



InForm™ Integrated Trial Management

InForm ITM Platform Benefits:

For Investigator Sites

The InForm ITM platform offers sites a highly efficient way to capture and manage clinical trial data by providing:

- An intuitive and secure application accessible via an Internet browser
- Built-in edit checks to reduce input errors
- Query management functionality to easily address discrepancies
- Real-time access to trial data for informed decision making and effective subject management

For Sponsors

The InForm ITM platform helps sponsors expedite the process of capturing and analyzing clinical data by providing:

- A flexible and efficient study design tool that helps reduce study build-time
- Roles-appropriate monitoring and data review workflows
- Process workflows that enable query resolution
- Real-time data access and visibility via an advanced reporting environment
- Integrated, multi-trial medical coding management that can be easily applied across all trials
- Scalability and performance management via a flexible system architecture
- Support for CDISC standards to facilitate regulatory submission
- A design to support regulatory compliance with Good Clinical Practices (GCP) and regulations applicable to the conduct of clinical trials

Driving the Clinical Data Management Evolution

The market acceptance of electronic data capture (EDC) has fueled new demands for electronic clinical data management (eCDM) solutions. The need to improve efficiencies and accelerate study times continues to grow, driving sponsors to seek an eClinical environment that provides: flexible, speedy trial design and build; robust data management; real-time data visibility, reporting and analysis; and global trial management and study scalability. As a pioneer in this evolution, Phase Forward continues to deliver innovative technology and clinical best practices that have been field-tested and clinically proven through a decade of development, service and experience. InForm ITM has evolved as the industry-leading EDC platform to meet these requirements.

Modularity Meets the Need

The InForm ITM solution has been designed with an eye to the future by anticipating growth in trial volume and size, as well as the ongoing need to broaden and deepen trial management functionality to serve all study stakeholders. With this focus in mind, InForm ITM provides a modular, Services Oriented Architecture (SOA) to better ensure scalability and best-fit solutions for different users. The InForm ITM solution can enable organizations to accommodate the full spectrum of study scenarios – from small population, rapid turnaround studies to multi-year, post-approval observational programs across tens of thousands of subjects.

The InForm ITM product's modular design, with the ability to run multiple trials in separate databases, is a key to scalability and is designed to allow organizations to:

- Upgrade trials independently to newer software versions
- Locate trials and their databases on different servers and in different domains to help optimize performance
- Make post go-live study design changes without impacting all trials
- Enhance data and system security through its use of a separate application and database environment for each trial
- Run detailed reports without impacting transactional performance at sites or sponsor locations

With the InForm ITM platform, modules for specific activities and users can be easily added and are designed to meet the unique needs of those operational areas (e.g., medical coding and system interoperability).

Streamline Study Design and Reduce Build Time

Companies are looking to maximize their operational efficiencies around EDC technology, specifically in the study design and build area. The process required to transform a protocol into a completely-built EDC study is critical – and can be very time consuming. Phase Forward's **Central Designer™** module, when used in conjunction with the InForm ITM solution, can help companies streamline the process for designing and building EDC studies by:

- Increasing study design efficiencies
- Improving component reuse and the application of standards
- Enhancing communication and workflow

Accelerate Study Development

The systems, processes and expertise required to deploy and maintain an EDC trial can be easily underestimated. Deploying integrated EDC studies reliably and consistently requires a proven system architecture and methodology. With unsurpassed experience in deploying thousands of trials, Phase Forward offers:

- Streamlined trial deployment utilizing our industry-leading Managed Application Hosting Services with 24/7 global support
- Standardized integration offerings that leverage common technology and industry standards for simple and reliable connections to other systems
- Efficient processes to quickly incorporate changes to active trials including immediate site readiness evaluations using an on-line **Auto Site Assessment Utility** to ensure each site has the correct hardware and software configurations
- Sponsor-enabled management of sites using the the integrated **User Management Utility** for more efficient management and control of users

Capture and Access Study Data, Easily and Securely

Clinical Researchers want to focus on caring for patients and spend as little time as possible sitting in front of a computer system. InForm ITM has become one of the most widely used EDC tools in the industry, by providing:

- A secure, roles-based environment, globally accessible via an Internet Web browser
- An easy to use Web-based application
- Optimized system performance for faster page turns
- Multi-lingual support for many languages, including Japanese
- On-line edit checks to reduce data entry errors
- An efficient way to address queries
- Easy batch loading of external source data
- Support for remote and off-line data capture using **InForm Unplugged**

Reduce Time to Database Lock

The processes that Data Managers, Monitors and others use to review the quality and consistency of data, and verify its authenticity, must be optimized to reduce overall time from first patient in to database lock. The InForm ITM platform offers unique functionality that enables teams to establish optimized workflows that are designed to reduce time to database lock through:

- Real-time access and reporting on all trial information
- Quick and easy processes for creating and closing queries for improved data quality
- Functionality that supports mid-study design changes
- User-driven filters and reports that simplify preparation for source verification and data review
- Complete support for remote on-line or off-line source verification
- An integrated medical coding environment – **Central Coding™ for InForm** – for coding drug terms, adverse event terms and medical history, with multi-study coding support for both the WHO-DD and MedDRA dictionaries
- Import and export support for CDISC LAB, ODM, and SDTM

Gain Immediate Access to Critical Data

Medical Monitors, Biostatisticians, and other stakeholders within the organization need continuous, real-time access to all facets of the trial information – from the number of patients enrolled at each site, to the statistical trends on patient data. With the InForm ITM platform, users gain immediate access to detailed reporting and data review capabilities through:

- On-demand, user-driven dashboard-style reports via an Internet portal
- Immediate access to reports available on the first day your trial goes live
- 32 out-of-the-box standard reports for reviewing operational data
- A simple, non-technical ad hoc reporting capability for generating reports, graphs and charts
- Export options including: Microsoft Excel®, PDF®, XML and CSV
- Scheduled SAS data extracts for customers using the Phase Forward ASP hosting services

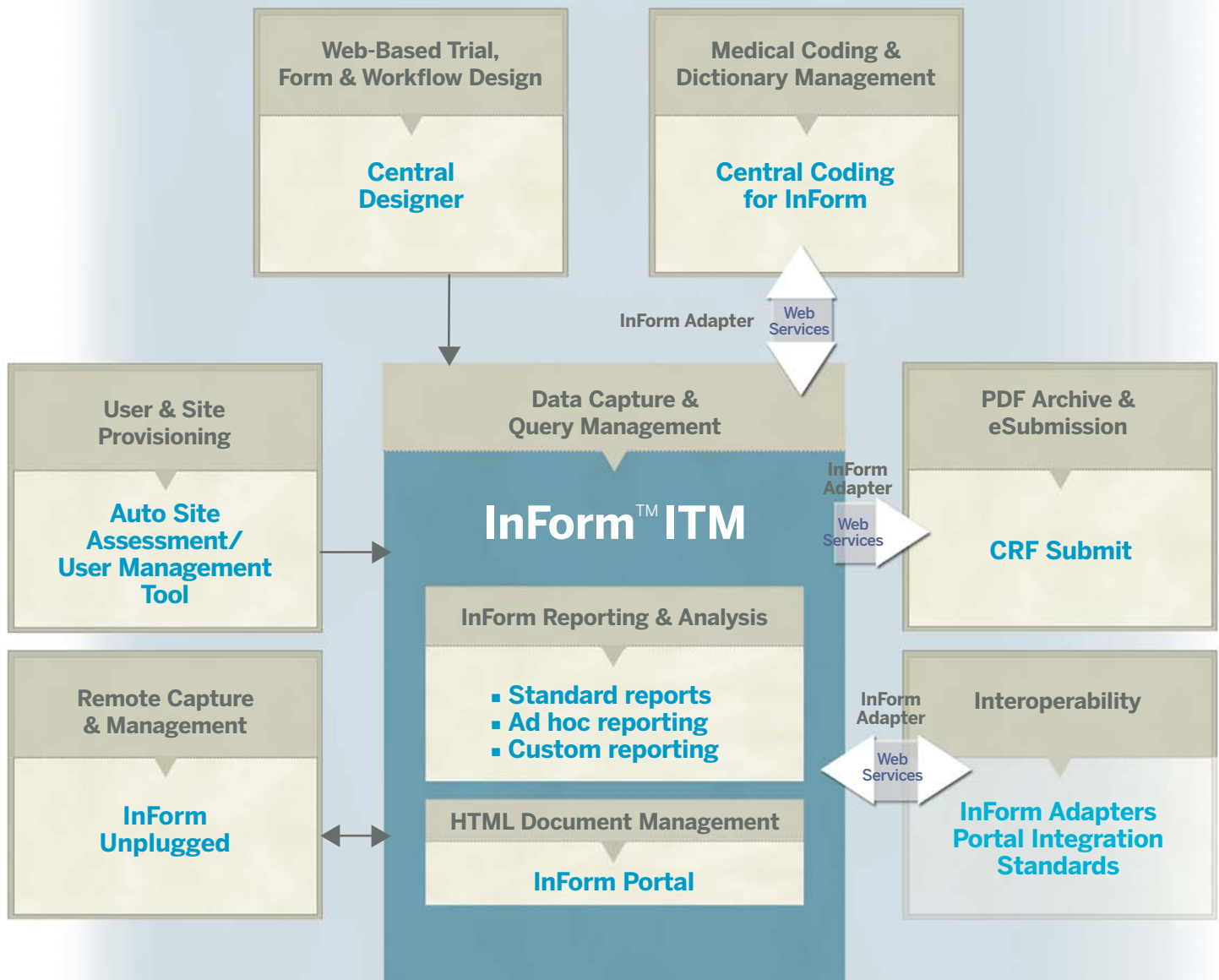
Implement Industry Standards

As an active member in CDISC and other standards committees, Phase Forward is committed to providing products that:

- Support CDISC LAB and ODM standards for data exchange
- Support SDTM data set delivery for analysis and submission

The InForm ITM Platform: Setting the Standard for Electronic Clinical Data Management

The InForm ITM platform's core electronic data capture and data management functionality, combined with centralized and integrated software modules, deliver flexibility and benefits for all key areas of electronic clinical data management.



From protocol to regulatory submission, InForm ITM delivers an electronic clinical data management platform sponsors and sites rely on to capture, manage and evaluate data collected from the smallest and earliest phase trials to the largest global trials.

Built on award-winning technology that features a Services Oriented Architecture (SOA), Web Services-based interoperability and native support for the Oracle® database, the InForm ITM platform delivers the clinical data management standard that life sciences companies demand when adopting electronic solutions.

Why InForm ITM for EDC?

There is much to consider when selecting an EDC solution. In addition to cost, the solution must provide the right level of functionality and services to successfully implement your trials and meet the specific needs of your organization. With over 10 years of experience helping life sciences companies capture, analyze and manage clinical data, Phase Forward has set the standard for what companies look for in an EDC solution.

Proven Usability

InForm is used by more than 23,000 investigator sites worldwide, providing a familiar and intuitive user interface that allows both sites and sponsors to efficiently capture and manage clinical information. The roles-based functionality within InForm is designed to make it easy for Clinical Researchers, Data Managers, Monitors, Biostatisticians, and others within the organization to streamline their process workflows and access real-time information needed to conduct trials.

Trusted Performance and Scalability

The InForm ITM solution is built on a tiered system architecture that provides consistent, reliable performance for any size trial, including large trials with thousands of patients running for many years. Using InForm, life sciences companies are able to quickly ramp up on EDC because of the system's inherent scalability. Today, InForm is a trusted EDC solution with a proven track record for helping customers run over 1,600 trials.

Flexible System Configurability

InForm is one of the most flexible EDC platforms on the market today, enabling our customers to configure the system to specifically address their business needs, such as: making connections with third-party systems; conducting trials in developing countries; developing adaptive trials; and running large-scale Phase IV registry trials. Our customers can also implement mid-study design changes quickly and without disruption to existing reporting capabilities.

Consistent and Reliable Delivery and Support

Phase Forward provides an array of InForm service offerings to help customers quickly leverage the full benefits of EDC. Phase Forward's global service offerings cover the clinical trial process from design and deployment through regulatory submission. Our experienced service professionals have extensive domain expertise in clinical and technology areas to ensure that our solutions can effectively meet your specific requirements.

InForm™ ITM

Deployment

Available as an Application Service Provider (ASP) hosted solution or enterprise adoption for in-house operation

Help Desk

Global 24 x 7 multi-lingual support

Regulatory Compliance

The InForm ITM platform has been designed to allow our customers to deploy it as part of a validated system compliant with GCP predicate rule requirements, laws and regulations applicable to the conduct of clinical trials, and US FDA 21 CFR Part 11 pertaining to the use of electronic records and signatures.

System Requirements

Please visit www.phaseforward.com/products for the latest requirements

Related Data Sheets

Central Designer™
Central Coding™ for InForm
InForm™ Adapter

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www.phaseforward.com

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