Beyond the Data-Hungry Beast

How has data spurred on clinical research and how can it make a difference to clinical trial management systems in the future?

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Digital information is so embedded in our everyday lives that it almost goes undetected. That may be a bit surprising, given the vast amount of data that we generate. Consider the fact that every minute of every day, over 41 million messages are exchanged through WhatsApp, 208,333 participants are in Zoom meetings, and 1,388,889 people make video or voice calls (1). The sheer volume of information that is being created, exchanged, and collected illustrates just how valuable data are in powering almost everything we do.

Nowhere is this value and growth more apparent than in clinical research. Over the past decade, the amount of clinical data used per trial has increased by 183%, while many sponsors are now using an average of five or more data sources per trial (2-3). Because drug development relies on the insights garnered from clinical trial data, this exponential increase presents a multitude of challenges in data management, which has led to trial delays.

The Evolution of CTMS

As clinical trial data have grown, so have the complexities of trial management. One of the key platforms for managing trials are CTMSs, which have more data to choose from than previously available, with more systems, including EDC, IVRS, and eCOA, now involved in research that can give early indicators of trial performance. These systems hold a wealth of metadata that are crucial in reporting on the operational progress of trials. The traditional model of CTMS was to pull data from a few key source systems and then use those data, along with site-based monitoring for definitive reporting on trial status and progress. As the industry has evolved with more trials being outsourced and more data sources being used, defining the source of truth, and what system is the most up to date has made CTMSs data-hungry beasts. Unfortunately, traditional CTMSs are sole repositories that do not easily connect with, or ingest, data from other CTMS platforms that CROs use, making it easy to track metrics across a portfolio that leverages different clinical outsourced partners.

This becomes an issue as pharmaceutical companies, particularly emerging and mid-market organisations, adopt a more highly outsourced research structure that involves multiple CROs. The reliance on outsourced CROs has also come into even sharper focus because of COVID-19, which has accelerated virtual trials and the necessity for remote monitoring. As a result of the pandemic, investigators reported that 57% of patient interactions

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and 79% of interactions between sponsors and CROs are now taking place remotely (4). Data loss is a serious concern, with the FDA even releasing guidance on how to maintain trial integrity during the pandemic (5).

It has become common practice for CROs to augment sponsors' data acquisition and management activities, but that also means that a single study can have many teams working on it – all using different CTMSs, especially if there are different CROs working across a large global programme. To ensure trial oversight, operational teams and project managers must reconcile reports from various CROs, or log into different CTMSs to replicate data into their own system. Staying organised by consolidating data manually in various Excel files for enrolment and clinical milestone tracking to ensure trial oversight and regulatory compliance is simply inefficient. With 46-78% of sponsors forecasting that the adoption of digital patient engagement technologies will increase post-COVID, and 34-52% predicting that trial decentralisation approaches like new site models, and online recruitment, will increase alongside that; the inefficiencies in a traditional CTMS must be addressed (4).

Turning to the Cloud

Against the current landscape of increasing data volume and outsourced CRO models, cloud-based CTMSs can support a path for organisations to improve the efficiency in collecting and analysing operational data. The lighter footprint, accessibility, and ease of integration found in these types of systems are what make them so compelling when compared to traditional CTMSs. Being on the cloud makes those data readily available from anywhere, but it also frees up resources, as there is no need to buy and maintain on-premise IT components. The low-cost implementation of cloud-based CTMSs is especially attractive to emerging companies that have more limited budgets and may not necessarily need a traditional system. With constant software updates supported by expert teams, cloud-based systems have built-in benefits that further reduce costs that would normally be associated with custom developed CTMSs.

That's not to say that a cloud-based CTMS isn't configurable. These systems are made to be flexible and scalable to grow with an organisation. The needs of a large pharma company are not necessarily the same as those for a smaller organisation. Some sponsors may require a site selection aid or site payment capabilities, while others might prioritise monitoring trip reports or subject visit progress. Whatever the requirement is, many cloud-based CTMSs are modular in design so that they can be configured to meet different patient portfolios and regional strategies. This also means that they can be deployed quickly.

Another key benefit to a cloud-based CTMS is the ability to combine all data into a single source of truth. Rather than juggle multiple spreadsheets and trackers, these systems can integrate with other CTMSs to create immediate value in terms of data visibility and oversight. Clinical operations teams can use operational data from CROs to optimise trials easily, and provide quick insight to stakeholders into the programme status. When it is part of an existing clinical data platform, a cloud-based CTMS further enables improved efficiency in streamlining data. Data that are already captured and mapped within these platforms can constantly feed into a CTMS, bringing the enhanced capability to track and communicate risks, accomplishments, and upcoming priority activities.

Modern CTMS for Modern Challenges

One of the most exciting prospects of a cloud-based CTMS is that it sets the foundation for artificial intelligence (AI) and machine learning capabilities to drive greater efficiency in trials. Faster study startup times are supported by AI, which reduces the time spent on trial designs. Trial processes can also be automated to minimise human error and manual input so that trial managers can focus on critical activities, such as analysing data. Data reconciliation and mapping can also be performed more efficiently with AI.

Speed and accuracy are crucial in delivering necessary therapies and treatments to patients, and that is why it is vital that every tool at the industry's disposal is used to increase operational efficiency. Pharma companies are now working against a growing pool of data streams and sources, increasingly outsourced CRO models, and decentralised trials, which are contributing to significant delays in clinical research. By establishing a modern CTMS within the framework of a clinical data platform, sponsors can own their operational data, increase data control and visibility, leverage trial metadata from the CTMS to facilitate activities like study configuration and design in the clinical data hub, and move beyond current data challenges to shape the future of clinical research.

References:

1. *Visit: https://web-assets.domo.com/blog/wp-content/uploads/2020/08/20-data-never-sleeps-8-final-01-Resize.jpg*
2. *Visit: www.centerwatch.com/articles/24688-covid-19-pandemic-could-impact-complex-protocol-designs-options-for-trial-participants*
3. *Visit: www.eclinicalsol.com/resources/the-tufts-eclinical-solutions-data-strategies-transformation-study*
4. *Visit: www.nature.com/articles/d41573-020-00150-9*
5. *Visit: www.fda.gov/regulatory-information/search-fda-guidance-documents/statistical-considerations-clinical-trials-during-covid-19-public-health-emergency-guidance-industry*

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