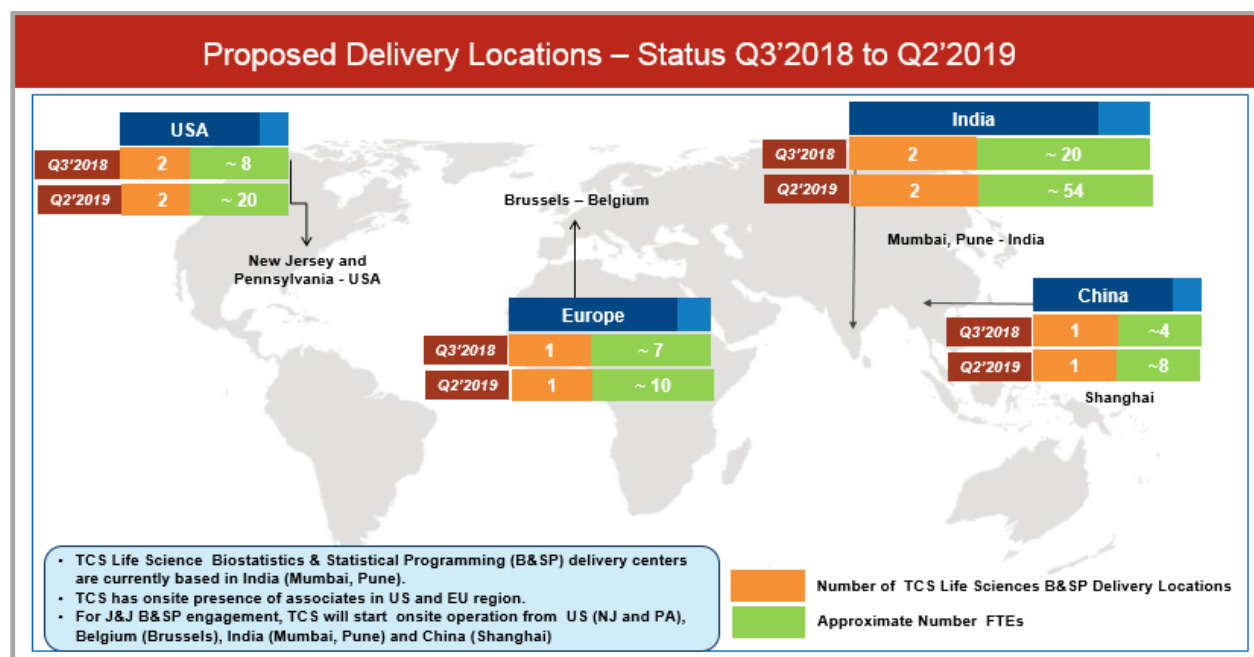


Provide a brief proposal for how your organization would support this working model (MBSM). Include the following:

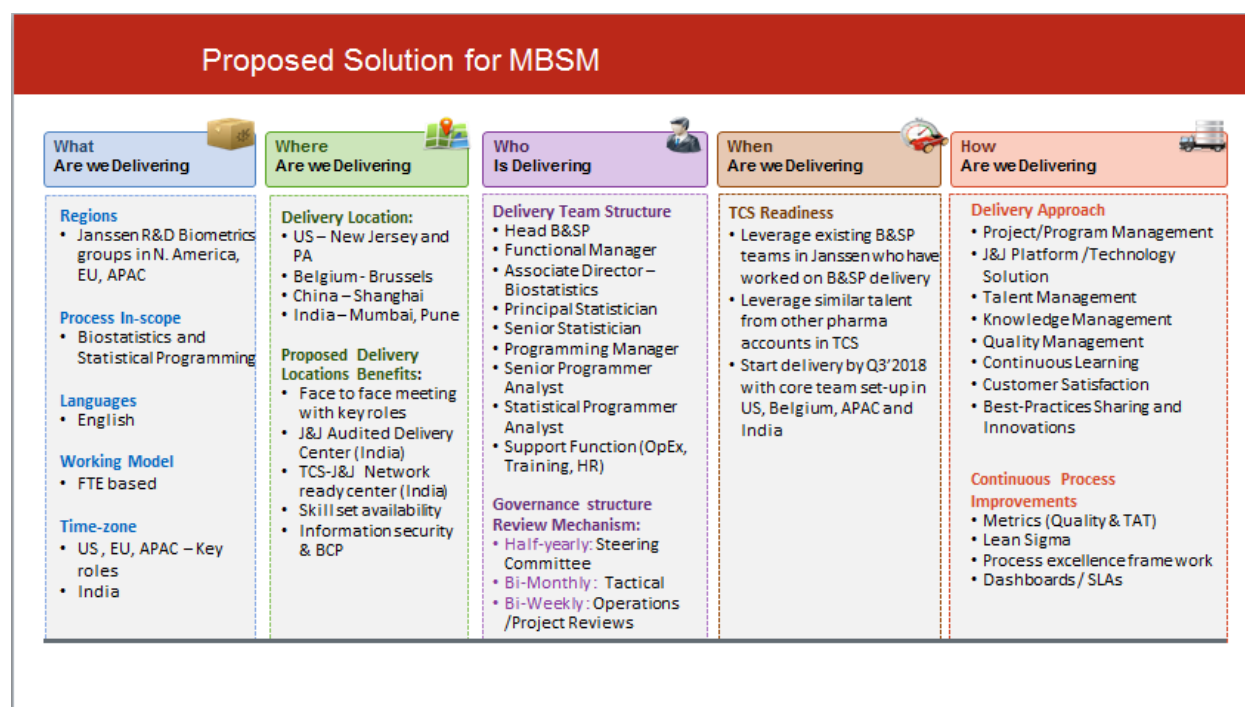
- Structure, core competencies and educational/professional background of staff overseeing managed biometric services. High level roles and responsibilities [proposed team structure];
- Ongoing maintenance and improvement of the engagement

TCS has been involved in MBSM like models with other pharmaceutical companies and TCS will leverage its experience and expertise from these engagements and implement the same for J&J. TCS is providing statistical programming services to J&J for the late phase delivery in Neuroscience therapeutic area, data anonymization, clinical trial results disclosure, etc. TCS is also managing core statistical and statistical programming work for J&J clinical pharmacology projects. A dedicated group of 30 statisticians and statistical programmers are already working on J&J late phase and clinical pharmacology projects, TCS will leverage its current expertise in J&J standards and systems while supporting the MBSM model requirements.

TCS is proposing an Onsite + Offshore model to cater to the current J&J MBSM requirement. TCS will have its delivery from US, EU, China region to support the requirement of near shore presence of key roles for face to face meetings and discussions. TCS will be deploying most of Biostatistics roles in the US and EU region. TCS will also deploy experienced Statistical Programmers (programming managers and senior programming analyst) in the US, EU and China region. India region will primarily work in collaboration with US, EU and China to ensure the model has good balance of onsite-offshore mix and it is functionally and commercially viable and long term sustainable. The detailed plan for start-up and ramp-up is covered in subsequent sections.



The below solution details the high level solution and implementation plan



This below section will cover details of the overall implementation of MBSM at TCS.

- 1) Planned roles to support MBSM implementation
- 2) Organization structure
- 3) Brief role description (detailed JDs are attached separately)
- 4) Start-up and Ramp-up schedule
- 5) Ongoing maintenance and improvements

Section 1: Planned Roles to Support MBSM Implementation

Based on the MBSM requirement, TCS is proposing following roles to be deployed for this engagement

Roles Planned for MBSM Implementation:

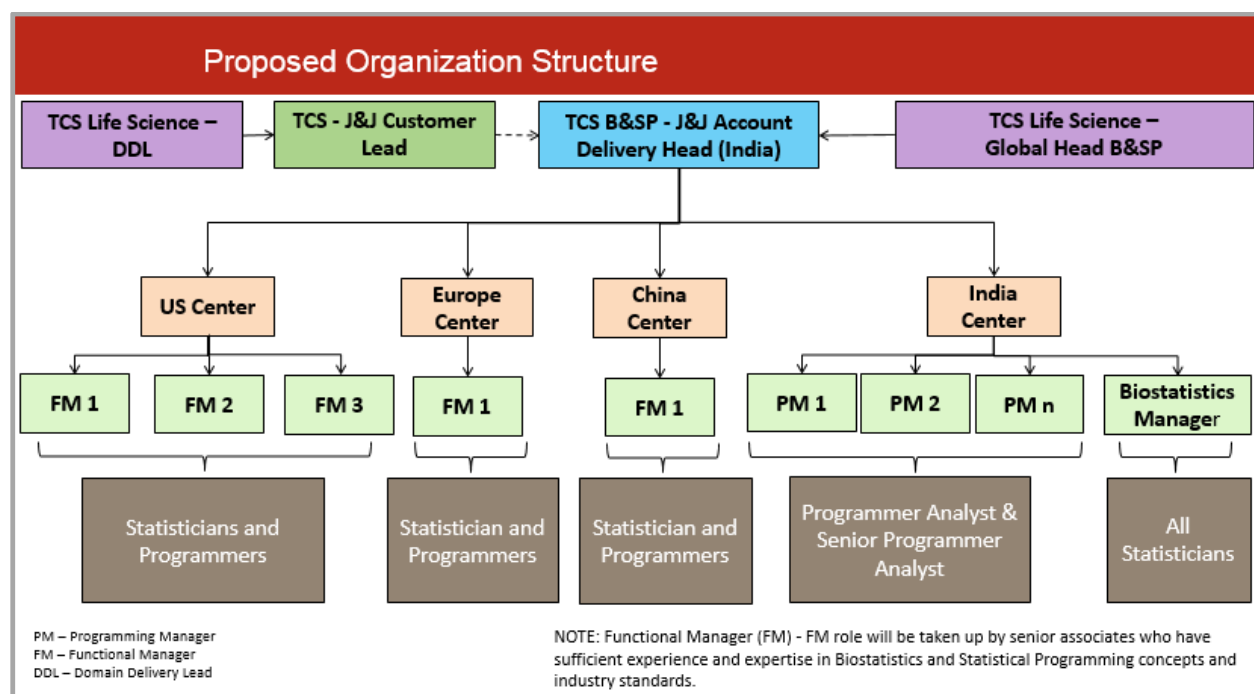
Category	Purpose	Role	US	EU	China	India
Management	Governance	B&SP – J&J Account Delivery Head	No	No	No	Yes
Management	Technical + Tactical	Functional Manager**	Yes	Yes	Yes	No
Biostatistics	Technical + Lead	Associate Director + Principal Statistician	Yes	Yes	Yes	No
Biostatistics	Technical	Senior Statistician	Yes	Yes	Yes	Yes
Statistical Programming	Technical + Lead	Programming Manager	Yes	Yes	No	Yes
Statistical Programming	Technical	Senior Programmer Analyst	Yes	Yes	Yes	Yes
Statistical Programming	Technical	Statistical Programmer Analyst	No	No	No	Yes

** Functional Manager (FM) - FM role will be taken up by senior associates who have sufficient experience and expertise in Biostatistics and Statistical Programming concepts and industry standards.

The above roles are defined to meet J&J expectations on managing both Biostatistics as well as Statistical Programming work from US, EU, and China region. To begin with, TCS will have a few key roles (Programming Manager, Senior Statistician and Principal Statistician) in China region and bulk of the work will be supported by India team. With the associates based in US, EU and China region, TCS will be able to provide an adequate overlap in terms of time zone support in the above defined model.

Section 2: Organization Structure

The roles defined in section 1 will be organized in below structure to provide adequate governance, agility and flexibility to the model. The core purpose is to form a technically & operationally competent team that is aligned to J&J vision of MBSM implementation. The focus is on having key roles (Functional Manager and other senior roles) at onsite location closure to J&J office to have face to face meetings, as and when needed.



The above team structure facilitates the requirement of having key resources placed in US and EU regions to have Face to Face meetings and discussions as per project need and criticality. Below are brief details of each role

Section 3: Brief Role Description

The below table shows the high level roles and responsibilities of each role involved in MBSM project

Category	B&SP Head	FM	AD	PS	Sr. S	PM	Sr. SPA	SPA	PL
<u>Project Management</u>									
Governance Meetings	Y	Y	Y	N	N	N	N	N	NA
People Management	Y	Y	Y	N	N	N	N	N	NA
Hiring and Retention	Y	Y	Y	N	N	N	N	N	NA
Training & Compliance	Y	Y	Y	N	N	N	N	N	NA
Issue Escalation	Y	Y	Y	Y	N	N	N	N	NA
<u>Technical</u>									
Study Related Communications	N	N	N	N	N	N	N	N	Y
Biostatistics Related	N	N	N	Y	N	N	N	N	Y
Statistical Programming Related	N	N	N	N	N	Y	N	N	Y
Project Working Group Meetings	N	Y	N	Y	Y	Y	Y	N	Y
Project Meetings	N	Y	N	Y	Y	Y	Y	Y	Y
TA / Disease Area Knowledge sharing	Y	Y	Y	Y	N	Y	N	N	Y
Hands on Project Work	N	N	N	Y	Y	Y	Y	Y	Y
Project Timeline Management	N	N	N	Y	N	Y	N	N	Y

NOTE: B&SP Head – B&SP- J&J Account Delivery Head, FM – Functional Manager, AD – Associate Director Biostatistics, PS – Principal Statistician, Sr. S – Senior Statistician, PM – Programming Manager, Sr. SPA – Senior Statistical Programming Analyst, SPA – Statistical Programming Analyst, PL – Project Lead.

The “Project Lead” role is defined at a study level. Depending on the scope of the study, either of the Principal Statistician or the Programming Manager will double up as Project Lead for that study.

High level role description is listed below for key roles. Detail job descriptions are attached with the overall proposal.

B&SP – J&J Account Delivery Head:

The overall engagement will be led by “B&SP – J&J Account Delivery Head”(B&SP Delivery Head) and will be primarily responsible for managing the overall J&J B&SP portfolio outsourced to TCS. Based in India and with strong governance structure, B&SP Delivery Head will be able to facilitate smooth communication with the key stake holders from J&J account. This role will

come with technical background and will have relevant experience and expertise in managing such engagements.

Qualification & Minimum Experience – Masters / Ph.D. in Mathematics, Statistics, Computer Science, or other scientific fields, 14+ years of relevant experience

TCS ramp-up plan over period of time to manage J&J expected volumes:

Cumulative Numbers	Q3'2018					Q4'2018 - Cumulative					Q1'2019 - Cumulative					Q2'2019 - Cumulative				
	US	EU	China	India	Total	US	EU	China	India	Total	US	EU	China	India	Total	US	EU	China	India	Total
Statistical Programmer Analyst	0	0	0	12	12	0	0	0	18	18	0	0	0	24	24	0	0	0	28	28
Senior Programmer Analyst	2	2	0	4	8	3	2	1	7	13	4	2	3	11	20	4	2	3	15	24
Programming Manager	2	2	1	2	7	3	2	1	4	10	4	2	1	5	12	4	2	1	6	13
Senior Statistician	1	1	1	2	5	2	1	1	2	6	3	3	1	4	11	4	3	2	4	13
Principal Statistician	1	1	1	0	3	2	1	1	0	4	3	1	1	1	6	4	2	1	1	8
Associate Director	1	0	0	0	1	1	0	0	0	1	1	0	0	0	1	1	0	0	0	1
Functional Manager	1	1	1	0	3	2	1	1	0	4	3	1	1	0	5	3	1	1	0	5
Total	8	7	4	20	39	13	7	5	31	56	18	9	7	45	79	20	10	8	54	92

Functional Manager (US, Belgium & China):

Functional Manager (FM) is the key role for this engagement and will be based out of US, Belgium and China. To start with TCS will have 1 FM each in US, Belgium and China placed near J&J location who will be available for face to face meeting at any given time point. As the team size grows, TCS will add 2 more FM in US to facilitate smooth functioning of delivery. FM is responsible to manage all the technical aspects of this engagement. FM will be a subject matter expert either in Biostatistics or Statistical Programming, and will primarily collaborate on technical and project related discussion with J&J point of contacts. The core responsibility of FM is to ensure domain driven delivery, maintain highest standards for quality. The FM will be the technical point of contact for all domain related questions from TCS as well as from J&J team. The FM will also impart/facilitate training on systems and process and ensure all associates on the engagement meet basic eligibility criteria before working on production deliverables.

Qualification & Minimum Experience – Masters / Ph.D. in Mathematics, Statistics, Computer Science, or other scientific fields, 10+ years of relevant experience

Associate Director Statistics:

Associate Director Statistics (ADS) is responsible for managing all assigned biostatistics related deliverables. The ADS also serves as a guide and mentor for the team on biostatistics related aspects. The ADS will work closely with the FM's in US, Belgium, China and the B&SP Delivery Head to ensure close collaboration between teams. The ADS will also be a technical expert for all biostatistics related queries from TCS as well as from J&J team, and will have relevant skills

with respect to TA/Disease area knowledge, statistical methods, protocol understanding and other aspects of clinical trials.

Qualification & Minimum Experience – Ph.D. in Statistics or related field with minimum 6 years relevant experience, or Master’s in Statistics or related field with commensurate years of relevant experience

Principal Statistician:

Principal Statistician (PS) is responsible for managing the all statistical aspects of a given clinical trials. To start with TCS will have 1 PS each in US, Belgium and China and TCS plans to grow this number to total 8 PS (4 in US, 2 in Belgium, 1 in China and 1 in India). PS will work closely with the FM’s in respective location (US, Belgium, China and India) to ensure FM is completely on boarded in the statistical aspects of a given study. For studies where biostatistics is in scope, PS will play the “Project Lead (PL)” role. PS will lead all of the study related statistical deliverables and will take ownership of quality. The PS is responsible to coordinate study aspects with the statistical programming team, clinical data management team and other relevant stake holders.

Qualification & Minimum Experience – Ph.D. in Statistics or related field with minimum 3 years relevant experience, or Master’s in Statistics or related field with commensurate years of relevant experience

Programming Manager:

Programming Manager (PM) is responsible for managing all statistical programming aspects of a given clinical trials. To start with TCS will have total 7 PM aligned to this engagement (2 in US, 2 in Belgium, 1 in China and 2 in India) and TCS plans to grow this number to total 13 PM (4 in US, 2 in Belgium, 1 in China and 6 in India). PS will work closely with the FM’s and PS in respective location (US, Belgium, China and India) to ensure FM & PS is completely on boarded in the statistical programming aspects of a given study. For studies where biostatistics is not in scope, PM will play the “Project Lead (PL)” role. PM will lead all of the statistical programming related deliverables and will take ownership of quality. The PM is also responsible to coordinate study aspects with the statisticians, clinical data management team and other relevant stake holders.

Qualification & Minimum Experience – Bachelor’s degree or higher and/ or equivalent in computer science, mathematics or other scientific field with 8+ years of relevant experience

Section 4: Start-up and Ramp-up Schedule

TCS will implement a two stage process for managing this engagement. Stage1 where TCS will set-up the core team in various regions and stage2 where TCS will ramp-up over period of time to manage J&J expected volumes.

Stage 1: TCS will set-up a core team of 39 statisticians and statistical programmers in stage 1 in 4 different geographies. The plan is to have all key roles in place and form the core team. This team will then ensure the stage 2 ramp-up is smooth delivery is as per J&J expectation

USA Strategy (8 FTEs): In USA, TCS will place resources in the New Jersey and Pennsylvania area so that they can have face to face meetings with J&J team at their ***Titusville, Raritan and Springhouse location***. TCS will have Associate Director Biostatistics who will oversee the US delivery. Apart from that other key and client facing roles will be placed in US including FM, PS, Sr. S, PM and Sr. SPA. TCS will not have any SPA role from USA.

Belgium Strategy (7 FTEs): In Belgium, TCS will place resources in the Brussels area so that they can have face to face meetings with J&J team at their ***Beerse office***. TCS will place one FM in Brussels who will oversee the Belgium delivery along with managing FM related activities. Apart from that other key and client facing roles will be placed in US including FM, PS, SS, PM and Sr. SPA. TCS will not have any SPA role from Belgium.

China Strategy (4 FTEs): In China, TCS will place resources in the Shanghai area. TCS will place one FM in Shanghai who will oversee the China delivery along with managing FM related activities. Apart from that other key and client facing roles will be placed in US including FM, PS, SS and PM. TCS will not have any SPA role from China.

India Strategy (20 FTEs): In India, TCS will leverage the current team experts who are working on J&J deliverables. TCS will align two Programming Managers from the current team to ensure the knowledge gained from current TCS-Janssen engagement is retained and carried forward in MBSM. TCS will set-up team of 20 FTEs with a mix of senior and junior roles. The India team will not have FM, ADS and PS role as they will collaborate with the global team on studies to ensure quality and efficiency is in-built in the delivery model. They will leverage global expertise to manage deliverables.

Stage 2: Once the core team is set-up, TCS will gradually ramp-up from 39 FTE in Q3'2018 to 92 FTEs in Q2'2019.

FM role will be primarily delivered from US, Belgium and China. SPA role will be delivered from India only and India team will work in collaboration with the US/Belgium/China team.

Section 5: Ongoing Maintenance and Improvements (WIP)

TCS is providing B&SP services to 9 global biopharmaceutical companies, of which for 4 biopharmaceutical companies TCS is supporting for more than 5 years. TCS understands the nuances of the model while in Business as Usual (BAU) phase.

Form ongoing maintenance perspective, TCS has robust system in place to manage

- Hiring
- Retention
- Training of associates
- Upskilling of associates
- Managing ad-hoc work requests
- TA and disease area knowledge upscaling and other aspects.

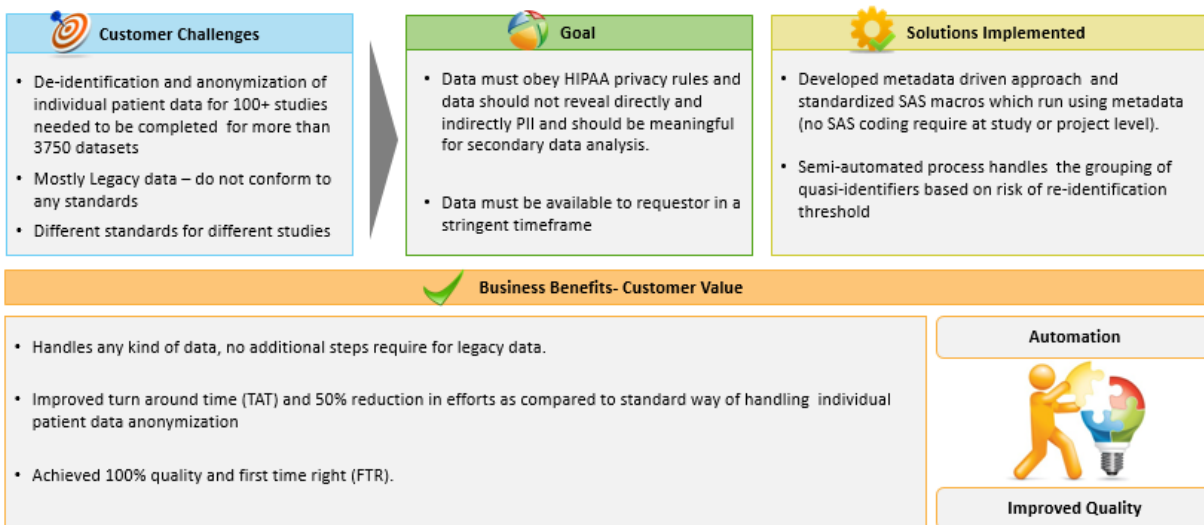
TCS has proposed and implemented many process improvements and point automation solutions to the pharmaceutical companies. From J&J current engagement too TCS has set-up “Metadata Driven” automated approach to create “De-identified/Anonymized Datasets”. Below is the case study detailing the same.

Data de-identification and Anonymization

TCS had set-up a team of 10+ associates who collectively have de-identified 6000+ datasets from 150+ studies as well as supported end-to-end study management including de-identifying documents (CSR, Narratives, etc.) till date. The team has developed a metadata driven macro based approach for de-identification of datasets. This set up ensures faster and efficient delivery of de-identified/ anonymized datasets. Some of the key differentiators are listed below:

- Associates trained on De-identification and Anonymization process
- Detailed training module
- Robust process and exhaustive documentation (work instructions, guideline, check list, etc.)
- Metadata driven approach (SAS driven macros)
- Quick turnaround time with quality deliverables
- Minimal / No sponsor oversight needed

Automation: Data Anonymization Process



TCS is also working with J&J team for standardizing and automating the “Anticipated Adverse Events” (AAC) requirement. TCS has created a dedicated team who has developed SAS macros to generate the AAC related outputs. The automation is still under testing and is expected to be finalized by Jun’2018 after testing it multiple studies.