eClinDirect™ CTMS

Genuinely Innovative. Truly Integrated.

eClinDirect™ CTMS

Clinical Trial Management System

*eClinDirect, DSG's web-based Clinical Trial Management System (**CTMS**), is a project management application designed for capturing and sharing a wide variety of clinical trial project status information across multiple studies.*

Online investigator visit monitoring reports enable access to critical status information at all times. Sponsors can selectively make this information available for review by key stakeholders on the project team.

Advanced reporting functionality provides easy access to metrics, workflow events, action items, documents collected, and protocol deviations.

Easily configurable, role-based security provides various levels of access control including read only, read/write, and workflow e-Signature authority.

Real-Time, Online Access to Information

Once entered into eClinDirect, CRA monitoring visit reports are available online, in real-time for all stakeholders with access. Role-based security provides various levels of access control.

Flexible, Easy Configuration

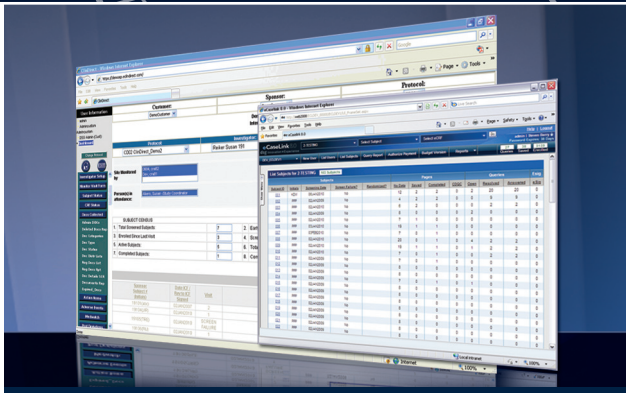
eClinDirect is easily configurable. The configuration process begins with a determination of desired access control levels and the electronic workflow of the monitoring visit reports. Next, online monitoring visit report forms are customized to the needs of the particular sponsor or study.

Online Visit Monitoring Forms Workflow

eClinDirect validates that CRAs completed the monitoring form questionnaires, and supplied comments for questions with negative answers. Online forms are routed via electronic workflow, using an e-signature design. E-mail notifications are available and all actions write to an Audit Trail.

Protocol Deviations

Extensive information about protocol deviations is recorded from within the visit monitoring form. Additionally, violation classifications are configurable.



Document Management

Paper documents collected at the sites are identified and electronic documents, if available, are uploaded into a repository. The extensive metadata stored with the document is used as filter criteria when running the various document reports. Document categories and types are configurable, and the collection status of essential regulatory documents is tracked.

Investigator Contact Information

eClinDirect stores investigator and other stakeholder contact information, status, and credentials. Updated contact information is immediately available online. Additionally, Investigator site information pre-populates in forms, reducing data entry.

Payments

Various payment categories and payees are configured and budget milestones defined. Payments are recorded against these budget milestones. A variety of budget vs. actual reports are available.

Reporting Functions

eClinDirect's real-time standard and customized reports provide easy access to metrics, workflow events, action items, documents collected, protocol deviations, and adverse events, summarizing the details needed to ensure the steady progress of any clinical trial.

About DSG

DSG Inc. supports clinical trial data collection and management with innovative technology solutions including Electronic Data Capture with specialized Clinical Data Management services, Electronic Patient Diaries, Clinical Trial Management Systems and digital on-demand Case Report Form publishing management software. DSG has successfully supported over 1,000 clinical trials for more than 325 companies, at over 18,000 sites in over 68 countries. Founded in 1992, DSG is a global company headquartered in Malvern, Pa., with additional offices in the U.S., Japan and India.

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