Ora

Creating vision
beyond what we see

Driving Breakthroughs in Ophthalmic Medical Device Research: Ora's Expertise, Experience & History of Success in Device Trial Management.

Over the past 50+ years, Ora has been a key player in the development and approval of ophthalmic products. At Ora, our experience goes beyond consulting projects and clinical trials in ophthalmology — it also encompasses our industry-leading expertise in medical devices.

With almost 150 years of combined experience, Ora's medical device team has proven expertise in ophthalmic medical device regulatory consulting, including pre-submissions to the Food and Drug Administration (FDA) and conducting clinical trials to support device approvals around the globe. In the last 7 years, we have conducted 65 projects including 36 FDA pre-submissions and 15 marketing applications – both IDE and 510(k). Over the last 5 years, Ora has worked with our innovative partners to with 9 ophthalmic device products to market.

Medical Device Expertise: Ora's device operations group has led all phases of clinical research to support regulatory filings globally.

1 Clinical Program Management

- Dedicated operations team specializing in device specific regulations.
  - 10+ years of ophthalmology and device experience.
  - 100% of operations team members have prior clinical site experience.
- Oversight in all phases, from start-up and enrollment to closeout.

2 Regulatory Strategy

- Clinical investigation plans (ISO 14155).
- Identification of relevant ISO/ANSI standards.
- Identification of control and predicate devices.
- Non-clinical development plans, including GLP testing and biocompatibility (ISO 10993).

3 Biostatistics & Data Management

- Statistical Analysis Plan development.
- Creation of analysis datasets (ADaM compliant) and STDM dataset.
- Electronic and Annotated Case Report Form (CRF) design and development.
- EDC training and support for all system users.

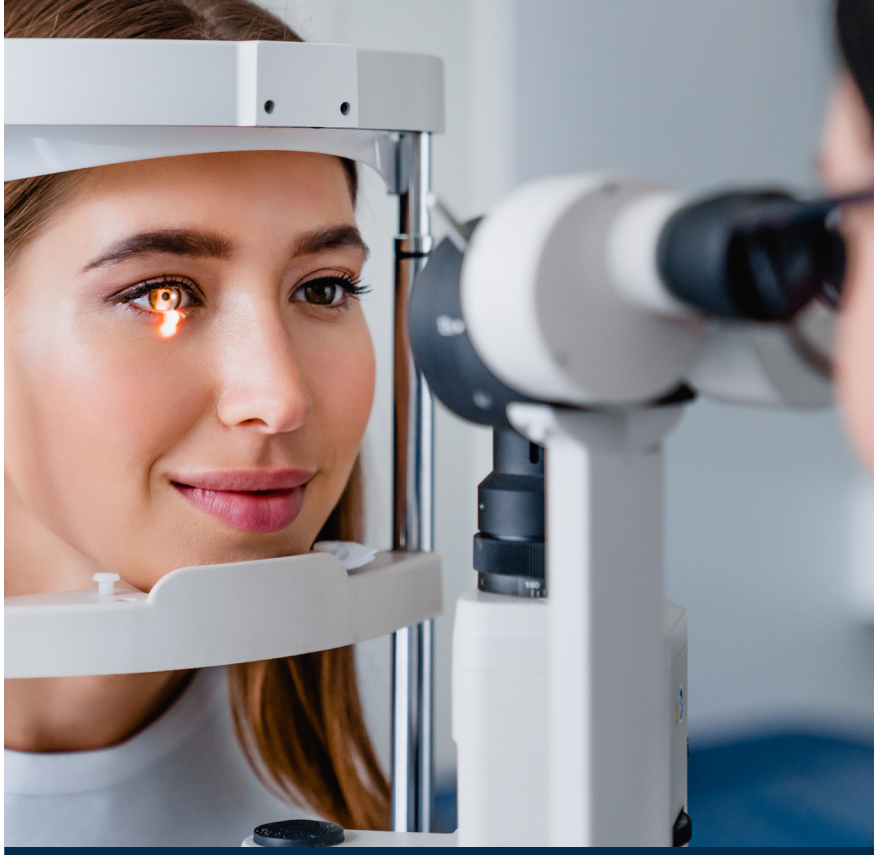
4 Site Operations Staff

- Ora can provide device operators, study coordinators and investigators dedicated to meeting study requirements.
- Development of customized recruitment and advertising campaigns to increase patient recruitment rates.

Medical Devices at Ora: A History of Success

Led by Caitlin Black, the Vice President of Clinical Operations for Anterior Segment and Medical Devices and a board-certified orthoptist with over 16 years of ophthalmology experience, the Ora Device team brings extensive expertise in ophthalmic device studies. Our team provides our partners with valuable insight into study design and operations to ensure your clinical trial is run on-time, completed within budget, all while maintaining strict protocol adherence.

Over the past six years, Ora's Medical Devices team has run 25 ophthalmic device trials. During that time, Ora utilized 90 sites in the US and Europe and enrolled 2,500+ subjects. The device trials range from first in human studies to multicenter, Phase 3 pivotal programs. Let our fundamental principles of scientific rigor and operational excellence at every operational level, across every stage of the process, drive your device study to be a success. Together, let's prove it!



Areas of Expertise

- Contact Lenses
- Intraocular Lenses (IOLs)
- Diagnostic and Imaging Devices
- Canalicular Plug
- Ophthalmic Viscosurgical Devices
- Retinal Laser Surgeries
- Glaucoma Device Studies
- Digital Visual Acuity Test
- Artificial Intelligence Software
- Pediatric Myopia

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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 45+ years of experience, the company has assisted in bringing more than 85+ 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.