

Data Evaluation Services

Evaluation of SDTM Data and Documentation

PharmaStat consultants evaluate the conformance and usability of SDTM data using OpenCDISC and a variety of other methods which catch additional issues. We review our findings with the Sponsor's staff, identify significant diagnostics, and recommend corrective action.

An SDTM database is not fully qualified without its associated define.xml, Study Data Reviewer's Guide and annotated CRF. Our define.xml validator checks technical conformance and also verifies the content of the define.xml against the database. It frequently identifies issues in the SDTM data that are missed by other validators.

Evaluation of ADaM Data and Documentation

We evaluate ADaM conformance using both manual and automated reviews of the ADaM datasets and documentation. In addition to running OpenCDISC and other automated checks, we manually assess the usability and reviewability of the data. As with SDTM, an ADaM database is not fully qualified without its associated define.xml and Analysis Data Reviewer's Guide. Our define.xml validator checks technical conformance and verifies the content of the define.xml against the database. It frequently identifies integrity issues in the data that are missed by manual review. The work product of the review is typically a summary of our interpretations and findings, which we review with our client's staff. The report includes an evaluation of OpenCDISC diagnostic messages and recommendations for corrective action.

Evaluation of Define.xml

Companies frequently seek out PharmaStat for our advice on define.xml conformance and content. When vendors provide define.xml and define.pdf with their deliverables it is sometimes the minimum required to avoid OpenCDISC diagnostics, and may not be useful as documentation. We evaluate define documentation with a variety of automated tools plus a manual review for accuracy and usability. As with our data evaluations, we review our findings with the Sponsor's staff, identify significant issues, and recommend corrective action.

SDTM Data Modeling and Review

When dealing with multiple vendors or internal project teams it is important that your SDTM modeling is aligned across all of your studies. PharmaStat can provide you with a set of modeling specifications to help create consistent and poolable data. PharmaStat consultants provide an aCRF, conversion specifications and business rules for each study or for the entire project. If you already have SDTM modeling in place, PharmaStat will evaluate your modeling and specifications as part of our review of the client's or vendor's conversion plan. This service ensures that the SDTM databases are complete, conforming, consistent with CDISC rules, and poolable across the submission.



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