Ora

FACT SHEET

Inspiring the Future of Ophthalmic Clinical Development

Allergy & Blepharitis

Over the last 40+ years, Ora has been at the forefront of supporting our customers in developing innovative products for the treatment of ocular surface disease. We are driven to bring better research models to you, providing you with more reproducible, clearer data. Ora's team of allergy experts has supported the clinical development of 17 anti-allergic agents for the treatment of allergic conjunctivitis. Our experience in both challenge and environmental trials will help bring your product to market.

Areas of Expertise

Allergic Conjunctivitis

Atopic Keratoconjunctivitis

Vernal Keratoconjunctivitis

Ocular Redness

Eyelid Swelling

Blepharitis

Meibomian Gland Dysfunction

Paul Gomes has held several roles at Ora since 1998, culminating in his current position of Vice President of Allergy & Blepharitis. He oversees a team of 28 and consults with clients to design cost-and time-efficient strategies for product clinical development. He provides regulatory services, clinical study design and operations, data analysis, and marketing consultation, as well as oversees profitability. He manages staff utilization and project revenue, and acts as a primary liaison with clients, vendors, senior management, and investigator sites as needed.

The author of numerous peer-review publications, Paul has led protocol design, operational execution, and data interpretation, and has overseen multi-center trials in both the US and internationally, regularly interfacing with European, Japanese, and US regulatory authorities. He also is a sought-after presenter at industry conferences.

Paul leads the Allergy Department's research and development. His areas of clinical research experience include ocular allergy, nasal allergy, ocular redness relief, blepharitis, and eyelid swelling. He has overseen development programs from initial clinical proof to concept through Phase IV for many products, including Zaditen®, Pataday®, Alaway®, Bepreve®, Lastacaft®, Pazeo®, Zerviate®, Lumify®, Dextenza®, Alaway® Preservative Free, and ACUVUE® Theravision® with Ketotifen, verifying their efficacy and safety, as well as conducting PK and marketing trials.

“For the past 24 years, I have had the privilege of collaborating with a dedicated team and alongside clients in developing drugs from concept to marketed product for the treatment of ocular surface diseases. The strong science-based approach of understanding the disease, developing and refining clinical models, and appropriately matching these to the candidate product’s mechanism of action has contributed to many drug approvals. Equally important in driving success is strong operational experience through our dedicated site network and continual research on research. The expertise exhibited by our Allergy & Blepharitis team members has contributed to the consistent success supporting efficient and cost-effective clinical product development at Ora in anti-allergy and anti-inflammatory.”

Ora-CAC® Allergen Model

For over 30 years, the Ora Conjunctival Challenge Model (Ora-CAC®) has been used to evaluate every anti-allergic agent for the treatment of allergic conjunctivitis. For most of these programs, Ora-CAC® model studies were pivotal for FDA approval of the drug.

While environmental studies continue to be used for the assessment of anti-allergic agents, the precision of the Ora-CAC® model study design allows for a more predictive and rapid study, with fewer patients, fewer sites, and a tighter dataset.

The variable nature of allergen exposure and sensitivity and the high placebo effect observed in ocular allergy studies are minimized by reproducing the allergic reaction in office under controlled conditions.

Precisely identifying the onset and duration of your anti-allergic agent

This model incorporates validated severity scales to grade the signs and symptoms of ocular allergy. These scales have been accepted by regulatory agencies around the globe. The Ora-CAC® Model study design can be modified to better suit the MOA of your anti-allergic candidate, which is done routinely for studying the anti-inflammatory effects of novel agents in chronic allergy.

The Enviro-CAC™ Model — a best-of-both-worlds hybrid

- If an environmental study is the chosen pathway, the Ora-CAC® response can be an essential patient enrichment tool that pre-selects patients with a modifiable sensitivity to a specific seasonal or perennial allergen
- Response to the Ora-CAC® can be used to identify patients with poor responsiveness to antihistamines or those who are sensitive to very low pollen concentration

Allergen BioCube®

Ora uses its proprietary exposure unit, the fully validated Allergen BioCube®, in clinical trials for allergic rhinitis and conjunctivitis. As a clinical model specifically developed to explore the science behind allergic rhinitis and conjunctivitis with select sub-populations, the BioCube® is both a stationary and mobile state-of-the-art allergen exposure chamber, designed to release calibrated quantities of pollen with precise and reproducible techniques. The Allergen BioCube® can be utilized alone or can be leveraged in conjunction with other clinical models to establish efficacy of allergic conjunctivitis products as pivotal studies.

Identical to Pollen Exposure

Ora verifies the delivery of aeroallergens to patients with real-time laser detection of particulates in the air. Turning an ISO Class 3 cleanroom into a controlled allergy environment, the BioCube® is validated to produce clinical results. Different from other models, patients exposed to pollen in the BioCube® experience the signs and symptoms of nasal and ocular allergy in a manner identical to pollen exposure in the environment.

Objective assessments

Clinician in the BioCube® to monitor patient reactions with objective assessments

Patient sensitivity matching

Tailoring of allergen levels to suit patient sensitivities, repre-senting real-world conditions

Homogenization of allergens

Full homogenization throughout patient positions, with capabilities to deliver multiple allergens

Allergen BioCube® results

Nasal Inflammation Scale (NIS), which provides quantifiable measurements

Label Expansion of Marketed Products for Ocular Indications

- *Your objective:* to determine whether the candidate is effective in treating the signs and symptoms of ocular allergic inflammation following single and repeated conjunctival allergen challenges
- *Ora's offering:* a Phase II Proof of Concept/dose ranging clinical study evaluating the safety and efficacy of a candidate in treating ocular surface inflammation, as induced by the Ora-CAC® model
- *Regulatory quality data outcomes:* measures of safety, tolerability, and efficacy (clinical signs and symptoms and inflammation as visualized by confocal microscopy) of different concentrations of IP compared to positive and negative controls

Ora-CAC® in Anti-Inflammatory

The Ora team has translated the Ora-CAC® model to help with your indication expansion and anti-inflammatory product development efforts. We use the eye as a surrogate for inflammation in a proprietary ocular allergic model to evaluate anti-inflammatory products. Using in-vivo confocal microscopy of the ocular surface, Ora can show — in real time — the impact a product is having on the various stages of ocular inflammation.

OPTION 1

Current route of translating

- Straight to the clinical trials process
- *Benefit:* quick decision on whether your product has efficacy in inflammation and can therefore usually be in the clinic within 12 - 24 months
- If efficacy in the POC is found, we can work together on a preclinical and clinical approach to change the route of administration to a new one

Our Services

- Regulatory support – USA, Japan, UK, and Europe
- KOL development
- Protocol development: design of clinical trials and sample size determination
- Market size justification/market access/pricing and reimbursement

OPTION 2

New route of administration

If you change the route of administration at the beginning of the process, you must first do a preclinical toxicology program before the clinical trial process.

Our Services

- Formulation support
- Preclinical ocular toxicity screening
- Regulatory support – USA, UK, and Europe
- Protocol development (design of clinical trials)
- Market size justification/market access/ pricing and reimbursement

Ora-NAC™ Allergen Model

Ora supports pharmaceutical companies needing reproducible results via on-site training and site support for intricate Nasal Allergen Challenge study procedures, administration, and biomarker collection. With more than 40 years of experience in this area, we help you implement standardized technical procedures for nasal allergen challenge and biomarker collection, through training and observation across all sites.

The Ora-NAC™ training model ensures proper procedures at each site, leading to a successful trial

- Training provided on Ora-NAC™ procedures and nasal fluid collection techniques, as well as site-specific SOPs ensures quality and consistency across all sites
- Investigatory and study coordinator training meetings to present Ora-NAC™ procedures
- Site-specific training is conducted at sites before each Ora-NAC™ procedure, as well as observation of site performance
- Success of our model is ensured by providing feedback and training in real-time

Ora's efficiency, quality, and precision allow for greatly accelerated timeframes, while low standard deviations increase the likelihood of your trial's success.

Regulatory Strategy & Expertise

Along with multiple innovative models for evaluating anti-allergic agents and unmatched expertise in the allergy space, Ora's in-house CMC (Chemistry, Manufacturing, and Control) and regulatory experts can guide you through your drug's development journey. Ora attains strategic relationships with GMP manufacturers and laboratories with favored scheduling. Our team can skillfully take on clinical and regulatory strategy and submissions.

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.