dsg | eClinical Innovation & Experience

eCaseLink™ Safety System

Streamline Recording and Reporting for Drugs and Devices

eCaseLink Safety System

Streamline Safety Recording and Reporting with

eCaseLink™ Safety System from DSG.

eCaseLink Safety System streamlines the safety recording-reporting process and data entry on Serious Adverse Events (SAE). Our system can store documents connected with the safety event that garner the generation and tracking of queries. eCaseLink Safety enables medical monitors to record the SAE information received allowing manual data entry into forms, as well as completed specific fields mapped from the eCaseLink EDC system. Key events, such as dates and the eCRF status are all easily tracked and managed. The Drug Safety system alerts the medical monitor to differences between the safety data and the data entered into eCRFs within the eCaseLink EDC system.

eCaseLink Safety System
Streamlines the Safety Process

eCaseLink Safety System Provides Extensive Tracking

- Online system records extensive tracking information about various safety events
- Records include the data and status of submission to the regulatory agencies
- Seamless uploading of documents regarding adverse events
- Convenient access to critical documentation at all times
- Facilitates the generation and tracking of queries connected to the safety event
- Simple workflow provides multi-level approval and collaboration
- Information is shared among departments and sites

Keeping safety at the forefront of your studies.

- Generation of SAE submission forms and storing of relevant documents
- ICH E2B compliant
- Monitors and tracks safety event queries
- Integrated with eCaseLink EDC or available as an independent product
- Capture safety data using only the data points needed
- Configurable workflow with multi-level approval
- Integrates with other regulatory and clinical trial management systems
- View a single case or span multiple protocols
- Easily generate tracking reports

Data Capture of a Safety Event

- Online data entry forms
- Facilitating data capture of extensive information about the safety events
- User generation of FDA 3500A MedWatch form
- User generation of FDA 3500A CIOMS form

eCaseLink™ Safety advantage

FLEXIBLE AND SIMPLE

- ISO 27001 : 2013 Certified
- Scalable for any study
- Fully integrated with the DSG eClinical suite
- Adaptable as a stand-alone offering

INTEGRATED EDC OPTIONS

- Standard and configurable reporting
- Real-time, on-demand reports for instant visibility
- Regulatory requirements easily audited and tracked
- Adaptive workflow

CUSTOMER SUPPORT

- The finest technical support team available in the industry
- 24/7/365 on-call in-house experts with years of deep problem-solving experience

About DSG

DSG, Inc. is a leading global eClinical provider with a fully unified suite of innovative technology solutions and data management services for the global clinical research community. DSG's eClinical software platform provides competitive advantage that is cost-effective with on-time project delivery. DSG solutions have been used in thousands of clinical trials around the globe with our award-winning eCaseLink™ platform and eCaseLink Designer for enterprise licensing. Founded in 1992, the company is proud to be recognized as the first provider of a fully integrated EDC and IRT Randomization and Trial Supply Management system with the SCDM Data Driven Innovation Award.

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