Ora

Creating vision
beyond what we see

Turning Down the Noise in Clinical Data to Drive Successful Dry Eye Disease Studies

Combining our expertise in trial design/execution, endpoint selection, study conduct, and patient recruitment to fuel successful DED clinical research.

Ora is leading the way for DED research efficiently executing DED programs and developing both visual scales and technology to help bring DED products to market. Our extensive site networks and block enrollment allow us to accelerate study timelines and enroll the right patients for your study. Having worked closely with many DED clinicians and patients, we know it is essential to bring new therapies to market to treat the complicated pathology of DED. With 30+ years of experience in DED and having partnered with the majority of the approved therapies on the market, let our expertise guide you on your journey through the drug approval process.

In the last 5 years, we have enrolled over 13,000 subjects in DED trials across 325 site locations in both the US, China, South America, Europe, & Australia for Phase 0, 1, 2, 3, and 4 programs.

30 investigational evaluations of broad-range mechanism of action DED therapeutics including: anti-inflammatory, secretagogue, anti-evaporative, hormonal, wound healing, and barrier function enhancement.

30+ years of DED clinical trial experience including protocol development, trial execution (Phase I through IV), regulatory (FDA, EMEA, PMDA , etc.), and turnkey program management, tailored for each sponsor's individual needs.

Close-knit relationships with experienced investigators who have been conducting successful DED studies for over 30 years. Our ophthalmologist partners are expertly trained and standardized on key clinical scales.

With our established databases of DED patients and by utilizing our exclusive OraNet™ site network and Ora Block Enrollment, we can decrease your timeline by more than 35% and reduce costs.

Extensive training of our specialized Clinical Research Coordinators (CRCs) and strict adherence to protocol procedures ensure clinical trial harmonization across multiple regions, leading to improved data consistency and quality.

Dry Eye Disease Highlights

Each DED study Ora performs meets the requirements laid out by the protocol design, site selections, and target patient populations. Unlike large Clinical Research Organizations (CROs), Ora will not try to force you into a one-size-fits-all program – we customize our processes and approach to set up your clinical trial for success.

Scientific rigor forms the foundation on which Ora stands. Our dedicated Anterior Segment team's deep understanding of DED can give your therapy the extra support it needs to make it through the gauntlet of the clinical trial process. Furthermore, all the Ora Anterior Segment project managers have delivered DED projects for sponsors of all sizes from around the world. Our vast indication specific experience will help guide you on the path to product approval.

Additional Ora offerings in the realm of DED technology include the Ora Controlled Adverse Environment (CAE®), the Ora Inter-blink Interval Visual Acuity Decay (IVAD) test, the Ora Ocular Protection Index 2.0© (OPI 2.0©), and Ora EyeCup™. These tools provide researchers with advanced methodologies to study the disease, evaluate treatments, and improve patient outcomes. The technologies specialized design and features cater directly to the unique challenges of DED research, making them invaluable assets in the pursuit of understanding and treating DED.

Over the last 30+ years, Ora has been at the forefront of supporting our customers in developing innovative products for the treatment of DED. We are driven to provide insights on trial designs, recruitment strategies, endpoint selection, as well as methods/models to reduce data variability. Ora has evaluated over 40 DED therapies including 4 novel approvals: Xiidra®, TrueTear®, Tyrvaya®, and VEVYE™. We understand your drive to find better therapies for DED patients and bring them to market. By partnering with Ora and utilizing our technologies and standardized endpoints, we will turn down the noise in your clinical trial, while increasing the likelihood of success.

Ora vs CRO Analysis

Fully Supports | Partially Supports | Does Not Support

	Ora	Small US-Based CROs	Large Global CROs
Tailored approach to every study to ensure optimal patients, sites, and execution	●	●	◯
Study leadership highly experienced within specific ophthalmic therapeutic area of research	●	◐	◯
Study site staff and monitors highly trained in ophthalmology	●	◐	◯
CRO staff retention year over year +90%	●	◯	◯
Have ophthalmologists, optometrists, and retina specialists on staff shaping protocols, leading core study components and medical monitoring	●	◐	◯
Ability to execute traditional CRO research or implement customized models and endpoints to design novel programs, whatever is needed to best prove out treatment effectiveness	●	◯	◯
Meticulously tested and documented SOPs and processes for phase 0, 1, 2, 3 and 4 research around the globe	●	◐	●
Priority and exclusive site relationships within the United States, Europe, LATAM, and APAC with top investigators and KOLs	●	◯	●

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 85+ 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.

85+ Product approvals

1000+ ophthalmic sites across the Europe, US LATAM & Asia

2000+ clinical studies and consulting projects

400+ employees across over 25 countries

25,000+ patients enrolled in the last 7 years