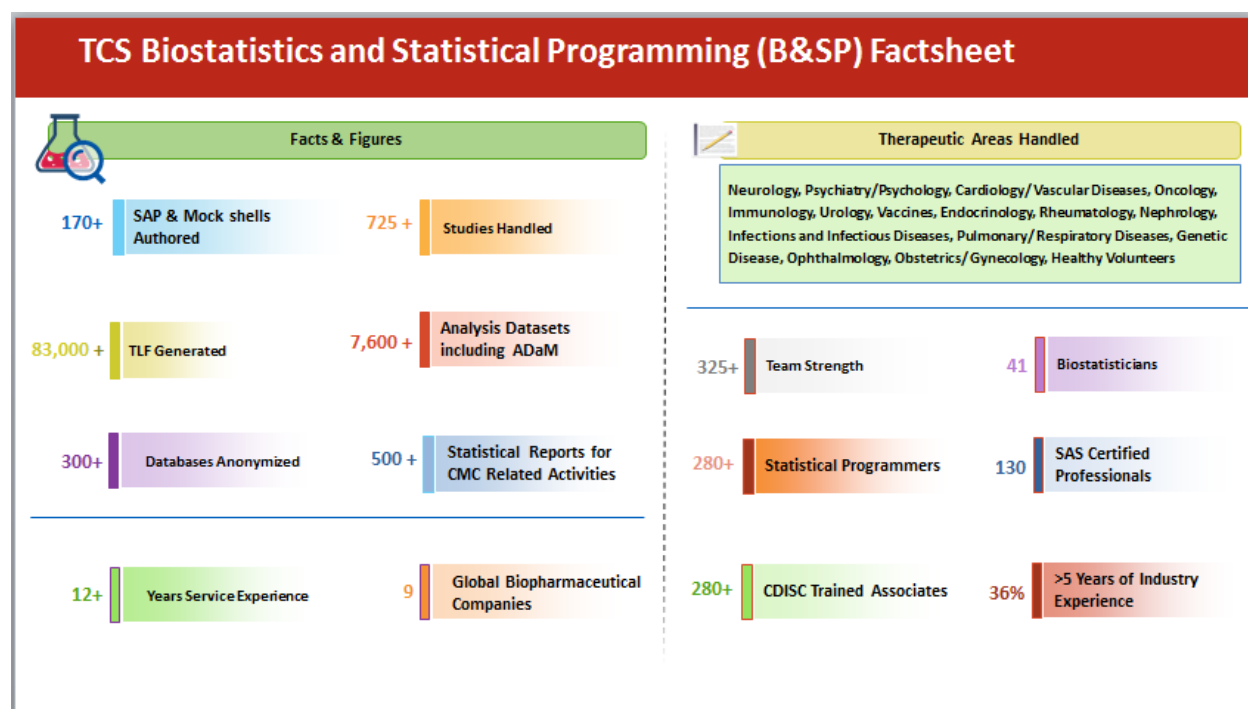Are you interested in partnering with J&J under a Managed Biometrics Services working model as described in the tab: Managed Biometrics Services Model? Please explain?

Yes, TCS is interested in partnering with J&J under the proposed Managed Biometrics Services Model (MBSM). TCS is supporting J&J Biostatistics and Statistical Programming (B&SP) services for Late Phase studies and for Clinical Pharmacology (CP) studies and has expertise in working on Janssen standards related to programming set-up, ADaM metadata, TLF standards and good programming practices. TCS is also well versed with Biostatistics standards for clinical pharmacology studies including statistical consideration for various CP types, drug-drug interactions, food effect, mass balance, BA/BE, etc.

Section 1: Overall TCS B&SP Capability:

TCS is a leading provider of B&SP services and is supporting other customers in MBSM. TCS has been providing services in the drug development space for the last Twelve (12) years, and has developed systems and processes to cater to varied business need of Pharmaceutical companies in the area of B&SP. TCS has flexible resource models and is working with other Pharmaceutical companies in full time equivalent (FTE) based, work package based, transaction based and other hybrid models. Our key highlights of B&SP services are portrayed below.

TCS Overall Snapshot:

TCS Biostatistics and Statistical Programming (B&SP) Factsheet

Facts & Figures

170+	SAP & Mock shells Authored	725 +	Studies Handled
83,000 +	TLF Generated	7,600 +	Analysis Datasets including ADaM
300+	Databases Anonymized	500 +	Statistical Reports for CMC Related Activities
12+	Years Service Experience	9	Global Biopharmaceutical Companies

Therapeutic Areas Handled

Neurology, Psychiatry/Psychology, Cardiology/Vascular Diseases, Oncology, Immunology, Urology, Vaccines, Endocrinology, Rheumatology, Nephrology, Infections and Infectious Diseases, Pulmonary/Respiratory Diseases, Genetic Disease, Ophthalmology, Obstetrics/Gynecology, Healthy Volunteers

325+	Team Strength	41	Biostatisticians
280+	Statistical Programmers	130	SAS Certified Professionals
280+	CDISC Trained Associates	36%	>5 Years of Industry Experience

The above snapshot details the overall TCS B&SP capability. The key highlights are
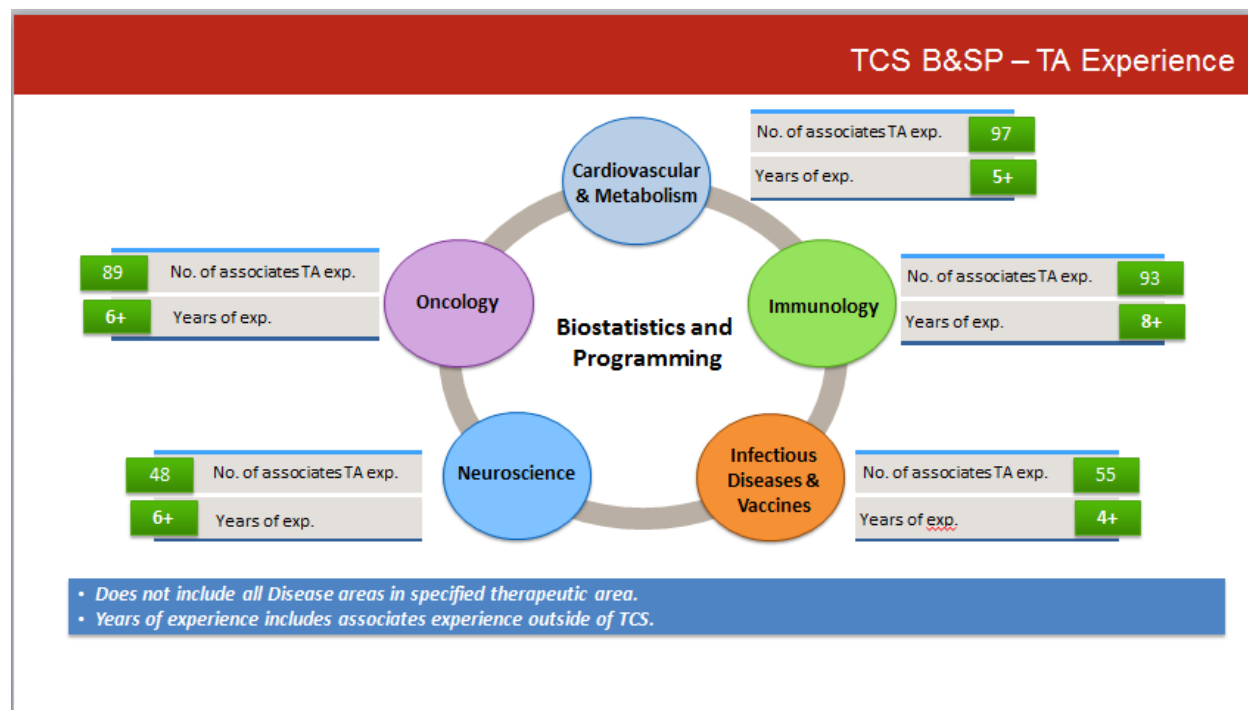
- Catering to 9 global biopharmaceutical companies

- 325 experienced biostatisticians and statistical programmers

- Flexible working models and resourcing models (FTE based, Work Package Model, Transaction Model)

- Supporting global companies on protocol development, statistical analysis plan, randomization schedule generation, CDISC deliverables, delivering tables, listings and figures, supporting ISS/ISE, support for health authority questions

- CDISC expertise – SDTM, ADaM and Define.xml

- Implemented metadata driven automated solution for data de-identification and anonymization, using SAS macros

- Supporting Chemistry Manufacturing and Control (CMC) related statistical and statistical programming activities

- Supporting end to end deliverables for clinical pharmacology trials

- Supported all major therapeutic areas (TAs) like Neuroscience, Cardiovascular and Metabolism, Oncology, Immunology, Infectious Diseases, etc.

Snapshot of various engagements:

Biostatistics & Statistical Programming – Selected Client Base

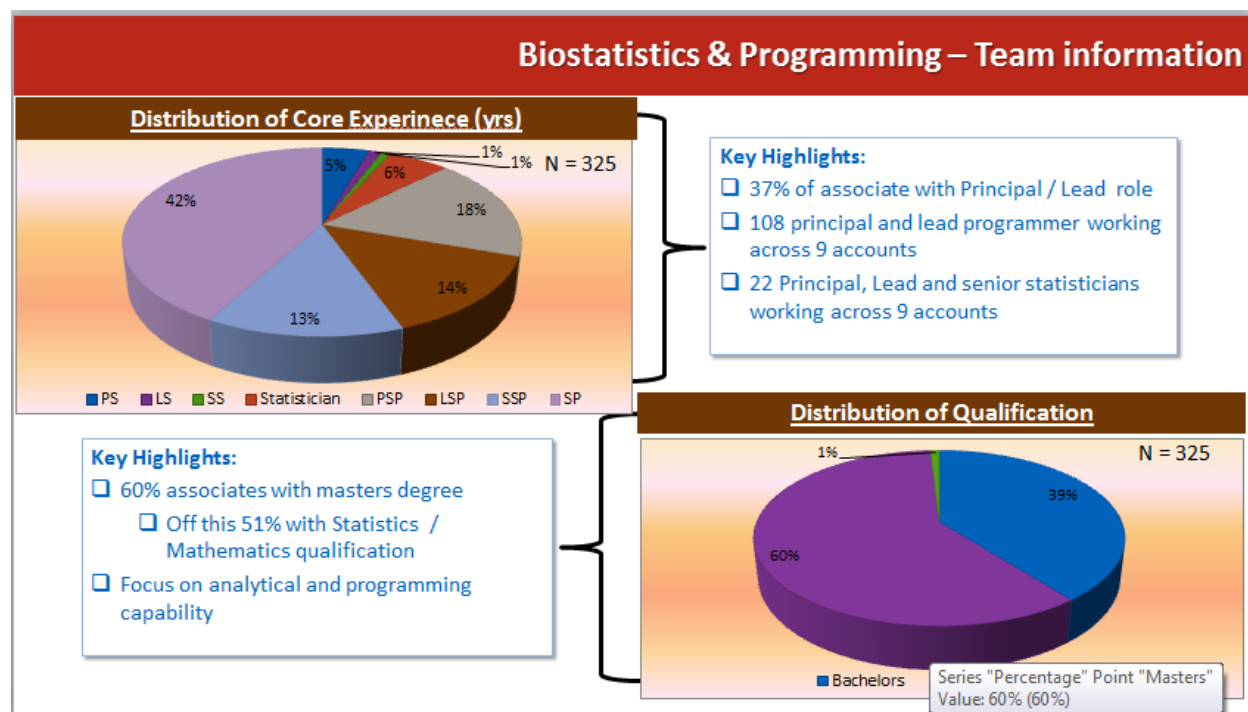|	Sponsor 1	Sponsor 2	Sponsor 3
Client	Global Top 3 US based Pharmaceutical Company	Global Top 5 Swiss based Pharmaceutical Company	Global Top European Pharmaceutical Company
Years of Partnership	8+	7+	8+
Delivery Center	India and USA	India	India and Denmark
Team Strength	82	75	26
Platform / SOP	Client Platform and SOPs	Client Platform and SOPs	Client as well as TCS 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
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
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

9   **TATA** CONSULTANCY SERVICES

Biostatistics & Statistical Programming – Selected Client Base

	Sponsor 4	Sponsor 5	Sponsor 6	Sponsor 7
Client	US based Health Care Company	Global Top 5 Pharmaceutical Company	Global Top 10 Pharmaceutical Company	Global Top 3 Biotech Company
Years of Partnership	5+	4+	6+	3+
Delivery Center	India	India, France and US	India	India
Team Strength	21	30	54	8
Platform / SOP	TCS Platform and SOPs	Client Platform and SOPs	TCS Platform and SOPs	Client Platform and SOPs
Scope of Work	Protocol inputs, SAP, Randomization, PK merge, SDTM, ADaM, TLFs, CSR inputs	SAP, SDTM, ADaM, TLFs, CSR inputs, data review and surveillance reports, DSUR, DMC, e-sub activities, patient narratives	SDTM, ADaM, TLFs, Data de-identification, End to end for Phase 1 and Medical Affairs Studies	Statistical Analysis for Chemistry, Manufacturing and Control
Working Model	TCS takes complete ownership of all deliverables.	TCS managing studies independently and working with global clinical teams	TCS managing studies independently and working with global team	TCS managing assigned work independently,
Quality Framework	Formal SLA / KPI for checking quality and timeline. Client performs random qc	Formal SLA / KPI for checking quality and timeline. Client performs random qc	No formal SLA / KPI for checking quality and timeline Client performs random qc	Formal SLA / KPI for checking quality and timeline. Client reviews reports

Depending on the client need, TCS is flexible to place the resources in onsite client location.

Snapshot of TA Experience:

TCS has extensive experience working on multiple TAs and has associates who have good TA specific expertise. TCS is currently supporting J&J on Neuroscience and Immunology TA.

Snapshot of Resource Experience:

TCS has 108 associates who are playing either principal statistical programmer or lead statistical programmer role across 9 B&SP accounts. TCS also has 22 principal, lead and senior statisticians who are working on core biostatistics related activities across accounts.

In course of the study the "Project Lead" (PL) role will be either played by "Principal Statistician" (PS) or "Programming Manager" (PM) depending on the scope and need of project.

PL will be primary contact for all the regular study level communication and discussions. Most of technical project level discussion will be handled by PL. This governance will look strategic aspects of the studies and will include

- ✓ Timeline tracking for each project
- ✓ Metric tracking in terms of quality and timeline
- ✓ Training and enhancing skillset of associates to meet project needs
- ✓ Project level and study level governance meetings
- ✓ Resource management for studies in scope, this includes
  - o Resources identification and training
  - o Attrition management
  - o Adhoc request management
  - o Health Authority Requests

The "Study Lead" (SL) role will be either played by Sr. Statistician or Sr. Statistical Programming Analyst (Sr. SPA) depending on the scope and need of project.
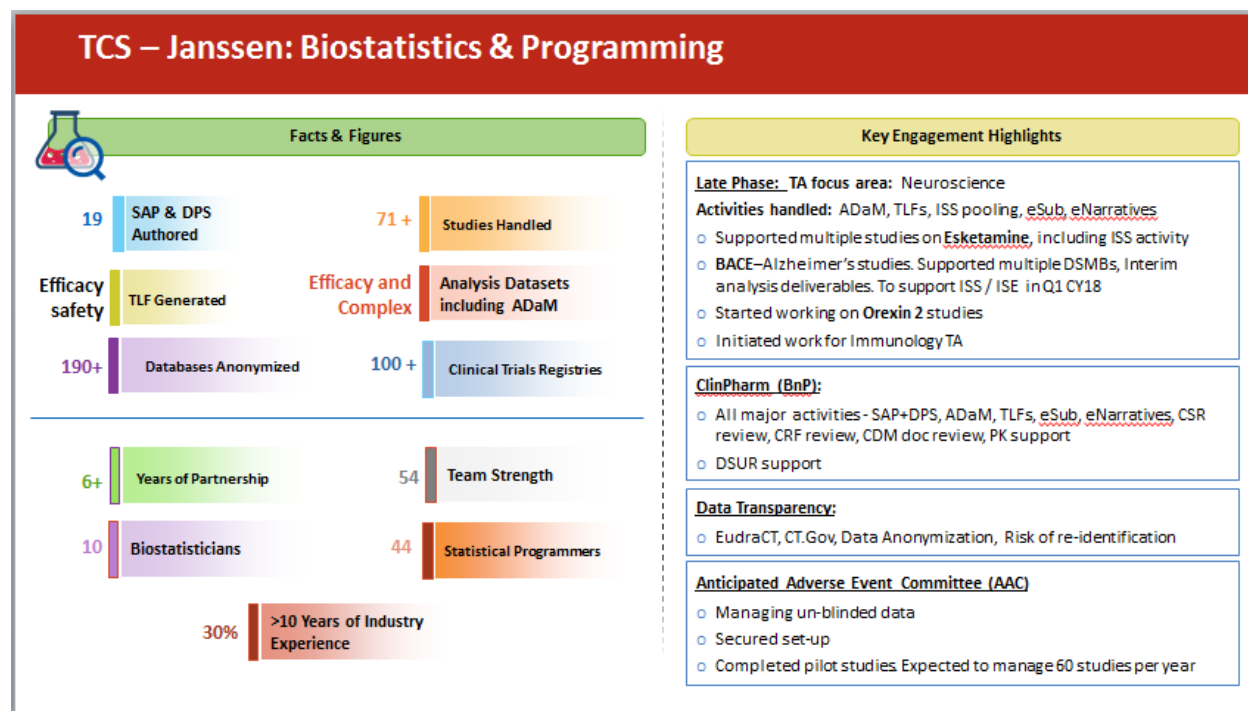
SL will be responsible to manage a given study and will interact with study team for all day to day study related activities. SL will manage following activities as his core responsibility

- ✓ Day to day study related discussions.
- ✓ Issues identification, tracking and resolution management.
- ✓ Manage all technical queries related to given study.
- ✓ Setup weekly/Biweekly meetings as agreed with the study team and share the Minutes of Meeting (MoM) post each meeting.
- ✓ Ensure study status tracker is up to date.
- ✓ Ensure the output delivered on time with highest quality.
- ✓ Will update the TCS Project Lead and study POC on the study status.
- ✓ Organize Lesson Learnt session with J&J to understand their expectation and incorporate the best practices.
- ✓ Organize Knowledge sharing sessions and Feedback sessions for team.

TCS will leverage the above expertise and experienced associates while forming the core team for the MBSM engagement. TCS will also on board leads and senior associates from the current Janssen engagement to for the core team.

Section 2: Overall TCS Janssen - B&SP Capability:

Given above facts and figures and TCS expertise working with Janssen B&SP team, TCS is committed to work closely with Janssen and is willing to make investments which cater to Janssen MBSM.

TCS Experience Supporting Janssen Late Phase Studies:

For Late Phase studies TCS is supporting the Neuroscience (NS) TA [ESKTEINTRD, SUI, MDD, ALZ] for statistical programming and have worked on generating ADaM datasets and TLFs. TCS is also supporting Health technology Assessment (HTA) related analysis for ESKETINTRD submission and is working on complex statistical tables included various statistical models [mixed model repeated measures (MMRM), Logistic Regression, Proportional Hazard Model, ANOVA/ANCOVA, sensitivity analysis for missing data, etc.). For other NS studies TCS is working on ADaM dataset generation and has good understanding of Janssen specific ADaM requirements.

Clinical Pharmacology (CP) Studies:

TCS is one of the preferred vendors managing CP studies. For B&SP, TCS is working right from SAP/DPS generation to ADaM, TLFs and inputs to Clinical Study Reports. TCS is well versed with Janssen CP standards and is managing CP deliverables with minimal oversight for both Biostatistics as well as Statistical Programming activities.

With 12 years of expertise in managing B&SP services and TCS understanding of Janssen standards, TCS is very well equipped to manage the J&J MBSM project.