Ora

Creating vision
beyond what we see

Increasing Chances of Success and Accelerating Timelines for Wet AMD Clinical Trials

Leveraging therapeutic area expertise and substantive site relationships to deliver high-quality clinical trials.

We know that patients with Wet Age-Related Macular Degeneration (wAMD) can be challenging to provide investigative care effectively. While current treatments offer substantial benefits of delay progression substantially better than treatments used in the past, there are still substantial opportunities to improve care and quality of life for these patients. Many patients treated with anti-VEGF therapy fail to exhibit the BCVA improvements demonstrated in controlled trials, and long-term fibrosis and atrophy remain a challenge in patients receiving long term anti-VEGF treatment. New treatments with greater durability, reduced patient burden and novel mechanisms of action offer potential innovations to advance patient care that are sought after by doctors and patients alike.

Ora is supporting the industry by building site relationships around the world to access the right patients for Wet AMD clinical trials. We share your drive to find the right therapies for these patients and bring them to market, and we are excited to offer our expertise and executional excellence to guide you to success.

Wet AMD Highlights

Over 45 retina trials during the last 5 years, including executing AMD research across 240+ sites in the US, Europe, Asia, and LATAM for Phase 0, 1, 2, and 3 programs

Execution of 10+ high-quality gene therapy and novel mechanism of action programs with both small and large patient populations

Significant investment in site networks across LATAM and Eastern Europe to access treatment-naive patients and provide clinical trials as a care option to under-served populations

Close relationships with all major reading centers, customizing your study analyses to best meet endpoint needs

Each study Ora conducts tailored to best meet the requirements imposed by protocol design, site selections, and target patient populations. Wet AMD programs can involve a wide range of patient types, from treatment naïve, to adequately treatment responsive (proven benefit from anti-VEGF) to inadequately treatment responsive, and each patient type is unique. Unlike large Clinical Research Organizations (CROs), that lack in-depth ophthalmology experience, we tailor our processes and program strategy to set you up for study success based on your product's mechanism of action and our knowledge of how to identify and recruit your target patient population.

Ora also maintains close relationships with global retina KOLs and regulatory bodies. Many of your known speakers and advisory board members collaborate closely with us as investigators, protocol consultants, and friends. We also meet with the FDA and EMA regularly to understand the latest guidance for, and collaborate on, appropriate endpoints. We pride ourselves both on ophthalmic knowledge and community connections to ensure we are giving you the best guidance we can on your program.

- Ora has conducted 8 Wet AMD programs the last several years including global and pivotal trials. Ora worked with a wide range of products from traditional IVT antibody therapies to unique gene therapy mechanisms.
- We excel at creating an operational strategy that fits product mechanism of action and target patient population (treatment naïve, treatment responsive, treatment failure) and frequently beat estimated enrollment timelines. Utilizing our OraNet™ site network, we can offer clients experienced and dedicated retina sites without competing programs to ensure study enrollment metrics are met.

Ora's Posterior Segment Division represents the fastest growing department of Ora, comprised of a >100 person, globally situated, operations team experienced in a myriad of retinal indications. With over 35 active programs, Ora's Posterior Segment division is likely conducting more retina studies than any other singular CRO. The team includes an on-staff retina surgeon, a theraputic area head with 20+ years of ophthalmic drug development experience, and an operations head that has conducted or overseen over 30 retina trials. Ora's Posterior Segment team also maintains relationships with the industry's top retinal imaging centers and develops novel endpoints to better understand and treat diseases of the retina.

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	Fully Supports	Fully Supports	Does Not Support
Study leadership highly experienced within specific ophthalmic therapeutic area of research	Fully Supports	Partially Supports	Does Not Support
Study site staff and monitors highly trained in ophthalmology	Fully Supports	Partially Supports	Does Not Support
CRO staff retention year over year +90%	Fully Supports	Does Not Support	Does Not Support
Have ophthalmologists, optometrists, and retina specialists on staff shaping protocols, leading core study components and medical monitoring	Fully Supports	Partially Supports	Does Not Support
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	Fully Supports	Does Not Support	Does Not Support
Meticulously tested and documented SOPs and processes for phase 0, 1, 2, 3 and 4 research around the globe	Fully Supports	Partially Supports	Fully Supports
Priority and exclusive site relationships within the United States, Europe, LATAM, and APAC with top investigators and KOLs	Fully Supports	Does Not Support	Fully Supports

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.

80+ 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