



Clinical

Data Insights: Identifying Early Signs of Safety and Efficacy in Oncology Clinical Trials

As science continues to evolve, the pharmaceutical industry, clinical teams and CROs rely on expert data analyses to ensure the safety and efficacy of investigational products. Recent advancements in data analytics use innovative collection methods, data environments and algorithms to transform complex, diverse datasets into creative insights for clinical trial use.

The heightened emergence of telemedicine during COVID-19 has also emphasized the need to ensure data integrity through complete and accurate reporting of datasets.

Collecting and analyzing patient data using appropriate visualization tools can provide unique insights into patient performance across a number of clinical variables, and in comparison, to other study participants. These data insights are key to identifying early indicators of drug safety and efficacy in Phase I oncology clinical trials.

Data management is essential for oncology research. CROs rely on data analytics to provide sponsors with continuous clinical insight of trends that could predict safety, and more importantly, efficacy for investigational products. It is important to identify these signals as early as possible so that adaptive trial recruitment can focus on the patients who are most likely to experience clinical benefit, that can also result in a path toward regulatory approval.

Expert Data Analytics

Phase I clinical trials focus on evaluating the safety and efficacy of an investigational product. Often, CRO interest is focused solely on safety data in an attempt to expedite regulatory review and approval. However, strategic translational oncology-focused CROs understand that all early-stage development trials are efficacy studies, therefore continuous data analyses are essential for identifying potential activity. For example, it is less common to observe dramatic response rates in Phase I clinical trials, therefore these trials enroll diverse patient populations. Data analyses using visualization tools can identify common variables and overall trends that provide tremendous insight for clinical teams. Translational CROs can also provide predictive clinical insight and strategic guidance for product trajectory throughout the clinical trial.

Data plots are effective visualization tools for clinical variable analyses. One variable often overlooked is a comparison of time on new treatment compared to the time on prior therapy. For example, as new medicines fail patients with advanced cancer, the general trend is that these patients are typically on the next therapy for a shorter duration. In this scenario, data plots that use the patient as their own control can reveal if the patient is remaining on the experimental treatment longer than the prior therapy. This indicates a potential signal that the drug is positively impacting the natural progression of the cancer.

Expert Oversight Plays a Critical Role

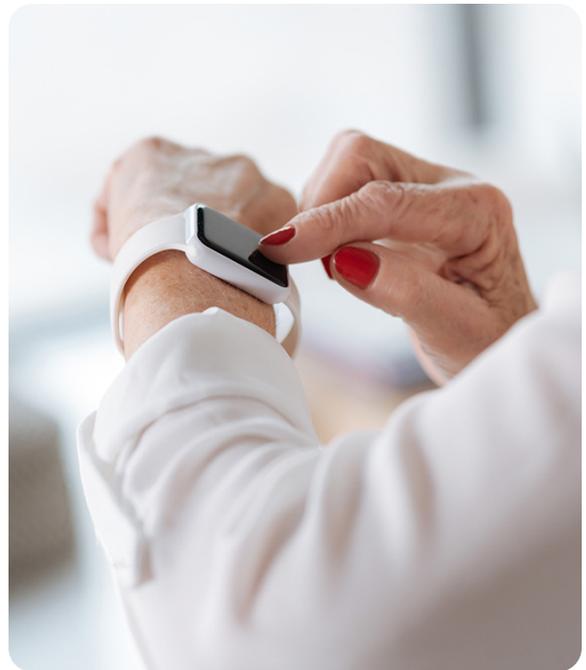
Effective data analyses report continuous, complex data throughout the clinical trial. To do so, CROs must have a robust and proactive data management team. Completing thorough, ongoing data review and monitoring is important to ensure complete and accurate data collection, data integrity and data availability at any time during the clinical trial. When analyzing the clinical data, the outputs must be carefully evaluated to ensure data errors in the electronic data capture (EDC) system are eliminated and data entry is complete. Points of interest must be confirmed against the source documentation before using the data for decision making purposes. Without extensive expertise and deep experience, it is more difficult to determine the importance of the data and interpret that information correctly. In short, human insight and experience is key to harnessing the data and utilizing the data to its fullest potential. Having a CRO partner that has been involved in the development of thousands of diverse drugs for cancer patients who is planning for dynamic real-time data analysis to accelerate your new medicine to patients who obtain clinical benefit.

Differences in Outcomes Based on Trial and Cancer Type

Regardless of the type of cancer or trial conducted, data analysis has proven to be essential in the clinical trial process. Data analyses need to be creative, continuous and communicated to sponsors and investigators to maintain the momentum of the trial, as well as encourage the recruitment of the most appropriate patients to the trial. There may be a variety of tumor types that are responsive to an experimental drug, but it is the CRO's responsibility to help the sponsor identify the fastest and most efficient path to market.

The Significance of Technology in a Remote World

Innovative technologies such as wearables and clinical devices have proven essential in data collection and analytics, particularly during COVID-19 as clinical trials remain operational remotely. The implementation and use of these technologies can alert clinical trial staff to changes in clinical variables including blood counts, mobility, body weight, compliance as well as identify safety signals that could require early intervention. Expert data management teams can track the real-time collection of these variables and integrate seamlessly into data analytics programs, providing additional data outputs for analysis that can impact clinical benefit.



Ready to Get Started?

Leverage a CRO like TD2 to take an earlier, closer look at your trial's data through this unique and innovative methods. With an extensive history of utilizing data analysis, TD2 understands that utilizing clinical experience and knowledge is a key differentiator when examining diverse data. Our team of clinical experts understand the different ways to look at data as well as identify the appropriate way to visualize it specific to each new medicine, allowing us to make the best decision when planning a drug's development path.

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