THE EVOLUTION OF DATA MANAGEMENT JOB MODELS IN THE EXECUTION OF CLINICAL TRIALS
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With almost 30 years of combined experience in clinical trials between the authors, an overview of changes and possible future evolutions in Data Management team structure is given.
INTRODUCTION:  
DIVERGENCE IN ROLES IN DATA MANAGEMENT

With the development, implementation and gradual evolution of IT systems, the Clinical Research / Clinical Trials industry has been undergoing years of ever-narrowing specialization. It seems self-evident that changes in the digital environment relating to all aspects of a Clinical Trial are not confined to classical „Clinical Data Management” activities. Instead, they are more and more prevalent across all operational levels within the industry e.g. Clinical Operations, Regulatory Affairs and Medical Monitoring or Pharmacovigilance.

Driven by pressures to reduce the operating costs and timelines, while increasing quality and number of services provided, both CROs and Pharmas focused on specialization as the key to successful functional teams. As a contributing factor, front-end software solutions were generally complex and a multitude of technologies was required to execute a study.

In the experience of the authors of this paper, the introduction of new and, consequently, decline of other methods intended to ensure the smooth operation of a study have been observed. These include: fax as a data transfer medium, SecurID „tokens” to facilitate log-in procedures to central Data Management systems, combinations of scanned (electronic) and copied (paper) documents to trigger data processing and legacy software requiring extensively specialized personnel to configure, optimize, and maintain the latter.

In order to manage the methods listed earlier effectively, numerous specialized roles were created across departments. Coupled with offshoring to low-cost regions, the specialization paradigm effectively split previously singular responsibilities into new roles and positions, e.g. CRF (and eCRF) designers, Reporting Specialists, Validation Programmers and Data Entry Associates, to name a few. This approach has for years been successful in delivering efficiencies.

However, when looking at all the recent changes in Clinical Trials industry and in Data Management more specifically, a question can be posed: Where will new efficiencies come from in the future?
SECTION 1:
OVERVIEW OF CLINICAL DATA MANAGER
ROLES AND PERSONNEL

1.1 Data Management Tasks

Running a clinical trial is a highly complex task. Even though Data Management (DM) plays just one part in ensuring a successful outcome, the amount of work needed still drives people involved to search for best practices in order to save time, decrease costs, ensure and improve quality and effectively utilize resources.

Depending on the characteristics of the study including phase, size, complexity, therapeutic area, etc. – both size of the assigned DM team and their applicable tasks may vary. However, the usually relevant required activities (not including Biostatistics) are listed in Table 1.

As illustrated, expectations from DM team and people involved can vary greatly starting from processing of the documentation (e.g. Study protocol review or creation of Data Management study-specific documentation) to team training, managing user access and database locking activities.

The question arises: *How can these tasks be most effectively distributed in the DM team while meeting quality, timelines and budget expectations?*
To get a better picture of how DM departments (or equivalent) from selected CROs have approached this matter, a simple web search was conducted to understand the in-house roles’ division and expectations. The findings were not too surprising: in most cases, it was noted that large CROs apply clear job descriptions, which implies they divide DM tasks among a number of roles and people filling those roles (see Table 2).

On the other hand, smaller CROs tend to be more flexible. The majority of tasks is completed and overseen by one person – Clinical Data Manager – a professional with a very wide range of skills and extensive knowledge (see Table 3). Possible benefits and risks will be reviewed and a simple evaluation conducted in the next section.

Let’s look at a fictional example. Table 4 illustrates an average role division when comparing a small and large DM team. While a number of people specializing in one skillset are involved in a large DM team example, all relevant tasks have been divided between only 2 roles in a small DM team example.

Both cases have their pros and cons and work best if the company environment supports the selected approach. With electronic data capture (EDC) systems becoming more user-friendly and requiring less technical knowledge for successful operation, many DM roles can be filled by a single person. This solution results in time savings, decreases costs and communication errors.
<table>
<thead>
<tr>
<th>DM team type</th>
<th>N° of roles in DM involved per study</th>
<th>Applicable roles</th>
<th>N° of studies per team member</th>
</tr>
</thead>
<tbody>
<tr>
<td>Large</td>
<td>approximately 6 – 8</td>
<td>Data Operations Lead, Clinical Data Manager, eCRF Designer, Data Validations Programmer, User Acceptance Tester, Data Reviewer, Medical Encoders, Laboratory Data Specialist</td>
<td>5 – 10</td>
</tr>
<tr>
<td>Small</td>
<td>2 – 3</td>
<td>Clinical Data Manager, Clinical Data Associates</td>
<td>2 – 3</td>
</tr>
</tbody>
</table>

Table 5 illustrates different aspects of DM tasks depending on a team size.

<table>
<thead>
<tr>
<th>Aspect</th>
<th>Small DM team</th>
<th>Large DM team</th>
</tr>
</thead>
<tbody>
<tr>
<td>Task division</td>
<td>• A number of roles can be filled by one professional</td>
<td>• Clear role division across a team of several professionals</td>
</tr>
<tr>
<td>N° of studies per person</td>
<td>• A single person can focus on a small number of trials at time</td>
<td>• A single person can work on multiple trials at time</td>
</tr>
<tr>
<td>Communication</td>
<td>• Clear and easy communication pathways within a team</td>
<td>• Communication can be time-consuming as various parties are involved</td>
</tr>
<tr>
<td></td>
<td>• Risk of communication errors minimized</td>
<td>• Communication errors are possible</td>
</tr>
<tr>
<td>Quality</td>
<td>• With fewer people checking each other’s work, strict QC procedures must be devised and followed</td>
<td>• As more people become actively involved in a trial, each other’s work is reviewed more frequently</td>
</tr>
<tr>
<td>Time</td>
<td>• Time-saving efficiencies are generated as a team is small and tasks efficiently divided</td>
<td>• As tasks are divided between a number of people, the process may be more time-consuming</td>
</tr>
<tr>
<td></td>
<td>• Team members can concentrate on the study at hand</td>
<td>• Team members must prioritize and switch between studies as needed</td>
</tr>
<tr>
<td>Knowledge of the study</td>
<td>• Each team member has a full understanding of the study protocol, its goals and specific details</td>
<td>• Since many studies are handled in parallel, not all study details are applicable for or known to all team members</td>
</tr>
<tr>
<td>Cost*</td>
<td>• Since time and the team efforts are efficiently managed and used, DM costs are decreased</td>
<td>• Costs per individual study may increase</td>
</tr>
</tbody>
</table>

*It is important to note that even though a small DM team can be very efficient in a smaller CRO with fewer studies handled simultaneously, a larger CRO may find clear role division (and therefore, also a larger DM team) more efficient as more studies can be handled in parallel using their relatively larger DM resources.*
As illustrated earlier, Data Management department is responsible for a large portion of a clinical trial. In case of a bigger Data Management team a Clinical Data Manager is primarily in charge of overseeing the study (ensuring that protocol specifics and industry guidelines are followed, sponsor’s needs met, review done and documentation regularly updated). In a small Data Management team, Clinical Data Manager role requires a more hands-on approach. This, in turn, means that Clinical Data Manager is also responsible for fulfilling more than just one role.

This approach results in a small study team, very clear lines of communication and an overview of the study at all times. Also, as Clinical Data Associates are very actively supporting the Clinical Data Manager in their work, their skillset exceeds the usual Data Reviewer’s one, thus making it easier for them to both support Clinical Data Manager in their everyday work and train them to become Clinical Data Managers themselves.

It can be said that the role division applicable to a small DM team is to be expected. Given the budgetary and personnel constraints, the process has been one of inverse specialization or generalization. Smaller teams mean fewer people having to handle all needed tasks – and in the past, this has led to niche or highly specialized Data Management departments focusing on a specific domain: oncology studies or early phase (I and II) development or pure data review work.

Besides guaranteeing the smooth conduct of a trial, the Clinical Data Manager is actively involved in designing the eCRF, programming edit checks and reports, testing the database, creating and maintaining documentation, performing data review and medical encoding on a need basis, managing laboratory data and external data reconciliation, performing QC and being the main point of contact between all involved parties. In a nutshell, the Clinical Data Manager is not just an expert in Data Management, but has also a thorough knowledge of the study they have been assigned to (see Table 6).
2.2 Clinical Data Manager in a large Data Management Team

A variety of systems used at different Data Management departments and the number of specialists required for the set-up, conduct or close-out operations require multiple layers of Project Management and other integration structures, leading to considerable managerial overhead for a study execution.

In a large CRO, this could be seen in various „cells“ created for specific tasks:

- **Start-up team** focusing on programming, CRF design and testing;
- **Conduct team** focusing on data review, reconciliation and encoding;
- **Close-out team**, focusing on database lock, statistical export and archiving.

All such cells would have been permanent organizational units requiring dedicated communication and managerial oversight (Table 7).

Under the described specialization each team member will be a specialist in their tasks which also means they have limited understanding of other roles, communication can be complicated (can take time and result in misunderstandings, e.g. eCRF Designer can describe their findings using different vocabulary than Clinical Data Manager) and training new people for a new role is more time-consuming than equivalent processes in a small DM team.

The pros and cons of both teams are described in more detail in Table 5.
1. Data Operations Lead
2. Clinical Data Manager
   - Documentation creation and maintenance
   - Training
   - User Account Management
3. eCRF Designer
4. Validation Programmer
   - eCRF creation
   - Validation Programming
   - UAT
5. Data Reviewer
6. Medical Encoder
   - Data Review
   - Encoding
   - Database Lock
7. Other departments / Vendors / Sponsor

DOL as the main point of contact with sponsor | CDM with other roles

All DM tasks divided between 6-8 roles

LARGE DM TEAM

Start-up
Conduct
Close-out

Table 7 | Source: KCR
Section 3: Conclusion - „New“ Clinical Data Manager / Trial Analyst

Over the last few years the industry has seen significant advances in software development, which opened doors to new opportunities. EDC, ePRO, eHealth, eSource and other IT tools are available for integration into the applicable study, while exerting a positive influence on time and costs efficiencies as well as quality of ultimate Data Management deliverables. Furthermore, these systems and their integration become more and more user friendly, as they require fewer technical skills and a greater process skillset in order to be effectively used. We are already witnessing the emergence of innovative software (and other) solutions that aim at providing multiple functions with the same means, such as, for instance, EDC packages that combine IWRS, medical encoding, IMP management suites and statistics output. Likewise, continued work of industry groups on defining and improving electronic data standards has led to FDA working towards publishing guidance that will require all study data to be submitted in compliance with CDISC standards.

What does this mean for the role of a Clinical Data Manager? Variations in how the tasks of Clinical Data Manager are completed decrease. The opportunities offered by new tools, including software, mean, however, the number of tasks completed by Clinical Data Manager can increase, which provides an opportunity to further drive efficiencies into the operational execution of clinical trials. By reducing layers of both activities and management as well as combining roles across different areas, we see a new role emerging. This role effectively combines the activities and skills of Clinical Data Manager, Project Manager and System Expert in order to provide input to Data Management start-up activities, data cleaning, DM reports and metrics analyses, plus guidance for risk-based or targeted monitoring (Table 8).

Table 8 | Source: KCR

<table>
<thead>
<tr>
<th>System Complexity</th>
<th>No Roles Involved</th>
<th>Cost</th>
</tr>
</thead>
<tbody>
<tr>
<td>HIGH</td>
<td>ROLES NEEDED</td>
<td></td>
</tr>
<tr>
<td>With high complexity EDC systems the number of roles needed is increased meaning more DM roles are involved</td>
<td></td>
<td></td>
</tr>
<tr>
<td>LOW</td>
<td></td>
<td></td>
</tr>
<tr>
<td>With low complexity EDC systems the number of roles needed is decreased meaning savings in time, human resources and overall budget</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Therefore, the following conclusions can be drawn to answer the question raised in the beginning of the article:

1. **Clinical Data Manager role is changing** together with the overall environment of clinical trials’ conduct. With the tools requiring fewer technical skills to operate, Clinical Data Manager role can be now combined with multiple roles within Data Management department (e.g. eCRF Designer, Validation Programmer, Data Operations Lead). Furthermore additional responsibilities can be given to Clinical Data Manager in relation to other departments (e.g. Project Management, Biostatistics, Clinical Operations).

2. Clinical Data Manager is a professional with a very wide skillset. A traditional hierarchy within Data Management department is changing as a considerable number of specialists with specific knowledge can be replaced with a small Data Management team.

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**About authors:**

**MIKE JAGIELSKI**

is a President and CEO of KCR, European Contract Research Organization (CRO). Mike is a seasoned leader with more than 15 years of experience in clinical trials industry focusing on global leadership, cross-cultural integration and management development across a wide range of geographical locations including the U.S., Colombia, India and China.

Mike Jagielski joined KCR as the Head of Data Management and subsequently took over the higher post of Head of Project Management, where he was in charge of providing strategic leadership to the team of experienced project managers responsible for the realization of all full-service and large-scale clinical research operations projects at KCR. In September, 2013 he was appointed to the position of the KCR’s CEO, bringing his global strategic clinical operations expertise together with international leadership experience to the KCR team.

Mike Jagielski received numerous awards including 2002 WHHM Marketing Award as Best Operational Initiative for “CDSP web-based data capture system” project in 2003, 2003 WHHM Marketing Award as Best Operational Initiative for “One Merck Clinical Trial Web Sites” project in 2004 and 2009 Merck Research Laboratories Innovation Award for “Product Safety Sourcing Project” in 2009. Mike Jagielski holds a M.S. degree in Electrical Engineering from the Berlin University of Applied Sciences.
KAIA KOPPEL
has 7 years of working experience in the field of clinical trials specializing in Data Management. For the last 2 years she has been working on the position of a Clinical Data Manager in KCR.

As a Clinical Data Manager in KCR she is responsible for a wide range of Data Management-related tasks starting from database set-up to study archiving and from departmental documentation creation to internal trainings. Currently, together with other co-workers Kaia is searching for the best way of implementing modern technologies into the everyday life of a CRO, while not losing the personal touch.

Kaia has a BA in Educational Sciences and a MA in Social Sciences, both obtained from Tallinn University in Estonia.

MARTIN NÖÖR
has 8 years of experience in Clinical Data Management. Starting out as a Clinical Data Associate, he then became, in quick succession, a Medical Encoder, a Clinical Data Coordinator, and an Associate Data Manager. For the last two years, he has been employed as a Clinical Data Manager in KCR, where his responsibilities stretch from study start-up to database lock, and comprise of everything Data Management-related that falls between.

KCR is a European Contract Research Organization (CRO) with a dynamic team of nearly 300 professionals operating across 18 countries in Europe as well as the U.S. With 17 years of experience, more than 350 trials executed, over 30,000 patients recruited and almost 3,000 sites contracted, KCR is a strategic solutions provider and a reliable alternative to global CROs, delivering the all-important flexibility.

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