Ora

PRECLINICAL

FACT SHEET

Preclinical Capabilities

Early stages in ocular drug development

Ora's preclinical ophthalmic research team has extensive experience, ranging from ophthalmic disease and custom model development to managing and executing animal efficacy, tolerability, and PK studies.

Experience across all facets of preclinical research

- PK, Ocular Irritation (non-GLP safety studies)
- Animal efficacy models (mice, rats, rabbits) spanning a wide range of ophthalmic diseases, including customized study design, depending on compound, indication, and MOA
- State-of-the-art clinical instrumentation and surgical capabilities
- Compound identification and ophthalmic formulation partnerships

COLLABORATIVE APPROACH

Applying synergy with Ora's clinical, regulatory, and CMC departments to customize your development programs

Developing and managing GLP toxicology programs to support regulatory filings

Summary of Preclinical Services

DELIVERY METHODS	• Topical eye drop • Intravitreal injection • Subconjunctival injection • Intracameral injection	• Subretinal injection • Systemic delivery including oral, subcutaneous, intraperitoneal, and intravenous
CAPABILITIES	• Fundus imaging • Fluorescein angiography • IOP measurements • Optical coherence tomography	• Electroretinograms • Safety, biocompatibility, and toxicity evaluations
STUDIES & SPECIES	• Tolerability/Irritation/Safety • PK/PD • Ocular efficacy models	• Ocular gene therapy/gene delivery • Ocular implant delivery/efficacy • Rabbit, rat, mouse

About our Vivarium

- Approx. 17,000 sq. ft.
- Located in Andover, MA
- Focus on ethics and safety
- OLAW and USDA certified

Ocular Disease Models

Animal disease models are modified to provide a customized and accurate screening in the most efficient and cost-effective manner. Ora also assists with development and management of GLP toxicology programs to support regulatory filings.

Preclinical Ophthalmic Device Development

- Customized study designs depending on device and indication
- Flexible study plans based on client needs – study extensions or early completion
- Ophthalmic-focused staff with specific disease experience across the entire ocular space
- Full clinical capabilities to facilitate smooth transition to first-in-human clinical trials

ALLERGIC CONJUNCTIVITIS

- Short Ragweed Sensitization (mouse)

DRY EYE

- Chronic Dessication Stress (Scopolamine/Low Humidity Chamber) (mouse)
- Acute Inflammatory Stress (ConA/Low Humidity Chamber) (mouse)

CORNEAL HEALING

- Mechanical wound (rabbit)
- Alkali burn (rabbit)
- Chemical burn (rabbit)

OCULAR INFLAMMATION

- Experimental Autoimmune Uveitis (rat)
- Endotoxin Induced Uveitis (rat)
- Post-operative Inflammation (rabbit)

GLAUCOMA – INTRAOCULAR PRESSURE

- Normotensive (rabbit, rat)

GLAUCOMA – RETINAL DEGENERATION

- Optic Nerve Crush (rat)

WET AMD

- Laser-induced choroidal neovascularization (rat)

DRY AMD

- Sodium-iodate retinopathy (rabbit, rat)

RETINAL VASCULAR DISEASE

- VEGF-induced vascular leakage (rabbit, rat)
- STZ-induced diabetic vascular leakage (rat)

CUSTOM MODEL DEVELOPMENT

- Based on client's needs

Ora

Think Ophthalmology. Think Ora.

+1.978.685.8900 | BusinessDevelopment@OraClinical.com

OraClinical.com