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A New Era for Data Management – The Redefinition of Collaboration

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ABSTRACT

Database setup, discrepancy management, and handling of electronically loaded data are classical data management tasks. Historically, data managers work with tools and systems to capture data, clean them and then hand over the data to the next receiving hand in the workflow. As such, data managers within study management teams are frequently regarded as service providers.

The limitation to pure process-oriented tasks does not utilize the full capability spectrum of data managers. The modern data manager can be a partner to the scientific representatives, enabling them to review the totality of data collected more effectively. With an efficient integrated data review process in place, decisions during study conduct (e.g. dose escalation decisions) can be taken faster and with more confidence.

We share how we position the work of data managers within study management teams and how proficient tools help with the daily data management work.

INTRODUCTION

In recent years, the pharmaceutical industry has changed. As a consequence, all departments within the industry are undergoing constant changes. Those changes can be fairly small or rather substantial.

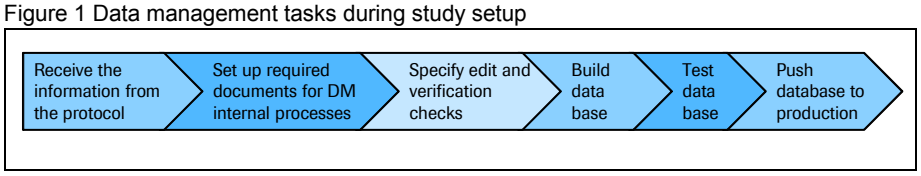
In this paper, the historic picture of data management is reviewed and the reasons why change is necessary are outlined. The implementation of those changes in our department within Pharma Research and Early Development (pRED) at Roche are described and how the mindset within the department as well as the perception by partners in pRED.is changing.

CLASSICAL DATA MANAGEMENT TASKS

Once a draft protocol (or a draft protocol synopsis) for a clinical study is robust, the activities for database build start. During this phase, the data manager translates information from the draft protocol (or synopsis) into the specifications required for the database build. Special documents are written to facilitate the communication within the data management department. The edit and verification checks for electronic data capture are defined, implemented, and tested, working in close contact with all functions within the department. Once the database is set up, it is tested and pushed into production.

The data management tasks during study setup are depicted in Figure 1.

Figure 1 Data management tasks during study setup



Once the study is ongoing, the study data manager looks into the various areas of discrepancy and query management. The ultimate goal is to provide clean data to be extracted and handed over to other functions such as biostatistics, pharmacology, clinical science, and modeling and simulation. A more detailed list of data management tasks during study conduct is given below:

- Review query log
- Raise manual queries
- Review answers to manual queries
- Handle science queries
- Clarify errors
- Check of process regarding coding of terms
- Arrange for loading of electronically loaded data
- Reconcile serious adverse event between clinical data base and drug safety database
- Generate dose escalation snapshots
- Amend the database when necessary
- Train sites/monitors for study conduct
- Provide metrics to study management teams
- Provide data listings to vendors
- Prepare for database closure
- Extract data and hand over for statistical analysis

PERCEPTION OF DATA MANAGEMENT

In numerous pharmaceutical companies, the data management department works on and is limited to the tasks outlined above. Within study management teams, data management and the study data managers are perceived as being at the receiving end of information - being asked to perform the work and acting as a service provider to the organization. As such, the role of data management is frequently named first when it comes to the identification of transactional tasks that could be outsourced or off-shored.

This trend indicates the common perception that the data manager works in isolation, provides a routine service, and is not an integral part of clinical teams.

We dispute this perception and argue that the skill set available in data management can provide much more, and the demands and the opportunities are real.

PROBLEM STATEMENT

Is there anything wrong with how the work is done currently? Of course, a data management department as depicted above is doing the job the organization expects. But, with the skill set available in a data management department, many more things can be done. The internal talents of the department are not fully used. This is not satisfying for the individuals as well as for the organization. The opportunities and the demands are present. Just one example: Scientists ask for help in first getting access to data and second in understanding the totality of data collected in our studies. This manifests an unmet need from our colleagues in the science departments.

This is why the answer to the above question should be ‘Yes’- there is something wrong.

RECENT CHANGES

Drug development has changed tremendously in recent years. The demands on departments are higher than they used to be and the pressure on the organization is increasing.

Increasing pressure on the industry manifests itself as

- Higher cost pressure in Health Care
- Increasing costs to get to market
- A decreasing number of NDA approvals
- The traditional development model questioned

Higher demands on the department manifests itself as

- The increased amount of data collection because of increased use of electronic medical records, technological advances in genomic sequencing and monitoring devices (BIG DATA)
- Higher complexity & heterogeneity of data
- Flexibility because of protocol amendments and interim data assessments
- Requests for access to data shortly after data entry has been completed
- Higher frequency of requests for early signal detection and continuous medical data review
- Faster decision making

An example for the higher demand regarding the amount of data comes from the drive for personalized health care: To personalize health care, biomarker research and diagnostic testing are essential. Both areas produce complex outcome measures with giant volumes of data. The data are not necessarily generated by the same laboratories or stored on the same system. The format of the data varies from lab to lab. In order to understand the entirety of data, the information needs to be combined from different sources and needs to be made available in a manageable way. This volume needs to be managed and processed.

Another challenge is the transfer, processing, and archival of medical images such as MRI data. In oncology, images are regularly taken at sites to investigate the disease and to measure the effect of the treatment. Usually these images are not transferred to the sponsor. However, this trend is now changing, particularly in early development phases, where more and more project teams request image transfer in-house to, for example, verify the mechanism of action. Because of size and format, images and related meta-data are not loaded to the classical data capturing systems. Other database systems are required to load and manage images. Those systems as well as the special kind of data need to be understood for appropriate and efficient processing.

RESPONDING TO THE CHALLENGES

Within Early Development at Roche we change the way data managers work and how they are perceived by other colleagues in study management teams. Both areas (within the department and outside the department) need to be developed in order to be successful.
Our starting point was to rename our department from Data Management to CDIS (Clinical Data & Information Sciences) to indicate the transition from a service provider to a scientific collaborator.

The accompanying vision and mission was adapted to read as follows:

CDIS Vision We are an agile team of Scientific Data Experts with curiosity and drive

CDIS Mission We aim at integrating clinical, scientific and operational information at the right time to enable learning and confident decision making

By using the terms “Information” and “Science” in the department name it became obvious within and outside the department that we are moving away from just handling data points. With the knowledge and skill sets available in the department, we are able to master information that is not limited to data captured in a clinical study and stored in an Electronic Data Collection (EDC) system. We are scientists mastering the discipline of data and information management.

CHANGES WITHIN THE DEPARTMENT

Within the department, we used different measures to reach out to everybody:

- Global videoconferences to introduce the change
- Local meetings to discuss the impact of the change
- Functional discussions to cover specifics
- Line-management one-on-one to talk about the opportunities and the concerns

We started with announcements in all staff and local meetings. The functional discussions helped clarifying concerns that were raised by parts of the department. During individual one-on-one sessions people were discussing their personal thoughts. It cannot be highlighted enough that constant dialogue and support is essential. It is not about talking at people but rather interacting with people and listening to their concerns and needs.

To ensure that members of the CDIS department get the right tool suite for them to operate according to the new vision, a mindset training was developed. The training focused on the competencies

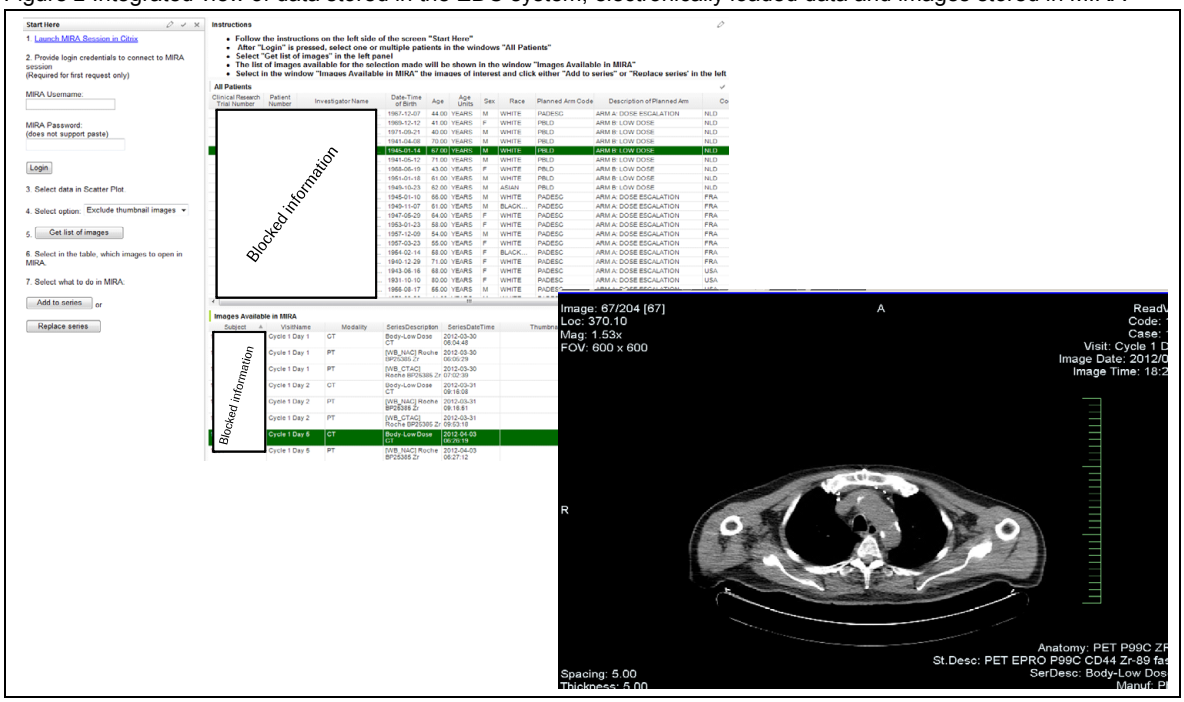
- Communication
- Collaboration & Teamwork
- Conceptual Thinking

CHANGE IN PERCEPTION

Aside from the internal department changes, a stakeholder management plan was executed where we were proactive in communicating with our stakeholders, sharing the new mission and vision. At the same time we offered more support to our study colleagues and started a partnership on both study and functional level. Two examples help us to illustrate this:

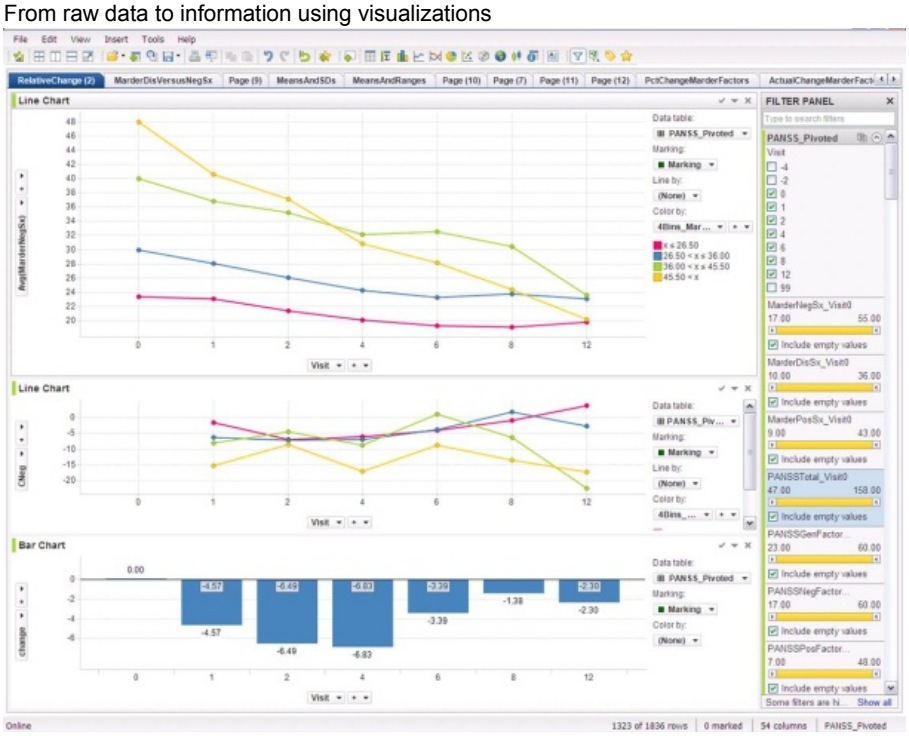
As outlined above, more and more project teams are requesting images to be made available to Roche-internal scientists. This is not only restricted to oncology indications but frequent requests arise from the central nervous system area as well. For such studies, we receive the clinical data via our EDC system (RAVE™). The images, received the image provider, are loaded by our department into a separate database (MIRA™). Thirdly, we receive the readings from the images as electronic data to be loaded. Following the old data management style, we would have provided to the scientists access to 3 systems to view the different types of data. Now, with our new mission, we established an interface between the systems. Spotfire® (Figure 2) is used to link all data types into one tool, providing an option for integrated review of all data, irrespective of origin or storage system used.

Figure 2 Integrated view of data stored in the EDC system, electronically loaded data and images stored in MIRA



Medical data review during study conduct is carried out to ensure the safety of subjects in the study. This medical data review used to be carried out via lengthy listings, all on paper. Particularly for large amounts of data (not necessarily linked to the number of subjects in the study), this method of reviewing data is very inefficient. To facilitate the medical data review of raw data during study conduct we created a new role - the Data Provision Specialist (DPS). A DPS combines the unique talents of understanding the data, the data structures, and the questions expressed by scientists as well as being an expert in the tool to visualize data. We use Spotfire® to share raw data to enable a state of the art medical data review (Figure 3). In close collaboration, at times sitting at the same desk, the DPS and the scientist focus on the data available, using visualizations to inspect the safety of subjects in the study

Figure 3 From raw data to information using visualizations



SUMMARY

All departments within an organization need to constantly adapt to the environment. This holds for data management, too. Moving from paper CRF to eCRF and electronic data capture was a major step. But once such a change is mastered, the next challenges are developing already and departments need to prepare. Within Roche pRED we transform data management into information science.

Once this transformation will be completed, we will not stop. More changes will come. Next on the horizon are other technologies that will produce different data types and integration of existing information that is used separately so far. If we seek opportunities to redefine collaboration, we will find them - for the benefit of the company and our department.

CONCLUSION

- Maintaining the status quo is easy, but opportunities are not used to their full potential
- Changes in the industry and in our own organizations need to be seen and proactively addressed in order to remain in the driver's seat
- Changing is not easy but worthwhile
- Change management is vital, members of our department need to be kept on board and motivate to see WHY change is good

CONTACT INFORMATION

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

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