Merging SAS Programming Groups: Phased-in Approach
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ABSTRACT

The pharmaceutical industry has been undergoing consolidation for some years. When large companies merge, departments need to combine staff. Integrating or merging SAS® programming staff who support analysis of clinical trials from what was once two separate companies presents logistical, technical and process challenges. The process of integrating SAS programming staff is a multi-year undertaking that provides opportunities as well as challenges. In this paper the authors continue a discussion from their NESUG 2011 paper of a phased-in approach to integrate two large SAS programming groups brought together as a result of a merger of two large pharmaceutical companies.

INTRODUCTION

SAS is a common programming language spoken by clinical trials programmers in the pharmaceutical industry. The complexities of integrating two departments of SAS programmers becomes apparent when a corporate merger occurs. Each department has their own clinical databases, computer platforms, account and access provisioning, standard operating procedures (SOPs), location, and even SAS competencies. An initial merger of the groups results in one SAS programming department operating like two separate departments. Over time, a phased-in approach helps the staff to eventually achieve a common technical platform with common SOPs. In the following sections, the authors will discuss some business practices in use to facilitate integration with the objective of maintaining business continuity.

PHASED IN APPROACH

This section discusses the phased-in approach to the integration of two large SAS programming groups which support analysis of both early and late development clinical trials. In our 2011 NESUG paper, best practices for the early phases of integration, such as organizational alignment and cross-training of staff on programming processes of the previously two separate companies, were discussed. In the following sections, technical and process alignment are discussed. In addition, sourcing models are explored.

COMMON PLATFORM

This section discusses the establishment of a common computing platform and clinical database to help facilitate the integration of clinical trials in a merged pharmaceutical environment.

UNIX PLATFORM

Establishing a common computer platform in a merged company takes time, money and extensive collaboration between cross-functional areas to achieve. Such an endeavor needs to become a strategic project with management sponsors and champions in all departments involved in order to be a success.

Rather than reinventing the wheel, the decision-making process can involve an assessment of the legacy technical platforms developed when the companies were separate in order to determine whether either legacy platform
could be adopted as the common platform. This approach has the potential to save considerable time and money. Factors to be assessed include interoperability, 21CFR Part 11 compliance, and performance, though this is certainly not an exhaustive list.

These factors led to the adoption of a UNIX platform which runs SAS. The favorable performance of this platform helps to ensure that programming staff are committed to the realization of the new platform. Moreover, SAS enables the programmer to be productive their first day on the new platform by providing an operating system interface for those utilizing their PC to access UNIX. This avoids a lengthy learning curve on a new operating system for those SAS programmers without UNIX experience.

Some considerations in using the UNIX platform for clinical trial programming include the access administration. Government regulation requires access controls be in place so that only individuals working on the study have access to the study data. Achieving study-level access controls can involve considerable effort on the UNIX platform.

CLINICAL DATABASE

Establishing a common clinical database in a merged company also takes time, money and extensive collaboration between cross-functional areas to achieve. This decision needs to be made in parallel with the decision on the technology platform to ensure that interoperability is achieved.

When choosing a common clinical database, like choosing the technology platform, the decision-making process should assess if any of the current legacy databases would be an option. Factors in choosing one common clinical database may include ease of implementation, compliance to regulatory requirements for clinical data, ability to incorporate external data, support for industry data standards, and performance. This is not necessarily an exhaustive list of considerations.

A clinical database that met the industry data standards of the Clinical Data Interchange Standards Consortium (CDISC) was chosen. The Study Data Tabulation Model (SDTM) standard format was chosen for the database implementation.

Choosing a clinical database that is built on industry standards has advantages. Use of SDTM standard format for the database facilitates the incorporation of external data and also facilitates New Drug Applications (NDA). Additionally, it supports the standardization of medical terminology to industry standards. Finally, control and upgrade of the standards are centralized to one organization.

COMMON PROCESSES

Common programming processes are necessary to help facilitate the integration of clinical trials programming in a merged pharmaceutical environment. The technology platform, clinical database and division of work among functional areas will drive the definition of processes.

Processes need to have excellent documentation. Clearly defined standard operating procedures (SOPs) are essential. Process flow diagrams with swim lanes are also important in that they provide both the sequencing of tasks and the role responsible for a task. Finally, work instructions or job aids that contain details on performing the tasks help ensure consistency in the programming effort and resulting programming deliverables. When developing the documentation, it’s beneficial to have input from someone who actually does the work to ensure clarity and accuracy.

SOPs, process flow diagrams and work instructions are important to maintain in a central location that all programmers can access. Updates to processes are very important to communicate to programming staff. A programming staff meeting is a good vehicle to communicate process changes and time should be allocated for questions and answers about the process changes.
PROGRAMMING SUPPORT MODEL

This section discusses an evolving programming support model to facilitate the business. Here it’s important to consider the support model for trials in older legacy systems in addition to a support model for current systems.

MIXED MODEL

At the time of the merger, each company had staff deployed globally who were supplemented with various off-shore and on-shore Contract Research Organizations (CROs). Support using current systems varied from complete internal programming resource support for some trials to a mix of internal and outsourced support. As is typical in the industry, the more routine work was outsourced. Over time, outsourced work was consolidated to streamline efforts. Moreover, the mix of internal to outsourced programming resources was adjusted and the type of outsourcing model changed.

GLOBAL MODEL

At the time of the merger, each company had globally-deployed programming resources where the model was US-centric. Over time, a less US-centric global model evolved with an increase in resources in emerging market countries.

OUTSOURCED MODEL

Generally, in the pharmaceutical industry, clinical trial programming work that is more routine or well-defined, is outsourced to CROs. Here we’ll examine an extended model where the more complex less well-defined programming work is outsourced to another type of organization.

Business Process Outsourcing (BPO) is an outsourcing alternative to the CRO in the pharmaceutical industry. BPOs focus on optimizing client business processes in addition to service delivery. This focus on process optimization differentiates the BPO from the CRO.

BPO provides the opportunity for an organization to improve their processes for greater efficiency which suggests that more complex work is a good candidate for a BPO. Our experience with shifting from a CRO to a BPO model has been evolving. Initially, some internal programming resources were shifted to the BPO with the objective of maintaining business continuity. Over time, the advantage of this arrangement has surfaced as programmers in the BPO who are familiar with the client processes identify activities that could be optimized. The BPO provides an automated mechanism for programmers to submit process optimization ideas for evaluation.

SAS PROGRAMMER’S OPPORTUNITIES AND CHALLENGES

Moving to a new computing platform, clinical database, ways of working and programming support model provide both opportunities and challenges for the SAS programmer. Opportunities include learning new skills for the new computing platform and database as well as learning skills to become more operational efficiency-oriented with the BPO programming support model. Additional opportunities of BPO may include learning to work differently, the chance to redefine your professional identity and expand your professional opportunities, and working in a less hierarchical organization. Some challenges of BPO can include working for a very large global organization, continuing to work with former colleagues still with the client, understanding how your role has changed and adapting to working differently.

In our 2011 NESUG paper, recommendations concerning what a SAS programmer should pay attention to while involved in an organizational change still hold and include receptivity to change, openness to new ideas and new ways of doing things; adaptive to the new business environment; openness to surprises; speaking up; and continuing to work on professional development.
In addition to these recommendations, SAS programming professionals should consider the following.

- The presence of BPO organizations supporting the pharmaceutical industry will be likely to keep increasing at a fast rate. As a result, both SAS programmers and managers need to learn concepts that were not necessary before they were part of the BPO. One key set of new skills deals with Operational Excellence (OE) fundamentals necessary to provide superior deliverables and improve business performance.

- Once the SAS programming staff move to the BPO, their former employer could potentially become their customer and, paradoxically, they now need to define exactly what are the deliverables provided to them. In other words, SAS programming staff must clearly identify what operational activities are linked to the contractual agreements with customers as opposed to previously when such contractual arrangements were not part of the job.

- The SAS programming staff should measure service performance by paying attention to its customers’ expectations related to Cost, Quality and Speed and also by creating and tracking metrics in order deliver to their customers’ expectations. Besides that, they must assure that service expectations will be consistently met by creating tools to measure if quality deliverables provided today will continue in the future.

- Besides learning OE concepts like the ones described above, SAS programming staff working for a BPO while supporting a pharmaceutical client, should consider that now they have the opportunity of working for a large company, perhaps even bigger than their former employer, which offers the possibility of redefining your professional identity by exploring job openings with other clients in the same industry or in a totally different role outside of pharma.

- SAS programming staff working for a BPO need to understand their new role and its limits. For example, contractual obligations like Service Level Agreements (SLAs) may preclude you from making decisions concerning what gets done and how it gets done in that the SLAs define these things. However, you are encouraged to make recommendations.

- SAS programming staff working in a team with former colleagues still with the client may feel uncomfortable. Former colleagues may feel uncomfortable as well. It’s important to understand your new role well and what you are responsible for so that you can exude confidence in such a situation.

In summary, there are many advantages when providing SAS programming support to the pharmaceutical industry while working in a BPO sourcing model.

CONCLUSION

A corporate merger of two SAS programming departments that support analysis of clinical trials presents both challenges and opportunities. The key challenge of integrating departments remains keeping the pipeline momentum on target. Merging departments also presents opportunities to rethink the computer platform, database and programming support model. This paper has discussed the complexities of integration using the phased-in approach with a focus on the final phases of integration, namely a common computer platform and database and the programming support model. Finally, challenges and opportunities experienced by the SAS programmer during technical and organizational changes are highlighted and suggestions concerning what a programmer involved in technical and organizational changes should pay attention to are noted.

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