

Please provide examples with other companies where you innovated the model or modified it to improve efficiency.

Example 1 – Europe based pharmaceutical company

In initial stage of engagement TCS was supporting on simple safety TLF and some basic programming and few peripheral activities. In addition later TCS has also started supporting on few complex activities (ADaM datasets, efficacy TLFs etc.). In the initial pilot TCS has met the client expectations on service level agreement (SLA)/ key performance indicators (KPIs). TCS has also build the expertise in client TA and disease area and started working. TCS and client agreed to form Central of Excellence (CoE) Model for managing multiple peripheral activities.

- 1) TCS setup the dedicated team of FTEs to support the COE related activities.
- 2) TCS along with Client setup a robust model to deliver the various activity with minimal or no oversight.
- 3) Under CoE TCS is supporting eSubmission, Data Anonymisation, DSUR/PBRER and Statistical Monitoring related services.
- 4) Value Addition / Innovation:
 - CoE Optimization: TCS is considering following aspects:
 - Automation of few process steps
 - Cross train resources
 - Manage peaks with cross trained resources
 - Setup training document for the

Example 2 – Europe based healthcare company

It's a small health care company where TCS is managing entire Biostatistics and Statistical Programming for client. Below are the standard documents and tools developed by TCS:

- 1) TCS has developed programming standards and programming setup on TCS environment.
- 2) Developed the standard SAP template and mock shells.
- 3) TCS has coordinated with CDM team to setup standards for CRF data capture using CDASH standards.
- 4) TCS has also implemented CDISC standards for the model; right from CDASH, SDTM and ADaM.
- 5) TCS is also generating final e-submission package for final regulatory approval including define 2.0. TCS is now working on implementing analysis results metadata for this client.
- 6) TCS also supports setting up Randomization scheme.

For this engagement TCS is managing core statistical end to end activities including developing the CRF, statistical analysis plan (SAP), developing SDTM, ADaM and TLFs and final eSubmission package.

Example 3 – Janssen Pharmaceutical Ltd.

TCS has worked on the below automation for J&J:

- 1) TCS has developed the metadata driven solution for Data De-identification using SAS tool. It's a standalone tool which handles both development and validation of the DEID data.
- 2) TCS has developed the macro for disclosure risk calculation (Risk for data de-identification).
- 3) TCS has developed the standard macros for the Anticipated Adverse Event (AAE). TCS is working on setting up the documentation for the AAE activity and macros.
- 4) TCS setup few of the template and utility macros for setting up the reporting macros which has helped bringing quality and efficiency in each deliverables with quick TAT.
- 5) TCS has also created a documentation/rules for migrating the programs/macros from S: Drive to LSAF environment. TCS has successfully migrated few of the Alzheimer studies.