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

• Set up for training of staff on: trends in the industry/ regulatory knowledge

How do you ensure biostatistics and statistical programming staff working in the MBSM are kept current on industry, technology and clinical advances?
Describe the type of training that you provide to your staff to ensure they maintain industry (including therapeutic area/disease area) proficiency.

At TCS, learning and sharing is based on organization needs, project requirements/unit needs & employee's career aspirations. TCS has a robust training system aligned to the Pharmaceutical industry requirements. The training programs have been designed taking into consideration **Industry Standards**, **Therapeutic Area**, **Customer Focus** and **Soft Skills** training.
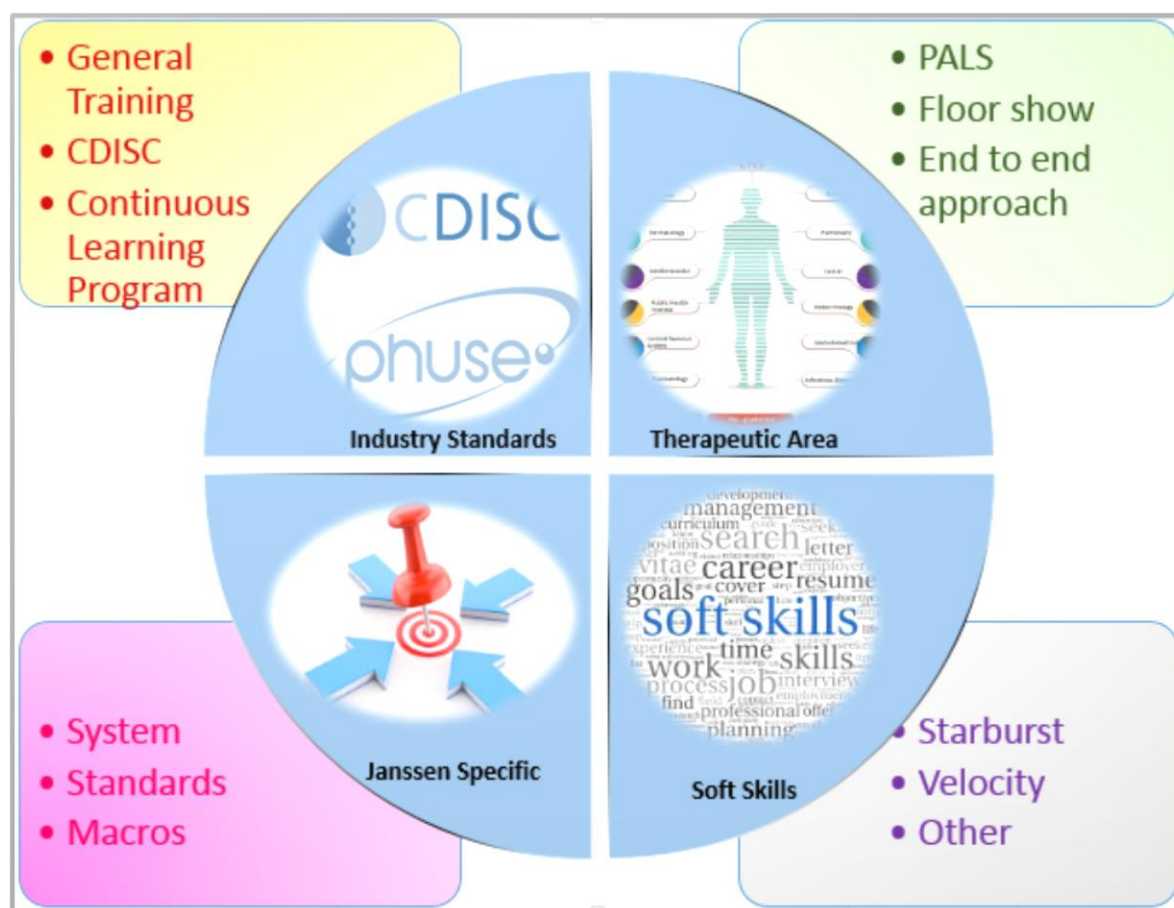
General Trainings –

An associate joining TCS undergoes the below listed training programs.

TCS Induction: All new recruits are inducted to the TCS culture and work values through a 3 day orientation program.

Based on the work experience of an associate, the Training and Development framework looks at the following:

1. In-house Talent Development program: Fresh Graduates

   Associates joining as a fresher go through 4 weeks of Initial Learning Program (ILP) before proceeding to client trainings.

2. Training for Lateral Hires

   All lateral hires are required to go through the client trainings and TCS SOPs.

Training for Lateral Hires – as needed

- Functional training for lateral hires
- Customized for client specific requirements

Bio-statisticians		Statistical programmers	
Statistical section of the protocol	On-the job by Sr. Statistician	Basic SAS Programming	Self Learning / Sr. Programmer
Objective and the related hypothesis	On-the job by Sr. Statistician	SAS exercises	Sr. Programmer
Sample size and power calculation	On-the job by Sr. Statistician	Specification Understanding (Requirement understanding)	Pilot study /on-the job by Sr. Programmer
Missing data imputation, Protocol violations vs deviations, Randomization and blinding	Classroom by SME/external	Analytical Thinking	Learning and Development Team / Sr. Programmer
Study designs and analysis with examples	On-the job by Sr. Statistician	Logic Building Training	Learning and Development Team / Sr. Programmer
SAS STAT procedures (GLM, MIXED, LIFETEST, etc.)	On-the job by Sr. Statistician	Quality Check Training (How to QC your code)	Team Leader / on-the job by Sr. Programmer
Adaptive designs, Bayesian designs	Classroom by SME/external	SAS STAT Procedures	Subject Matter Expert (SME)
SAP preparation and review	On-the job by Sr. Statistician		
Data Management process	Classroom by CDM SME		

3. For the in-house associates, there are various classroom trainings and Webinars conducted periodically to upgrade with industry norms, domain specific trainings and soft skill trainings.

Sample Biostatistics Training Plan

Sample Statistical Programming Trainin

4. Employees will also be exposed to *external accreditations, certifications, publishing white papers, extracts* and participation in live forums and *blogs*.

Continuous Learning Program ensures team to keep updated with Health Authority regulations. This is coupled with the Competency Development Methodology which helps identify the associate of the gaps and have a robust self-development plan in discussion with the manager.

CDISC focus group – *CDISCussion* consists of SMEs and SAS programmers with extensive experience on CDISC standards working across different accounts. These trainings are conducted periodically. Few of the trainings conducted by the group are as follows: Therapeutic Area specific data standards, SEND, Define 2.0 xml hands of workshops.

Trainings on R software: Regular trainings and workshop on R software.

Sample R Programming Train
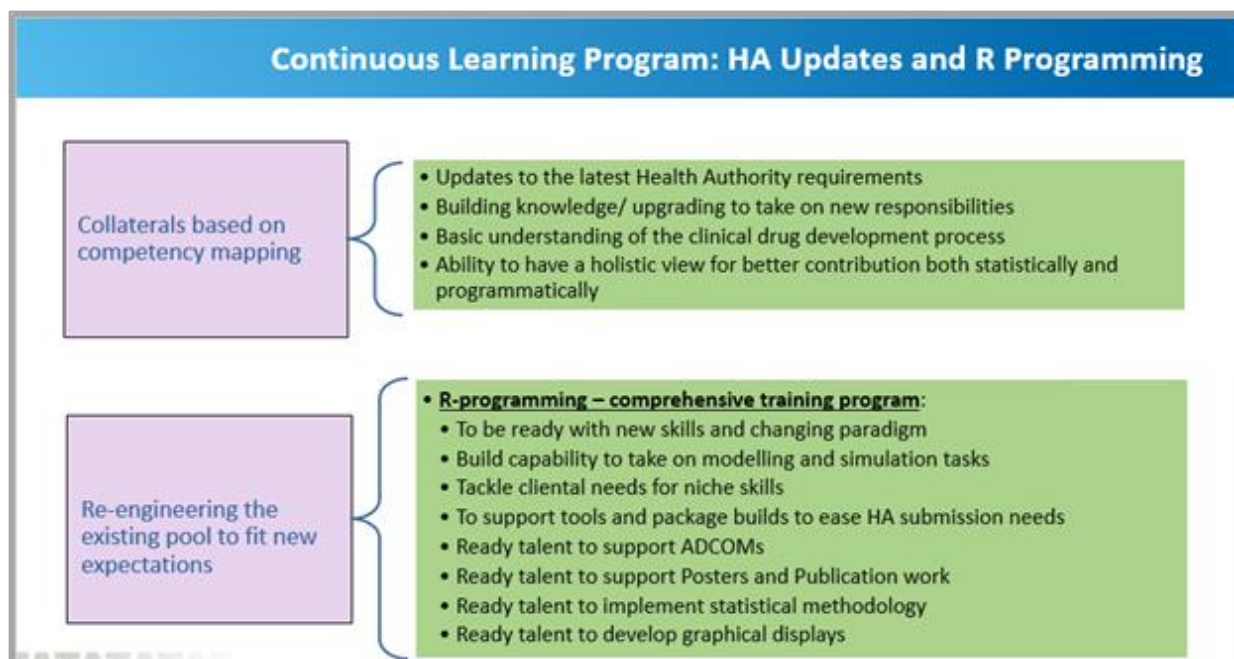
Thereaputic Area Trainings –

TCS PALS (Pharma Academy of Learning & Sharing) team is a dedicated team of domain experts that cater to all domain training requirements. This team has dedicated members for domain competency growth, comprising qualified and experienced physicians, life science graduates and instructional designers. Training are imparted via various modes (Instructor Led Trainings, eLearning modules, self-read, demos, WebEx and video conferencing), and at different levels of competency (overview, basic, advanced, workshop) as appropriate, to train project team.

J&J Specific Trainings –

TCS has been instrumental in delivering ADaM datasets and efficacy as well as safety reports for one of the breakthrough compound "Esketamine". With the experience of 10 studies over 2 years, TCS has come up with J&J specific training and documentation that help new associates to get familiar with J&J system, standards and reporting efforts.

System – TCS has been involved in 10 studies in Neuroscience portfolio, so far. Team has also supported migration studies. i.e., from STAR system to LSAF. TCS has created in-house document listing the procedure of migration and technical challenges faced during the execution. The document serves as reference for a new project on SAS Drug Development (SDD).

Standards – TCS has created programming standards documents that serves as easy access to current/new programmer to be aware of standards practices that need to be followed in Esketamine studies. TCS is trained on *new DPS standards* and started delivering reports for the first project *SUI3001*. J&J specific *METADATA* training is one of the key training sessions where ADaM standards, specification related to important data sets, macro associated to metadata has been discussed. This helps associate to be delivery ready and confident while working on live studies.

Macros – Exclusive training on J&J specific macros and coding standards have been conducted for each associates joining the group.

J&J Specific Thereaputic Area Trainings –

Floor Show – Therapeutic Area experts from across Clinical Data Management (CDM), Medical Writer (MW) and Biostatistics and Statistical Programming (B&SP) teams conduct floor shows to present the disease area, drug mechanism, specific protocols related points to entire account per quarter. A collaborative learning where different data collection strategy, importance of critical data point from analysis perspective and challenges faced while executing a study are discussed.

End to End approach – Study leads from CDM, B&SP, and MW teams meet on a frequent basis to discuss trial protocols. The cross functional team brings different aspects of the protocol and the critical points and perspective for data collection, analysis and reporting. This approach minimizes/avoids the last minute data issues and possible impact (delay) in timelines for respective teams.

__Soft Skills__ –

Based on the experience of an associate, various trainings ranging different competency level are assigned via *__TCS-iEvolve__* management.
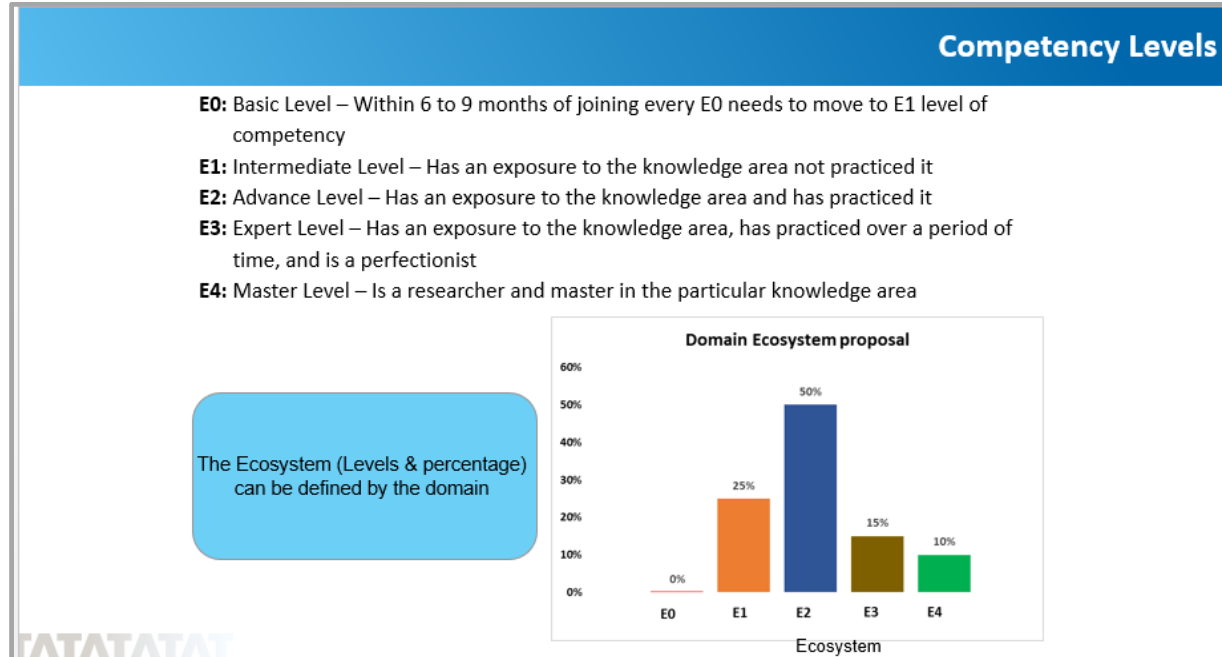
Further, competencies have been categorized into 2 parts 1) Functional, and 2) Behavioral
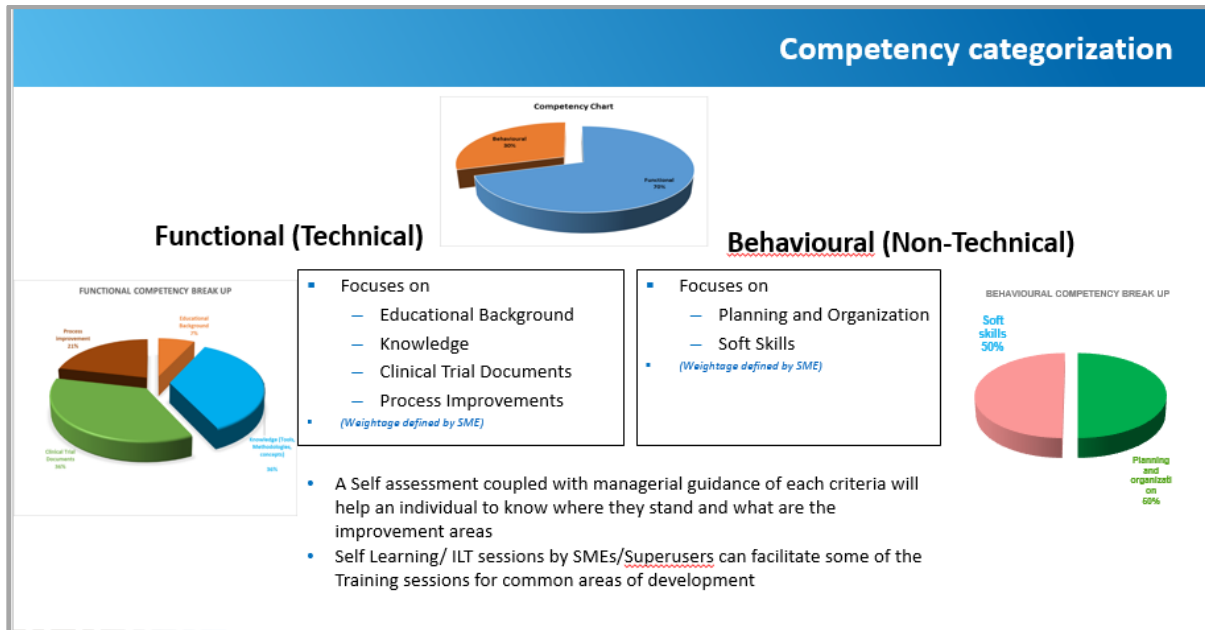
Depending on competency level, TCS and experience of associates designed specific training programs like **_Velocity_** that focuses of grooming team members, create and maintain healthy team environment, **_Starburst_** emphasis on proactive learning and value creator for associates.