

A Collaborative Approach to Analysis Standards

Who are the players?



Analysis standards team, containing programming and statistics experts.

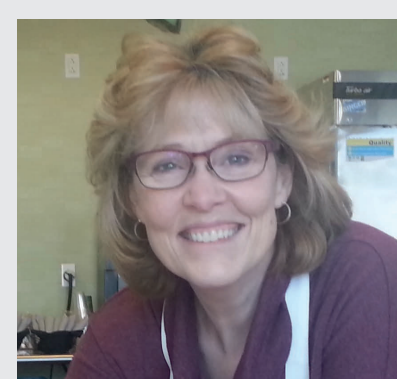
Subject matter experts (SMEs) in topics relevant to clinical trial analyses such as Adverse Events, Pharmacokinetics (PK), Labs.

Statistical programmers and statisticians from our therapeutic areas and clinical trial teams.

What are analysis standards?

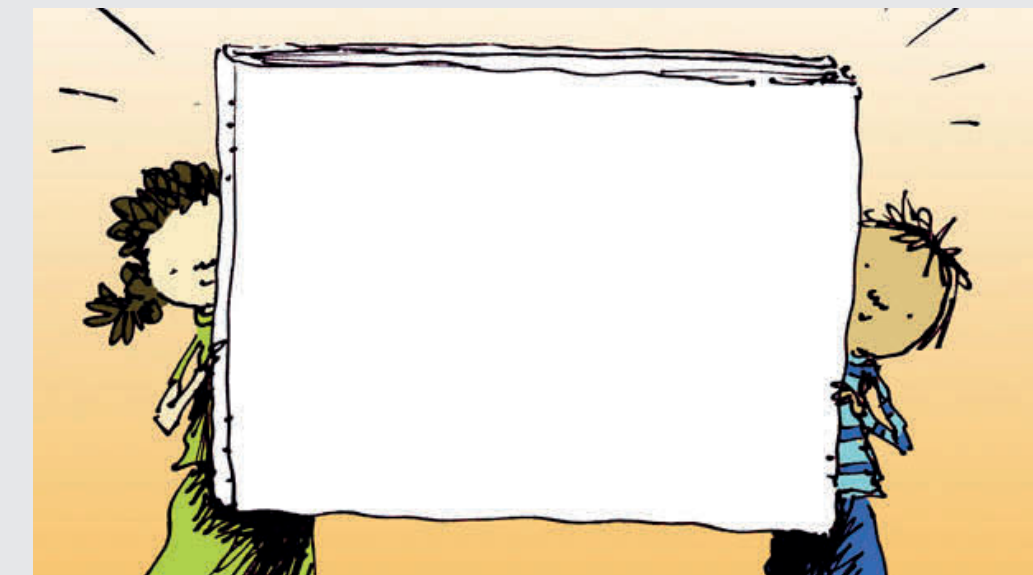


Analysis standards include global document templates for Statistical Analysis Plans (SAP), Data Presentation Specifications (DPS), template SAS code for analysis datasets and macro SAS code for tables, listings and figures.



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Examples of collaborations on global standards



New Analysis Standard

Typically this is a result of a new or updated requirement by the FDA or CDISC. The analysis standards team will work with the SMEs from the relevant topic areas to develop the new standard deliverables.



Question about an existing analysis standard

- Questions are posted on a portal and emails are auto-generated to the standards team.
- The standards team will respond to simple questions. If the question is complex it will be "triaged" by the standards team and escalated to the topic SMEs.
- The topic SME's will respond. If there is disagreement on the response, the lead SME makes the final decision on the appropriate response.
- If an update is needed to the standard, a change request will be created (see below) to correct the error.



Request a change to an existing standard

- A change request that results from an error in the analysis standards will be completed and deployed as soon as successful testing is completed.
- A change request for improving existing standards will be discussed between the analysis standards team and SMEs. If approved for implementation it will be deployed with a future planned release of standards.

"But the standards don't fit my study"



The needs of a study always take precedence over the use of global standards. We're not trying to fit a square standards peg in a round study hole.

To mitigate this challenge and help our study teams, the analysis standards group and SME's from selected disease areas have worked together to develop standard study documents and code customized for each selected disease area.

Measure the value of using analysis standards



- Using analysis standards across studies makes the study deliverables more consistent.
- Use of standard code for common analyses results in more time for developing code for more complex analyses