CDASH - the model for the collection of clinical trial data - is the new rising star among the CDISC standards. Using CDASH Case Report Forms (CRFs) upstream in the process flow provides time-savings when going downstream in the process flow towards SDTM and AdA M because of the standardization opportunities that ripple through the complete life-cycle of each clinical trial. CDASH is therefore a key-item for a true end-to-end CDISC implementation!

DESIGNING CDASH COMPLIANT CRF’S

The Data Management team at SGS is equally proficient with designing paper Case Report Forms as with designing electronic CRFs for deployment in an EDC application. The CDASH specifications have been translated into a library of CDASH CRF pages at SGS that can be instantly integrated in a paper CRF or that allow drag-and-drop into the eCRF design tool.

PROCESSING DATA COLLECTED IN CDASH CRF’S

SGS’s Data Management and Biostatistics departments have implemented a stream-lined process that smoothly integrates the CDASH, SDTM, AdA M and define.xml standards. Starting from the CDASH library that is in place at SGS, the CRF designers can very efficiently build a Case Report Form that covers all clinical trial protocol requirements.

Afterwards, the Clinical Data Manager adds SDTM annotations to the well-known CDASH compliant CRF pages in order to prepare for the conversion of CDASH collection data to SDTM datasets. At the data management level, CDASH brings in a number of important time-savers.

Finally, the Biostatistics department creates AdA M datasets that are the final deliverable of the end-to-end CDASH-SDTM-AdA M implementation that is in place at SGS.

CDASH CRF pages:
- Guarantee less intensive effort when SDTM annotating the CRF since standard CDASH CRF pages have standard SDTM annotations
- Reduce the need for sponsor-specific controlled terminology
- Speed-up the process of developing the Extract-Transform-Load (ETL) mappings from CDASH to SDTM because of code re-use opportunities across trials

EDC-CDASH-CDISC: END-TO-END IMPLEMENTATION FLOW

Connor K. Bocian
Senior Director, Data Management

SGS
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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