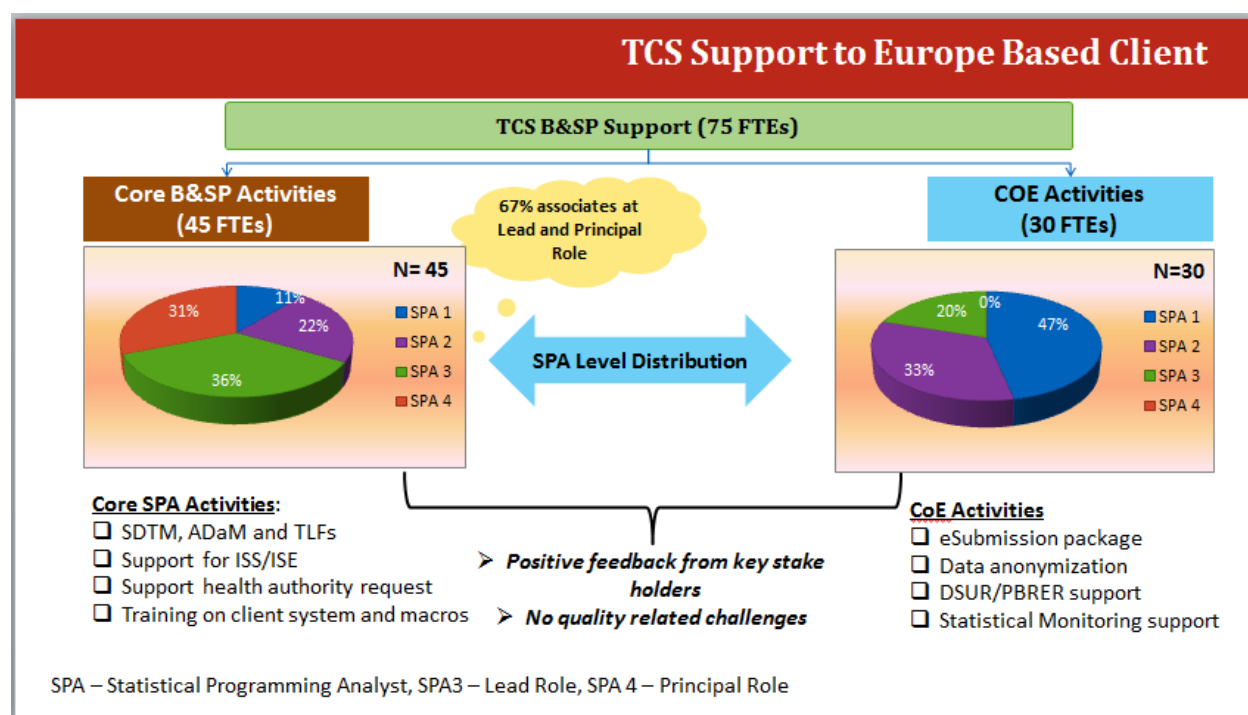


PROVEN EXPERIENCE USE CASE: Please select an actual example of a sponsor program filled in Table M15 above describing your process of scaling up.

Case Study 1 –

TCS is working with a Europe based pharmaceutical company since last 9+ years in a model similar to MBSM. TCS is working on FTE based model and is following client systems, SOPs and processes. There are total 75 FTES supporting various activities for this project. The below chart represents the distribution of FTE and the activities the team performs.



Initial Phase:

While the engagement started way back in 2008/2009, the expectation was to work on simple safety TLF and some basic programing activities. TCS set-up a core team of 20 associates and managed all defined service level agreement (SLA)/ key performance indicators (KPIs) which resulted in client expecting TCS to take up more activities. There was client oversight in the initial stage and client use to perform some quality control work.

Additional ADaM work:

TCS and client agreed to add more complex activities (ADaM datasets, efficacy TLFs etc.) around 2011/2012. TCS on-boarded key senior resources to ensure there is a core team of experts who can deliver to client expectation. Client did complete double programming of the initial outputs and datasets to ensure competency. The initial pilots were successful and TCS delivered to client expectation on SLA/KPI. By this time TCS has developed expertise in client TA and disease area. TCS started functioning as an extended arm for the client. By 2013, TCS started managing entire project deliverables with minimal / no oversight.

Complex Work and Lead Roles:

Around 2013/2014, client requested TCS to take up lead role which will take responsibility in managing entire compound related activities. TCS also supported client in developing various delivery models and helped creating training material for the same.

By this time TCS has become an integral part of client strategy and have started taking up more lead roles and started coordinating directly with other vendors and other stake holders form client team.

Central of Excellence (CoE) Model:

TCS was working with client on eSubmission related activities since 2010, however in 2014 TCS and client agreed to form COE for managing multiple peripheral activities. TCS started dedicated team of FTEs to support the COE related activities. As of 2018 under CoE TCS is supporting eSubmission, Data Anonymisation, DSUR/PBRER and Statistical Monitoring related services and has dedicated team of 30 FTEs working on this model.

Value Addition / Innovation:**CoE Optimization:**

TCS is now working with client on CoE optimization model under which TCS is considering following aspects

1. Automation of few process steps
2. Cross train resources
3. Manage peaks with cross trained resources

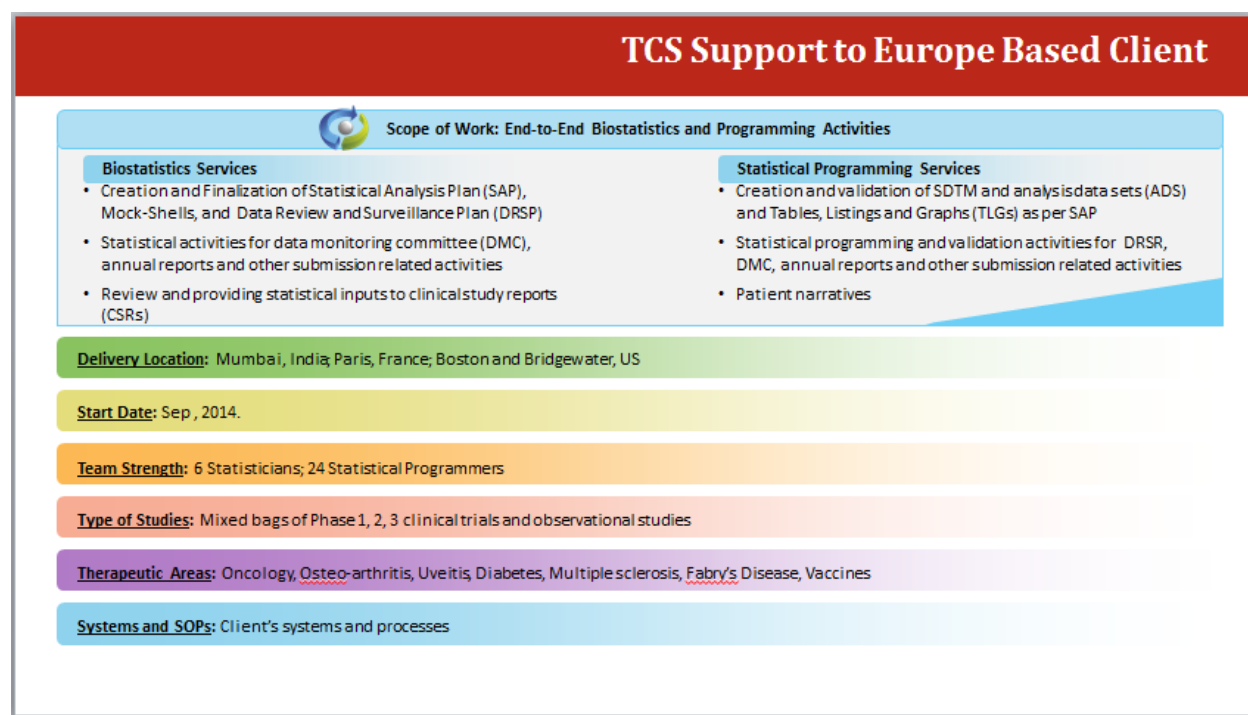
Apart from this, TCS has also worked with client to develop the overall outsourcing strategy under “Lead” model. This is currently implemented for multiple projects. TCS has created the training material for this model and presented to all client partners.

Under this engagement, TCS is also supporting SDTM delivery for the client. In initial phase client was doing validation however now TCS owns the complete package including the pinnacle 21 checks, SDRG and define.xml.

Thus for this client TCS started with 20 FTEs and TCS is having a team of 75 FTEs supporting the B&SP deliverables. TCS started with some client oversight and have now moved on to delivering project independently and has scaled up to manage project as Leads and coordinate with client as well as other partner key stake holders.

Case Study 2 –

TCS is working with a Europe based pharmaceutical company since last 3.5+ years in a model similar to MBSM. TCS is working on FTE based model and is following client systems, SOPs and processes. There are total 30 FTES supporting various activities for this project. The below chart represents the distribution of FTE and the activities the team performs.



For this engagement TCS is managing core statistical activities including developing the statistical analysis plan (SAP), leading and chairing the DRSR meetings as Lead Statistician, managing Independent Data Monitoring Committee (IDMC) deliverables and generated outputs for “Open” and “Closed” sessions of DMC review. TCS unblinded team is also responsible for coordinating with the client as well as external unblinded members for the IDMC.

Under this model TCS has placed resources in US and Paris region to ensure TCS staff is available face to face for all critical meetings and discussions. TCS lead statistician is coordinating with various groups with client for study related discussions.

TCS is now setting up COE model for this engagement and is setting up team of 10 associates to manage data anonymisation work for this client. TCS has also set-up a separate dedicated team for managing eNarratives activities and for the same TCS has placed resources in US and EU.

TCS started with a team size for 12 associates with SDTM, ADaM and TLF work in 2014 and today are supporting SAP, SDTM, ADaM, TLF, eNarratives, eSubmission, Data anonymisation activities for the engagement with 30 FTE team. TCS is working on client SOPs, systems and processes.

For both 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.