

How to Navigate the New CDISC Standard

Quintiles – a CDISC Registered Solutions Provider – helps you get every detail right.

The Clinical Data Interchange Standards Consortium (CDISC) has developed a set of standards that the FDA has cited as their specification for electronically submitted data. And proposed rules are likely to make the electronic submission of data mandatory in the near future.

Quintiles, a CDISC Registered Solutions Provider, has experience preparing data that complies with the standards at both the clinical data systems level and for submissions.

What CDISC Does and Why It Matters

Databases are wonderful things, but only if the data in them can be readily accessed and compared. That's not always the case for clinical data today. If an urgent safety issue arises, for example, the FDA may need to correlate safety data from trials on two different products in the same class. It can't do so easily because the datasets are typically incompatible.



CDISC has established standards that will help boost efficiency, improve safety monitoring and help streamline the review and approval process for pharmaceutical and biotech products. Use of the CDISC standard can also add value to a compound in development, because potential buyers or merger partners can fold the study data into their own systems and work with and integrate the data more efficiently.

CDISC standards are quickly becoming the industry standard. With Quintiles' experience, we can make your transition seamless. ▶

QUINTILES CDISC EXPERIENCE*

Nine different Quintiles Data Management and Biostatistics sites have contracted to conduct almost 200 studies to CDISC standards.

- > 24 CDISC Version 2.0 Studies
- > 20 CDISC Version 3.0 Studies
- > 144 CDISC Version 3.1 Studies
 - 80 Phase I
 - 4 Phase I/II
 - 37 Phase II
 - 18 Phase III
 - 3 Phase IV
 - 2 NDA (iss + ise)
- > 9 CDISC Version 3.1.1 Studies

**As of February 2007.*

In-Depth Understanding of a Complex Set of Rules

The implementation of CDISC, like any other unfamiliar process, can be difficult without an in-depth understanding of its assumptions, structures and rules. Relying on the expertise of a Registered Solutions Provider (RSP) like Quintiles ensures that you are adhering to SDTM standards.

RSPs are qualified consultants, system integrators and subject matter experts who are certified by CDISC for their understanding of the standards and their ability to implement them. Quintiles is the first global provider of the full range of drug development and marketing services to be recognized as an RSP.

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We are close to completing an aggressive training program. With 75 percent of relevant staff trained, our goal is to have all employees who need it complete CDISC SDTM Theory & Application training by the end of 2007.

In addition, we have played an active role in supporting CDISC as a Corporate Sponsor, and in developing the standards, with Quintiles employees serving on the CDISC Board of Directors, CDISC Standards and Pilot Teams, the Industry Advisory Board and CDISC Coordinating Committees worldwide.

Please contact us to learn more about CDISC and how we can help you better understand its implementation.

At Quintiles, *it's all about results.*

QUINTILES CDISC SERVICES

- > Laboratory Data (LAB) provided in CDISC format in both SAS and ASCII formats (available in XML upon request)
- > Clinical Data structured to facilitate its flow into CDISC Study Data Tabulation Model (SDTM)
- > Submission Datasets created in SDTM format, with data delivered as submission-ready SAS transport files and CRFs annotated to SDTM data variables for raw variables



The Development Group of
Quintiles Transnational