ALTASCIENCES
PRECLINICAL SERVICES

OPHTHALMOLOGY NONCLINICAL RESEARCH SERVICES

With over 50 years of experience in ophthalmology research, Altasciences offers a full range of nonclinical services, including lead identification, lead optimization, and safety assessment. Our specialized techniques and qualified management team have set the foundation for the commercial success of numerous ocular therapeutics that are on the market today.

Altasciences' research has supported numerous global regulatory submissions, with no study ever having been rejected for reasons of design, conduct, or data integrity.

Altasciences uses many different types of formulations and routes of administration, including:

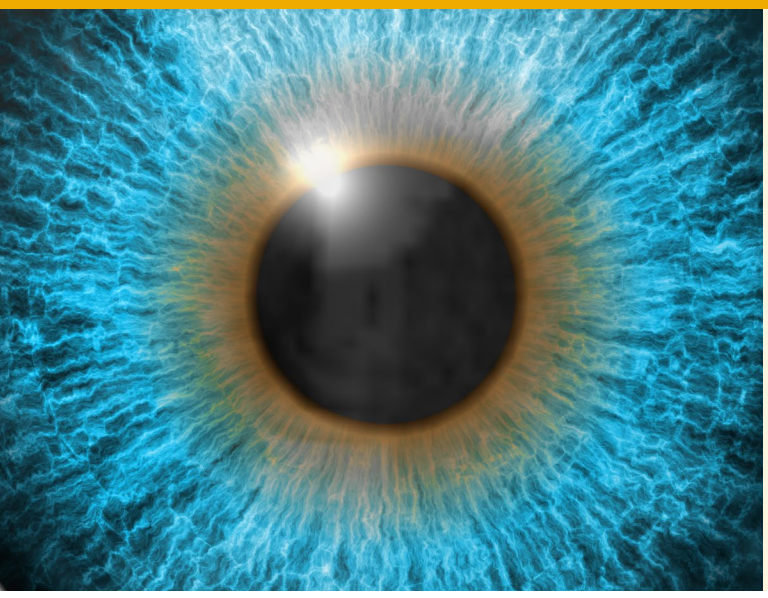
- Topical administration
- Intraocular implants
- Systemic administration
- Subretinal injections
- Intravitreal injections
- Suprachoroidal injections

In addition, Altasciences has significant expertise in developing small molecule ocular drugs, including nanomilling, suspensions, and pre-sterilized injectables.

Ocular pharmacokinetic studies have been performed via the aforementioned routes in multiple species:

- Rabbits
- Dogs
- Nonhuman primates
- Miniature swine
- Rats

Study durations have ranged from single-dose acute studies to studies of six- and nine-months' duration.



Altasciences' Nonclinical Safety Testing Capabilities

- Broad solution offering across dosing routes and specialized techniques
- On-site Diplomate, American College of Veterinary Ophthalmologists (DACVO)
- Significant investment in specialized equipment, such as optical coherence tomography (OCT) and RetCam
- Comprehensive range of services, from lead candidate selection to clinical proof of concept, and beyond

contact@altasciences.com
altasciences.com

Typical Ophthalmologic Endpoints Used in GLP Ophthalmic Studies

Ophthalmic Exams

Exams are performed by a board-certified veterinary ophthalmologist utilizing highly specialized equipment like a slit lamp biomicroscope, indirect ophthalmoscope, and various lens diopters.

Intraocular Pressure (IOP)

Our facilities are equipped with TonoVet Plus, TONOLAB, TonoPen XL, and TonoPen Vet, offering a great range of equipment to obtain the intraocular pressure from different species—with or without the need of topical anesthesia—when a test article may be affected by the use of concomitant drugs.

Electroretinogram (ERG)

The ERG evaluates retinal function based on the electrical response of the retina produced by exposure to a light stimulus. An ERG is used to assess the functional part of the central nervous system, the retina, which can easily be visualized using an ophthalmoscope. ERGs are collected and analyzed by the consulting electrophysiologist.

In veterinary ophthalmology, the ERG is used to diagnose patients with acquired or inherited retinal diseases, assess retinal function in patients with opaque ocular media (e.g., cataracts), and exclude an outer retinal component in patients with retinal ganglion cell or post-retinal dysfunction. In safety studies, this equipment allows us to evaluate the effect of the test article administered orally, intravenously, or ocularly (i.e., topical, intravitreal, or subretinal) on the function of the retina.

Ocular Tissue Harvest

Our necropsy staff is trained for specific eye tissue collection. Either for ocular studies or pharmacokinetic purposes, eyes can be harvested and dissected to isolate the following: aqueous humor, vitreous humor, lens, cornea, iris/ciliary body, retina, choroid, sclera, and optic nerve.

Ocular Observations

Harvested eyes are scored according to the Draize scoring system or the McDonald and Shadduck method.

RetCam Shuttle Camera

Detailed fundus photos are taken with our RetCam camera to reference images of the back of the eye. The equipment is designed to allow a quick and easy capture of wide field, high resolution, fully digital images of the eye after an intravitreal or subretinal injection, a lesion at the back of the eye, or a normal fundus.

Optical Coherence Tomography (OCT)

OCT is a noninvasive evaluation of the retina and the optic nerve that is conducted by imaging the back of the eye. It offers the ability to evaluate the retinal and optic nerve thickness *in vivo* progression of a number of ophthalmic and neurological diseases.

This technique allows for OCT monitoring of the retina over the duration of a safety assessment study, minimizing the number of animals required in a study. The equipment enables assessment of the corneal thickness and evaluation of the iridocorneal angle, a technique that is particularly suitable for topical ocular toxicology studies.

Altasciences has a long history of partnering with clients to successfully develop unique and novel techniques and procedures in the field of ocular research. We are your go-to partner for ophthalmic research.

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