Ora

Creating vision
beyond what we see

Advancing Diabetic Eye Disease Therapies to Combat the Global Epidemic

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

With aging populations and the incidence of comorbid conditions on the rise, diabetic eye disease is now a global epidemic. It's why investments are being made by companies every day to find the next new therapy that slows progression or even prevents onset. From anti-VEGF therapies to anti-inflammatories to gene therapies and sustained release delivery mechanisms, new pathways are being explored every day to help diabetic eye disease patients achieve a better quality of life.

It's why Ora is invested in accelerating clinical timelines and building site relationships around the world to access the right patients for diabetic eye disease studies. We share 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 involving 250+ sites globally during the last five years, including Diabetic Eye Disease research from NPDR to PDR to DME across 75 sites globally

Experience with both early stage and global Diabetic Retinopathy (DR) and Diabetic Macular Edema (DME) programs

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

In house BCVA lane certification and close relationships with all major reading centers, customizing your study analyses to best meet endpoint requirements and maintain overall program timelines

DR/DME Highlights

Each study Ora conducts is tailored to best meet 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 process and approach to best set you up for study success.

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. Our novel visual function endpoints offer opportunities to assess vision impacts in early-stage diabetic retinopathy before clinically meaningful loss in visual acuity occurs, creating an alternative to traditional anatomical endpoints such as DRSS in establishing proof of concept. 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 recently conducted 11 programs in DME and 2 programs in NPDR with a wide range of products administered both systemically, topically, and intravitreally. Many of these products include novel anti-inflammatory MOAs which could serve as second line therapies to anti-VEGF treatment or first line therapies in NPDR.
- Ora maintains an extensive global network of sites with diabetic eye disease patients in the Southwest US, Europe, and South America. Leveraging these strong site networks, Ora rapidly enrolls DME studies.

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 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	●	○	●

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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