CASE STUDY

OmniComm® eClinical Solutions for Life™

LARGE SPECIALTY DRUG LONG-TERM REGISTRIES

INTUITIVE SOFTWARE AND A COMPLIANT PROCESS

CLIENT
Global Pharmaceutical Company, US and EU locations

PRODUCTS/SERVICES
TrialMaster® EDC
Transformation Services

HIGHLIGHTS

- Client needed registry data extracted from legacy system into OmniComm's TrialMaster® platform
- TrialMaster's modern technology afforded opportunities to transform the data during the migration
- OmniComm's Transformation Services team expertly mapped out a migration plan complete with data transformation, completing the transfer in a validated manner.

CLIENT CHALLENGE

A large global specialty pharmaceutical company has multiple long-term rare disease registries that were running on a variety of older EDC technologies. These registries each play a vital role in the ongoing safety and efficacy assessment for these transformative drug therapies – each drug having critical life-sustaining significance for their relatively small population of patients.

The customer was challenged with several different legacy EDC platforms that each raised unique concerns around data quality, patient privacy, site satisfaction and overall ease of use. Also, there existed some unmet reporting requirements, along with an overall system robustness that was missing in some of the legacy EDC tools.

The customer began an evaluation of EDC technologies that would meet the following long-term requirements:

- Intuitive EDC interface, that is straightforward for casual users to learn and use
- Flexible interface, that allows for eCRF design paradigms that meet the unique needs of a drug registry structure
- Capability for unplanned visits, and optional data to be collected at any time – a common model for non-interventional studies
- Strong standard and ad-hoc reporting capabilities, to allow for ongoing evaluation of both the clinical data and operational aspects
- A robust eLearning platform, to allow global site users and CRAs to get just-in-time training on the EDC
- Ability to meet global pharmacovigilance requirements through the use of an autoencoder, notifications, an SAE transmission tool, and various reports and export capabilities to support interim analysis and ongoing safety surveillance.

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CASE STUDY

OMNICOMM SYSTEMS SOLUTION

OmniComm's TrialMaster Electronic Data Capture software suite was chosen as the foremost solution to propel this customer's portfolio of rare disease registries onto a state-of-the art EDC platform. OmniComm delivered a world-class blend of technology, services, and experience to this late stage business.

For the initial two large global registries:

- OmniComm designed, developed, tested, and deployed a new set of EDC deliverables including over 50 unique electronic Case Report Forms (eCRFs), flexible visit structures, and unique configuration options that met distinct global registry needs.
- OmniComm Transformation Services, using our proprietary OmniAdvance™ methodology, migrated over 10 years and 2000 subject's worth of registry data, including significant data transformation and date cleaning activities.
- Through a variety of learning platforms, including eLearning, OmniComm the global registry user community.
- OmniComm deployed the TrialMaster autoencoder, and engaged a third-party business partner to encode all the legacy adverse event and medication verbatim terms against MedDRA and WHODRUG.
- OmniComm developed custom reports, exports, and notifications to ensure that the pharmacovigilance team had timely access to all SAE data entered or updated within the system.
- OmniComm deployed and migrated the final database with minimal down-time, and high quality data migration, documentation, and validation.

RESULTS

- Site satisfaction and system adoption has increased steadily in the year since the first new registry was deployed.
- Training records, autoencoding, custom exports, and notifications are all recorded and audit trailed in a compliant manner.
- The pharmacovigilance team is receiving regular reports and notifications.
- The customer has engaged OmniComm for a third registry migration, and is in discussion with OmniComm for additional large registry deployments.
- OmniComm's SafetyLink and ePRO solutions are being considered for future deployment.

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