from multiple sources at once
- Centralized access for all authorized personnel – including carefully restricted access for external partners
- Detailed control of investigator budgets and drug supplies
- The tracking of planned costs per study with detailed projections of over/under spending

### Intuitive Workflow

From start to finish, IMPACT® CTMS raises the level of productivity in the clinical trial process. There

are ready-made startup routines, and user-specific templates, with alerts and warnings guiding you to imminent problems. Companies can set up their own trial types, each with different milestones to track, and required fields to complete, depending on the level of detail required. An information dashboard allows each user to analyze their progress, and dissect sites from countries, as well as trials from programs. In short, the planning and running of trials and programs is revolutionized.

### Easy Data Access for Accurate Planning

Users can view recruitment issues and other key activities across all sites assigned to a monitor and use a risk-based approach to plan site visits. Other benefits include:

- Affiliates in all time zones have instant access to up-to-the-minute information
- Online and offline access to site management and monitoring capabilities, including MS Outlook integration for site visit planning. Site visit information feeds into Perceptive MyTrials®

Data-Driven Monitoring to provide true monitoring oversight, and the ability to manage a risk-based monitoring approach

- Milestone planning, issue tracking and recruitment for both office and field-based monitors

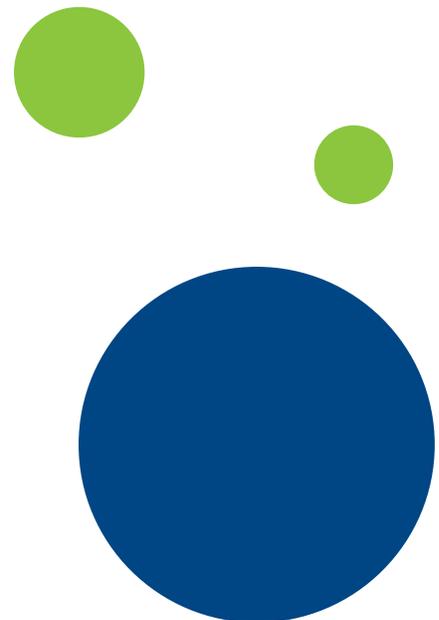
### Compatibility & Capture

IMPACT® CTMS integrates with other systems capturing valuable patient, site and other information in a standard language. This delivery of consolidated data into a single place gives the trial manager a competitive decision-making advantage. Users benefit from:

- Interchangeability and interconnectivity of data with RTSM systems such as IVR/IWR and EDC
- The IMPACT system can act as the master site database, communicating site demographics and study readiness to other eClinical systems in the Perceptive MyTrials® framework



**25,000+**  
**TRIALS**  
**MANAGED**



# THE IMPACT<sup>®</sup> CTMS COMMUNITY

The IMPACT<sup>®</sup> CTMS User Group Community is run for the customers, by the customers with organizational support from PAREXEL.

As a member of this community, you will be invited to gather in some of the world's most dynamic cities with fellow IMPACT<sup>®</sup> CTMS users to share your experiences and network in a productive yet social setting.

The agendas include company updates, training initiatives, new regulatory and operational challenges, and news on the integration of acquired products. Participating companies are always at the forefront in making presentations and sharing best practices. The events are a good opportunity to establish strong relationships.

PAREXEL also run regular web-hosted sessions to provide our customers with a chance to review the design of new versions of the system with the feedback being utilized as a key component in the development cycle.

## On Hand to Help

**Support Site:** Trained IMPACT<sup>®</sup> CTMS experts offer unparalleled support to our customers whenever help is needed. Live phone support is available as well as a comprehensive knowledge base on our support website.



# TIME TO MARKET... BETTER, SAFER, FASTER

## BETTER...

The use of the IMPACT® CTMS tracking and data integration efficiencies relieves marketplace and regulatory pressures, reduces development costs, and accelerates time-to-market.

## SAFER...

IMPACT® CTMS helps improve regulatory compliance, monitoring quality and data visibility, helping users with the primary consideration of patient safety.

## FASTER...

Competition to market is fierce and costly. Stakeholder investment recovery begins "at market." The IMPACT CTMS advantage of integrated, fluid, up-to-the-minute data gives the company a true competitive edge.

## THEN & NOW

### The Evolution of CTMS

Planning, starting, and monitoring clinical trials, as well as collating their data, was once an inefficient, manual process. Driven by the demand and pressure on the pharmaceutical/biotech industry to get drugs to market faster, companies responded by introducing systems to help streamline the process and bring process automation to the clinical trial space. The advent of clinical trials management systems (CTMS), to optimize the preparation, start up and execution of clinical trials was the first step towards realizing this vision. Today's CTMS provide flexible solutions that allow all authorized personnel—both inside and outside the company—to access trial data and metrics in a centralized location. As the market continues to evolve, IMPACT® CTMS provides both on-premise and hosted solutions based on your unique needs.



**883,000+**  
**SUBJECTS**  
&  
**383,000+**  
**SITES**

# IMPACT<sup>®</sup> EXPRESS

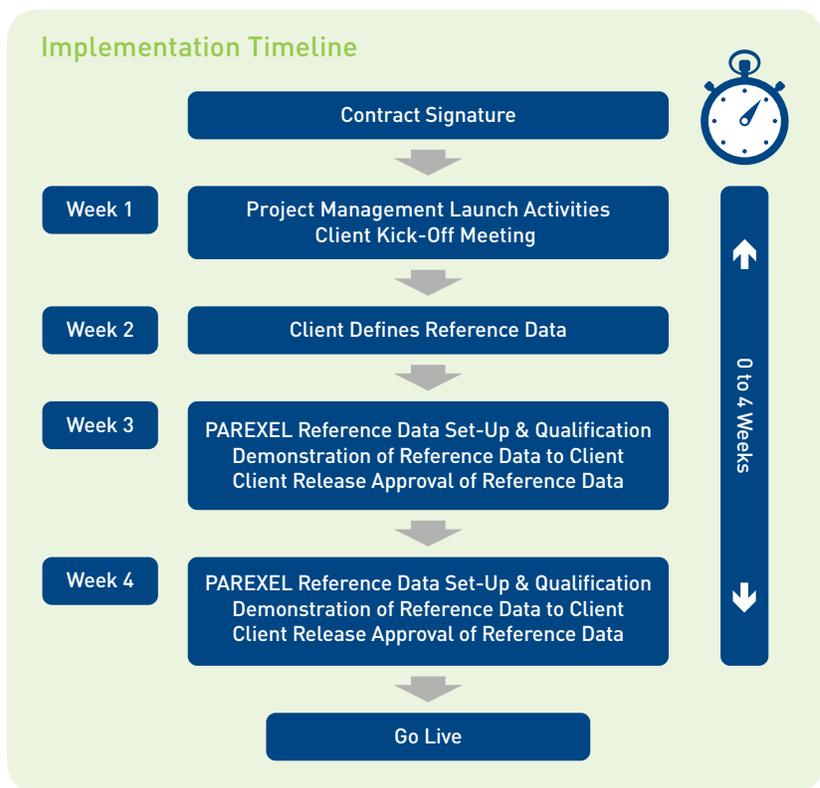
Conducting clinical trials is a complex, challenging series of tasks that involves generating and consolidating data, managing and organizing people, and making informed decisions. PAREXEL's IMPACT Express offers a quick-to-deploy, easy-to-learn solution that is ideal for small to mid-size companies in need of a robust CTMS solution.

## IMPACT<sup>®</sup> Express Delivers:

- Accelerated trial startup at a low price point
- Enhanced decision making through greater study visibility, metrics and consolidated data
- Single source of globally accessible clinical trial management data
- Improved monitoring efficiency with automated generation of visit reports
- Effective control and management of site contracts and payments

## Why Wait When You Can Go-Live In 4 Weeks?

IMPACT<sup>®</sup> Express' process-driven approach is focused on affordability and flexibility. Its simple, out-of-the box deployment means no need for technical infrastructure or resources. And since it includes comprehensive training, your users will be running the system confidently from trial startup to trial completion.



# THE TRIAL MANAGEMENT SUITE

The IMPACT® CTMS comprehensive suite of modules complement each other seamlessly, yet allow users flexibility in selecting module add-ons. Each module is robust and feature-rich.

## Impact Heart of the Application

**IMPACT® Progress:** Impact Progress handles the planning and tracking of all projects and trials. This includes everything from the countries and sites involved, to details of the patients and their progress. All details of the trials may be held with visit designs, timelines, enrollment and site activation summaries, and detailed issue/contact tracking.

## Optimal Site Management and Monitoring

**IMPACT® MySites:** Impact MySites is an online/offline web-based tool that supports all aspects of site management and monitoring, including the collection of site monitoring data, milestone planning, issues and recruitment. Data collected within MySites is used to automatically generate the monitoring visit report, with the entire review and approval process being managed within the IMPACT system. It is even available on a flash drive—the ultimate in system portability.

## Managing Fiscal Responsibility

**IMPACT® Clinical Cost Tracking:** This module manages the planning, projection and tracking of costs associated with clinical trials by employing multi-center, multi-currency and full-cost analysis functionality. There is a sophisticated and automated investigator payment facility which can be integrated with corporate accounting systems to provide a full payment generation, review and approval process, allowing financial management of hundreds of sites at a time.



### Dynamic Investigator Performance

**IMPACT® Investigator:** The Investigator module provides control over all sources of investigator data and allows selection of the best investigators and sites for a trial. The system helps enhance the value of data, analyzing investigator performance, experience and expertise. Dynamic lists are created to be discussed, shared, refined and used as the basis of feasibility faxes and e-mails, as well as for assessment visits.

### Ensuring Regulatory Compliance

**IMPACT® Regulatory Document Tracking:** Getting investigative sites recruiting on time is made all the more difficult by the enormous amount of documents that need to be collected, reviewed and approved before supplies can be sent and a single patient enrolled. Verifying that all documents are in place for government or ethics approval is equally problematic. The Impact Regulatory Document Tracking module can be changed on a trial-by-trial, country-by-country basis to monitor different documents but is detailed enough to track every aspect of each one—whether a 1572, an informed consent approval or a protocol version.

### Supplies Maintenance

**IMPACT® Clinical Supplies Tracking:** Our Impact Clinical Supplies Tracking module forecasts and tracks the dispatch, return and destruction of drug and other clinical supplies—to ensure that the correct trial supplies are available at the right sites, at the right time.

The IMPACT® solution is an integral part of Perceptive MyTrials®. Perceptive MyTrials provides an application framework through which we are able to converge our integrated suite of clinical trial software applications. Designed to maximize the benefit of natural trial process workflow, the Perceptive MyTrials solution enables users to plan, design, collaborate and conduct their clinical trial programs from a single place.

The automated integration with ClinPhone® RTSM (Randomization and Trial Supply Management), DataLabs® EDC applications and Perceptive MyTrials® Data-Driven Monitoring allows users to seamlessly share trial data without having to duplicate activities, helping your entire organization benefit from the true power of CTMS.

*COMMITMENT.  
INNOVATION.  
SOLUTIONS.*

Committed to delivering comprehensive services and innovative research solutions, PAREXEL is a recognized leader in all phases of the drug-to-market process, earning its reputation with thousands of users.

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PERCEPTIVE  
**MyTrials**<sup>®</sup>



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

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