

Identifying Sponsor Checks for Outsourced Deliverables



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“purpose is to provide insight for effective review”

- Two Parts to Oversight:
 - *Analysis Oversight Strategy*
 - *Analysis Oversight Planning*

- Analysis Oversight Strategy
 - This is the Sponsor’s programmatic strategy to conduct oversight of the Third Party Supplier’s contracted deliverables to ensure the product meets expected quality and integrity standards.

- Analysis Oversight Planning
 - This includes an array of topics for successful management of oversight activities. When these topics are combined, they produce a complete picture of oversight interaction with your Third Party Supplier.

Analysis Oversight Strategy



A Categorical Approach

- Review of Protocol, SAP, and dataset Specification documents
- Always important to assess risk at each stage, continue to check logs, and review entire output reports
- Categorize your ADaM Datasets & TFLs (tables, figures, listings) into the following groups:
 - Standard
 - Core datasets & TFLs, commonly produced, include lowest level of study specific programming
 - Examples: ADDS, ADCM, ADDV
 - Typical
 - Common datasets & TFLs produced within a Therapeutic Area / at Compound Level
 - Example: Virology analysis datasets (within Infectious Disease TA), ADSL
 - Atypical
 - These datasets & TFLs include critical components for correctness and accuracy of the trial headline (or top-line) reporting when trial analysis is deemed complete

- For *Standard* analysis deliverables
 - Macroize a comparison of the dataset specification (read in as a dataset) to a proc contents of the delivered dataset from Third Party.
 - Compare Analysis dates with SDTM dates and Date Imputation flags for consistency of assignment
 - Post processing includes: Phase / Period algorithms, unique flags, analysis timing reference variables
 - At the TFL level, use frequency tables to confirm counts for population subsets

- For *Typical* analysis deliverables
 - Macroize a comparison of the dataset specification (read in as a dataset) to a proc contents of the delivered dataset from Third Party.
 - Reference studies within a therapy area or at the compound level provide a strong foundation of grouping, count, and flag variables found within *Typical* datasets
 - ADSL: Often, the added variables to ADSL outnumber the common (or core) ADSL variables. These custom ADSL variables trend within a therapy area (or even more at the compound level) and very few variables fall into the grouping of strictly study specific. Often, referencing past studies within a therapy area can set a strong foundation of ADSL grouping, count, or flag variables.
 - For *Typical* TFLs, `Proc Freq` and `Proc Means` allow you to produce and compare values to Third Party Supplier deliverables.

- For *Atypical* analysis deliverables
 - To truly ensure atypical deliverables are correct, we recommend they receive the most time allotted for complete independent programming by the sponsor.
 - In this category, many of the TFL outputs capture primary and secondary endpoints, along with dosing compliance data.
 - Full double programming done by the sponsor for this category opens the way for any questions or debate of design, interpretation from the SAP, algorithm design inquiries to arise between sponsor and contracted party.
 - Allowing time for debate among sponsor and contracted teams can be helpful to highlight issues or work out design details possibly overlooked or only recently applicable as new data cuts are added.
 - It is the inclusion of multiple perspectives that develops and delivers a robust analysis package. Thinking all the way through the process and discussing with colleagues lowers the risk of missed errors.

Setup for Success

- Set correct expectations: scope of work and timelines with Third Party Supplier
- Have necessary documentation ready (protocol, SAP, other guidance material)
- Determine programming support needed on both sides
- Setup intermediate timelines and treat as seriously as Final deadline
- Have repercussions in contract for poor quality / missed timelines

Analysis Oversight Planning



Trackers

- A QC Plan is a document that contains all components of the study
 - Datasets, TFLs, Programmer Names, Dates work occurred

Data Group	Display Section	Display Type	Display Number	Display Title	Target Date Ready for QC	Actual Date Ready for C	Target Date Passed QC	Date Passed QC	Overall for TFLs
ADSL	Study Population	Table	1.1.	Summary of Study Populations	22-Feb-18		#####		#####
ADSL	Study Population	Table	1.2.	Summary of Subjects by country and investigator	22-Feb-18		#####		#####

- Issue and Decision Tracker maintains the flow of communication between Sponsor and Third Party Supplier outside of regular scheduled meetings.
 - Questions, Findings, Responses, Resolutions

GSK Stats/Stats Programming FSP: Oversight Issue Tracker														
Status		Count												
Open		0	GSK Lead Statistician	XXXXX										
In Progress		0	GSK Lead Programmer	XXXXX										
On Hold		1	Other GSK Resources	XXXXX										
Escalated		0	Quanticate Lead Statistician	XXXXX										
Closed		112	Quanticate Lead Programmer	XXXXX										
			Quanticate Team	XXXXX										
Ref #	Impact	Type	Issue / Action / Risk Description	Further details	Status	Raised by	Raised Date	Assigned to	Due Date	Escalated to	Closed Date	Resolution Actions	Solution / Decision	Comments
		Action / Risk												

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- Meetings: Communication is Key
 - Kick off Meeting: a few weeks before the start of programming
 - Introduce study, timelines, contact persons, expectations
 - Status Update Meetings: weekly or every other week
 - Prepare Agenda prior to Meeting, take minutes, record ACTION items
 - Ask for a status update, include % of work complete up to current time point and progress from the past week
 - Programming Team
 - Try to maintain team members throughout
 - Ensure proper training is received prior to start
 - Ensure a staggered experience level of programmers
 - Time Off
 - Track upcoming availability, have a back up plan to cover scheduled vacations

APPENDIX1

Quick Comprehensive Checklist

- ☐ Have study folder setup
- ☐ Copy in all necessary standard macros
- ☐ Save study related material in the study folder. Eg: SAP, Protocol, etc.
- ☐ Save any / all required company specific templates in the study folder. Eg:
Template for Meeting Minutes, etc.
- ☐ Create a Timelines sheet.
- ☐ Create Study Specific QC Plan with current study information.
- ☐ Create Issue and Decision Tracker with current study information.

Conclusion & Contact Information



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- Questions?
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