DSG Builds Unified Decentralized Platform for Pharmaceutical Company Running Phase 2 Study for Critically Ill COVID-19 Subjects

Summary:

DSG was approached by a pharmaceutical sponsor during the beginning of the pandemic with the request to provide a decentralized platform including eSource/ePRO for direct-data-entry, Randomization, eConsent, Telehealth, Remote Monitoring and Data Management for a multi-site Phase 2 study for patients with SARS-CoV-2 in the hospital. The sponsor specifically was looking for a team with decentralized clinical trial experience, and specifically a unified platform that could operate through one central login for all solutions. In addition to software solutions, they also needed a partner with data management capabilities.

Sponsor Challenges:

The sponsor had identified unprecedented concerns of how to navigate this clinical trial without relying on traditional solutions such as consenting in-person on paper at a clinical site, utilizing double data entry from paper transcribed into the EDC, and onsite monitoring. The sponsor expressed concerns regarding timelines, COVID restrictions and obstacles, as well as providing consent for subjects in the hospital that were critically ill. As a result, the sponsor requested that DSG propose a workflow that could assist their specific needs along with the corresponding modules that could be used.

Our Solution:

The sponsor selected DSG to support the database build of eSource/ePRO, Randomization, eConsent, Telehealth and Remote Monitoring, as well as conduct including Data Management. DSG's solution was to provide an experienced team, all working together to ensure rapid implementation and effective conduct services.

To achieve these outcomes, DSG engaged a team comprised of experienced project managers and data managers with decentralized clinical trial experience. These domain experts were then coupled with eCaselink implementation specialists who could then take the input from the SMEs and configure the different modules such as eSource/ePRO, eConsent, Telehealth and Remote Monitoring in the most optimal manner taking into account the specific design and workflow needs of the program.

DSG was able to provide subjects and caregivers eConsent and TeleConsent options, along with Telehealth accessibility throughout the study to engage with the Principal Investigator and Study Team.

Our Solution: *(continued)*

DSG's combination of technology and the therapeutic experience allowed the team to efficiently build all the protocol specific eCRF's within the eSource and create study specific reports to monitor various aspects of the study. The study team was able to see the data immediately upon being entering into the eSource because DSG's unified platform is integrated in real-time. This made remote monitoring simple and efficient due to the workflow between eSource and EDC improving completeness and compliance while reducing queries at the site level. The synergy of the study team and the data management team working together from the beginning resulted in providing analytical dashboards for study trends ensuring a fast delivery and early submission.

The Result:

DSG was able to implement a multitude of decentralized solutions into the eCaseLink unified platform specifically for critically ill SARS-CoV-2 subjects in the hospital two weeks faster than the proposed timeline, while taking into account all the study needs including custom workflows and real time analytics. The DSG team performed the system build per the needs of the protocol, with necessary validations, reconciliations and compliance checks built in, which enabled the data management team to ultimately ensure excellent data quality and timely database locks. DSG accommodated the everchanging and unprecedented COVID-19 pandemic with decentralized solutions ultimately empowering the sponsor to provide a workflow feasible to carry out their potentially lifesaving clinical therapeutic while keeping the cost at a minimum.

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