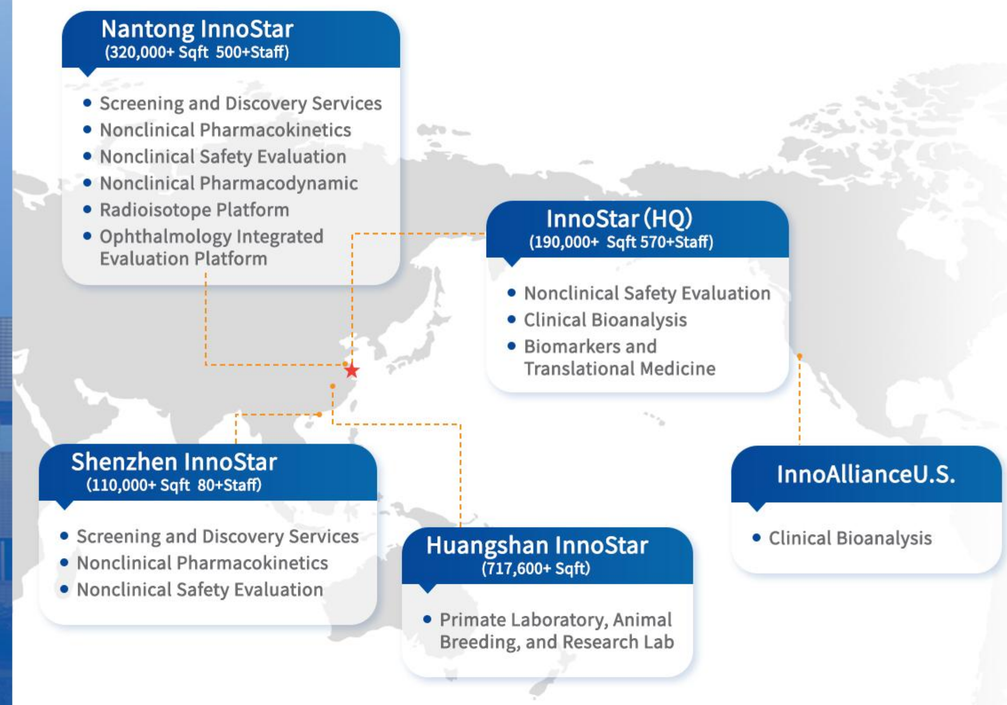
InnoStar

Integrated Ophthalmology Assessment Platform

Specializing in R&D Services and
Empowering the Healthcare Industry

Shanghai InnoStar Bio-tech Co., Ltd. (InnoStar) was established in 2010. As a leading contract research organization, we strive for excellence through our services with high quality, win customers by recognized reputation, add values by technical innovation, and maintain efficiency by streamlined management. Our business scope covers screening and discovery services, nonclinical pharmacodynamics, nonclinical pharmacokinetics, nonclinical safety evaluation, clinical sample bioanalysis, biomarkers and translational research. InnoStar was listed on the STAR Market of Shanghai Stock Exchange on September 3, 2024 (Stock code: 688710).



NMPA GLP AUT | U.S.FDA GLP INSP | OECD GLP AUT | AAALAC AUT | 美国CAP AUT

SCOPE OF BUSINESS

InnoStar Provides One-stop Service From Nonclinical to Clinical Translation

PCC
- Screening and Discovery Services

IND
- Nonclinical Pharmacodynamics
- Nonclinical Pharmacokinetics
- Nonclinical Safety Evaluation

NDA
- Clinical Biological Sample Testing
- Biomarkers and Translational Research

Services of differentiated solutions designed by experts covering the life cycle of drug development

PROJECT EXPERIENCE

920+
Already served
New drug development clients

100+
Annual average IND package completed amount

30+
Annual NDA/BLA package completed amount

200+
We have served on both international and domestic "first-of-its-kind" innovative drug research and development projects.

140
Overseas IND Application Successful

3
FDA NDA/BLAs

Note: Data statistical interval: 2015-2024.12.31

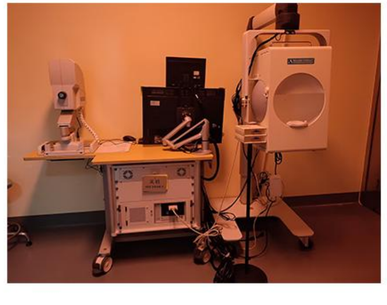
Scan the QR code for more business inquiries

目录页

www.innostar.cn

Ophthalmic examination equipment

- Heidelberg Bluepeak Optical Coherence Tomography (OCT)
- Roland RETI-Scan21 Precision Multifocal & Traditional Electrophysiology System
- Celeris Diagnosys Small Animal Visual Electrophysiology System
- Leica M822F40 Ophthalmic Surgical Microscope
- Geuder Megatron S4 Vitrectomy System (Germany)
- Quantel Medical VITRA Laser Photocoagulator
- Konghua APS-BER Fundus Camera/Fluorescein Angiography System
- Konghua SL-8E Slit Lamp Microscope System
- Suzhou 66 YZ25C Direct Ophthalmoscope
- KJ5S1 Handheld Slit Lamp
- WPI Microinjection Pump
- iCare Tonometer



Integrated Ophthalmology Assessment Platform

Platform Introduction

Our Ophthalmology Integrated Evaluation Platform focuses on ophthalmic drug use, integrating six major disciplines including toxicology, pharmacodynamics, pathology, ophthalmology, molecular biology, pharmacokinetics, etc., and realizing a specialized platform for the evaluation of “efficacy-pharmacogenetics-toxicity”, with laboratories certified by GLP, FDA, OECD and other certificates, and with data supporting the filing requirements of China, the United States, Europe and many other countries. The platform provides a variety of ophthalmic models, including conjunctival disease, dry eye, keratoconus, uveitis, fundopathy, cataract, glaucoma and myopia. It also has a variety of precision delivery technologies, such as vitreous cavity injection and subretinal injection. We have strong cross-species translational research capabilities, ranging from mice to rabbits to non-human primates, and can provide highly predictive models for preclinical studies. Service categories include gene therapy, mini-nucleic acids, dual-antibodies, small-analyte chemotherapeutics, stem cells, and soon.

Services

Animal Models of Ocular Diseases

- Subconjunctival injection
- Peribulbar/posterior injection
- Anterior chamber injection
- Anterior chamber implantation
- Vitreous Injection
- Vitreous Implantation
- Subretinal Injection
- Suprachoroidal Injection

Special ophthalmic drug delivery technologies

- Ocular Tissue Sampling and Pathologic Diagnosis
- Eye Pathology Sampling and Diagnosis
- Eye tissue samples were extracted

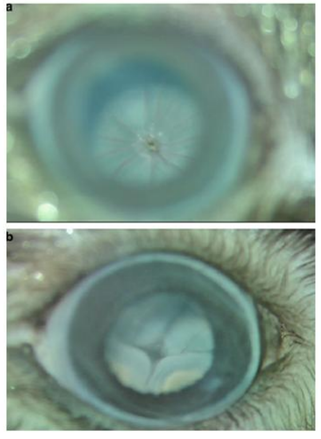
Ophthalmology Category Service Capabilities

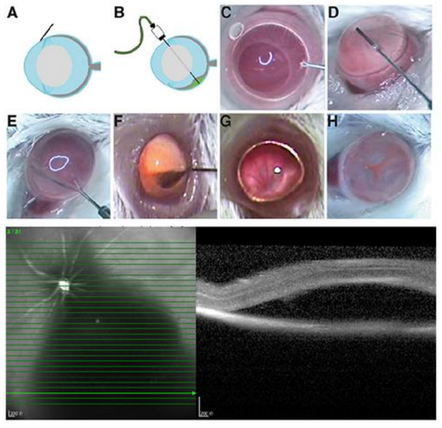
- Conjunctivitis of the eyelid
- Xerophthalmia
- keratopathy
- Uveitis
- fundi disease
- Cataract
- Gaucoma
- Myopic eye
- Implantation Models

Clinical grade ophthalmic specialty drug delivery techniques

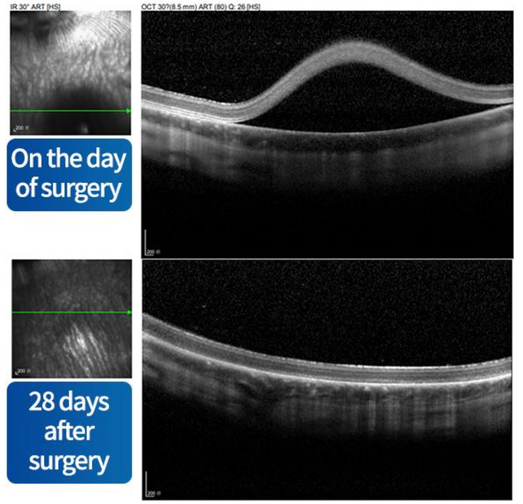
	Mouse	Rat	Rabbit	Dog	Pig	Monkey
Subconjunctival injection	✓	✓	✓	✓	✓	✓
Peribulbar/posterior injection	✓	✓	✓	✓	✓	✓
Anterior chamber injection	✓	✓	✓	✓	✓	✓
Anterior chamber implantation		✓	✓	✓	✓	✓
Vitreous Injection	✓	✓	✓	✓	✓	✓
Vitreous Implantation	✓	✓	✓	✓	✓	✓
Subretinal Injection	✓	✓	✓	✓	✓	✓
Suprachoroidal Injection	✓	✓	✓	✓	✓	✓

C57Subretinal Injection in Mice





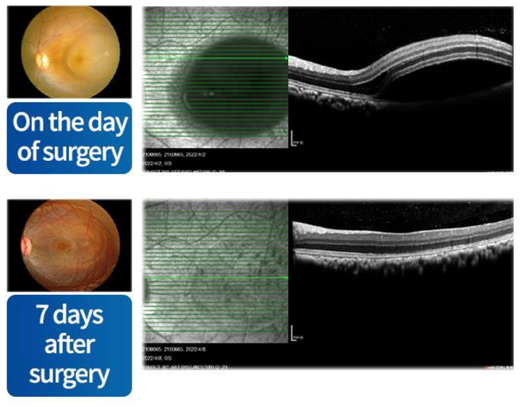
Subretinal injection in Rabbit



Clinical surgical pathway

【Standards and Guidelines】Expert Consensus on Recommended Operating Procedures for Subretinal Gene Therapy Drug Injection in China (2022) Chinese Journal of Experimental Ophthalmology 2022-10-17

Subretinal injection in crab-eating monkeys



Clinical surgical pathway

【Standards and Guidelines】Expert Consensus on Recommended Operating Procedures for Subretinal Gene Therapy Drug Injection in China (2022) Chinese Journal of Experimental Ophthalmology 2022-10-17

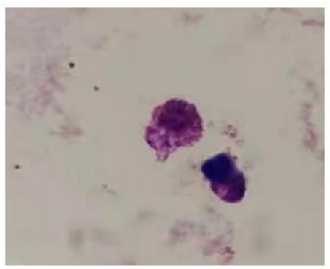
Ocular Tissue Sampling and Pathologic Diagnosis

Ocular Tissue Sampling

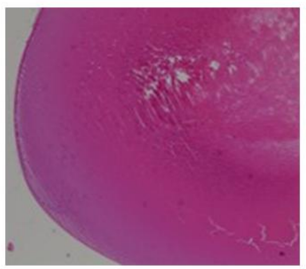
- Eyelids
- Conjunctiva
- Cornea
- Atrial fluid
- Iris
- Lens
- Vitreous humor
- Retina
- Choroid
- Sclera

Ocular Histopathology

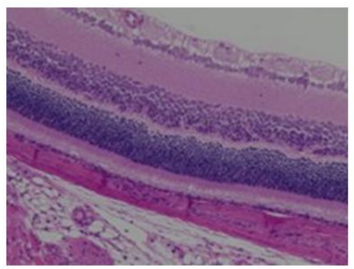
- Hematoxylin-Eosin (HE) Staining
- Immunohistochemical staining (IHC)
- PAS Stain
- Masson's Stain Eosinophilic Stain



Eosinophil
(type of white blood cell)



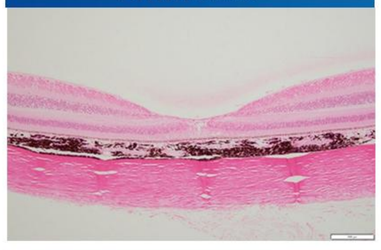
rat lens



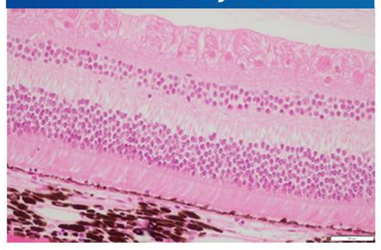
rat retina

Eye Pathology Sampling and Diagnosis

Crab-eating monkeys-
10X-maculae

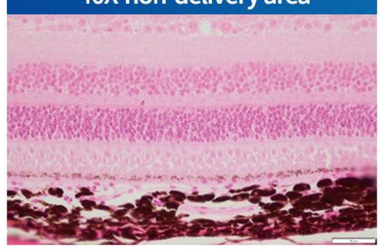


Subretinal AAVx Injection
40X-Delivery Area

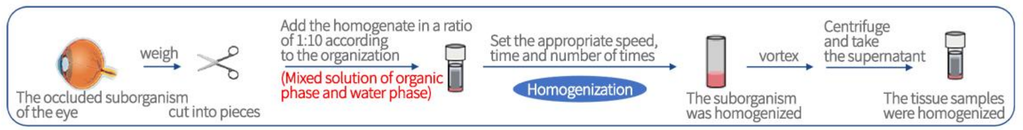


Crab-eating monkey-
10X-normal

Subretinal AAVx injection
40X-non-delivery area

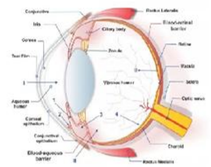


Eye tissue samples were extracted



Eye tissue processing procedure

Substructure		Characteristic	Process mode
fibrous coat	cornea	The vascular-free connective tissue constitutes 1/6 of the entire fibrous layer, which is tough and elastic	The tissue was cut into small pieces with a scalpel or a corneal scissors and homogenized (8 ms-1,40s, 4 times), ultrasonically, centrifuged, and the supernatant was taken
	sclera	It accounts for 5/6 of the fiber layer, which is composed of dense collagen and elastic fibers. It is hard and magnetic white in texture	
	conjunctiva	The thin transparent mucosa is a transparent film formed by stratified columnar epithelium and a small amount of connective tissue. It is soft, smooth and elastic	
tunicae uveae	iris	It is mainly composed of connective tissue, containing pigment, blood vessels and smooth muscle	Homogenate (28s-1,4 min, once)
	chorioid	It is mainly made up of blood vessels	
inner membrance	retina	A layer of soft, transparent neural and pigment epithelial tissue	
dioptric media	crystal	It is composed of lens capsule, lens epithelium, lens fibers and suspensory ligaments. It is vascular-free, elastic and enveloped by a transparent capsule	The suborganism was cut as much as possible to break the connections between suborg-anisms and homogenized (5 ms-1,30s, 2 times)
	vitreum	The gel-like semi-solid structure is transparent and has no blood vessels or nerves. It is mainly composed of collagen fibers and acidic mucopolysaccharide tissue, and its surface is dense	
	aqueous humor	The main component is water, with a water content of 98.75%	dd homogenate and vortex (1000 rpm, 10 min)



Ophthalmic disease model

- **fundi disease**
  - -Retinal pigment degeneration model*
  - -Age-related macular degeneration (wet & dry)*
  - -Premature infant retinopathy model (hyperoxia)*
  - -Retinal neovascularization (DL-aaa) model*
  - -Retinal vein occlusion (laser induced)*
  - -Diabetic retinopathy (STZ)
- **Myopic eye**
  - -Model of defocus myopia*
  - -Model of myopia deprivation by shape perception*
- **Implantation Models**
  - -Anterior chamber implantation*
  - -IOL Implantation*
  - -Artificial Corneal Replacement*
- **Conjunctivitis of the eyelid**
  - -Marginal keratitis (mites)*
  - -Immune conjunctivitis*
- **Xerophthalmia**
  - -Hyoscine induced dry eye*
  - -ovariectomy*
  - -Induced by benzylamine
  - -hypertonic saline
- **keratopathy**
  - -Corneal neovascularization (stitch method)*
  - -Corneal epithelial injury model*
  - -Corneal acid-base chemical injury model*
  - -Corneal endothelial injury model*
- **Uveitis**
  - -Experimental autoimmune uveitis (EAU)*
  - -Endotoxin-induced uveitis (EIU)*
- **Cataract**
  - -Sodium selenite induces cataracts traumatic cataracts*
  - -senile cataract
  - -metabolic cataract
- **Gaucoma**
  - -Acute high eye pressure model*
  - -Chronic high eye pressure model*

Note: * is a model with a clear modeling methodology and successful project experience

Ophthalmology Drug Development Services Program Experience

90+
Ophthalmic Disease Drug Development Services Program Completed

5
IND (NMPA | FDA | TGA)

- Service Ophthalmology Product Categories
- Gene Therapy
- Small nucleic acids (siRNA)
- Antibody Products
- Small Molecule Drugs
- Other Biological Products

Star Projects

- Gene therapy drug NFS-02 (rAAV2-ND1) (enrollment of the first patient in the Phase I/II clinical trial in the U.S. is currently complete).

Neurophth 纽福斯

- Gene therapy drug NFS-05, designed to treat autosomal dominant optic nerve atrophy (ADOA), has completed clinical trial registration with the Therapeutic Goods Administration (TGA) in Australia and has been approved to begin clinical trials.

Note: Statistical Interval for Experience Data of InnoStar Ophthalmic Drug Development Services: January 1, 2021 to March 31, 2024.

Overview of Project Experience

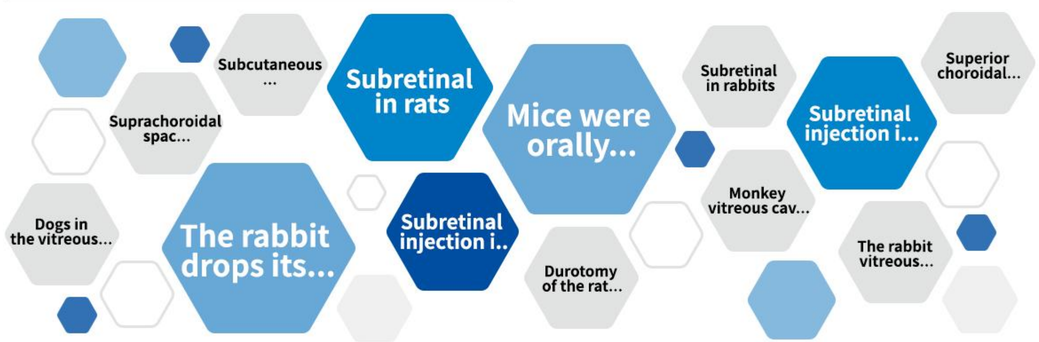
Representative project experience

type	indication	Method of administration
Gene therapy products	Cryoglobulin retinopathy	Subretinal injection
	Dominant hereditary optic atrophy	Intravitreal injection
	pigmentary degeneration of retina	Subretinal injection
	RNV	Subretinal injection/vitreous cavity
	CNV	Subretinal injection / Intravitreal injection/intracanalular injection
	diabetic retinopathy	Subretinal injection
Animal induction and phenotypic identification	diabetic retinopathy	intragastric administration
Phenotypic identification	Cryoglobulin retinopathy	-
drug screening	-	Subretinal injection, vitreous cavity injection
Dual antibodies	CNV	Intravitreal injection
chemical drug	glaucoma	Eye drops
siRNA	Dry macular degeneration	hypodermic injection
biologicals	xeroma	Eye drops

Note: The statistical interval of InnoStar experience data in ophthalmic drug research and development services is 2021.7-2024.2

Rich project experience

Statistics on the number of doses given by different routes in 2023



INNOSTAR

益诺思 INNOSTAR

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