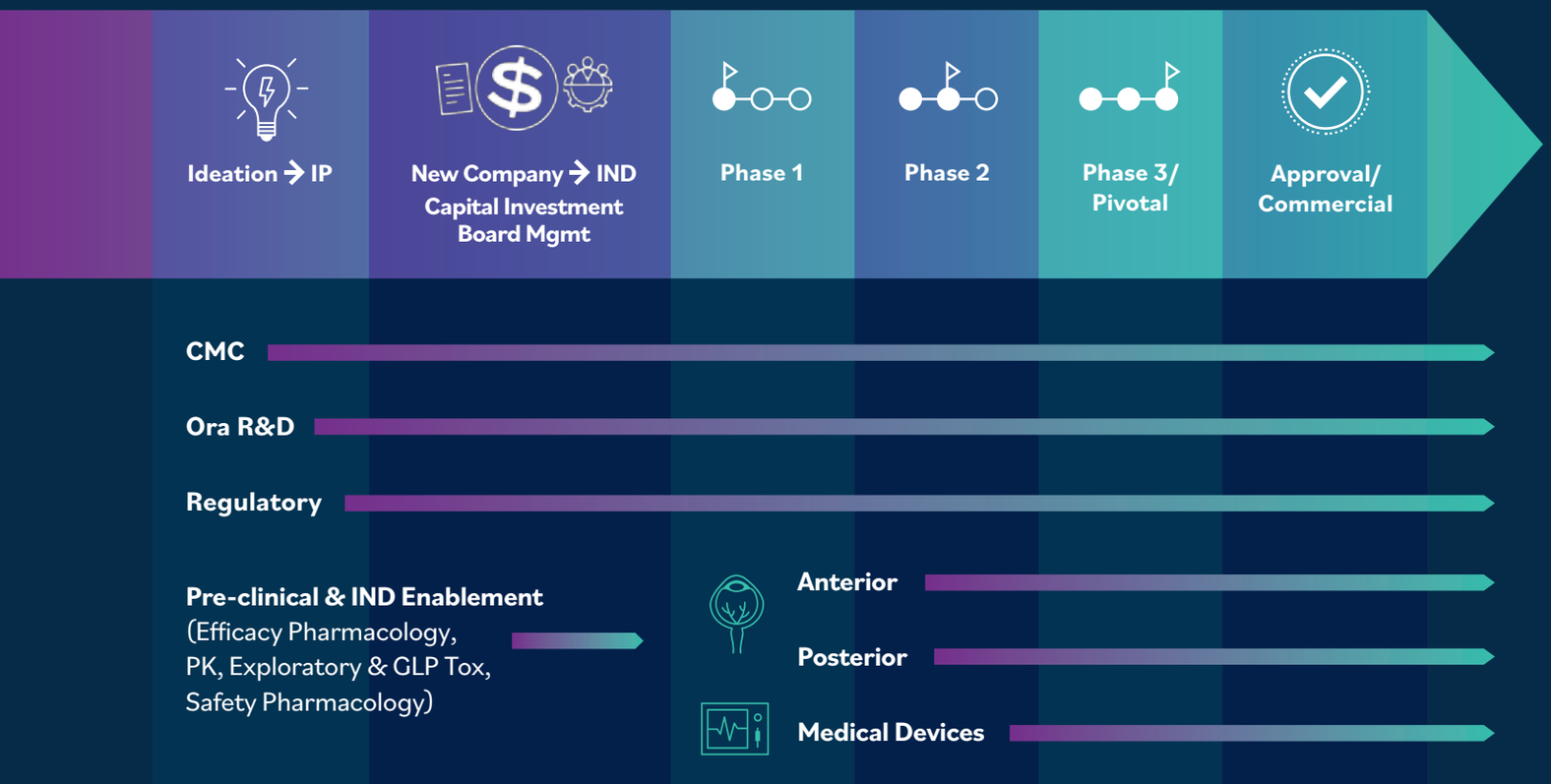
Ora

Creating vision
beyond what we see

The trusted guide of ophthalmic innovators for over 40 years

End-to-end global support across every phase of development

to give your product the best chance of success.



When your product shows promise, let's prove it.

Regulatory strategy. Covered.

Proactive planning and the right relationships matter

- Frequently meet with international regulatory agencies, including the US FDA, EMA, PMDA, NMPA and other notified bodies on behalf of sponsors multiple times per month across all phases of development
- In-house CMC and Preclinical therapeutic area excellence helping you to navigate through CMC and preclinical pathway with GMP manufacturers and GLP laboratories
- Experienced medical writing team for drafting clinical protocols, considering CMC and toxicology factors, with comprehensive understanding of regulatory specifications

Data & safety monitoring. Triple checked.

A higher standard of quality for streamlined success

- Medical and risk-based monitoring for protocol design, patient enrollment, safety oversight, and data fidelity tailored to your ophthalmology program
- Ora's team of in-house ophthalmologists, who serve as skillful medical monitors, bring more than a decade of academic and pharmaceutical experience and are available 24/7 for safety-related concerns and questions
- Pharmacovigilance services for your approved products in association with our partner company, Statistics & Data Corporation (SDC)
- SDC is Ora's exclusive global data services provider, implementing specialized data services, including Biostatistics, Clinical Data Management/EDC, Interactive Response Technology (IRT), and Data Monitoring Committee (DMC/DSMB) services

Delivering more qualified patients. Faster.

- Customized enrollment strategies are designed in close collaboration with investigators to optimize enrollment speed, reduce overall number of sites, and thereby minimize data variability
- Data-informed inclusion/exclusion criteria along with innovative multi-channel patient advertising campaigns condense enrollment timelines
- Patient education and advocacy initiatives to build an engaged and well-informed patient community

OraNet™

Exclusive global research community

Building relationships to help you reach success

- OraNet™ is our exclusive global research community of dedicated investigative partners, yielding strong site relationships and thereby driving science and product development forward into therapies
- Dedicated to optimizing clinical research site preparedness, study execution, and data quality
- Close partnerships with sites lead to operational transparency, tighter feedback loops, and turbocharged study timelines

A system developed over 40 years of helping clients achieve their goals

Value to Sponsors

- High performing sites will expedite clinical trial timelines, including study start-up and execution
- More patients enrolled per site means fewer overall sites needed, leading to more consistent data
- Support at sites from Ora Study Coordinators, ensuring highly experienced study oversight
- OraNet™ sites are focused on Ora sponsored studies and do not take on competing trials
- Bringing new sites into research opens untapped patient populations, avoiding diminished returns and overburdened sites
- Protocol-specific training for relevant sites and studies

Value to investigators

- Access to Ora's clinical trial pipeline
- Provides entry into clinical research for new-to-research sites
- Training on clinical research fundamentals and Ora's SOPs
- Access to on-site research resources, like clinical trial coordinators and imaging technicians
- Recruiting and marketing services provided to supercharge trial recruitment
- Support with equipment costs when needed

Bringing local insights to a global scale

Ora provides global reach with local teams around the world to accelerate the development of your ophthalmic therapeutic or medical device and bring life-changing therapies to patients worldwide.

Europe

- Prioritized access to 240+ sites
- Strong patient diversity across ethnicities
- Globally influential KOLs with extensive Phase 2 & 3 trial experience
- Provide strategically-placed high-enrolling sites that meet our unique criteria
- Europe wide and Eastern Europe specialized scientific advisory board, comprised of leading European KOLs with a wide range of therapeutic expertise

Asia

- International offices in Beijing, China as well as Osaka and Tokyo, Japan
- In-country teams facilitate clinical development with key partnerships and cultural insights to streamline operations and navigate regulatory approvals
- Strategic business development models to support entrepreneurs, biotech, startups, and research entities
- Prioritized access to over 20 sites, with a strategic network across tier 1 and 2 cities

Latin America

- Large untapped patient population with high-quality, highly-educated physicians
- High-profile KOLs with global influence
- Access to diverse patients who are interested in clinical research as a care option
- OraNet™ has sites ready to go for the right studies and sponsors

United States

- Several offices, including scenic remote work destinations, on the East Coast where Ora was founded
- Around 300 US-based full and part-time employees dedicated to advancing ophthalmic research for patients combatting ocular disease
- Over 850 clinical research sites across the US

Visionary research technologies

Key novel endpoints for anterior and posterior segment indications

Ora CAE® dry eye challenge

- Exposes study participants to regulated changes in humidity, temperature, airflow, and visual tasking, forcing the ocular surface to react to added stress — creates a consistent response, which is reproducible over time
- Provides endpoints that demonstrate relevant change with intervention
- Identifies and enrolls the appropriate patient population

Ora-CAC® allergen model

- Within a controlled environment, patients are exposed to a specified dosage of allergen
- Extremely precise and reproducible
- Reduces the number of patients and sites needed to gain tighter, more meaningful datasets, minimizing variability
- Highly standardized grading systems increase sensitivity

Ora EyeCup™ Smartphone Device

- Captures high-resolution images and diary entries, which can be reviewed in real-time
- Takes high-quality photos 98% of the time and can record adverse events on the ocular surface
- Can be custom-designed, including treatment reminders, symptom tracking, imaging requirements, and post-capture analyses

Ora-VNC™ mobility courses

- Immerses patients in a 360-degree visual challenge environment, determining impact of therapies on IRDs by assessing improvements in patient mobility
- Clinically meaningful assessment of vision
- Customizable to different difficulty levels to cater to a variety of patient populations

Ora-VCF™ contrast test & Ora's low luminance tablet reading test

- Can differentiate between normal and early dry AMD
- Potential endpoints for retinal trials, including dry AMD and NPDR trials
- Possible screening tools to identify subjects with underlying visual dysfunction

Creating vision beyond what we see

We weave together people, processes, and technologies to support innovation in ophthalmology around the world.

Ora

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Unsurpassed operational excellence

THE RIGHT PEOPLE

THE RIGHT PROCESSES

THE RIGHT TECHNOLOGY

- 1,000+ ophthalmic expert accessible sites
- 2,000+ clinical studies and consulting projects
- 25,000+ patients enrolled during last 7 years
- Industry leaders in the anterior and posterior segment, as well as ophthalmic medical devices
- 100% of Therapeutic Area Heads with 18+ years of ophthalmic experience

For over 40 years, Ora has proudly helped our clients earn more than 85+ product approvals. We support a wide array of organizations, from small startups to global pharmaceutical and device companies, to efficiently bring their new products from concept to market.

Learn more about what we do at  OraClinical.com  +1 (978) 685-8900