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What Are the Main Challenges of Modern Clinical Trials?

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With a cumulative total of almost 478,000 globally registered trials from the year 2000 to 2023, and growing at around 10 per cent a year in the last five years, the pharmaceutical industry continues to invest in clinical trials as the gold-standard test of therapeutic safety and efficacy. In addition, as the world's economies and populations move in new directions, the share of non-US trials has reached 54 per cent, a trend that is likely to continue, driven by demographics and epidemiology. As the pace accelerates, trial managers and clinicians face a significant challenge: the explosive growth of data volumes. To succeed in the future, clinical trials need to increase efficiency and better utilise clinical trial data to support informed clinical and operational decision-making.

While the increasing volume of clinical data is welcome in many respects, clinicians and trial managers often struggle with timely access to data held in multiple repositories, and face issues around quality, complexity, and format. To address the problem, the biopharmaceutical sector has invested large sums in data warehouses and data lakes, but timely access to analytics-ready data remains a serious challenge for non-specialists.

Some of the difficulties themselves stem from prior approaches. Manual solutions for data extraction, such as custom programs or scripts, can be costly to develop, deploy and maintain. A network of point-to-point data exchange services soon becomes inordinately complex as new sources are added, and the lack of centralised management can hinder or prevent team collaboration and efficiency.

For example, a cross-study analytics project to review drug safety information across a portfolio of oncology products would naturally need access to clinical data from multiple trials. The combination of different protocols, cohorts, data gathering, and formats soon leads to ballooning complexity as each trial is added to the project.

Solving or reducing data management challenges would immediately release time for better and deeper analytics, supporting the true purpose of a clinical trial, to discover the efficacy and efficiency of new therapies. Ultimately, the less time spent on wrangling data and the more time spent on investigation, the better.

Closing clinical trials data prep gap

To reduce the time preparing clinical data for analytics means removing manual processes and automating data management wherever possible. The key is to enable a centralised clinical data science information hub, acting as a single, unified resource. This change of architecture removes the complexity and tedium of manual point-to-point connections and embeds a simple structure that provides self-service access to robust, reliable data that is ready for analysis.

This information architecture is designed to connect input sources from almost any data type, including flat files, online databases, and a wide range of industry-standard electronic data-capture solutions. The majority of modern software solutions, usually based on open standards, offer application programming interfaces (APIs) that enable easy and reliable data integration. The beauty of the centralisation approach is that connections, even hard-coded links to legacy systems, are built only once. Subsequent data interrogation uses the new unified resource as the classic ‘single source of truth.’

Creating true understanding by extending trial data

Good clinical trials will raise at least as many questions as answers. If a trial shows therapeutic advantage, the natural response will be to drill down into the data to discover the root cause. In some cases, extending the analysis factors – such as income group, ethnicity, gender and more – can prove invaluable.

Health analysts are very aware of the potential for bias in clinical trials: a 2021 review showed that, globally, 62 per cent of trial participants were white (rising to 84 per cent in the US). For clinicians without a data science background, locating and integrating relevant data for analysis can prove to be highly complex, requiring significant effort.

Again, the essential point is that creating a unified resource allows data to be harmonised and standardised, to which clinicians can then apply their preferred analysis tools. Humans, and increasingly AI solutions, are exceptionally good at identifying patterns and exceptions, particularly from visualisations. Rapid visual presentation of trial data, complete with interactive drill-down, enables clinicians to follow their instincts, explore anomalies and test new ideas quickly – all helping to bring new therapies to market more rapidly than ever.

The right clinical data and analytics solution

Naturally, there are multiple clinical trial data management and analytics solutions available with various capabilities, including Revvity Signals Solutions. The possibilities are plenty, but the key decision factors when reviewing the market are likely to centre around near real-time, self-service access to clinical trial data and cloud-native design, with software that is almost invisible to the user.

In a connected world, where clinical development programs are conducted across geographies and completed by teams assembled from partner organisations, self-service access to timely data is essential so clinicians can apply advanced analytics to get a complete picture of patient safety, treatment efficacy, and trial progress. Costly, closed, proprietary systems are likely to lead to another data warehouse dead-end in a world where collaboration is key.

Similarly, cloud-native means finding a solution that takes advantage of connectivity, scalability, and security from first design principles. A pure-cloud solution eliminates the challenges associated with building and maintaining an on-premises data store and provides immediate access to high-performance, highly visual clinical trial analytics.

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