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 fast discrepancy resolution
- On-demand 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 more efficient clinical data management 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.

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 provides scalability and performance and 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 Deployment
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:
• State of the art hosting facilities with disaster recovery and world class global support
• Centralized site management and provisioning across trials and applications, streamlining access and identity management and tracking site readiness
• Standardized third-party integration offerings that leverage common technology and industry standards

Access an end-to-end Integrated Clinical Research Suite
The Phase Forward Integrated Clinical Research Suite helps automate and standardize the integration of InForm with other Phase Forward best-of-breed solutions to efficiently manage the clinical development process. This includes:
• Central Coding™ – Centralized cross trial Web-based medical coding and dictionary management environment
• Phase Forward™ IRT – Flexible Web-based randomization, trial supply management and forecasting solution
• Phase Forward™ Clinical Development Center – Integrate, manage and analyze clinical information
• OutcomeLogix™ – Comprehensive, easy to use Web-based ePRO solution
• Empirica™ Safety Solutions – An integrated suite for life cycle pharmacovigilance and risk management

Capture and Access Study Data, Easily and Securely
Clinical Researchers want to 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:
• 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

Reduce Time to Database Lock
The InForm GTM platform offers unique functionality that enables teams to establish optimized workflows 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 and adverse event terms across trials globally and includes 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 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
The InForm™ GTM Platform: A Complete Solution for Global Clinical Trials

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

From protocol design to regulatory submission, InForm GTM delivers an electronic clinical data management platform that 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 GTM platform delivers the clinical data management standard that life sciences companies demand when adopting electronic solutions.
**Deployment**
Available as an Application Service Provider (ASP) hosted solution or enterprise adoption for in-house operation

**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.

**The Phase Forward™ Integrated Clinical Research Suite**
InForm GTM is part of our global integrated clinical research suite to meet drug development needs from study set-up through analysis and submission.

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**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 3,800 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.