Ora

Creating vision
beyond what we see

Increasing Chances of Success and Accelerating Timelines for Allergic Conjunctivitis Clinical Trials

Leveraging therapeutic area experience, expansive site relationships, and proprietary technology to deliver high-quality clinical trials.

Today, an estimated 20% of the general population suffer from Allergic Conjunctivitis, the equivalent of over 50 million people within the US. Despite the availability of various prescription and over-the-counter treatments, 30-40% of Allergic Conjunctivitis sufferers still report little to no relief with current therapies. Clearly, new Allergic Conjunctivitis therapeutics are still needed to provide relief to suffering patients.

Ora is at the forefront of Ocular Allergy research, executing Allergic Conjunctivitis programs and developing both visual scales and technological endpoints to help bring ocular allergy products to market. Our established site relationships allow us to accelerate clinical timelines and find the right patients for your study. Let's work together to bring new and innovative Allergic Conjunctivitis therapeutics to market.

In the last 5 years, we have enrolled nearly 3,000 subjects in Ocular Allergy trials across 71 site locations in both the US and Japan for Phase 0, 1, 2, 3 and 4 programs.

Ora has an extensive and experienced allergy trial site network with large, detailed patient databases. We are able to refine searches by disease and allergen sensitivity.

By utilizing our exclusive OraNet™ site network and Ora Block Enrollment, we can decrease your timeline by more than 35% and reduce costs.

Ora has overseen developmental programs from initial clinical proof of concept through Phase 4 for many products, including Patanol®, Zaditor®, Elestat, Pataday®, Alaway®, Bepreve®, Lastacaft®, Pazeo®, Zerviate®, Lumify®, Dextenza®, Alaway® Preservative Free, and ACUVUE® Theravision® with Ketotifen, verifying their efficacy and safety, and conducting PK and post marketing trials.

Ocular Allergy Disease Highlights

We understand every clinical trial is unique and requires both proven processes and procedures with a deep understanding of your specific project's mechanism of action and target patient population. Unlike large CROs, Ora will never try to force you into a one-size-fits-all program – we tailor our processes and approach to set up your Allergic Conjunctivitis study for success.

Ora has innovated and leveraged impressive proprietary technologies that enhance the efficiency of Ocular Allergy clinical trials. For 40+ years, the Ora Conjunctival Challenge Model (Ora-CAC®) has been instrumental in evaluating anti-allergic agents for the treatment of Allergic Conjunctivitis. Most of these assessments using the Ora-CAC® model have been essential for obtaining FDA approval. The Ora-CAC® model offers a more accurate and expedited approach, requiring fewer patients, fewer sites, and a tighter dataset compared to traditional environmental studies.

The Ora Mobile Allergen BioCube® (mABC®) is a state-of-the-art allergen exposure chamber for the controlled, safe, and uniform release of allergens, providing increased precision and higher quality data sets. The mABC® provides the advantages of an environmental clinical trial while conducted in a controlled setting. Additionally, the mABC® endpoints are highly adaptable to sponsor specific studies based on the disease indication. Our partners who use the mABC® for their clinical trials experience reduced data variability leading to a lower required sample size, fewer sites, and a more robust data set.

The future of Allergic Conjunctivitis therapies is bright, with advances focusing on improving drug efficacy, patient convenience, and reducing side effects. We are seeing innovations in biologic therapies, gene therapies, immunotherapy advancements, and new and improved antihistamines and mast cell stabilizers. By partnering with Ora, we can usher in a new generation of Allergic Conjunctivitis therapies together, with a shift toward more targeted, long-lasting, and patient-friendly treatments.

Over the last 40+ years, Ora has been at the forefront of supporting our partners in developing novel therapeutics for the treatment of Ocular Allergy. Our adept science-based approach of understanding the disease, developing and refining clinical models, and strong operational experience has helped our partners achieve success in their Allergic Conjunctivitis clinical trials. Furthermore, Ora's team of allergy experts has supported the clinical development of 20+ anti-allergic agents for the treatment of Allergic Conjunctivitis. Let our track record of expertise and operational excellence support and guide your novel product to market.

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	●	○	●

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