Driving Change in Clinical Data Management: A Vision for the Future

Rapidly evolving technology is addressing the pharmaceutical industry’s need to manage cost pressures and shorten the time for drug approval. Strategies to make processes leaner are being revisited, bringing in approaches such as risk-based monitoring and the use of Electronic Health Records (EHRs). Data-oriented changes have included:

- Capturing data in real-time
- Graphic and customized slice-and-dice views of data at different points in time to assess patient safety during the trial
- Seamless conversion of data into meaningful information using semantic interoperability supported by data standardization and employing appropriate data governance models.

While Electronic Data Capture (EDC) and outsourcing were harbingers of change in the clinical data management industry, the clinical data manager needs to rapidly adapt to better technology and leaner and faster processes.
About the Author

Dr. Nimita Limaye heads the Biometrics and Medical Writing function at Tata Consultancy Services Pvt. Lt., India and plays a key role in contributing to the strategic vision of the life sciences business.

She has 17 years of experience working across both the pharmaceutical and the CRO sector across diverse functional areas, and has been responsible for leading strategic partnerships, across CDM, medical writing and BSP.

She is the Past Chair of Society of Clinical Data Management (SCDM), head-quartered in the US. She also chairs the DIA India Medical Writing Working Group, represents India on the SIAC Leadership Council and is the Program Co-Chair for the DIA India Annual Conference. In addition, she is the member of the National Committee on Drugs and Pharmaceuticals (2012-2013) of the Confederation of Indian Industries.

She has spoken at various international forums and has several publications to her credit.
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The Drivers of Change

Clinical data management as a profession is in a very dynamic state, with multiple factors driving this change:

- New guidances released by the FDA, such as the Risk-Based Monitoring Guidance and eSource Guidance
- Rapid strides in technology and medicine. For example, data is transmitted wirelessly when a tablet is consumed, via Ingestible Event Markers (IEMs), to the investigator’s database
- EDC, EMRs, and multiple Commercial Off The Shelf (COTS) applications are available in the market
- The industry is increasingly undergoing mergers and acquisitions, resulting in large quantities of data with different structure and standards, residing in multiple databases and often in different applications

The need to drive seamless interoperability across applications within the clinical trial life cycle, so as to minimize the duplication of effort and follow the critical path as driven by the Clinical Trial Transformation Initiative, is a fundamental need today.

The cost of taking a drug from discovery to commercialization is close to $1.38 billion, as per Tufts R&D Outlook for 2011. This has reportedly increased 7.4% annually over the past 20 years, owing to diverse reasons, ranging from increasing protocol complexity, larger, global multi-centric trials, the increasing cost of technology and stringent compliance criteria to ensure patient safety, to name a few. Thus, companies are facing huge cost pressures, resulting in increased outsourcing, complemented by the need to follow a lean approach and deliver high quality data that ensures approval and patient safety, albeit at the lowest cost.

Evolving business models are apparent – where earlier large pharmaceutical companies chose to work with multiple vendors, vendor consolidation seems to be the current trend. Also, non-linear growth drivers, such as cost-effective, vendor-managed, hassle-free e-clinical solutions, which drive the integration of data from multiple legacy applications and help sponsors partly buffer the impact of ‘sunk costs,’ seem to have become integral to the business solution.

Standardization, Integration and Interoperability

The industry is striving to reverse the existing ‘Data Rich, Information Poor’ scenario, focusing on gathering requisite, reliable and accurate data and building in supporting analytics allowing for the meaningful and timely interpretation of the same. As data traverses through multiple channels such as (Clinical Data Management Systems) CDMS, (Clinical Trial Management Systems) CTMS, (Clinical Data Repositories) CDR, and SAS Analytics tools, repeated entry at multiple stages not only involves extra effort and delays in timelines, but it also increases the possibility of errors. In addition, with over 700 mergers having occurred in the second half of the last decade, consolidation has become the norm. Related challenges like disparate technology platforms, differing data standards and varied business processes actually defeat the core objective of consolidation, namely to bring a drug to the market faster. Various initiatives are helping companies work towards more cost-efficient and faster approvals:
Clinical Data Interchange Standards Consortium (CDISC's) Shared Health and Clinical Research Electronic library (SHARE), which helps provide standardized metadata definitions which enhance communication across trials and applications in studies worldwide

Biomedical Research Integrated Domain Group (BRIDG), which allows pharmaceutical companies to make more informed decisions by leveraging information used in clinical trials

Clinical Data Acquisition Standards Harmonization (CDASH), which defines data collection fields that align with those required for data submissions for regulatory approval

As business models change from transactional to strategic, vendors also work towards providing cost-effective and innovative integration solutions and thus also providing a value-add to the partnership. Cloud-based solutions are being designed to provide both scalable and flexible architecture, which would allow companies to:

- Patch on additional applications (vendor or sponsor-specific)
- Involve reusable CDISC compliant data structures
- Drive process automation allowing data to be pulled seamlessly from multiple sources into a standardized format and stored in a clinical data repository
- Create real-time trending reports across patients and studies through user-friendly graphic user interfaces (GUIs)
- Support meta-analyses

These address an important gap, as the integration of multiple sources of data to provide trending reports that provide a holistic overview of the condition of the patient or the study is often missing; in addition, close to 100% of companies that are using e-clinical technologies are still using external software to support analytics. Blue-tooth enabled data transmission, viewing reports real-time on one's mobile or IPAD are not a futuristic vision, but also a happening reality.

Centralized Risk-Based Monitoring and DDE

It is ‘e’mpirical that technology-enabled business models supporting Targeted Source Data Verification (SDV) and Risk Based Monitoring are established, wherein viewing data real time and leveraging real-time trending reports across patients would contribute significantly to risk assessment and enhanced patient safety. While 30% of the cost of a trial is contributed by monitoring, 46% of the monitoring effort is associated with SDV. However, even with 100% SDV being performed, barely 3-5% of the data is really subject to change. A phase II trial conducted under a US IND application in 2011, demonstrated that centralized risk-based monitoring, coupled with Direct Data Entry (DDE) into an e Clinical Trial Record (eCTR), similar to an EMR, followed by the data being directly pulled into the EDC database, practically eliminates the need for SDV. A web-based pdf file was generated, which was then viewed in a read-only eCTR viewer which serves as a trusted third party environment. The results were indicative of faster database lock timelines, higher data integrity as minimal transcription is involved and a reduction in the monitoring effort to the order of 50% to 60%.
EDC – Evolving Perspectives

It is also expected that more than 50% data will flow from alternative sources such as labs, device data, ECGs, scanners, or get pulled in from EHRs. Thus, appropriate governance needs to be established to ensure data integrity and appropriate data flows. The advantages of viewing data in real time, the benefits of rolling locks allowing for the provision of interim data for data safety monitoring boards, interim reviews, or submission, and the need for real-time data insights to support the increasing number of adaptive trials to allow for dynamic mid-trial modifications in study design, have resulted in over 50% of the industry using EDC solutions today. That being said, the cost benefits haven't translated as planned, as trials become increasingly global and involve multiple stakeholders; with this the added on user license costs and the 24/7 helpdesk support costs (across multiple languages) have often been prohibitive. In addition, for large pharmaceutical companies with 300–500 studies running simultaneously, the impact of a technical glitch stalling all trials for some time is mind boggling. The dependency on capable IT support and the need for a technologically fluent user base are also critical to the success of EDC deployment. The value of this tool is lower when conducting phase I studies, as against phase II-IV studies. Further, EDC is not always the most cost effective solution for smaller players owing to the overall cost implications. Hence, while most companies are either there or are making a conscious effort to adopt EDC, one must take cognizance of the costs and the associated risks as well.

The Future Vision – It’s About Transformation

We foresee a shift from an FSP approach, where specific activities within the data management life cycle are outsourced, to an end-to-end outsourcing approach, where sponsors are looking for a one-stop shop. In addition, sponsors are looking at vendors who can also provide the IT capability to consolidate all their data, provide all the necessary IT support, and ensure data security and privacy. Pharmaceutical companies are looking for the ability to pick up all the data that has been pulled in from multiple databases and to map the same in a format that is Study Data Tabulation Model SDTM compliant and submission ready. They are also looking for tools that allow real-time visualization of reports and data trends, and GUIs that are extremely user-friendly and accessible.

The role of the data manager is also potentially evolving to one showing increased ownership of the quality of the data, as remote, risk-based monitoring seems not so distant a vision. The passive data processor is transforming into a person who not only is the first to see the data, but also remotely monitors data, identifies trends and issues, and flags the need for a limited number of targeted site visits. Further, the data manager should be cognizant of industry best practices as defined in the Good Clinical Data Management Practices (GCDMP) – an SCDM publication. The fundamental ability to perform data validation or site monitoring has become a hygiene factor and one clearly needs to evolve to a different level to meet the need of the day.
Conclusion

As pharmaceutical companies look into the future, it is about adapting to changing technologies, business models, and evolving roles without losing sight of the associated risks. Increasing complexities of studies, global teams partnering to reduce timelines and manage costs, enhanced needs for data security as personalized medicine and the use of e-source start coming into the picture, are all factors impacting the way data will be managed.

A willingness to challenge status quo and to drive transformation, both in process and in mindset, is the need of the day.
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Contact
For more information about TCS’ BPO contact bpo.imo@tcs.com

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