Today, SDTM is the general framework for organizing clinical trial information that is submitted to the FDA. SDTM can be developed at different stages in the clinical data management process.

SGS Life Science services can assist you with:

**CONVERSION OF LEGACY DATA**

SGS Biostatisticians have converted legacy data into SDTM for more than 230 trials on behalf of multiple clients. Over the years our team has set up and validated generic scripts and processes in SAS®, resulting in a very efficient and faster approach. SGS Biostatisticians have an extensive background in SDTM interpretations, making them SDTM experts advising our clients on the advantages and disadvantages of different implementation approaches.

**CONVERSION FROM STUDY START ONWARDS**

While the Biostatistics department was gaining experience in the conversion of legacy data using SAS®, our Data Management group developed an Oracle® based generic SDTM mapping tool, a client dependent metadata and code-list library, and standard procedures to consult this library. SGS Data Management started converting to SDTM in 2005 and has already handled more than 150 trials.

Today our Data Management delivers validated SDTM datasets within 1 month after Go-Live. Our check library is built on SDTM, resulting in less trial specific validation work and faster cleaning start-up. SGS Data Management works according client specific interpretations and we also have our own SDTM Implementation Guide. Already in multiple cases, the SGS Implementation Guide was used as the foundation for the development of a sponsor specific guideline.

**CONVERSIONS BEFORE DB LOCK WITH CLEANING ON SOURCE DATA**

For clients’s working/keeping CDM activities in-house and wanting to keep the efficient processes/standards they built up during the years, the SGS Biostatics department converts your clinical study data to SDTM during trial conduct, resulting in SDTM datasets available before database lock and the start of the statistical analysis.

The conversion into CDISC SDTM involves multiple challenges such as:

- Sponsor-vendor collaboration
- Decision making on the logical interpretation of SDTM concepts
- Meeting the timelines

In order to meet the above expectations good documentation is a must. SGS uses the SDTM annotated CRF as the master specification for all the downstream programming and testing. We first annotate the SDTM database structure on the (e)CRF using Adobe® Acrobat® and halt the process until approval is obtained from our client in order to avoid re-work, waste of time and money. As soon as the programming process is initiated, in-house developed software continuously checks the compliance between the annotated CRF and the final SDTM products, including define.xml.

*Communication, collaboration and documentation are the key factors for successful SDTM conversion projects.*
IN ADDITION

Over the past decade, the SGS Biometrics team built up extensive experience in CDISC standards. This investment was very recently rewarded with the registration of SGS as Registered Solution Provider (RSP) by CDISC.

- 16 Contract Research Organizations and IT solution providers worldwide have been approved as CDISC RSP as of early 2011
  - 11 are approved for SDTM
  - 8 are approved for Define.xml
  - 5 are approved for ADaM

- SGS is one of only 3 providers approved for the unique combination of SDTM, ADaM and define.xml

ABOUT SGS

With innovative study designs, optimal facilities and strong regulatory intelligence, SGS can favorably impact client’s drug development timelines and decision-making process.

Registered Solution Providers are subject matter experts acknowledged by CDISC having sufficient knowledge and experience in implementing various CDISC standards.

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