Staying on Top of Shifting Sands as Clinical Research Transforms

From COVID-driven shifts in working patterns and the growing use of advanced technologies, to rapidly evolving processes and regulations, the clinical research industry is standing on the precipice of great change.

It means we have a golden opportunity to shape the future of our sector, using all the skills and tools at our disposal to create a more efficient, data driven, patient-centric CDM discipline. With this in mind, the Society of Clinical Data Management (SCDM) held a two-day Leadership Forum event, bringing 70 data experts from across the spectrum of the industry together to discuss the big questions, and how best to proceed from a people, technology, regulation, and process point of view.

People

The world of work has been turned upside down by COVID, with working from home and hybrid patterns becoming the norm overnight.

Post-lockdown, organizations need to transform how they onboard, train, and engage with their staff remotely. They must enable the flexibility of workspace, and digitally support co-located staff and projects. In addition, businesses need to be agile enough to adapt as virtual work continues to evolve.

During break out discussion sessions, delegates at the Leadership Forum discovered that there were many similarities to how organizations were coping with this change. "A lot of companies tried to keep their interactions engaging (i.e. face face to face) like using video to be able to see each other," said Tanya du Plessis, Chief Data Strategist and Solutions Officer at Bioforum, adding that this helped to "build bonds and keep the camaraderie in teams."

Remote onboarding was highlighted as a challenge, and many delegates said their companies used regular video meetings to help new starters feel engaged in and encouraged during the onboarding period.

Reporting from her breakout session, Catherine Celingant, Executive Director, Data Monitoring & Management - Oncology TA Lead at Pfizer., said the remote model had actually opened up opportunities for communication. She said: "You used to have colleagues in the next building, so it's faster to ping them to see if they are available for a quick chat."

Many organizations have seen an increase in productivity, Celingant went on. "The flip side of this is long, fluid working hours that mix with your private life which is not necessarily healthy." Looking ahead, her group said companies should avoid "defaulting to cost cutting measures" such as closing offices and restricting travel as the world opens back up. Instead, they should invest in a "well thought out, deliberate, hybrid model approach" that considers which interactions are best suited to remote or in-person working.

People and organizations both need to nurture a specific set of skills if this new working model is to be successful, said Patrick Nadolny, Global Head, Clinical Data Management at Sanofi. “Organizational skills will be crucial to being able to work remotely in the post-COVID era, as will self-management,” he said.

Providing team members with guidance on “when to open the laptop” and how to use technological features such as “do not disturb” could help people to draw the line between their work and home lives, he said.

On a positive side “Micromanagement does not work in remote work,” Nadolny went on. “Managers have no choice but to empower staff to work more independently and autonomously.” All the delegates agreed that clear communication of the organization’s goals, mission, and “why” were a crucial to aching this.

Pfizer’s VP and Global Head Data Monitoring and Management, Demetris Zambas, agreed, explaining that his breakout group had discussed the increased importance of “soft skills”, including emotional intelligence, in the remote or hybrid workplace. However, we should “not forget the basics”. Future training especially for newer staff, should always include the “fundamentals of the discipline”, he said.
Summing up the conversations in her breakout group, Ami Mehr, VP of Strategy at Veeva Systems, said there had been “some generational differences” that contributed to how people had adapted to remote working. But the group had agreed that technology had helped to remove many of the traditional silos within companies. She added that remote working had got easier over time, as people learnt how to use the technology, how best to interact virtually, and how to build bonds and trust online.

Overall, the delegates agreed that empathy was key to successful team working in the virtual environment.

Technology
Advanced clinical trial technologies are changing the face of drug development, enabling adaptive designs, risk-based approaches, remote monitoring, and much more.

Use of such solutions accelerated during the pandemic, as “nice to haves” became “must haves”. Now we are out of the eye of the storm, delegates were asked to “take a step back” and consider how these innovations could best be integrated into routine research.

Reporting back to the meeting following a breakout session on the topic, Jennifer Stewart, US Director at Research Partnership, said “breaking down barriers to interoperability” and ensuring all data was available as soon as it was captured was key. It would, she went on, allow data scientists to “take decisions, take action, and course correct”.

“Another key idea was that, regardless of the innovation, we keep in mind that quality, reliability, privacy, and security are all important,” she said, adding that if banks have managed to do this, then pharma should be able to too.

Merck’s Global Data Management and Standards at Merck, Adam Colley’s group also spoke about compatibility and integration.

“We need to align around better structures,” he said, “there was talk about a medical device regulation (MDR) or knowledge databases where we can drive the building of systems more semantically, rather than starting with an electronic data capture (EDC) and adding parts to make it work.”

Arshad Mohammed, Executive Director, Data Management at LabCorp, suggested including data managers/data scientists much earlier on in the clinical trial lifecycle. By giving them “a seat at the table” when protocols are being designed, sponsors can be sure that available data sources are being used to their maximum potential, he said.

Irina Sher, VP of Data Management at Bioforum Ltd, said her breakout group looked at the question of what tech developers needed from pharma. “We have a huge need for integrations and validations… which can be quite challenging for start-ups, small companies without the resources for this type of support.”

Derek Perrin, Executive Director, Data Management at Astellas Pharma, agreed, saying that pharma often required too much customization of solutions, making it difficult for providers to build tools served a larger audience. “One of our biggest challenges is our own internal drive for perfection and trying to find a solution that will meet all needs for all purposes, rather than focusing on what is acceptable and fit for purpose,” he said.

Perrin’s group also spoke of the importance of having tech savvy people in all functions. They can collaborate with the IT teams to ensure solutions need the needs of the business.

Process and regulation

Traditional data streams are increasingly being transformed, thanks to the addition of alternative methods of data capture. Decentralized trials, real-world evidence, eSource, and sensors are all playing a role in this revolution, multiplying the number of data points being captured and processed.

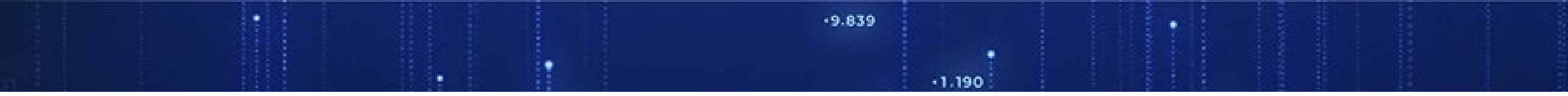
At the same time, sponsors are facing an evolving regulatory environment, made up of regional directives, regulations, and guidelines, international harmonization recommendations, and whitepapers and initiatives from industry groups and agency workshops.

Navigating this landscape may be challenging, but it is essential to releasing the potential of this new paradigm.

Jean Mulinde, Senior Policy Advisor in the FDA’s Division of Clinical Compliance Evaluation, said: “We're here because we recognize the need for executing clinical trials for quality, so that we have the information we need to further develop products, healthcare teams have sound clinical evidence on which to base decisions, and patients can make well informed decisions about their own health care.”

Trials must be built on strong foundations that ensure quality is “baked into the protocol and all the associated plans that it takes to operationalize and complete the study”, she added.

One challenge to this, said Jonathan Andrus, Chief Strategy Officer at Clinical Ink, following the breakout sessions, was a lack of international consistency in regulatory requirements. He used the example of telehealth, explaining that some countries mandated the audio recording of consent, whereas others deemed this inappropriate.



“Nadolny agreed and said sponsors would like to see more international agreement on how to use technologies. “An ICH-aligned consensus could help us drive the implementation of the right approach across the world, instead of having these very specific region-by-region regulations,” he said.

Multi-modal data collection adds complexity to data flows, which can impact inspection readiness the delegates agreed. “With all these data streams, we’re trying to differentiate how it was collected, where it was captured, and how, as best we can,” said Mr. Zambas. “The challenge comes into what extent we can apply risk-based thinking to this.”

RBQM

The FDA, said Mulinde, has published several guidance documents on risk-based quality management (RBQM), but was concerned about a slow uptake of the approach across industry.

During the breakout sessions, the delegates discussed what could be done to encourage more companies to step into the risk-based arena.

Reporting back, du Plessis explained that while risk-based monitoring (RBM) had been around for a while, many organizations have been outsourcing it to technology vendors. It means they have not built up the skills they need to use the tools and fully deploy the method, which is key when processing the thousands of data points that are now being collected.

A lack of international alignment on risk-based approaches also poses a problem, delegates said, explaining that Japanese regulators, for example, call for 100% data monitoring.

“Many others have submitted with a fully RBM approach to their data, and there are a lot of success stories out there. It would be great to see those case studies – it would be really encouraging for smaller companies,” said du Plessis. Such a resource could also include guidance documents that help to define quality tolerance levels, for example.

The group also suggested the SCDM collaborate with regulators and tech providers to test the available methods and publish the outcome.

De-centralized Trials

Sponsors embraced de-centralized clinical trials (DCT) during the pandemic. While they proved invaluable, such operational designs do present challenges in terms of processes and regulation.
Dr Rick Ittenbach, Professor of Paediatrics at the University of Cincinnati College of Medicine and Cincinnati Children’s Hospital, said: “The problem is how best to impose enough order on these massive data to get them to the investigators and relevant parties with authenticity, and in a way that they can be fully used and implemented.

“The challenges we talked about (in our breakout group) included the cumbersome nature of a large amount of data crossing countries, with different conceptual and organizational boundaries, and many with different rules in place for gathering the data.”

It means data flow management processes need to be flexible enough to adapt, but structured enough for people to follow, the group agreed.

Regulators shouldn't dictate this, but rather offer guard rails. The SCDM or another industry group could put together the definitions, a playbook, etc."

The group also discussed the technology of DCTs, saying it should "empower the transformation", and agreed that despite becoming the default core of DCTs, EDC was "not the place to aggregate data from disparate systems". Eventually, traditional EDC will be obsolete and/or replaced with gathering hubs such as a data warehouse, they said.

They added that the technology the industry needs already exists, but needs to be reviewed, repurposed, and pieced together for pharma use. It means companies must invest in people with the skills to carry out this evaluation.

The solution, again, lies in collaboration and sharing best practice, they agreed. "More information sharing across companies in the industry would help us move a concept like DCT forward," said the group.

A Collaborative Future

Technological advances, exponential increases in data points, changing work patterns, and a greater focus on patient centricity are reshaping the world of clinical research before our eyes.
This change is driving the shift from clinical data management to clinical data science – and, as our delegates agreed, it's a journey we should all be taking together.
If the sector as a whole invests in the right people, process, and technology, aligns across national and regional borders, and shares best practice, it can shape the future of drug development for the better.

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