LEVERAGING EXPERTISE AND EXPERIENCE TO HELP COMPANIES SUBMIT QUALITY CLINICAL DATA

Life sciences and pharmaceutical companies face daunting challenges when navigating the complex regulatory review process to get new drugs approved. But, there is an easier approach.

CSC’s Biometrics and CDISC (Clinical Data Interchange Standards Consortium) capabilities span the total life cycle of clinical data-conversion services, including the Study Data Tabulation Model (SDTM), Analysis Data Model (ADaM) and Standard for Exchange of Nonclinical Data (SEND). CSC has strong operating procedures in all of its data service offerings, and we offer CDISC data mapping services for both SDTM and ADaM, define.xml and Case Report Form (CRF) annotations, as well as provide statistical programming and biometrics support.

The functional responsibilities provided by CDISC services include validation of external and internal CDISC packages, internal automated and manual quality control tools and methodologies, and expertise with Pinnacle 21 Community data fitness-assessment software. This approach allows CSC to provide standardized and up-to-date deliverables that meet regulatory requirements.

KEY BENEFITS

Regulatory Expertise: CSC deploys experienced full-service programmers and analysts onsite or at remote sites to meet all data-conversion needs and get them right the first time. In addition, CSC can articulate sponsors’ trial data from inception to submission, with the unique qualification of being a one-stop solution provider with a strong focus on delivering end products on time and at the highest quality.

Regulatory Experience: CSC’s professionals have many years of CDISC data articulation experience with strong backgrounds in drug development, research and development, pre-clinical and clinical development, as well as familiarity with new software tools used for automation, process intelligence and reporting.

Flexibility: CSC is flexible, and our professionals have a deep commitment to working toward collaborative goals, while closely safeguarding patient privacy and intellectual property.

Data Standardization: CSC meets data standardization requirements in a complex and quickly changing regulatory environment by focusing on reliability, repeatability and accuracy when working with clinical trial data.

End-to-End Data Conversion: From statistical programming to biometric data articulation, CSC handles all aspects of the data conversion process with publishing packages and integration of converted data into client systems.
WHY CSC?
CSC delivers industry-leading electronic document management and collaboration solutions. Our broad range of software options and offerings gives customers a flexible solution that meets their needs.

Comprehensive cloud, big data analytics and consulting capabilities allow for simplified delivery of a fully-validated global clinical standards governance solution, either on-premises or offsite. In addition, we take data confidentiality, security and privacy very seriously.

Beyond the technology, CSC has a skilled team of experts able to streamline the submission process. Our biometrics team has extensive experience and deep knowledge of the ways reviewers use CDISC and other data to review applications. CSC’s Biometrics and CDISC Services provides the ideal solution, one that is scalable, flexible and client-suited, meeting the specific needs of the always changing regulatory environment.

KEY FEATURES

Tailored Mapping
At the outset, CSC develops a detailed, tailored mapping plan specific to a company’s data needs to help create submission-ready datasets from any source data. We analyze data conformity to CDISC standards and develop data mapping and formatting that meet CDISC standards.

Regulatory Awareness
CSC drives dynamic responsiveness to the complex regulatory submission process by analyzing patient data with leading-edge tools — eliminating rework with faster and less expensive processes. We remain at the forefront of regulatory and CDISC updates to ensure that all data mappings and output meet the latest requirements.

Statistical Programming
Leveraging the experience of CSC’s clinical SAS programming team, we produce high-quality CDISC SDTM-compliant datasets via a double programming approach. Services include data integration and reporting for clinical summaries of safety and efficacy, with tables, listings and graphs that comply with regulatory standards.

Statistical Analysis
Using SDTM datasets, CSC develops a statistical analysis plan and other relevant study documentation to create analysis dataset specifications compliant with ADaM guidelines. We also produce an analysis dataset package using the same skilled and experienced programming team that produces the SDTM datasets, so we can ensure consistency across the package.

Regulatory Consulting
CSC’s expertise in CDISC and hands-on experience working with worldwide regulatory agencies provides efficient, start-to-finish submission services, as well as consulting for regulatory submissions. We can provide consultation in total life-cycle clinical data standardization processes such as trial protocol development, review deficit data identification and fulfillment, answer review queries, and provide training to the sponsor’s workforce.

CSC’s Biometrics Approach
CSC’s biometrics team has deep experience in helping companies plan, prepare, validate and ensure the quality of comprehensive data packages. We are highly focused on data quality because we know that getting biometrics data right is crucial for gaining approval.

We also spend considerable time working with data: summarizing, analyzing and cleaning it. CSC clinicians and statisticians often become key contributors to an essential component of the submission process: the reviewer’s guide. CSC aims to create a high-quality reviewer’s guide, bringing in experts as needed to provide updates throughout the process.

In addition, we can handle critical tasks, such as compiling the required table, defining packages or managing ADaM specs, to help fit the pieces of the puzzle together.

Learn more at csc.com/life_sciences.

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