

Change Management – An ICON approach and case study

Anagha Pradhan, ICON Clinical Research, Marlow, United Kingdom

ABSTRACT

In the pharmaceutical industry, reporting of tables, listings and graphs is done using various platforms and systems. Most pharmaceutical companies have their own reporting system for analysis and reporting. This paper describes the change management steps required to ensure a successful transition from one reporting system to another. The paper will cover authors' own experiences, while transitioning from one reporting system to another, describing the challenges and successes along the way, as well as steps taken to avoid potential failures. I will also speak about the effect of the decision to transition on other factors e.g. timelines, documentation, data structures, personnel and so on.

INTRODUCTION

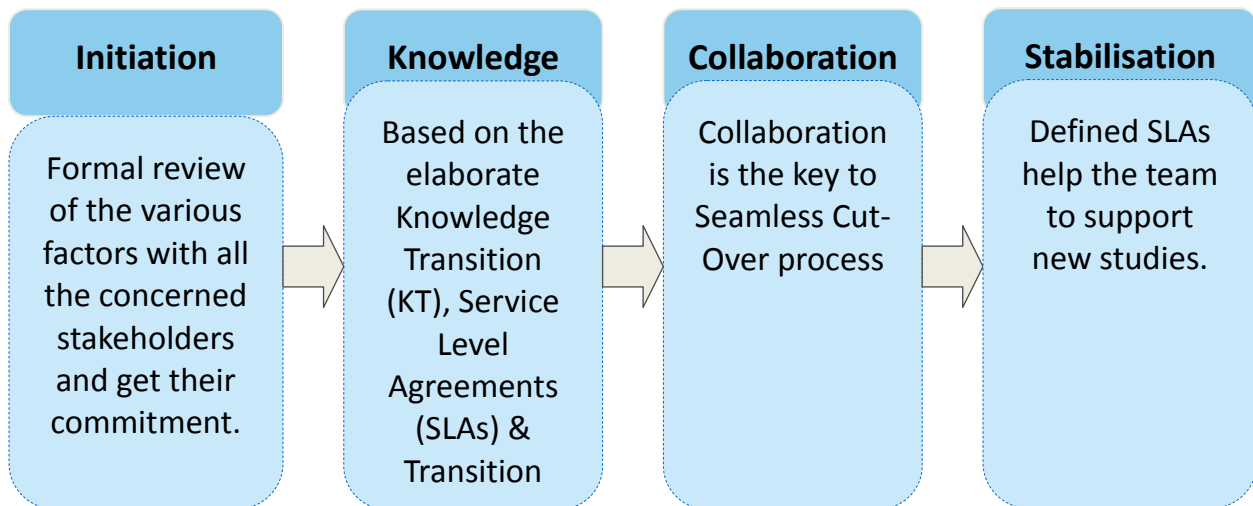
ICON has been supporting Clients on Study Reporting for several years on ICON's market ready platform. One of the Clients wanted to leverage its own platform; hence decision was made between ICON and client's management teams to transition studies from one reporting system to another.

A list of studies and specific reporting events that needed transition was provided by the client along with expected timeframe for transition.

The transition lead identified by ICON was entrusted with the responsibility to not just strategize but also to manage the transition.

The entire transition was phased over one year. ICON initiated the transition with one study and gradually increased the scope to provide coverage for a wider range of studies.

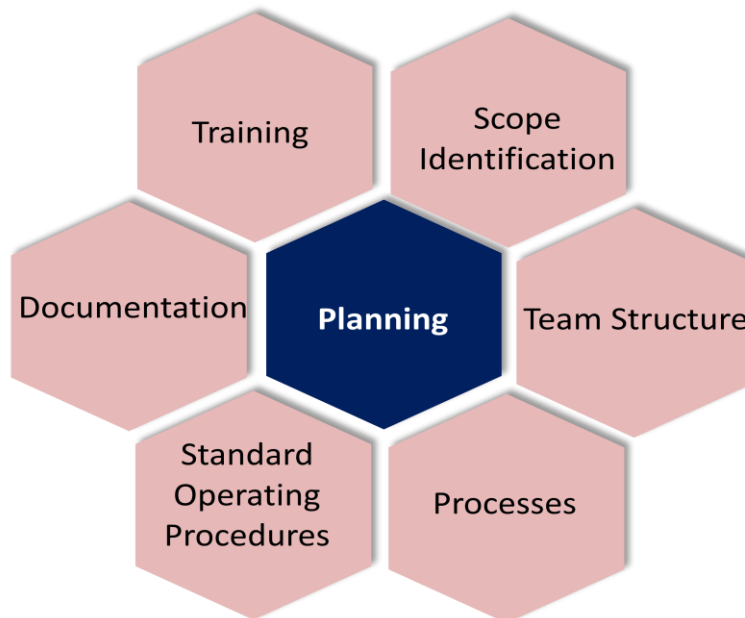
This transition process was coupled with detailed quality checks to pass the stringent acceptability criteria. All the phases were closely managed by the Transition Manager.



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CRITICAL STAGE: EXCELLENCE IN PLANNING

It was very important to identify the key elements which ensured success to the transition. The planning was done by a core team comprising of the client and ICON.



Key Elements of Planning

SCOPE IDENTIFICATION:

Setting the boundaries is key to ensuring both parties are very clear of the deliverables and expectations.

PROCESSES:

Determine if the new reporting system requires input data in particular structure/data standards and further determine the processes for data flow depending on the database source.

STANDARD OPERATING PROCEDURES (SOPS):

Determine whether client SOPs or ICON SOPs or a combination will be followed.

DOCUMENTATION:

Decide what documentation will be required. Assess whether document templates already exist and whether any updates are needed or any new documents required.

TRAINING:

Plan what training needs to be delivered. Identify appropriate trainees from Global offices. Determine mode of training e.g. webex, face-to-face, etc.

TEAM STRUCTURE AND GOVERNANCE MODEL:

Idea was to ensure that we utilize a team structure very similar to the regular project team with some minor changes. While the team structure was being put in place, it was also critical to have a governance model which works very effectively and efficiently. The roles and responsibilities of all the team members should be clearly defined.

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COSTS

Determine the training and on-boarding costs and who (client/ICON) will bear what percentage of these. Determine implementation costs and what change orders will need to be raised.

RISKS

The key risks have to be identified and mitigated:

- There is a potential risk to the quality of the deliverables as the transition to the new platform may or may not be successful.
- Not receiving data on time can add to the risk of an extended implementation
- Any transition to a new platform requires adequate and proper training. The human element in training can lead to varying levels / quality of training, hence risking the transition and future deliverables.
- Under estimating transition timelines can set the transition for failure.
- Any new platform requires some settling in time. The associates working on the new platform may take longer time to settle in.
- Not having template documents and processes in place adds to the risk of delaying the transition
- Technical difficulties with accessing the new reporting system may further hamper the smooth transition.

IMPLEMENTATION

Steps to successful implementation:

- The Client-ICON Transition team made the plans, which were approved by the project sponsors in both companies.
- The team of programmers to be trained on the new reporting system was identified and gradually ramped up.
- As part of the initial set-up, all the team members were provided access to the new platform
- The new reporting system needed data as per specific standards since there are hundreds of automated programs already written in this reporting system. This meant we had to understand what that structure is, and how the existing data collected on various databases will be mapped to this new structure. We determined which system will be used to do this mapping of data and which functional line within ICON will manage this work. Processes and required document templates were setup for how this mapping would be conducted and this varied depending on the source of database. Training was identified and this team was ramped up. Timelines were determined for mapped dataset deliveries to Statistical Programming.
- A combination of ICON's and client's SOPs was needed to be followed, a list of these was determined.
- A combination of client's required study documents and ICON's required study documents was used. Templates were developed for equivalent client documents and ICON templates were updated for the new reporting system.
- Initial trainings were delivered remotely via webex, recordings were provided for future use. After that face-to-face trainings were conducted by the client.
- There was no change in team structure and governance model since the entire team was going to work as is. New resource estimations were needed for working in the new system.
- The teams were now ready to start working on studies.
- The Client-ICON transition team continued to have oversight of each project that was being transitioned until the first reporting event. After that the study and transition team went through a close out process to complete the transition for that study.
- As the transition was happening, other functional lines within study teams were also made familiar with the new data flow processes along with expectations around delivery timelines.

SOME CHALLENGES FACED BY THE TEAMS

- The data mapping team was completely new and were in the ramp up phase. This led to a delay in data set deliveries due to which timelines needed to be re-worked.

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- The unforeseen delays led to cost increases which required close monitoring

SOME BEST PRACTICES

- Short term and long term strategies were identified.
- A separate distribution list was setup for sharing information specific to this reporting system. Internal knowledge share meetings were setup at ICON.
- SMEs were identified at ICON and each new study team was assigned a percentage of SME time.
- Process was setup on how the queries will be internally resolved prior to sharing with the client.
- Weekly meetings were setup with the client to raise any queries that could not be resolved internally at ICON.
- We benchmarked the time per task by using the actual effort tracked on the timesheets, giving us an opportunity to help size future studies.
- Overwhelming amount of documentation was provided, so the team organized the same with condensed summary tagged to every document.
- Internal training plan was developed and organized training was rolled out.
- Maximised the use of pre-existing automated programs to minimize the costs.

BENEFITS OF THIS TRANSITION

The accelerated transition model leveraged by ICON, not only helped streamline the process of taking over the large and complex studies from the client, but, also, built capability and capacity within ICON. By showing a strong commitment to the transition, ICON developed a strong working relationship with SMEs at the client allowing problems to be resolved and knowledge to be developed quickly. Successful implementation of the transition provided more transparency since the client had on-demand access to data, TFLs (tables, listings & figures) and programs. This helped ICON gain a trusted partner status with the client.

CONTACT INFORMATION

Your comments and questions are valued and encouraged. Contact the author at:

Anagha Pradhan
ICON Clinical Research
2 Globeside, Globeside Business Park
Marlow SL7 1HZ
Work Phone: +44 1628 496300
Email: anagha.pradhan@iconplc.com

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