Examination of Roles in Data Management in Clinical Research
Resource Organisation – As a Key to Achieve Efficiency (Part 2)

With the development, implementation and gradual evolution of IT systems, the clinical research industry had undergone years of ever-narrowing specialisation. Changes in the digital environment also meant changes in classical 'clinical data management' activities, as they became more and more prevalent across all operational levels within the industry. Those functions may be medical monitoring, project management, statistical programming, pharmacovigilance and several other functions. CDM has to be on top of a trial on an ongoing basis.[1]

With the introduction of new technical approaches, which still ensure the smooth operation of a study, there has been a decline of earlier methods requiring extensively specialised personnel to configure, optimise and maintain them (e.g. fax as a mean for data transfer, SecurID 'tokens', legacy software). Since new technical solutions do not require a whole team to manage them, more can be done with fewer people.

When looking at all the recent changes in the clinical trials industry, and in data management (DM) specifically, there is a question regarding where to look for new efficiencies in the future.

Data Management Activities and their Complexity
Clinical data management is a critical phase in clinical research, which leads to the generation of high-quality, reliable and statistically sound data from clinical trials. Even though data management 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 utilise resources in the most efficient way. Depending on the characteristics of the study including phase, size, complexity, therapeutic area, etc., both the size of the assigned DM team and their applicable tasks can vary. The usually relevant required activities (not including biostatistics) are listed in Table 1.

DM tasks
Protocol revision and input (already to protocol draft, if possible)
Timelines set-up and maintenance
DM budget revision and maintenance
Establishing communication pathways
User Account Management
Trainings (e.g. DM team, site/CRA training)
DM documentation management (creation, maintenance, archiving)
eCRF design, maintenance and archiving
User Acceptance Testing (UAT)
Data validations (programming of automated validations and reports)
Data cleaning (e.g. data review, medical encoding, query management)
Data reconciliation (SAE data, other external data)
Database locking and archiving

Table 1 (Source: KCR)

As illustrated, expectations from the DM team and people involved can mean a long list of very different tasks, starting from technical activities (e.g. designing eCRF and programming validations and reports), validation and user acceptance testing, to processing of the documentation (e.g. study protocol review and creation of data management study-specific documentation), team training, user account management, database cleaning and locking activities). The tasks need to be effectively allocated within the DM team to ensure that quality, timeline and budget expectations are met.

DM Roles Based on Organisational Size
To get a better picture of how DM departments (or equivalent) from various organisations have approached this matter, a simple web search was conducted to understand the in-house roles' division and expectations.

In most cases, it was confirmed that large organisations apply clear job descriptions, which implies they divide DM tasks among a number of roles and people filling those roles[2]. This model allows one professional to work on a large number of projects at the same time, completing similar tasks in each (Table 2).
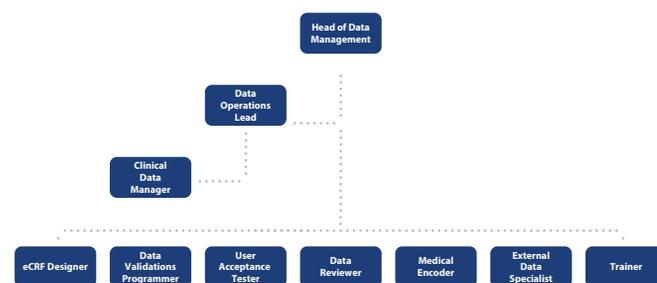

Table 2 (Source: KCR)

On the other hand, smaller organisations tend to be more flexible. The majority of tasks are completed and overseen by one person – a clinical data manager (CDM) – a professional with a wide range of skills and extensive knowledge. This model means one person can work only on a limited number of studies at a time while being fully involved in a wide range of activities (e.g. a CDM doing, among other tasks, UAT, data review, encoding, account management, external data imports and training).

This approach results in a small study team, very clear lines of communication and a thorough overview of the study at all times. The role division applicable for a small DM team is to be expected. Given the budgetary and personnel constraints, the process has been one of inverse specialisation, or generalisation. Smaller teams mean fewer people having to handle all needed tasks and thus, the narrow role and activity attribution one

would expect in a larger DM team is absent. Instead, the members of a DM team have a wide skillset overlap with other members, allowing studies to be handled with a minimal amount of personnel assigned. (Table 3)
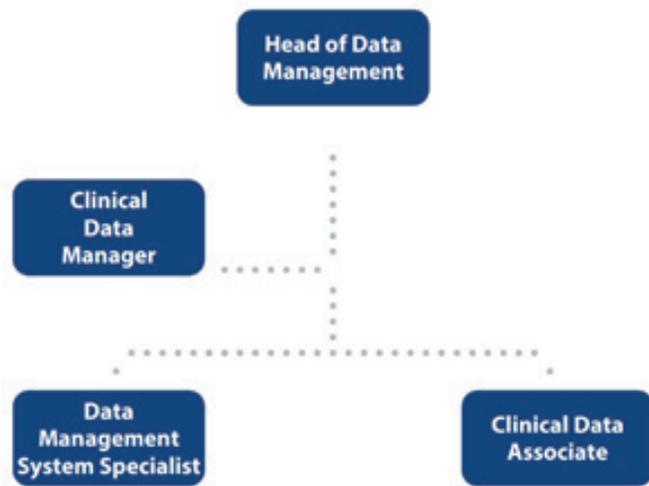

Table 3 (Source: KCR)

Table 4 illustrates an average role division when comparing a small and large DM team. While a number of people specialising in one skillset are involved in a large DM team example, all relevant tasks have been divided between only 2-3 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.

DM team type	# of roles in DM involved per study	Applicable roles	# of studies per team member
Large	Approximately 6-8	Data Operations Lead Clinical Data Manager eCRF Designer Data Validations Programmer User Acceptance Tester Data Reviewer Medical Encoder Laboratory Data Specialist	5-10
Small	2-3	Data Management Protocol Lead Data Management System Specialist Data Reviewer(s)	2-3

Table 4 (Source: KCR)

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

Aspect	Small DM team	Large DM team
Task division	A number of roles can be filled by one professional	Clear role division across team of several professionals
# of studies per person	A single person can focus on small number of trials at time	A single person can work on multiple trials at time
Communication	Clear and easy communication pathways with a team – risk of communication errors minimized	Communication can be time-consuming as various parties are involved – communication errors are possible
Quality	With fewer people checking each other's work, strict QC procedures must be devised and followed. Still, it is simpler to communicate updates to team	As more people become actively involved in a trial not everyone might be aware of all study specific details, therefore clearly documented guidelines are needed
Time	Time-saving efficiencies are generated as team is small and tasks efficiently divided, team members can concentrate on the study at hand	As tasks are divided between a number of people, the process may be more time-consuming; team members working on multiple studies must prioritize and switch as needed
Knowledge of the study	Each team member has a full understanding of the study protocol, its goals and specific details as involved in more than one task	Since many studies are handled in parallel, not all study details are applicable or known to all team members
Cost	Since time and the team efforts are efficiently managed and used, DM costs can be decreased	Costs per individual study may increase

Table 5 (Source: KCR)

As can be seen from the tables 4 and 5, in the case of a smaller DM team, the number and scope of tasks remain consistent compared to a larger DM team. However, differences are introduced when one considers the fact that in a smaller team all the tasks identified must be handled by a smaller number of professionals.

This has an impact on nearly all areas of trial execution, beginning with (DM) study set-up and ending with database lock. Indeed, this is to be expected – as the required tasks are constant, the smaller team must focus on flexibility and comprehensive scope, rather than attempting to compete with larger teams that have, roles and departmental structures created with the explicit goal of supporting a large DM team.

Instead, in a smaller DM team, we begin to witness the efficiencies gained from rapid switching between roles (e.g. the clinical data manager can perform user acceptance testing for one study, and then switch to performing eCRF design in another study), without the need for training in between; additionally, the scope of experience afforded to each member of the team allows for a good contingency approach – should a member of the team be unavailable due to illness, holiday, etc., another member is likely available to cover for all needed activities.

The Future Scope of the Clinical Data Manager Role
Over the last few years, the industry has seen significant advances in software development. Consider the improvements in EDC, ePRO, eHealth, eSource and other IT tools; all these and many more are available for integration into the applicable study, while exerting a positive influence on efficiencies, as well as the quality of data management deliverables[3]. Furthermore, these systems and their integration have become more and more user-friendly, so the needs for technical skills decrease and the opportunities for process skills increase.

We are already witnessing the emergence of innovative solutions that aim at providing multiple functions with the same means, such as EDC packages that combine IWRS, medical encoding, IMP management suites and statistics output. Likewise, the continued work of industry groups on defining and improving electronic data standards has culminated in the FDA confirming that all study data to be submitted should be done in electronic format and in compliance with expected standards (CDISC SDTM, SEND, ADaM, and Define XML, in addition to CDISC controlled terminology) as of December 2016[4]. Standardisation also drives efficiency while allowing standard libraries of code to enable 'assembly' of EDC systems more readily with less technical demands on experienced DM personnel.[5]

What does this mean for the role of a clinical data manager? Certainly, variations in how the tasks of clinical data manager are completed will decrease. The opportunities offered by new tools, including software, mean, however, that the *number of tasks* completed by a single clinical data manager can increase, providing an opportunity to further drive efficiencies into processes and the operational execution of clinical trials.

By reducing the number of roles performing activities, including the resulting layer of oversight/management and communication, and combining roles across different areas, we see an increased value in the new generalised clinical data manager 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, as well as guidance for risk-based or targeted monitoring in the EDC environment.[6]

As with any changing paradigm, moving from a specialised focus role to a generalised role must be thoughtfully managed and results must remain aligned with sponsors' goals. At least in smaller organisations, the previously dominant teams with data management specialists performing one task as their main daily activity is giving way to data management specialists capable of performing a wide range of tasks in scope – constantly learning, developing and gaining new skillsets – and with this, also making DM more attractive as a broader knowledge career path.

References
1. Proeve, J. (2016). What does the future hold for the Clinical Data Manager? http://www.clinicaltrialsarena.com/news/data/what-does-the-future-hold-for-the-clinical-data-manager-4812642
2. Krishnankutty, B., Bellary, S., Kumar, N. B. R. & Moodahadu, L. S. (2012). Data management in clinical research: An overview. Indian Journal of Pharmacology, 44(2), 168–172. http://doi.org/10.4103/0253-7613.93842
3. Capterra (2016). Top Clinical Trial Management Software Products http://www.capterra.com/clinical-trial-management-software/
4. Clinical Data Interchange Standards Consortium (2016). FDA Final Binding Guidance on Standards Now Available http://www.cdisc.org/FDA-Final-Binding-Guidance-on-Standards
5. Slack, M. A. & Fitzmartin, R. (2015). Electronic Submissions – The Requirement for Standardized Study Data http://www.fda.gov/downloads/Drugs/UCM433492.pdf
6. Haque, Z. (2010). Ensuring on-time quality data management deliverables from global clinical data management teams. Perspect in Clinical Reaseach; 1(4): 143-145.

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Martin Nöör has 10 years of experience in clinical data management. Starting out as a Clinical Data Associate, he then worked as a Medical Encoder, a Clinical Data Coordinator, and an Associate Data Manager. For the last four years he has worked as a Clinical Data Manager at KCR, a contract research organisation (CRO), and has been responsible for all DM activities from study start-up to database lock, and all data management that falls in between. Martin has an excellent overview of and experience in the full lifecycle of clinical trials, and has greatly benefitted from KCR's CTMS project, for which he was the lead designer, by recognising the fact that sometimes, innovative solutions are simply a question of readjusting one's perspective.
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