

Please share a summary of the critical service level metrics you would propose to monitor this engagement?

TCS is working with J&J where currently Risk Based Quality Review (RBQR) approach is deployed to assess the quality of deliverables produced by TCS. For the clinical pharmacology project, J&J is currently working on defining metric to capture the quality and productivity related data. TCS is in process of working with J&J clinical pharmacology team to streamline the definitions for the metric.

In general, TCS is tracking metrics across all the 9 Biostatistics and Statistical Programming engagements. These metrics are discussed and agreed with the client at the start of the engagement. Throughout the life cycle of the engagement, these metrics are assessed and amended as per revised service level agreement (SLA)/ key performance indicators (KPIs). The periodicity of reporting and review of metric is discussed and agreed with clients.

The performance of the team is tracked at each deliverable level. A project/engagement specific quality control plan (QCP) is created for every engagement in consultation with clients and is documented in work instruction. TCS categorizes metrics under heads, namely, "Qualitative" and "Quantitative".

Qualitative Metric:

One of the metrics implemented to assess performance is the client satisfaction survey. This is assessed using a feedback mechanism on the parameters defined below at every milestone:

KPI	Parameters	Reporting
Study/Project Feedback	Feedback on the study/project deliverable (milestone) within 2 weeks of submission on below parameters <ul style="list-style-type: none"> ▪ Quality of Deliverables (<i>how do you rate quality of deliverables like DMC, Dry run, Key and final reports, and other milestone deliverables produced by TCS project team</i>) ▪ Timelines (<i>how do you rate the TCS members' ability to meet the agreed upon timelines on the project</i>) ▪ Quality of Question (<i>How do you rate quality of questions/queries raised by TCS project team</i>) ▪ Communication Overall & SLA (<i>how do you rate verbal and written communication by TCS team on your project</i>) ▪ Ownership & Responsibility (<i>how do you rate Ownership & Responsibility taken by TCS project team on your project</i>) ▪ Feedback on a scale of 1-5 	Milestone

Rating instructions for each parameter is classified as below, as an example.

Rating scale	Outcome
1.0 – 1.9	Not Satisfactory
2.0 – 2.9	Below Expectations
3.0 – 3.8	Meeting Expectations
3.9 – 4.5	Above Expectations
4.6 – 5.0	Outstanding

The overall satisfaction parameters are summarized and shared during the entire engagement life cycle and continuously assessed for any updates and/or changes depending on the feedback and / or revised deliverables. We can customized the parameters and thresholds upon discussion with the clients

Quantitative Metric:

The following metric is typically implemented in consultation with client

Sample B&SP Client: Metric					
KPI	Parameter	SLA	Definition	Measurement	Reporting
Quality – TLF, Datasets	FPQ – Major (FPQ-MJ)	TBA	FPQ-MJ to be computed based on all milestone deliverables where feedback is received and finalized between TCS and Client	# of outputs delivered without minor findings/ # of outputs evaluated and finalized * 100	Milestone
	FPQ – Minor (FPQ-MR)	TBA	FPQ-MR to be computed based on all milestone deliverables where feedback is received and finalized between TCS and Client	# of outputs delivered without minor findings / # of outputs evaluated and finalized * 100	Milestone
Quality – Documents	Major Comments	TBA	This is applicable to all documents developed by TCS which are internally reviewed by TCS senior resource.	Number of major comments received on 1st draft submitted for client review	Milestone
	No. of Iterations	TBA	This is applicable to all documents developed by TCS which are internally reviewed by TCS senior resource.	No. of iterations needed to complete document	Milestone
Timeline	OTD %	TBA	On time deliver (OTD) as per agreed timeline between TCS and Client	# of milestones with OTD/ # of milestone delivered * 100	Milestone
<div> <ul style="list-style-type: none"> SLA will be agreed after monitoring the KPI initially The number will be measured & reported once Milestone is delivered Client to perform risk based quality control approach Major & Minor Quality will be discussed and agreed </div> <div> <ul style="list-style-type: none"> FPQ = First Pass Quality MJ = Major, MR= Minor </div>					
Disclaimer: ¹ Input documents should be stable or close to final.					

Sample B&SP Client: Metric

Responsibility	KPIs	Parameter	SLAs*	Actual Score	SLA Reporting
TCS	Quality – TLF, Datasets	FPQ – Major (FPQ-MJ)	>=xx%	xx%	Milestone
TCS	Quality – TLF, Datasets	FPQ – Minor (FPQ-MR)	>=xx%	xx%	Milestone
TCS	Quality – Documents	Major Comments	<=xx comments	xx%	Milestone
	Quality - Documents	No. of Iterations	<=2 iterations	xx%	Milestone
TCS	Timeline	% OTD	=100%	xx%	Milestone
TCS	Feedback	Client Study Feedback	Qualitative	Ratings	Milestone

Major Comments

- Count in tables not correct
- Subjects not listed in the listing
- Wrong population selected while producing TLF's
- Layout & details not in agreement with mock shell
- Complete data points not mapped on the figures
- Axis in figures not correctly spaced
- Wrong title displayed
- Wrong derivation of analysis variable/s
- Wrong mapping of SDTM variable/s

Minor Comments

- Minor comments are agreed and defined during the knowledge transition phase.
- Formatting issues
- Spelling mistakes
- Capitalization issues

Disclaimer:²Input documents should be stable or close to final.

SLA will be agreed after monitoring the KPI initially

- The number will be measured & reported once Milestone is delivered
- Definition of major & minor findings will be discussed and agreed.