

## eCaseLink 8.2™ DSG Drug Safety

### Streamline Safety

*DSG's eCaseLink Drug Safety system streamlines the safety recording, reporting process, data entry on Serious Adverse Events (SAEs), and can store documents associated with the safety event that facilitate the generation and tracking of queries.*

The Drug Safety system enables medical monitors to electronically record the SAE form information received from a site. Enter data into forms manually, as well as pre-fill certain fields mapped from the eCaseLink EDC system. Key events, dates and status are all easily tracked. The Drug Safety system alerts the medical monitor to differences between the safety data entry form and the data entered into eCRFs within the eCaseLink EDC system.

### Data Capture of a Safety Event

Online data entry forms facilitate the capture of extensive information about the safety event. A User can generate an FDA 3500A MedWatch or CIOMS form containing the entered data.

### Extensive Tracking

In addition, the DSG Drug Safety system records extensive tracking information about the safety event, including the date and status of submissions to the regulatory agencies.

The DSG Drug Safety system makes it easy to upload documents associated to the adverse event, making it convenient to access critical documentation at any time.

The system can also facilitate the generation and tracking of queries associated with the safety event. The configurable workflow allows multi-level approval and collaboration within different departments and sites.



- Generates SAE submissions forms and stores associated documents
- ICH E2B compliant, generates FDA 3500A Medwatch and CIOMS forms
- Generates and tracks safety event queries
- Integrated with eCaseLink edc, or available stand-alone
- Capture Safety data using only the data points you need
- Configurable workflow with multi-level approval
- Integrates with other regulatory and management systems
- View a single case or span multiple protocols
- Easy to generate tracking reports

## 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 thousands of clinical trials for hundreds of clients, with millions of patients across 93 countries, for over two decades. 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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