The Download from ARVO 2022

Challenges and Innovations in Ophthalmic Clinical Trial Management

We had a great time being back in person at ARVO 2022. After taking some time to de-brief, we are sharing some of our key takeaways.

State of The Market

With the rising need for better ocular therapeutics driving demand for more compelling biomarkers, improved analytics in 3D ophthalmic imaging is also surfacing as a market trend. Advanced technologies in the fields of image analysis and machine learning not only increase the accuracy of the endpoints but also improve the efficiency and lower the cost of ophthalmic clinical trials.

CROs, sponsors, and reading centers alike have a vested interest in overcoming the many challenges of clinical trial management. Identifying and recruiting clinical trial participants can be a logistical nightmare. Numerous trials are competing for a limited patient pool and there is no organized and efficient structure for identifying and recruiting these participants. Data monitoring and management is another obstacle, as the average duration of an ophthalmic clinical trial is about 7.5 years, making management of data over such a long time operationally challenging. Lastly, upon trial completion, full evaluation of the outcomes along with post hoc analysis of the data have not been feasible given most clinical trials are managing decentralized data from multiple ophthalmic devices that do not adhere to existing data standards meaning analysis tools are limited in the data that can be processed.

Given these challenges, it was encouraging to see special interest groups led by governing bodies such as the National Eye Institute encourage the industry to address these pain points for the common good. Here are a few highlights:

Accelerating Patient Enrollment

Did You Know?
40% of clinical trials are cancelled due to poor recruitment. With trials competing for participants amongst a limited patient pool, the logistics of identifying the correct patients can be a challenge and create costly delays.

What's New
Identifying eligible patients can be facilitated through a secure, yet accessible platform, gathering all patient data in one place. Patient pre-selection and validation becomes more efficient, accurate and cost-effective. Solutions that offer a platform where all patient data can be reviewed and searched from anywhere using any device are alleviating recruitment bottlenecks.

"The ophthalmology DICOM working committee spent a lot time developing these standards, so why isn't anyone using them?"

- Aaron Lee, MD, MSc, University of Washington

Comprehensive Trial Data Monitoring

Did You Know?
The average length of ophthalmic clinical trials from start to market is about 7.5 years. With these lengthy time spans and large amounts of data, collaborating and monitoring trial progress has been difficult and onerous.

What's New
Comprehensive trial status and real-time access to underlying data can be achieved through cloud-based data management. Using a cloud-based solution gives all parties direct access to all data, with multi-site and multi-trial management capabilities making it possible to monitor trials in real time, and efficiently communicate and collaborate. These solutions also create centralized storage of all data to ensure data is secure and preserved.

Advanced Analysis of Outcomes

Did You Know?
Most clinical trials are incorporating data from multiple ophthalmic devices, making potential post hoc analysis difficult and requiring different software for each image format. This process is quite time consuming and results in more errors caused by repeated human touchpoints and variant measurements; or worse, the research grinds to a halt.

What's New
Newly released, AI-driven technologies are making it possible to analyze vast amounts of data and images more easily. In addition, expanded post hoc analysis can provide valuable insight into any trial and help discover new data relationships as solutions to the data standardization problem do exist. Furthermore, by leveraging an ophthalmic graph database, searchable on any data point or entity, any party can readily access data across multiple sites and patients. Now trial managers have the ability to visualize data across all ophthalmic devices, and they can then leverage the interface to derive key correlations between the data and clinical outcomes.

Conclusion

There are numerous technological developments emerging in the ophthalmic clinical trial space and we are excited to see the progress as more solutions evolve and are brought to market. Whether you are a reading center, CRO, or pharma company, this new wave of cloud-based, AI-backed technologies can improve every step of a clinical trial, lowering costs, streamlining workflows, and providing more accurate data by reducing human touchpoints and manual measurements.

If you are looking to learn more about innovative platforms that can create efficient clinical trial management and facilitate advanced OCT analysis, we would love to give you more insight into our iNebula platform. Get in touch with us today or, visit voxeleron.com to learn more and request a demo.

"If you have cloud-based data management, everyone has access immediately to the data which reduces the cost and time spent sending the data to different platforms."

- Marion Munk, MD, PhD
  University Hospital of Bern

Sources:
· ARVO 2022 Speaking Session: AI and digital tools for patient enrollment, data monitoring and evaluation of outcomes in clinical studies

· ARVO 2022 Speaking Session: Improving data quality and interoperability through adoption and expansion of ophthalmic data standards