Ora

Creating vision
beyond what we see

Accelerated recruitment through the power of insight

Current challenges in anterior segment patient recruitment, and the latest tactics to overcome barriers and accelerate timelines

The Challenge

Consistently in today's market there are several challenges we face that hinder recruitment in anterior segment clinical trials such as Dry Eye and Ocular Allergy programs. Many drug and device programs require more precise patient targeting to address multifactorial disease and novel mechanisms of action, often with more complex protocol designs. At the same time, studies are facing increased no-show rates and database attrition in this Post-COVID world, along with competing programs at top investigator sites.

In the spirit of innovation and continuous process improvement, Ora looks to drive trial acceleration and improved quality with every step. With this in mind, recent studies have provided opportunities to bring new approaches to anterior segment recruitment that directly address these challenges.

This paper will walk you through details of this new recruitment blueprint to rapidly accelerate enrollment of the right patients, including novel pre-screening visits, intelligent Accelerated Database Outreach (ADO), and enhanced block enrollment combined with increased patient outreach and retention touchpoints. Following these reliable approaches thus far has led to tremendous success.

Rapid pre-screening

Typically when a study starts, the first thing we do is assess the site's patient database for applicable patients. We know during the COVID era, patients moved or switched doctors, and in today's environment patients may be less engaged with their doctor compared to years prior. As Ora recognized these database challenges, we identified an opportunity to support clinical sites in rebuilding databases with a stand-alone, rapid pre-screening protocol prior to any study site activation.

Ora's study-agnostic pre-screening protocols were designed to collect thorough patient characterizations of signs and symptoms through standardized scales and diagnostic procedures. This detailed patient characterization is highly valuable, given drugs in development today may have unique mechanisms of action requiring targeted patient populations. These quick screening visits create significantly robust databases with detailed patient characterizations to jump-start database outreach once study protocols are activated. This also creates a much more efficient screening rate once studies begin, significantly reducing screen failure and overall study timelines.

This approach creates investigator loyalty as we partner on substantial database growth, driving preferred engagement with Ora programs when competing trials occur. It maximizes program efficiencies and creates substantiative value for the sponsor, the sites, and the patients, driving rapid enrollment.

Using these approaches in a study with complex inclusion/exclusion criteria, Ora scheduled 1200+ patients and enrolled 250+ patients in less than 8 weeks.

Intelligent Accelerated Database Outreach (ADO)

When was the last time you picked up a call from an unknown phone number? While centralized recruitment is a streamlined approach to calling patients, and digital outreach can also drive engagement, the reality is, a patient is significantly more likely to pick up a call and engage with their doctor and known local staff compared to a centralized call center.

Recognizing this pattern, Ora evolved patient database outreach with our intelligent Accelerated Database Outreach (ADO). Ora-provided staff traveled directly to local sites to work with local staff, and together drove coordinated high-volume call campaigns where up to 3,000 patients were contacted in a single weekend directly from the investigator's office. Many of these patients were subsequently characterized using our single-visit, non-interventional pre-screening approach, leading to a more intelligent targeted patient pool that decreases screen failure and provides evidence of reliable, stable disease with consistent signs and symptoms. Weekend pushes were made, as metrics demonstrated increased patient engagement during Saturday/Sunday timeframes. Ora's staff of trained professional recruiters worked within IRB-approved, HIPAA-compliant requirements throughout this process.

These personalized interactions with site and practice staff at a local site level provide an opportunity to establish both site and patient rapport. By recruiting patients for a brief pre-screening study visit, patients who may be research-naïve have an opportunity to experience a study in a low-intensity setting, thereby increasing comfort level and reducing potential barriers to future clinical trial participation. ADOs facilitate direct communication at a local site level, allowing our team to clarify study requirements, ensure participant understanding, and address any misconceptions or fears that may hinder enrollment. Additionally, we are providing patients with an opportunity to participate in a trial that may be helpful in relieving their symptoms.

Block Enrollment

These novel innovative approaches are executed in preparation for Ora's proprietary approach to block enrollment on a clinical trial. Ora ensures well-ordered and productive clinical trial visits at our sites through block enrollment. This unique offering concentrates visits into a condensed window of time, allowing sites to implement dedicated research days to increase efficiency and consistency across study assessments.

This in turn sets clear timelines for accountability and results in a higher volume of quality subjects per site, thereby requiring the involvement of fewer sites, leading to higher quality data with less variability. This streamlines investigator scheduling, study coordination, and monitoring visits for efficiencies and cost savings across the timeline.

With this offering, Ora provides highly-trained clinical research coordinators and other dedicated research staff for on-site study execution. This improves the consistency of trial conduct and the quality of obtained data. Ora's block trials enroll >35% faster than traditional anterior segment studies.

Combining digital tech with Ora's innovative outreach improved patient identification, visit attendance, and retention. This included strategically scheduled phone, text, and email reminders to maximize patient attendance.

Conclusion

The need to recruit more targeted patients, address increased patient no-show rates, and database attrition have demanded proactive recruitment innovation and new solutions. Utilizing these tactics concurrently proves to be effective in addressing barriers and challenges currently faced by clinical research particularly in Dry Eye, Ocular Allergy, and other Anterior Segment conditions. As a result, researchers can enroll a diverse pool of optimal participants who align with the trial's objectives and requirements, leading to more efficient identification of the right patient and acceleration of study timelines.

Companies seeking to conduct research in Anterior Segment diseases can greatly benefit from partnering with Ora. The organization's people, processes, and technology make it an ideal choice for successful and impactful research. These innovative approaches pioneered by Ora keep trials on-time, on-budget, and on-quality, leading to a more satisfied sponsor, investigator, and patient experience.

For more information please reach out to:

BD@oraclinical.com

978-685-8900

Ora

Ora is a global full-service ophthalmic drug and device development firm with vast capabilities through all steps of clinical research, including preclinical, clinical, CMC & regulatory, and patient and site evaluations. Through Ora's 40+ years of experience, the company has assisted in bringing more than 80 products to market. Ora's team of experts utilizes global regulatory strategies, integrated research operations, and extensive site and patient engagement to accelerate product development in anterior and posterior segment, as well as ophthalmic devices.