

## InForm Electronic Data Capture (EDC)

The InForm EDC platform is renowned for trusted performance and scalability. It is used in over 3,000 clinical trials worldwide. InForm EDC's interface and query management features drive efficiency through the clinical data management process. Right up to submission, InForm eases the process with fully compliant CDISC SDTM exports. The data summary and reconciliation reports were developed in a Cooperative Research and Development Agreement with the FDA. InForm provides the leading functionality in electronic data management.

InForm EDC's flexible architecture and integration capabilities facilitate easy implementation. The deployment as a hosted solution reduces hardware cost, validation efforts and organizational impact. With a full suite of reporting and transfer features, InForm EDC provides you with everything you need to run a clinical study from setup to submission.

## Why Eclipse

Eclipse is a clinical technology company that collaborates with you to deliver the RIGHT technology solutions and clinical data management services to ensure your clinical trial is a success. We're ISO9001:2008 registered, a testament to our commitment to providing products and services that meet client quality expectations.

Through our partnership with Oracle and with our own proprietary products, we help companies leverage best-in-class technology solutions, but it's our unwavering commitment to client satisfaction that separates us from the competition. We are not satisfied until you achieve your goals - a trait our clients affectionately refer to as a genuine obsession with client service.

## Eclipse InForm Benefits & Capabilities

- **Robust scalability**
- **High-performance and accessibility with our world-class hosting facility**
- **Quick study design and implementation with library features (includes standard CDASH library)**
- **Easy data entry and management with our intuitive interface with workflow driven navigation**
- **Improved data quality with automated multivariate queries**
- **Driven data completion with integrated query resolution tools**
- **Remote monitoring and sophisticated source verification tools**
- **Multi-Study Drug and Event coding with integrated eclipse Coder**
- **Easy data transfer and integration in CDISC formats**



## The Benefits of a Modular Design

InForm EDC allows for the development of content libraries. InForm libraries allow for the reuse of eCRFs and edit checks across studies. This reduces the time of development and provides consistency across studies improving the overall quality of the data. InForm EDC also provides comprehensive support for industry standards such as CDISC to speed trial setup, increase efficiency data quality, and help ensure compliance. Standards allow clinical trial professionals to make faster, more informed decisions about their studies.

## Advanced Query Management

InForm electronic data capture provides comprehensive online edit checks and an online query processes to easily assess and capture clinical trial data and rapidly reconcile discrepancies. InForm delivers data transparency, reduces backend cleaning of data, and provides faster data extracts to minimize data entry errors and quickly resolve data discrepancies. Through the InForm data viewer clinical data management can work with all queries from a single screen, and take management actions on multiple queries at the same time. The end result is higher-quality data, allowing you to reach database lock more quickly.

## Targeted Source Data Verification (SDV)

InForm provides flexibility to set targeted source verification strategies that allow for increase or decrease of the source verification workload based on the data quality. It offers automatic updates, remote online source verification, easy batch loading of external source data, and user-driven filters. SDV reports simplify preparation for source verification and data review. With InForm targeted SDV, you significantly reduce the time and cost of verifying data, accelerating trial timelines without adding risk.

## InForm's Data Viewer

InForm Data Viewer feature gives you real-time, 24/7 actionable visibility into trial data with a single click, for internal or outsourced trials. You can instantly review and manage clinical data across visits and sites with built-in export to your chosen format on every screen, easily filter by site, subject, visit, and data status, and immediately identify and filter on data that is new or updated since a previous review. There's no waiting for reports to be generated, and no need to rely on someone with programming expertise to mine the data.



With Data Viewer, you get to database lock much faster and with far less manual effort by assessing and locking a site, multiple sites, or even an entire trial in a matter of minutes – simply by selecting, locking, and confirming. Data viewer significantly reduces trial costs by accelerating study closeout, eliminating redundant queries and saving time and effort checking the system against multiple spreadsheets. Lower your trial risk through real-time, actionable visibility to trial data and by minimizing data errors.

### **Rich Reporting and Easy Ad-hoc Reporting**

InForm provides the comprehensive visibility required to manage a trial and its data effectively. The solution offers real-time, web-based, on demand, user-driven dashboard-style reports, immediate access to reports on trial go-live date, standard reports for reviewing operational data, and simple, non-technical, ad hoc reporting for reports, graphs, and charts – all without impacting transactional performance at site or sponsor locations. You can establish and track key performance and operational metrics such as data entry, enrollment, aging and cycle times to quickly identify underperforming sites and develop corrective action, ensuring that trials stay on track.

### **Automated Randomization**

Eclipse IRT automated randomization systems use the latest statistical methods, programming and validation procedures. This ensures quick, accurate patient assignments and balanced and valid subject assignments. Eclipse IRT is fully integrated with InForm, giving you the ability to randomize subjects, dispense and capture eCRF data through the InForm application. You can access real-time subject and supply information, conduct drug reconciliation as well as self-service data edits with no support desk required.

### **Centralized Coding of AEs and Con Meds and Safety**

Eclipse Coding software provides comprehensive, integrated, multi-trial medical coding and dictionary support for drug and adverse event terms. Eclipse coding is integrated seamlessly with InForm and applies across trials globally. In addition, the application enables mid-trial dictionary upgrades with full impact analysis capabilities and support – reducing manual coding and data errors while increasing efficiency.

### **EKG and Document Exchange**

Eclipse can establish a document exchange portal to allow sites to upload EKG images and other redacted documents from multiple EMR systems. The portal can provide a trial hierarchy of folders for documents side-by-side with an InForm single viewing window. Oracle InForm provides an integrated and market-leading solution through trial design and build, site and user management, patient randomization and trial supply, data capture and management, and medical coding. Together with its intuitive user interface, multi-language capabilities, and extensive software modules, the solution delivers a more streamlined workflow with superior accuracy. Eclipse InForm EDC services can drive your clinical trial decision-making – accelerating clinical trials while reducing cost and risk.



RIGHT SOLUTIONS. RIGHT NOW.

42 Hampton Rd Exeter, NH 03833

**Phone:** 603.294.4580 **Fax:** 866.585.1267

**[www.eclipsesol.com](http://www.eclipsesol.com)**