Ora

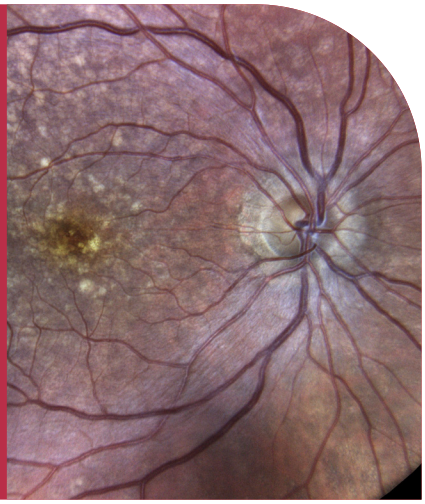
Creating vision
beyond what we see

# Optimizing Clinical Trials for Dry AMD & Geographic Atrophy

Combining deep retina therapeutic area expertise with substantive site relationships to deliver high-quality clinical trials.

As one of the main causes of blindness in the developed world, there is a substantial drive among companies to find treatments that slow the progression and even prevent the onset of Dry Age-Related Macular Degeneration (AMD) and Geographic Atrophy (GA). With the recent approvals of intravitreally injected complement inhibitors, industry focus on Geographic Atrophy is at an all-time high, with multiple companies exploring novel therapies that have the potential to improve the efficacy level demonstrated by anti-complements or reduce patient burden.

Ora is at the forefront of Dry AMD/GA research, executing multiple global GA programs and developing both imaging and functional endpoints to help bring Dry AMD products to market. We have established site relationships that allow us to accelerate clinical timelines and access the right patients for Dry AMD clinical trials. We understand your drive to find better therapies for these patients and bring them to market, and we are here to offer our expertise and executional excellence to guide you to success.



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

**Experience conducting both small and global Dry AMD and Geographic Atrophy programs, including therapies with both IVT and systemically administered MOAs**

**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**

## Dry AMD Highlights

Each study Ora conducts meets the requirements imposed by protocol design, site selections, and target patient populations. Unlike large Clinical Research Organizations (CROs), we don't try to fit you into a one-size-fits-all program — we tailor our processes and approach to set you up for study success.

Ora also maintains close relationships with global retina KOLs and regulatory bodies, and is closely involved in the latest imaging strategies for both FAF and OCT based assessments of RPE and photoreceptor loss. In GA we support our clients with both science and execution. 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 4 independent GA programs over the last several years, including global trials with traditional IVT complement inhibitor products as well as systemically administered products with new mechanisms of action.
- During the Covid-19 pandemic, Ora was able to enroll our IVT complement inhibitor program faster than all other programs in this indication. We attribute this success to our relationships with sites and

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 therapeutic 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


| | 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 indications 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 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**