Decentralised Clinical Trials

With increasingly large data sets becoming the norm in trials, how can new approaches to digitalisation help keep the patient experience in focus?

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Over the past few decades, information technology has undergone a drastic transformation – an evolution from floppy disk to laptops and data lakes. The clinical trials industry has unfortunately not ridden the arc of technology at the pace of other industries. This left it flat-footed when an epochal event, a global pandemic, struck in 2020. With so much at stake, the time has come to maximise the efficiencies of clinical trials, and there is evidence that this change is underway.

As the practices in which clinical trials are conducted and monitored continue to modernise at a rapid pace, there is an urgent need for digital transformation in the industry.

If sponsors are to realise their goals of running flexible, decentralised clinical trials (DCT), risk-based management (RBM), or adaptive trials while adopting Big Data, artificial intelligence/machine learning (AI/ML), the emphasis must now be on technology solutions that optimise clinical trial data workflows by bringing the technology to the data.

The Clinical Trial Solutions Landscape

Aided by the shift from traditional clinical trials to DCT during 2020, the industry found itself at a loss. Many contract research organisations (CROs) were unable to conduct drug trials they had planned due to the lack of digital

solutions implemented that enabled data capture from any site, in any country.

Since then, the industry has seen an increase in the eClinical solutions market and, in 2021, it was estimated at $7.2 billion and expected to expand at a compound annual growth rate of 13.6% from 2022 to 2030 (1).

This growth is driven by the demand to handle an increasing number of clinical trials and the sponsors' heightened appetite for outsourcing studies, while containing increasing costs. These drivers intensify the challenges faced by sponsors today, including the complex recruitment requirements across multiple centres and countries.

When looking at what technology enablement means for the industry in more detail, there are benefits ranging from radical and real-time transparency, to game-changing efficiencies, more secure workflows, and data sharing. Digital transformation throughout the various phases of clinical trials can help to attract and retain more participants as well as gain deeper data insights with the help of analytics.

Patients also benefit from the digital aspects as the trial becomes decentralised and self-assessment is easier, giving them more flexibility and higher personalisation at the same time. The good news is that for the larger, more mature organisations, the foundations are already in place. By implementing a critical analysis of their current state – systems, processes, resourcing, the development pipeline – combined with their experience, they can select the best-fit solutions to adopt, adapt, and implement. Many of the big pharmaceutical companies are already actively pursuing solutions that will revolutionise the way they conduct clinical trials and give them an advantage over their competition.

So, where does this leave the larger portion of the clinical development industry: the small- and mid-sized biotechnology, pharmaceutical, and medical device companies?

They have neither the bandwidth nor the financial backing for elaborate technology initiatives. For them, it is always 'go' time, and they need to identify partners who can enable their own data transformation with a solution that does the heavy lifting and addresses the core needs of aggregating, integrating, and interrogating their clinical data in real-time.

Every Patient is the Source, and Their Data is the Story

Innovative sponsors are having to assimilate much more data than they were just five years ago. This is especially true in sleeker study designs and in early Phases I-II where they may be trying to open only a handful of sites, maximise enrolment, and limit the exposure of patients to the least amount of potential risk with new medications as possible. It becomes imperative, even in the smaller early-phase studies, to have all relevant data at hand immediately. Particularly with the evolution of biologic oncology treatments and precision medicine, this data is vital to the patient as they seek alternatives to help with their condition.

For instance, an early phase dose escalation programme needs data to determine the safety of an oncology drug. A few patients might be enrolled at that dose cohort level and their data is crucial to determining the next steps in clinical development because that is going to trigger the next dose escalation. Whether it is a rare oncology condition or relapse refractory patients, who are much sicker, the sponsor is really relying on those three patients' data to determine what that next dose cohort looks like.

If, during the lifetime of the trial, the scenario in which patients' data may be examined in real-time does not occur, there could be considerable delays in the next dose escalation due to the absence of safety data, a late lab sample, or a patient who did not dose appropriately. As a result, it is critical to examine that data at all levels, holistically, and in real-time in order to provide insights that directly point to that patient's source data.

Data Sources are Expanding

Beyond electronic data capture (EDC), more than 70% of clinical trial data lies outside of the study database (2). The volume and variety of data sources

is only increasing – electronic health records (EHR) and electronic medical records (EMR), real world evidence (RWE), electronic patient reported outcomes (ePRO) and electronic clinical outcome assessments (eCOA), wearables, genomics and biomarker laboratories, imaging, and clinical trials management systems (CTMS), to name a few.

Connected devices, wearables, and the possibility of continuous monitoring during clinical trials open new opportunities in terms of the quality of the data captured and the overall insights that are produced. However, to create these insights, very large datasets need to be handled, derived from diverse patient populations. It is critical to have a defined data strategy and improve efficiency, but also to identify the right trial data that sponsors can rely on throughout their clinical development.

As with all clinical trials, ensuring that disparate data can be easily integrated and is immediately available to users for review, to aid fast decision making, is critical for the clinical programme, compliance, and safety of patients. When assessing the positive impact of digital technologies on recruitment, patient engagement, quality of data, adjusting treatments and protocols, and improving the agility of studies, it is easy to recognise the value these changes will bring.

A Unified Solution

Currently, one of the problems experienced is that while the technology used in clinical trials has advanced, sponsors are still trying to make use of a patchwork of separate, disparate systems with poor interoperability to gain new functionalities in order to meet trial needs. Today, it's not uncommon for a VP of Clinical Operations at a small- or mid-size biotech to aggregate various data sets in Excel, create complex pivot tables, or even dig up the bit of SAS they know to generate reports for interim analysis, regulatory submissions, endpoint adjudication committees, and investors.

It's important to note that the choice of data technology must be holistic, user-centric, and purpose-built, with the primary aim of removing complexity, reducing data friction and silos, and streamlining processes. A platform that can capture the range of different data types that is needed, whether that be from traditional clinical trial data or more innovative data points such as wearables. The right mix of a clinical data platform and best-of-breed point solutions will make the user experience easier because they can acquire the data when needed while streamlining study conduct and reducing site burden. Furthermore, in most of the newer indications that are being developed, the site is also the patient's doctor, so holistic clinical data insights provide benefits in terms of site and patient engagement.

To do so, small- or mid-size companies will need to demonstrate an appetite for adopting these new technologies. Maximising the use of analytics and AI/ML means the trials of tomorrow will increase job satisfaction and study quality, reduce patient burden, and improve efficiency. Failure to implement such unified solutions could have a long-term impact on their business. This will in turn boost speed-to-market and allow clinical research teams to join the digital revolution that so many other sectors have already realised.

Conclusion

Clinical trials are slowly shifting in order to address concerns around their efficiency and small- or mid-size organisations need not be left behind. Companies can streamline their clinical trials, cut costs, and minimise the risk of development. They will be able to increase the number of clinical studies, develop and test more treatments simultaneously, reach remote and even smaller patient groups, and create better protocols to test their treatments.

These changes have the potential to offer competitive advantages to any clinical trial sponsor, with advanced data technology now empowering their virtual or DCT.

Although all the questions are yet to be answered, there are some revolutionary technologies on the market to support CROs and sponsors through the digital transformation journey. Forward thinking life science companies are defining their trial vision and looking for like-minded partners to execute it. With greater data access and more robust technologies in place, the pharmaceutical industry can focus more on improving the patient experience.

References

1. *Visit: grandviewresearch.com/industry-analysis/eclinical-solutions-market*
2. *Wilkinson M, Assessing clinical trial data volume and diversity and its impact on data management timelines, Tufts Center for the Study of Drug Development, Presented at DIA conference, September 2020.*

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