Article

Data-Driven Adaptive Trials: Enhancing Safety, Accelerating Progress and Boosting Economics Through Enhanced Insights

Technology Networks Drug Discovery: By Chris Driver, Director, IT Architecture, IQVIA

The idea of utilizing "big data" in the context of clinical trials has been a topic of conversation for more than a decade. Trial sponsors are faced with vast amounts of diverse data and corresponding endpoints spanning all trial sites linked to their study design. When equipped with the right technology, a sponsor can integrate extensive statistical information within an adaptive trial, allowing for real-time interim analysis.

This ever-changing technology expansion in a data-driven landscape empowers sponsors to make more informed decisions about whether to continue funding a trial, modify or introduce new treatment arms, or implement other essential changes throughout the study's duration. Tapping into vast amounts of data has become significantly more manageable. However, deriving meaningful insights from this data remains a complex task. Clinical technology providers offering interactive response technology (IRT) are leading the way to help sponsors overcome these challenges. Providing guidance on optimizing and achieving improved ROI related to extensive data collections and the various endpoints associated with clinical studies, IRT technology can bolster this approach for sponsors.

Utilizing live data across the entire span of a clinical trial

IRT and computational capabilities provide effective and valuable insights into emerging patterns, whether in recruitment or supply chain management. Data visualization is a key component in this process, especially within present-day trials involving connected devices, where we process numerous data points that undergo analysis and optimization to deliver clear feedback and visual representations to sites and sponsors. Frequently, in Phase II trials, sponsors and site staff investigate the ideal dosage for effectiveness and safety by examining data and assessing various treatment arms. With real-time data insights, both site personnel and sponsors can start to determine if there is a significant distinction between treatment arms. Sponsors may introduce another arm to explore whether a subject can withstand a higher dose and if it offers increased efficacy.

In a similar vein, in contemporary multi-phase, intricate oncology studies, if interim findings indicate that the sponsor surpasses endpoint objectives and has effectively identified a superior medication compared to any other available option, they can withdraw subjects from the placebo, transition to an open-label, and commercialize the drug as quickly as possible. Conversely, a sponsor can terminate a trial more swiftly if they ascertain that the treatment is not more effective than a comparator drug or placebo.

Extensive data sets have intriguing applications at both the beginning and end of the process – for high-value startups focusing on drug discovery and in post-approval studies. From the perspective of supply chain management, the integration of data-driven methodologies and visualization in adaptive trials has advanced rapidly and is now shifting towards employing artificial intelligence (AI) and machine learning (ML) for generating visualizations and insights. This development offers a substantial opportunity to revolutionize the way clinical trials are executed.

Distributing the risk for enhanced quality of life

In our risk-averse field, there is often cautious hesitancy to revolutionize clinical trials. However, there is no valid reason to avoid leveraging modern technology that supports near real-time insights into valuable trial data. Patient safety and caution will always guide our approach within clinical trials. Embracing technology will enable better data-driven decisions and insights, leading to improved overall efficiencies.

Large pharmaceutical companies must be willing to assume additional risks and acquire evidence for regulators and the rest of the industry. Many of these companies have innovation groups where experimentation is taking place. Successful decentralized trials are being conducted across the industry, providing a more patient-centric approach and improving patient retention. Although these innovation groups constitute only a small fraction of big pharma's R&D, steady progress is being made.

Regulatory authorities can also play a pivotal role in driving changes, as evidenced by their involvement in adaptive trials. These bodies can offer guidance to help sponsors navigate the regulatory challenges associated with managing big data, AI and ML within their trials. By addressing sponsors' concerns and clarifying the regulatory landscape, regulators can mitigate apprehensions related to adopting these advanced technologies. To encourage and support the adoption of big data, AI and ML in clinical trials, regulators need to clearly define the acceptable parameters and, if necessary, expand the boundaries within which these technologies can be employed. This will enable a smoother integration of cutting-edge solutions in the clinical trial process.

IRT specialized system design and R&D teams are collaborating closely with clients to determine the most effective ways to harness data-driven approaches within the adaptive trial model, with the aim of innovating and delivering high-quality studies. Beyond IRT, cross-study data presents an opportunity to aid clients in generating insights and making more informed decisions.

The integration of data-driven insights in clinical trials is well underway, enabling clinical research to better accommodate trial participants, enrich their quality of life, and refine trial procedures more effectively.

Author's Bio: *Chris Driver is currently Director of IT Architecture at IQVIA, with over 21 years of experience in the IRT and biotechnology space, and across a number of R&D and information technology functions. Chris's experience and background in infrastructure architecture, global health platforms and more recently, decentralized trial adoption through real-time integrations, drives his enthusiasm for the future state of patient-centered health care. In his "downtime", Chris enjoys spending time with his growing family, advocating for adoption, especially for those blessed with an extra chromosome!*

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CONTACT US

OrchestrateYourTrials@IQVIA.com | iqvia.com/IRT