

Since 2003 Quintiles has delivered CDISC SDTM data in over 300 studies for more than 80 sponsors.

There is an increasing global requirement for Clinical Data Interchange Standards Consortium (CDISC) -based standardized data for regulatory submissions. At Quintiles, we have proactively addressed this need by training our staff, gaining experience, and developing and implementing innovative solutions for creating data that adhere to current CDISC Study Data Tabulation Model (SDTM) specifications.

As one of the first companies to be certified as a CDISC Registered Solutions Provider, Quintiles is uniquely qualified to be your CDISC SDTM-compliant data provider. We offer seamless, cost-effective solutions for your electronic data submission needs, meeting the standards of regulatory bodies around the globe.

The benefits of having Quintiles standardize your data to adhere to CDISC SDTM specifications include:

- > Saving valuable time, as the finished product for your study includes data that has already been standardized.
- > Facilitating data warehousing, with the ability to generate reports across a range of studies, including multiple indications.
- > Reducing time for CRF development and database setup when standard CRFs are used.
- > Using standard CRFs and databases developed on recently published CDASH collection forms.

WHAT IS SDTM?

The Study Data Tabulation Model (SDTM) defines a standard structure for study data that are to be submitted as part of a product application to a regulatory authority.

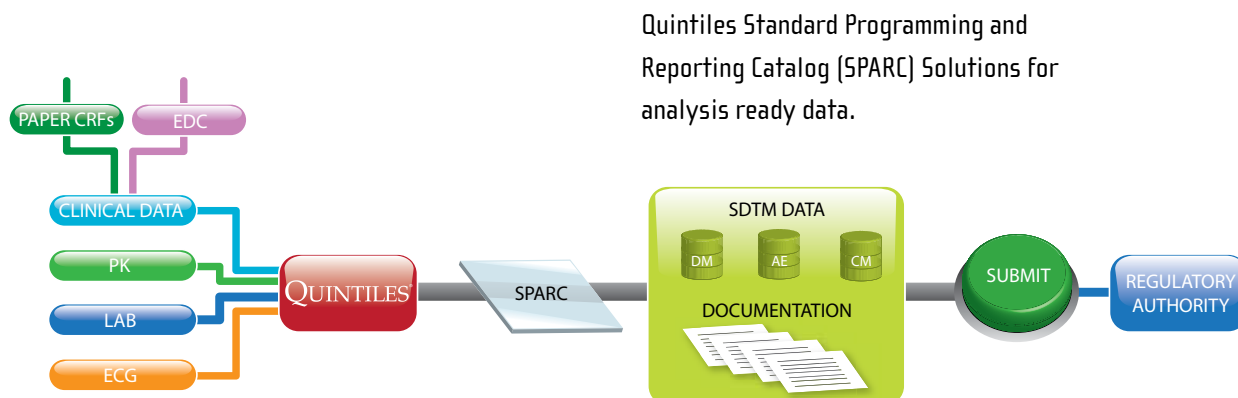
It is expected that through the implementation of data standards, companies gain by achieving more efficient time to market and lower development cost. It is anticipated that in the future all electronic submissions using the Electronic Common Technical Document (eCTD) specifications will require data to be in CDISC SDTM format.

For more information on CDISC and SDTM, please visit: www.cdisc.org

CONSIDER THESE CDISC ISSUES:

- > Do you have completed studies that are not yet in submission-ready (CDISC SDTM) format? We can help you convert them to CDISC SDTM-compliant databases. This can be completed independent of other submission work.
- > Which version of CDISC SDTM requirements will you follow? It is expected that CDISC SDTM Version 3.1.2 will be available by 2009.





Quintiles Standard Programming and Reporting Catalog (SPARC) Solutions for analysis ready data.

ACCESS TO GLOBAL RESOURCES

With more than 1600 employees in 14 offices from New York to Beijing, Quintiles Biometrics has the flexibility and resources to work with your specific needs. Our certified staff are trained in house on CDISC SDTM Theory and Application training.

DEPTH AND BREADTH OF CDISC KNOWLEDGE

Quintiles has contributed through participation on the CDISC Board of Directors, the Industry Advisory Board, the Laboratory Data and Submissions Data Standards teams, as well as the European CDISC Coordinating Committee and Japan CDISC Group. Our involvement provides us a unique and beneficial perspective in compiling CDISC SDTM-compliant deliverables.

INNOVATIVE CDISC SPARC SOLUTIONS

Quintiles has developed our own standardized SDTM solution based on an EDC platform. This integrated solution will provide you with a standard set of products to increase efficiency and lower costs by implementing reusable, validated components, as well as an efficient basis for repetition across studies and during the submission preparation period. As regulatory expectations further develop and evolve, we will upgrade our solution to continue to provide the best match between submission requirements and your needs.

Quintiles Biometrics welcomes the opportunity to tell you more about how we can help you meet your CDISC submission requirements.

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