



The Changing Organisation and Data Management Roles Resource Roles Revisited for New Optimisation

Abstract

Anyone who has been involved in clinical development, and data management (DM) in particular, for a long period of time will recognise how the organisation of staff to perform the wide range of data collection and management tasks has changed to better align with advancements in technology.

Consider the pre-electronic data capture (EDC) era, when all trials, regardless of size, collected data on paper case report forms (CRFs). This method had a long lifespan, and as such had quite established practices which also drove operational organisation. The use of paper to record information drove processes, and the processes in turn influenced how staff were organised to perform tasks.

Workflow Depended on Monitoring

For example, it was typical in the paper CRF environment to have clinical research associates (CRAs) perform source data verification (SDV) during site monitoring visits, collect the completed SDV'd CRFs and submit them in a "batch" to a central data management department for entry into an internal system, where data management personnel would perform data review. Therefore, workflow for the data management staff depended on monitoring visit cycles. This created a bolus of work at times, and then a steady decrease until the arrival of the next "batch". Staff assignments had to deal with this ebb and flow of work. As a result, the typical data manager had to have many assigned study related tasks to make full use of their time.

Classic Staff Assignment

Traditionally, for every trial there was a clinical data manager who performed as a "lead" who would have overall responsibility for the design/development of internal systems to collect data from the paper CRFs, create DM-related documentation, organise and train a team of data reviewers – dependent on the size of the trial and volume of data, perform data review, complete encoding, manage external data integration, facilitate meetings, manage communication with other operational areas, evaluate and escalate risks and manage timelines to ensure delivery of the final quality study data for statistical analysis. This clinical data management (CDM) "lead" role was assigned to the more senior, experienced staff, with junior staff taking on primarily data review, with other tasks gradually added commensurate with their level of experience. Depending on the duration of a trial, the team of individuals, and the CDM lead in particular, would work for many months or even years on a study.

For many years the DM environment and processes remained fairly constant, and the role of a clinical data manager in organisations also remained consistent. However, two major "events" converged that had a major influence on the way clinical data management and supporting roles evolved.

Financial Pressures and Cycle Time

The pharmaceutical industry came under great pressure as costs in healthcare escalated, and there was an increased focus on the cost of prescription drugs as a contributor. This scrutiny caused pharma to look seriously at opportunities for cost efficiencies, which in turn generated heightened interest in processes; including evaluating what and how people performed tasks. "Lean" became an important goal! And faster execution of tasks meant faster completion to reduce the data review cycle time, allowing studies to potentially complete submissions earlier. Processes were evaluated and changed at a more rapid pace as the industry adopted the mindset of continuous improvement. The way of doing business started changing much more rapidly than in the past as companies tried aggressively to manage costs.

Changing Technology

With the introduction of new technical advances, emerging personal computing capability, a technology-savvy population and the internet, the approach for capturing clinical trial data was ripe for change. Opportunistically, EDC software products came to market allowing for entry of clinical trial information into systems at the physician's site. While this did not eliminate source documentation, it did change the paradigm of recording clinical data on paper CRFs. This technology also held the



promise of more near-term entry of patient visit data into a “system”, reducing the amount of questions or queries that would have to be generated during data review, and ultimately leading to higher-quality data at the point of capture, as data could be electronically “checked” for accuracy at the point of entry. As such, it was expected that the review work for the clinical data manager would decrease and also the method of review would become more efficient. To achieve these goals, systems had to have more and more sophisticated, integrated features, taking into account all the activities that were previously handled independently. The change to EDC technology required different skill sets for data management staff and new processes and ways of organising resources to perform those tasks.

Consequences to Data Management and Resource Management

One could say that the change from paper-based process to EDC processes, and the impact on organisational demands, was seen as a significant breakthrough in time and cost. However, the transition did not happen overnight for pharma or CROs. Once the technology door opened, data management and the roles individuals played faced many challenges. Ongoing studies in one process had to either complete or transition, and staff had to retain knowledge to support the “legacy” work. They also needed to learn the new way of doing business. As a result, staff had to learn and manage multiple processes, including the constant further evolution of technologies. People who were experts suddenly had a brand new learning curve, and if an individual remained on a study for more than a year, they faced another learning curve when assigned to the next study because technology advancements were occurring at a fast pace, and driving process change to keep up as well.

Facing this challenge, data management organisations arrived at what can be termed a “functional resourcing” solution. By taking the data management tasks that previously were managed by one person – who had to be an expert at all – and breaking them into smaller segments for assignment, it became easier for staff to become a master of the task, as well as stay current with the fast pace of technology and process changes, since they encountered them more frequently. These “functions” became production lines for the specific study tasks within data management. The new functional norm broke down personnel organisation by tasks; i.e. start-up activities – which involved system design and testing, conduct – which involved review and query management, and data base lock – which concentrated on bringing the trial to closure on time with clean data. This organisational design also required an overall project manager to be sure that handoffs went smoothly and timelines were met. From the clinical data manager perspective, now instead of supporting one study from beginning to end, depending on their functional assignment, they did their task for the study and moved on to perform the same task for the next study. The goal was operational efficiency due to

repetitive tasks and constant learning and improvement that specialisation would bring.

As with any major shift in conducting work, the influence of technology and the resulting organisation change for data management brought its own NEW set of challenges, so the quest for how to do work most efficiently continued its cycle. While EDC technologies continue to evolve, there has been a push to make the tools more intuitive and diminish the need for specialisation to perform a wide variety of tasks. As a result, today some data management departments are again examining what is the best way to organise tasks and people to deliver quality EDC studies and data efficiently, and to determine whether there is a benefit to do so with a broadly skilled staff who see their work as a more meaningful career path.

References

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