

Q:

Have you thought about data validation lately?



From **Clinical Data Collection**
to **Regulatory Submission**

Breakthrough Outsourcing

World-Class Consulting

Game-Changing Software

Octagon
Research Solutions, Inc.[®]
Don't **Compromise.**

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CheckPoint Data Validation Services

Are you generating SDTM compliant datasets?

Do you need to confirm that your datasets will pass the FDA SDTM validation checks?

Do you need assistance interpreting the results of SDTM validation checks on your data?

Do you need assistance assessing and correcting data so that it is SDTM compliant?

CDISC (Clinical Data Interchange Standards Consortium) SDTM (Study Data Tabulation Model) has become the preferred format for submission of electronic clinical trial data to the FDA. When the agency receives the data, it passes through a validation process before it is accepted for submission. Most companies wish to validate clinical study data prior to submission to ensure that they do not receive a “refuse-to-file” based on the content or format of their electronic data.

Octagon continues to lead the industry by promoting the implementation of process controls and data standards. In alignment with this tradition, Octagon has developed, CheckPoint Services, a new offering that provides validation of over 300 checks (including the 105 FDA published checks, plus 4 additional JANUS checks) against the CDISC SDTM specification and implementation guide.

Octagon’s CheckPoint Services facilitate the early detection of potential data conversion and compliance issues. Our internal expertise allows us to offer deeper insight by going beyond the standard automated checks and providing optional guidance in interpretation and correction of data compliance issues.

Our three-tiered approach offers flexibility and provides an opportunity for clients to leverage our expertise to improve data integrity. Through this service clients may look to Octagon for:

1 Basic Validation: Octagon conducts basic validation of datasets (105 FDA checks, plus 4 JANUS checks). Client receives a standard report listing any validation issues.

2 Enhanced Validation: Octagon conducts enhanced validation, which goes above and beyond the basic validation and includes an additional 200 checks that verify SDTM compliance. Deliverable to client includes a prioritized interpretation of all issues identified during enhanced validation.

3 Expert Consulting: Octagon conducts enhanced validation in concert with expert consulting. Once datasets are validated, Octagon’s expert consultants work with the client to resolve issues and refine processes.

Octagon’s enhanced validation offers extended value by raising the bar on compliance checks. Our additional checks:

- Cover both safety and non-safety standard domains defined in the SDTM Implementation guide
- Verify all variables with SDTM controlled terminology
- Fully recognize all forms of ISO 8601 date/time duration
- Validate metadata between SDTM datasets and define.xml

Competitive offerings require high-priced software license fees or rely on error-prone, manual checks. CheckPoint Services combines Octagon’s practical knowledge of CDISC SDTM with automating technology to provide a cost effective alternative.

For more information, please visit www.octagonresearch.com or **contact us** at 610.535.6500.

Ask us about CheckPoint—Octagon’s innovative new software solution addresses the tedious, manual and labor-intensive process of validating data for CDISC SDTM Compliance. CheckPoint automates these tasks and simplifies the effort so that your team can identify errors and issues of non-compliance before data is submitted to the agency.

www.octagonresearch.com

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