

Do you have experience supporting working models similar to this MBSM? If 'Yes'; please describe?

TCS has experience working on models similar to MBSM. TCS is supporting top Pharma companies from US and EU on MBSM type models. TCS is having 212 Full Time Equivalent (FTE) working on MSMB model supporting 5 major clients. The below snapshot provides details on the team size, delivery location, activities handled etc.

Biostatistics & Statistical Programming – MBSM Model Support				
	Sponsor 1	Sponsor 2	Sponsor 3	Sponsor 4
Client	Global Top 3 US based Pharmaceutical Company	Global Top 5 Swiss based Pharmaceutical Company	Global Top European Pharmaceutical Company	Global Top 5 Pharmaceutical Company
Years of Partnership	8+	9+	8+	4+
Delivery Center	India and USA	India	India and Denmark	India, France and US
Team Strength	82	75	26	30
Platform / SOP	Client Platform and SOPs	Client Platform and SOPs	Client as well as TCS Platform and SOPs	Client Platform and SOPs
Scope of Work	SDTM; Programming support for standards development.	SDTM, ADaM, TLFs, e-Sub support, DSUR/PEBRER, Statistical Monitoring	SDTM, ADaM, TLFs, DSUR, publication support	SAP, SDTM, ADaM, TLFs, CSR inputs, data review and surveillance reports, DSUR, DMC, e-sub activities, patient narratives
Working Model	TCS supporting global team. Delivery entire package / work as team member with global team	Integrated model, TCS resources are part of global team. For few projects, entire deliverables are by TCS team	Entire deliverables are by TCS team	TCS managing studies independently and working with global clinical teams
Quality Framework	Quality assessed based on random sample quality control. No formal SLA / KPI	Feedback from global lead for each deliverable. Quarterly satisfaction surveys to measure engagement health	Quality assessed based on random sample quality control. No formal SLA / KPI. Feedback from client study lead	Formal SLA / KPI for checking quality and timeline. Client performs random qc

**Sponsor 1 (US Based Company):** TCS is working with US based Pharma for last 8+ years supporting them on MBSM like model. TCS is having a team of 82 FTEs supporting this project. The scope includes Statistical Programming for SDTM, ADaM and for few studies TLF. The team is working on client system using client SOPs and processes. TCS has placed few resources onsite in the US region to ensure TCS staff is available for all critical F2F meetings and discussions. TCS are discussion around expanding the onsite scope for this engagement. In this engagement, apart from regular dataset generation, TCS team is also supporting client on generating, maintaining and managing global macros which are used for generating SDTM and ADaM datasets. Given the nature of work, TCS has well defined plan for on-boarding associates on a short notice period. There is well defined training module which caters to specific needs of project requirement.

**Sponsor 2 (Europe Based Pharma):** TCS is working with Europe based Pharma for last 9+ years supporting them on MBSM like model. TCS is having a team of 75 FTEs supporting this project. The scope includes Statistical Programming (SDTM, ADaM, and TLFs), DMC/Interim analysis,

DSUR/PBRER, eNarratives, eSubmission package, Data Anonymization and statistical monitoring work. For statistical monitoring TCS has aligned statisticians with working knowledge of JMP and SAP.

For core statistical programming activities, TCS team works on 3 different modules.

Work Force Extension – Under this model, TCS associates are part of projects lead by client project lead and they work as extended arm for the project from offshore India location

Conduit Model – Under this model TCS lead assumes the project lead responsibilities and coordinates with client and external vendor resources along with TCS internal resources on project deliverables.

Work Package Model – Under this model, TCS is assigned work package (set of ADaM, TLFs etc.) and TCS lead is solely responsible to deliver the package working with TCS resources.

For this client TCS is working on client Systems using client SOPs and processes. After initial training TCS is responsible for implementing Train The Trainer (TTT) model for all new employees.

**Sponsor 3 (Europe Based Pharma)**: TCS is working with a small Europe based Pharma for last 8+ years supporting them on MBSM like model. TCS is having a team of 26 FTEs supporting this project. The scope includes Statistical Programming for SDTM, ADaM, TLF, DMC/Interim analysis, DSUR and publication support. The team is working on client system using client SOPs and processes. TCS has placed few resources onsite in the EU region to ensure TCS staff is available for all critical F2F meetings and discussions. TCS are discussion around expanding the onsite scope for this engagement. TCS is also discussing scope of Statistician for this project in the EU region.

**Sponsor 4 (Europe Based Pharma)**: TCS is working with Europe based Pharma for last 3+ years supporting them on MBSM like model. TCS is having a team of 24 FTEs supporting this project. The scope includes Statistical analysis plan (SAP), CSR review, Statistical Programming (SDTM, ADaM, TLFs), DMC/Interim analysis, DSUR, eNarratives, eSubmission package, Data Anonymization work. TCS has placed senior (10+ yrs. experience) resources onsite in US and EU. These resources are responsible for coordination between India and client team, F2F client meetings, time zone overlap, ensure quality of deliverables. The team comprises of Statisticians and Statistical Programmers supporting various aspects of a given study. The resources are aligned by Therapeutic Area and are aligned to the same project to ensure knowledge retention and deliver efficiency.

For all of the above engagements, TCS project lead is responsible for managing TCS FTE in terms of line management, hiring, ramp-up, training, quality feedback and overall growth plan for the associate. TCS is working on client systems using client SOPs and processes. Train the Trainer (TTT) approach is deployed for training TCS associates and TCS lead is responsible for the same.