



### InForm GTM Platform Advantages:

Phase Forward's InForm GTM platform helps expedite the process of capturing and analyzing study data by providing:

- Scalability and performance via a flexible system architecture
- A study design and library management environment to reduce build time
- Integrated, multi-trial medical coding
- Roles-appropriate monitoring and data review workflows
- Query workflows that enable discrepancy resolution
- On-demand real-time data access and advanced reporting
- One study environment for multi-language or regionally based trials
- eCRFs can be designed once and translated into multiple languages
- Support for CDISC standards

### For Investigator Sites

The InForm GTM platform offers sites a highly efficient way to capture and manage study data by providing:

- A user friendly interface with efficient navigation and effective workflow
- Built-in edit checks to reduce input errors
- Query management functionality to easily address discrepancies
- Real-time access to trial data for effective subject management
- eLearning tools for convenient and easy learning

## InForm™ GTM Global Trial Management

### A Complete Solution for Global Clinical Trials

The broad market acceptance of electronic data capture (EDC) technology, coupled with an industry moving toward more complex and global clinical trials, has fueled new demands for electronic clinical data management (eCDM) solutions. Sponsors and sites need an eClinical solution with a flexible platform that can consistently speed study design and accelerate study deployment, while scaling to global trials with large patient populations. As an EDC pioneer, Phase Forward continues to deliver innovative technology and champion best practices that have proven effective through more than a decade of development, deployment and services experience.

The InForm GTM solution's scalable platform allows for flexible, speedy study design and build; robust data management; real-time data visibility; standard- and user-driven reporting tools; and advanced analysis capabilities. Systems such as IVRS, CTMS, Imaging, and ePRO can easily integrate with the InForm environment, through the support of Web Services and industry standards. Modules for randomization and trial supply management (Clarix™), study design (Central Designer™), and medical coding and dictionary management (Central Coding™) can be added—to provide a comprehensive eCDM solution.

### Scalability and Performance Through Modularity

A modular Services Oriented Architecture (SOA) ensures scalability and allows best-fit solutions for different needs. The InForm GTM solution can accommodate the full spectrum of study scenarios—from small-population, rapid turnaround studies to complex, multi-year trials, or post-approval observational programs—across tens of thousands of subjects.

The modular design, with the ability to run multiple studies in separate databases, provides scalability and performance. When combined with Phase Forward's investments in technology, this approach allows organizations to:

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

## Streamline Study Design and Reduce Build Time

Phase Forward's Central Designer™ module, used in conjunction with the InForm GTM solution, helps streamline the process for designing and building EDC studies by:

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

## Accelerate Study Development

Deploying integrated EDC studies reliably and consistently requires a proven system architecture and methodology. With unsurpassed experience in deploying thousands of trials worldwide, Phase Forward offers:

- Streamlined trial deployment utilizing Phase Forward's industry-leading Managed Application Hosting Services with 24 x 7 global support
- Standardized integration offerings that leverage common technology and industry standards for simple and reliable connections to other systems
- Sponsor-enabled management of sites using the integrated User Management Tool for more efficient management and control of users

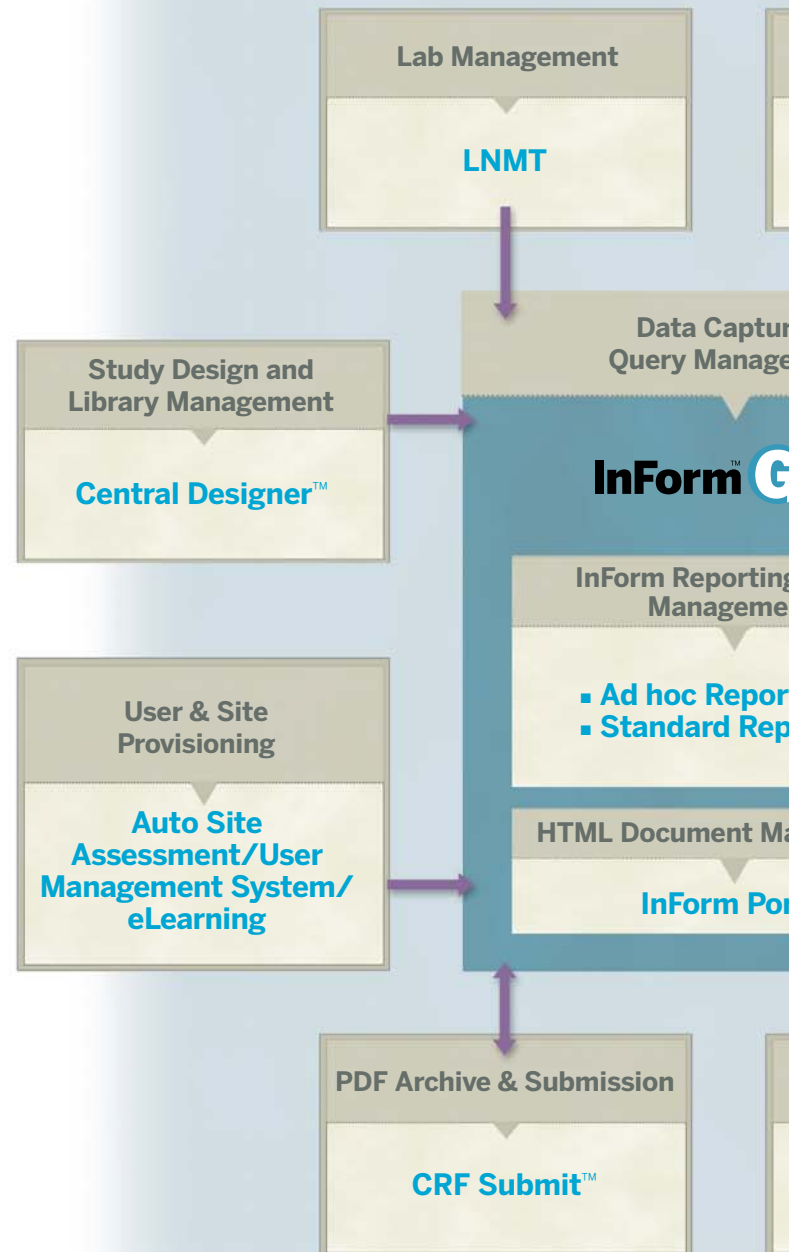
## Capture and Access Study Data, Easily and Securely

Clinical Researchers want to focus on caring for patients and spend as little time as possible sitting in front of a computer. The InForm solution 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 browser
- An easy-to-use Web-based application with a modern user interface and intuitive navigation
- Optimized system performance for rapid user interaction
- Support for multilingual studies, including Japanese
- Online edit checks to reduce data entry errors
- Efficient data discrepancy resolution through online query process
- Easy batch loading of external source data

# The InForm GTM Platform for Global C

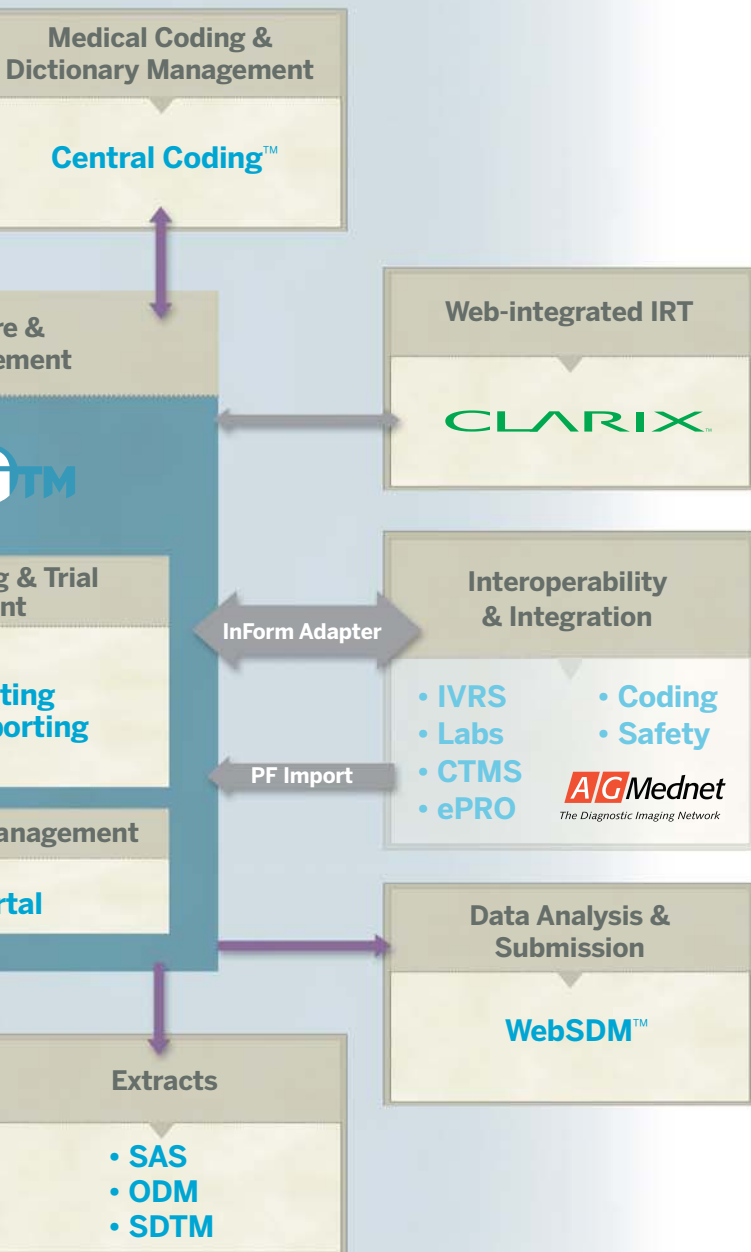
The InForm GTM platform's core electronic data capture and data management software modules, delivers flexibility and benefits for all key areas of



From protocol design to regulatory submission, InForm GTM delivers... and sites rely on to capture, manage and evaluate data collected from... Built on award-winning technology that features a Services Oriented... native support for the Oracle® database, the InForm GTM platform... companies demand when adopting electronic solutions.

# InForm GTM: A Complete Solution for Clinical Trials

management functionality, combined with centralized and integrated of electronic clinical data management



ers an electronic clinical data management platform that sponsors from the smallest and earliest phase trials to the largest global trials. and Architecture (SOA), Web Services-based interoperability and delivers the clinical data management standard that life sciences

## Reduce Time to Database Lock

The InForm GTM 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 study 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 online source verification
- An integrated medical coding environment—Central Coding™—for coding drug terms, adverse event terms and medical history, with multi-study coding support for WHO-DD, MedDRA, MedDRA-J and J Drug
- Import and export support for CDISC LAB, ODM, and SDTM

## Gain Immediate Access to Critical Data

Medical Monitors, Biostatisticians, and other stakeholders within an organization need continuous, real-time access to all facets of study information—from the number of patients enrolled at each site, to the statistical trends on patient data. With the InForm GTM 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 study-go-live date
- Out-of-the-box standard reports for reviewing operational data
- A simple, non-technical ad hoc reporting capability for generating reports, graphs and charts
- Ad hoc export options including: Microsoft Excel®, PDF, XML and CSV
- On-demand data extracts (i.e., SAS, RDE) for customers using Phase Forward hosting services

## Implement Industry Standards

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

- Include a certified CDASH library
- Support CDISC LAB and ODM standards for data exchange
- Support SDTM data set delivery for analysis and submission

## Deployment

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

## Help Desk

Global 24 x 7 multilingual support available

## Regulatory Compliance

The InForm GTM 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](http://www.phaseforward.com/products) for the latest requirements

## Related Data Sheets

- Central Designer™
- Central Coding™
- InForm™ Adapter

## Why InForm GTM 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 clinical studies and meet the specific needs of different organizations. With over a decade 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

The InForm environment has been used in more than 3,000 trials 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 the InForm software is designed to make it easy for Clinical Researchers, Data Managers, Monitors, Biostatisticians and others within an organization to streamline their process workflows and access real-time information needed to conduct trials.

### Trusted Performance and Scalability

The InForm GTM solution is built on a tiered system architecture that provides consistent, reliable performance for any size study, including large trials with thousands of patients running for many years. Using the InForm GTM environment, 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.

### Flexible System Configurability

The InForm environment is one of the most flexible EDC platforms on the market today, enabling life sciences companies to configure the system to address their unique business needs, such as making connections with third-party systems; conducting studies in developing countries; developing adaptive trials; and running Phase I, II, and III clinical studies as well as large-scale Phase IV registry trials. InForm customers can also implement mid-study design changes quickly without disrupting trial activities.

### World-Class Delivery and Support

Phase Forward provides an array of InForm GTM Services offerings to help customers quickly leverage the full benefits of EDC. These global offerings cover the entire clinical trial process—from design and deployment through regulatory submission. Phase Forward's experienced services professionals have extensive domain expertise in clinical and technology areas to ensure that its solutions effectively meet the specific requirements of any size organization.

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