

Partnering with a Fortune 500 global pharmaceuticals company to provide CDM

Highlights:

Cognizant was engaged by a Fortune 500 pharmaceutical client to provide end-to-end clinical data management services, for all its global R&D sites.

The execution of this complex transition involved:

- 350+ FTEs ramped up in less than 6 months;
- 7 R&D sites in 4 countries;
- Re-badging of client employees onshore;
- Transition to two offshore locations (Mumbai and Chennai) and one nearshore location (Budapest);
- Diverse set of processes, and more than 50 global applications, centralized in a single Data Management Center (DMC);
- High customer satisfaction scores from a survey, carried out during transition.

*"This is a fantastic achievement and is a result of a tremendous amount of hard work by all involved!"
Global Head, Clinical Data Management"*

"The Data Management project has this week achieved a significant milestone in the transfer of our data management activities to Cognizant and everyone in Clinical - project teams, DM teams, line management, and support teams - should be rightly proud of this fantastic achievement"

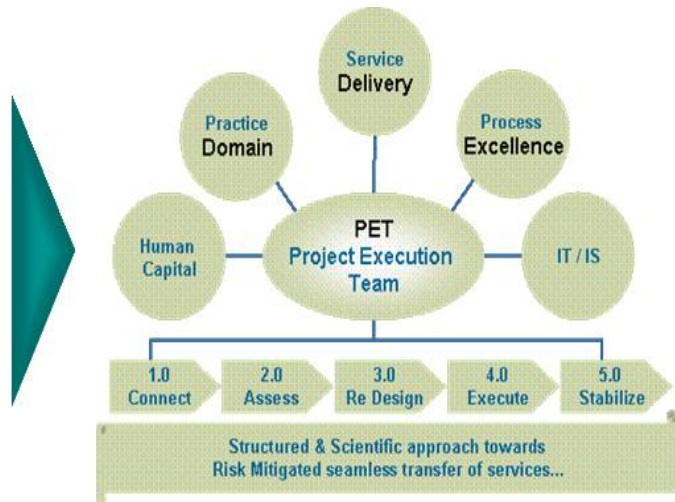
"A huge amount has been delivered in a very short space of time - new processes, new structures, new ways of working and a new partnership with Cognizant which is very impressive."

-Global Head R&D.

Business Need:

Clinical Data serves as the basis for many activities in the life cycle of a new pharmaceutical compound, such as submission, approval, labeling and marketing. The value of a drug may not be fully realized if the clinical data is not accurately organized, not easily available or not systematically documented. Maintaining accuracy of the clinical data and having adequate controls in place are vital to our client's data management process.

Our client faced major challenges in data sanctity, because multiple sources fed related data into a number of different systems across different datacenters. A corporation-wide initiative was launched to move to a new, centralized datacenter. In addition, our client sought to implement a standardized platform, so that all the systems and applications would meet the same level of uniformity.



Transitioning processes that were decentralized, non-uniform and managed from multiple centers was a major challenge. Having been chosen as the preferred partner to shoulder the responsibility of providing Clinical Data Management Services, Cognizant was faced with the following challenges during the transition phase:

- Meeting the client's need to establish a centralized datacenter for business prioritization of data from seven separate R&D sites in Japan, Sweden, the United Kingdom and the United States;
- Introducing consistency in the systems by bringing all the data onto one platform for all the new studies;
- Setting up a universal or uniform format for reporting, across all the regions;
- Timeliness and accuracy of the data being available on all the systems with correct information;
- Cost effectiveness, with efficient service delivery in accordance with client expectations;
- Understanding roles and responsibilities and documenting exhaustive details, to make the transition effective;
- Building a Data Repository in case of any emergency;
- Working in parallel on the existing and new studies during the transition period;
- Enforcing dependency on systems rather than paper, and the implementation of online web tools or portals, to effect uniformity of data;
- Mobilization of skilled resources, who can manage and interpret the data effectively.

Solution:

Cognizant was the preferred partner owing to its experience in managing clinical data from offshore. Successful migration of processes from different locations to two delivery centers (Hungary and India), and creating a uniform platform, required an exceptionally strong transition framework.

Cognizant adopted its proven transition and implementation framework - 'CARES'. A definitive transition plan was created using this framework in order to effectively overcome all issues impacting transitions, both from a risk management and a change management perspective. This transition model also helped in the structuring the plan through its different stages. Some of the highlights of this framework are:

Connect:

This phase essentially lays the foundation to match the customer expectations and available current capabilities. At this stage the client and Cognizant agreed on drawing each other's expectations and familiarize with possible challenges and plan controls for these challenges for this transition.

Assess:

After familiarization and setting expectations, the following actions were taken:

- We carried joint assessments and deployed interventions to induce momentum across all regions;

- A SWAT team was created within the client's organization, to understand and document expectations;
- A design was laid out and the whole structure for data management was established, which helped in clearly defining and demarcating roles and responsibilities for focused training and knowledge transfer;
- As the end state envisaged a centralized platform, Cognizant undertook a study of all the systems and processes; these were duly documented and inventoried;
- To manage the multilingual challenges various steps were taken:
 - Language experts and interpreters were used;
 - Data received from each region were analyzed and standard templates were designed based on the analysis;
 - Comprehensive and extensive documentation was created;
 - The SWAT members had bi-lingual capability (particularly addressing Japanese);
 - Seasoned data management and transition experts were stationed in the Japanese center;
 - Regular interventions and close supervision were effected;
- The activities were continuously monitored and measured at every stage to check if the objectives were being met within the established timelines. This served as an effective control measure;
- Cognizant ensured especially that the agreed process of receiving the data in new, standard templates from multiple regions was followed, and also ensured that the language experts were aware of the criticality of uniformity of the data;
- Cognizant's IT skills were leveraged in the effort to migrate all the systems onto a uniform platform.

Re-design:

At this phase of the transition, Cognizant focused on Operational Risk review and validation of training and knowledge transfer activities. Cognizant had set clear demarcation boundaries, which helped to avoid rework. The Knowledge Transfer process made use of the formal Process & Risk Analysis Framework tool - MORE. Also, the 'To-Be' process was tested and made operational. Multiple dry-runs were conducted to verify the effectiveness of the agreed terms of the project. Any delay in the data was addressed with the

help of language experts and domain specialists. At every stage of the transition the SWAT team was mandated to review progress and address barriers, and ensure smooth transition. Setting up the systems and transferring all the new case studies on to the new designed system.

Execute:

This phase is where Cognizant takes ownership of the operations after process transition. The SWAT team, client process owners and Cognizant agreed and signed off all the required standard operating procedures and training documentation, which were to be used during process delivery. We gradually ramped-up the operations in a controlled manner. It was vital that the processes were meeting each of the set service levels of the client. Cognizant and the client assessed and monitored the performance reports during this phase. There were multiple operational queries raised by Cognizant and answered by the client, which were strictly documented for future references.

Stabilize:

At this phase Cognizant's emphasis changed to operational delivery and quality initiatives. Specialized quality teams were deployed during the course of transition and post transition to monitor the process steps and validate the non value added activities, and to automate a small number of steps which had been carried out manually to improve productivity. Standard dashboards and metrics were shared and agreed with the client, to monitor ongoing operational delivery. Transitioned over 100 studies across seven different datacenters using over 50 applications (overall ~100 instances).

Benefits:

Cognizant transitioned the process, through a strongly-managed team with a significant breadth and depth of prior experience in transitioning outsourced processes. The entire project was customized in accordance with the clients' needs. In particular, Cognizant:

- Prepared exhaustive and detailed documentation on the process that were off-shored, thus ensuring minimal leakage of knowledge during the process, and building a basis to cross-reference and train more resources at later stages;

- Setup two new locations (Hungary and India) for maintenance of uniformity of data and systems. High quality of data and assured continuity of operations were some of the highlights of the transition phase;
- Introduced a common platform that was implemented across the organization for clinical data management. All new studies were maintained on the new platform whereas existing studies were maintained on the legacy systems, thus ensuring data sanctity. The systems across the client's locations were synchronized to ensure accessibility, cross referencing and smooth integration with the client's existing setup;
- Successfully changed an initially negative/hostile mindset of client personnel towards third party outsourcing by consistently exceeding the client's expectations and delivering excellence in services;
- Effectively transferred multiple client resources to our Hungary delivery center and established business as usual status;
- Successfully transitioned the processes in parallel waves (phases) from seven client R&D centers in four countries, Japan, Sweden, the United Kingdom and the United States;
- Received a customer satisfaction survey score during transition which stood at 8.3 points on a scale of 1 to 10, where 10 is the highest score. This presented Cognizant with an opportunity to improve and further exceed the client expectations in the next transition waves;
- Developed trainers, certified by the client, in nearly 50 client applications, which are used globally;
- Exceed all client expectations by ramping up over 350 FTEs in two Cognizant delivery centers, ahead of the planned milestone date.

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".....I would like to recognize the core DM team and Cognizant for the enormous effort invested to reach this point and to acknowledge the partnership approach between our two organizations to make this happen....."

- Vice President and Head of Global Clinical Development

About Cognizant

Cognizant (NASDAQ: CTSI) is a leading provider of information technology, consulting and business process outsourcing services. Cognizant's single-minded passion is to dedicate our global technology and innovation know-how, our industry expertise and worldwide resources to working together with clients to make their businesses stronger. With more than 40 global delivery centers and approximately 61,700 employees as of December 31, 2008, we combine a unique onsite/offshore delivery model infused by a distinct culture of customer satisfaction. A member of the NASDAQ-100 Index and S&P 500 Index, Cognizant is a Forbes Global 2000 company and a member of the Fortune 1000 and is ranked among the top information technology companies in BusinessWeek's Hot Growth and Top 50 Performers listings.

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