



DSG's Experience and eCaseLink™ System Delivers Rescue for Global Phase 3 Study in Record Time

Summary:

DSG was approached by a sponsor with the request to provide EDC, IRT, Data Management and Biostatistics for two global phase 3 projects. The sponsor also requested DSG to rescue the first of the two phase 3 studies. The sponsor needed a system that could handle multiple products such as EDC and IRT for two large multinational studies collecting tens of millions of data points seamlessly. In addition, they also needed a project team including data management and biostatistical experts that had experience managing similar studies, and the migration of millions of data points with precision.

Sponsor Challenges:

The sponsor had identified difficulties establishing and maintaining timelines with their previous data management vendors, as well as an inability to find a cohesive solution which included services for data management and biostatistics. Their primary concerns were around meeting timelines for large multinational trials with dozens of languages and thousands of patients, and how mid-study changes would be handled. As a result, the sponsor needed a vendor with multiple products in the eClinical domain including EDC and IRT. They needed a team with proven experience in data management and biostatistics running substantial studies successfully and with a history of approvals. They also needed the database build and migration to be done promptly to mitigate the ongoing impact associated with their current platform; disrupting data capture and poor user experience. Therefore, they wanted a fast and seamless transition to minimize all risks while maintaining an intuitive process for users when adopting the new platform.

Our Solution:

DSG was selected as the preferred vendor for the global support of the database build, migration, data management and biostatistics, providing an intuitive unified solution which would lead to enhanced data quality. The combination of DSG providing cutting-edge software solutions along with an experienced data management and biostatistical team resulted in dramatically improving the build and study conduct.

To achieve these outcomes the following were deployed:

Rapid Implementation: Within four weeks of the contract agreement, DSG fully implemented a migration plan and executed the data migration to the exact format of the Sponsor's request. Because the DSG project managers are trained eCaseLink™ system experts, the data migration was done efficiently and effectively under the proposed timeline.

Dedicated Teams: DSG assigned designated teams including a 24/7/365 support team, a project management team, a data management team and a biostatistical team all working together as a unit that were able to support five patient population and randomization schema changes in over 85 sites, 30 in China. The sponsor's randomization went from 8 to 32 stratifications mid-study while keeping the original 8 intact in their original stratifications. The unified team also executed database and SAP changes in 10 protocol amendments between both studies. These teams were the point of contact for all communications through the entirety of both studies with no turnover.

Unified Platform Cost Benefits: DSG leveraged internal processes and system capabilities that enabled the project team to work in unison coordinating the integration and migration tasks accordingly, which resulted in a shorter start-up timeline, ultimately lowering costs significantly.

Cross Study Reusability: DSG leveraged its systems expertise to use the tools on-hand in the most productive way possible. DSG's experience working with various sponsors and partners made reusability for different processes possible, which enhanced the efficiencies of data management resulting in a fast study build and reduction of costs for the second global phase 3 study. DSG utilizes CDISC standards for the initial build to help expedite and standardize the process.

The Result:

DSG was able to execute the study migration with an improved and efficient database that allowed for faster data capture for millions of data points in a record time. In addition, DSG was able to provide customized features and reports not possible with their current provider. DSG was able to beat the study start up timelines in deploying EDC, IRT, Data Management and Biostatistics for both global phase 3 projects. The DSG team was able to accommodate multiple changes to the study design throughout the conduct of both studies very effectively. The sponsor was satisfied with the data quality, the reliability of the system and the ease of use for site users and CRA's. DSG was successful in delivering high quality solutions and services consistently for both studies having met all of the sponsor's needs during implementation and ongoing support.



About DSG:

Founded in 1992, DSG 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. Our cloud-based eClinical software platform, eCaseLink™, provides capabilities that deliver operationally efficient results that are cost-effective. DSG's solutions have been used in thousands of clinical trials leading to approvals by global regulatory authorities such as the FDA, EMA, MHLW and CFDA.

Our Mission:

Innovate today to provide valuable solutions for tomorrow.

Learn more: dsg-us.com