

Preclinical & Clinical  
**Ophthalmology**  
Research Services Worldwide



A GLOBAL SERVICE PROVIDER OF PRECLINICAL AND CLINICAL RESEARCH IN OPHTHALMOLOGY



“*The cutting-edge knowledge in ophthalmology of Iris Pharma staff, along with a forward-thinking state of mind have helped us lead our products intelligently through the preclinical and clinical stages.*”

**Director Pharmaceutical R&D**  
French Ophthalmic Pharmaceutical Company



Iris Pharma

**A Trustworthy Ophthalmology  
CRO Since 1989**

Iris Pharma **A trustworthy ophthalmology CRO since 1989**

## SPECIALIST CRO FOR OCULAR DRUG & MEDICAL DEVICE DEVELOPMENT

Iris Pharma is an independent Contract Research Organization (CRO), dedicated to preclinical and clinical research in ophthalmology. Since 1989, the experienced staff of Iris Pharma has been offering ophthalmologic drug and device development services to pharmaceutical and biotechnology companies worldwide, from newcomers to specialists in ophthalmology.

	Drug Discovery	Ophthalmic Preclinical Development	Ophthalmic Clinical Development	Registration	Marketing & Promotion
	• <i>in vitro</i> research	• Animal proof of concept • <i>in vivo</i> regulatory development	• Phase I • Phase II • Phase III		• Phase IV • Marketing survey
Preclinical formulation		●			
Proof of concept		●			
Safety		●			
Pharmacokinetics		●			
Efficacy		●			
Animal models (research)		●			
Histopathology		●			
Bioanalytical testing		●	●		●
Project management	●	●	●		●
Medical writing			●		●
Monitoring			●		●
Global drug development	●	●	●	●	●
Strategic consulting	●	●	●	●	●

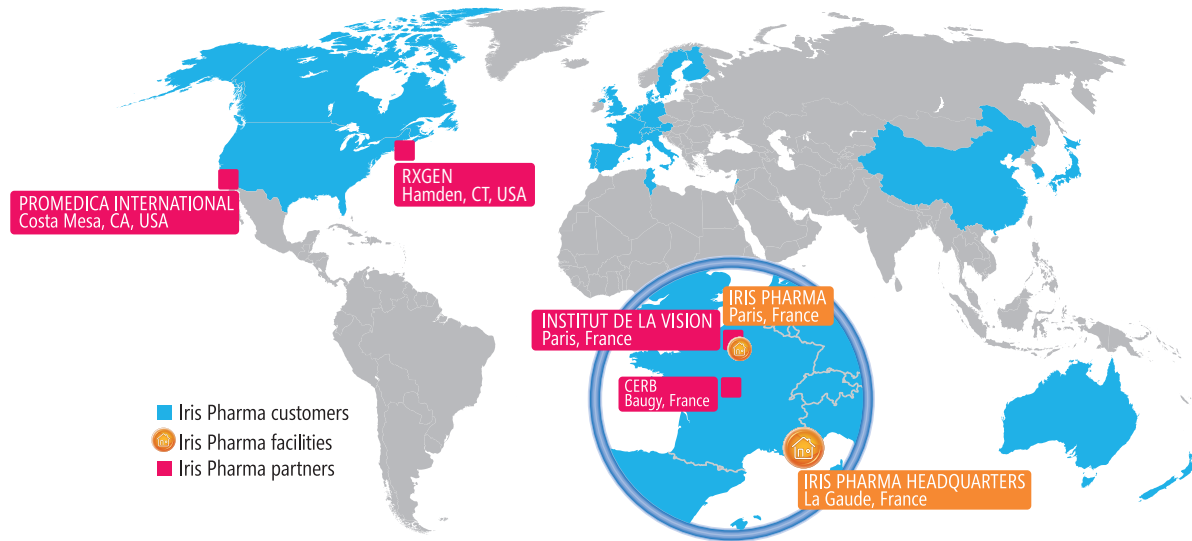
❖ **Stand-alone service or global support**

❖ **Compliance with GLP and ICH-GCP requirements, international guidelines (FDA, OECD, EMA, etc.) and local regulatory laws**

❖ **Translation of more than 40 ocular drugs and medical devices from the laboratory to marketing approval in Europe, the United States, and all around the world**

# A WORLD-CLASS COMPANY

Get the best research services in ophthalmology wherever you are



- ❖ **230+ international clients including start-up, biotechnology and pharmaceutical companies**
- ❖ **Network of experts and strong partnerships with research facilities, scientists, partners and CROs around the world**



“ We have now worked with Iris Pharma on front, middle and back of the eye projects. ”

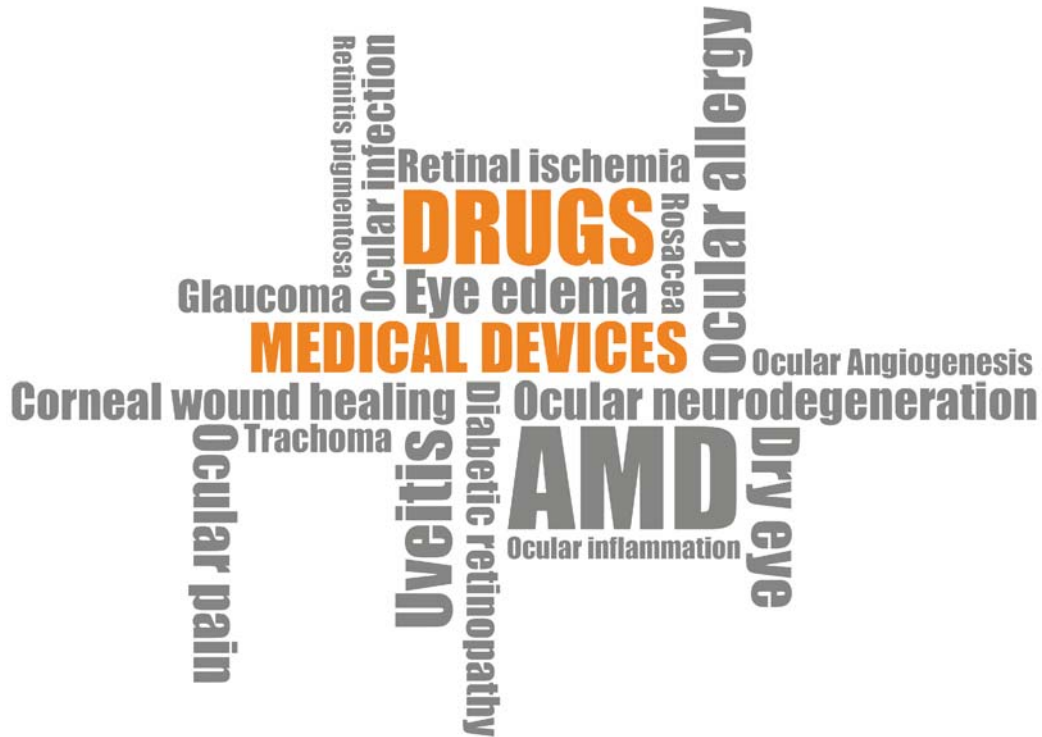
VP R&D – International Pharmaceutical Company Specialized in Ophthalmology

Iris Pharma

**Comprehensive Ocular Expertise**

## Iris Pharma Comprehensive Ocular Expertise

Since its founding in 1989, Iris Pharma has based the company on and expanded its expertise in the science of ophthalmology.

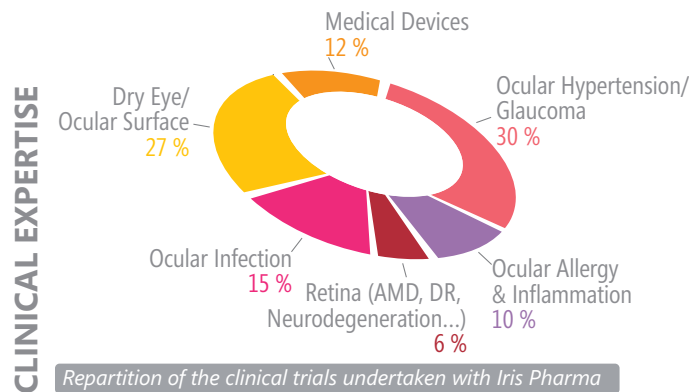
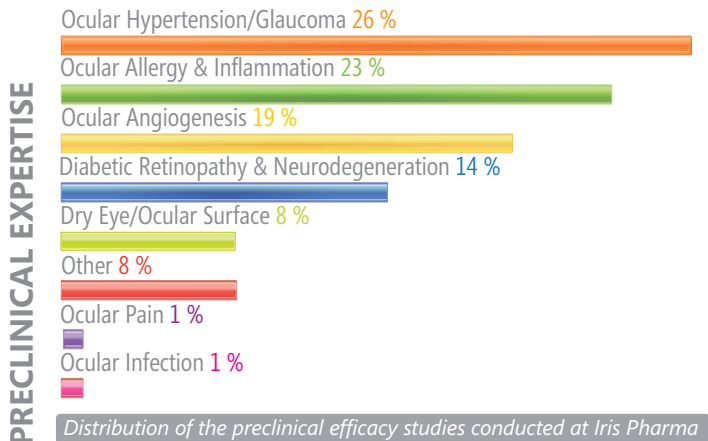


❖ Therapeutic specialization: the solution to reduce the time to market



# MASTERY OF ALL OCULAR PATHOLOGIES IN PRECLINICAL AND CLINICAL DEVELOPMENT

Iris Pharma partners with clients to carry out preclinical and clinical studies involving all areas of the ophthalmology field, from the ocular surface to the posterior segment of the eye.



“*Their stellar study conduct and expert advice have been crucial for advancing our AMD program.*”

**Team Leader Preclinical Research** – German Biotechnology Company

“*Iris Pharma was instrumental in our entry into ophthalmology.*”

VP R&D – International Pharmaceutical Company Specialized in Ophthalmology



Iris Pharma

# Cutting-Edge Services For Drug & Device Development In Ophthalmology

## Iris Pharma **Cutting-edge services for drug & device development in ophthalmology**

Iris Pharma provides a one-stop solution for ophthalmology drug and device development, which brings significant advantages in terms of flexibility and efficiency.

### PRECLINICAL SERVICES

#### **IN VIVO STUDIES**

- Pilot & proof of concept studies
- Regulatory studies (GLP)
- Ocular toxicology studies & safety assessments
- Ocular pharmacokinetic studies
- Ocular efficacy studies

#### **R&D SUPPORT SERVICES**

- Animal model development.
- Animal imaging & surgical facilities

#### **PRECLINICAL FORMULATION**

- Preclinical ocular formulation development & drug delivery optimization. Dosage form development

### BIOANALYTICAL TESTING SERVICES

- Analytical services in multiple biological species & rare ocular matrices
- Assay method development, validation & transfer

### CLINICAL SERVICES

- Regulatory affairs
- Quality assurance
- Clinical study management including escalation scheme (Ph I, II): Ph I, II, III, IV, medical marketing survey
- Study monitoring & site management
- Project management
- Data management & biostatistics
- Medical writing
- Pharmacovigilance
- Investigational Medicinal Product (IMP) management
- Central laboratory services

### CONSULTING SERVICES

"Step-by-step" consulting, strategic & global drug development consulting, expert meeting, training

❖ **Benefit from the unmatched experience and respected background of an expert in ophthalmology through all stages of the drug development process**

## CONSULTING SERVICES

Unique and extensive experience in ophthalmology. The guarantee of the best advice and expertise in drug development strategy and decision making.

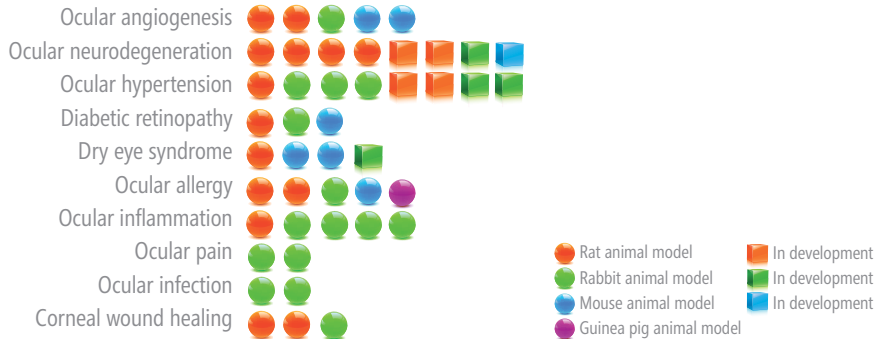
Iris Pharma supplies the necessary understanding and experience to guide new ophthalmic products through the development process.

- …❖ **“Step-by-step” consulting**
- …❖ **Strategic and global drug development consulting**
- …❖ **Study design**
- …❖ **Determination of the appropriate indication**
- …❖ **Expert meeting**
- …❖ **Training**

## PRECLINICAL STUDIES IN OPHTHALMOLOGY

Iris Pharma manages the required ophthalmic development of drugs and devices on animals using state of the art apparatus (Spectralis HRA+OCT, Luminex LX200, confocal microscope, tomograph, ERG, laser flare meter, etc.). All studies are performed in house in its own laboratories and animal houses.

- Applied research (set up and validation of new and existing models and methods)
- Proof of concept studies
- Pilot studies
- GLP regulatory studies: ocular pharmacokinetics and safety
- Ocular efficacy models
- *In vivo* screening



Efficacy models available at Iris Pharma

*The responsiveness, flexibility and preclinical study advice we received from Iris Pharma helped us to reach proof of concept very quickly.*

VP R&D – International Pharmaceutical Company Specialized in Ophthalmology

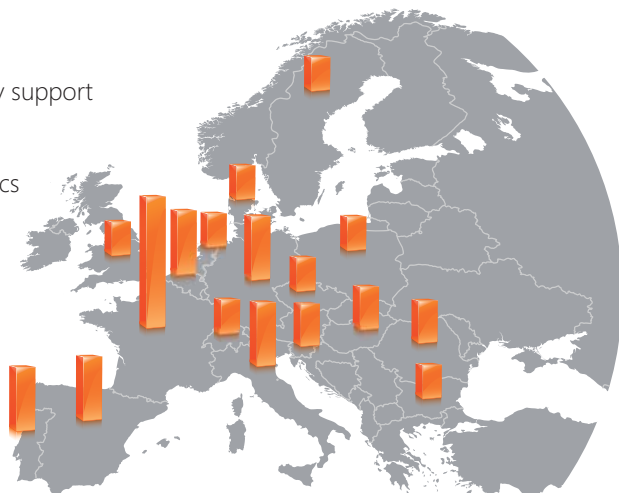
- 40+ customizable *in vivo* models mimicking the human's eye conditions for preclinical studies and *in vivo* screening
- More than 2,200 ocular preclinical studies performed since 1989

# OCULAR CLINICAL TRIALS

## Facilitation and acceleration of phase I to IV clinical trials and marketing surveys

Iris Pharma provides services necessary to evaluate new drugs on patients in compliance with regulatory authority requirements.

- Phase I to IV
- Marketing surveys
- Medical writing and regulatory support
- Monitoring
- Project management
- Data management and statistics



European repartition of the clinical trials: **3,700** clinical sites and **24,000** patients

*Iris Pharma's extraordinary background in ophthalmology facilitates thoughtful consideration of factors that may impact development and/or implementation of clinical study protocols.*

Executive VP – American CRO

- ❖ **Nearly 100 clinical trials conducted in Europe, North America and North Africa**
- ❖ **Expertise in all clinical study phases**
- ❖ **All ophthalmology indications including pediatrics**
- ❖ **All administration modes: topical, systemic, via device**

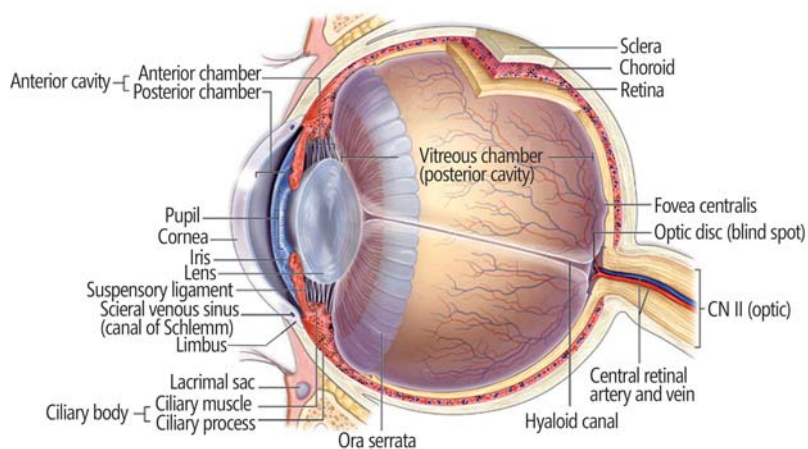
## BIOANALYTICAL TESTING SERVICES

Iris Pharma develops, customizes and validates assays for drugs and their metabolites used in preclinical and clinical studies according to GLP standards or not.

### EXPERIMENTAL DESIGN:

- Quick Mini PK
- Non-radioactive PK studies: RRLC-MS/MS, HPLC-MS, HPLC-UV, ELISA (methods development and validation are required)
- Radioactive PK studies:  $^{14}\text{C}$ ,  $^3\text{H}$ ,  $^{125}\text{I}$  (beta-gamma counter, RIA)
- Autoradiography: macro & micro
- Regulatory safety GLP program according to guidelines (OECD, FDA, French competent Authority) or non-GLP evaluation

Iris Pharma offers routine bioanalytical testing in multiple biological species and rare ocular matrices.



Tears  
Palpebral conjunctiva  
Bulbar conjunctiva  
Aqueous humor  
Cornea  
Lens  
Iris  
Iris-ciliary body (I/CB)  
Vitreous  
Retina  
Choroid  
Sclera  
Optic nerve  
Plasma and blood

*Main available matrices at Iris Pharma*



## **NON-GMP PRECLINICAL OCULAR FORMULATION**

Iris Pharma offers innovative technology and techniques to move new ophthalmic products from discovery to development.

The aim is to develop appropriate formulation of drugs to be tested in preclinical studies, depending on the chemical properties of compounds and the dosage form desired.

Iris Pharma can also evaluate and improve the solubility of compounds, with or without preservatives.

- **Gel** • **Eye-drop** • **Implant** • **Emulsion** •
- **Solution** • **Ointment** • **Suspension** •



*“We have helped bring more than 40 ophthalmological drugs and medical devices to the American and European market for glaucoma, allergy, infection, inflammation and dry eye. Your compound could be the next!”*

**Pierre-Paul Elena** – Iris Pharma CEO

# Iris Pharma **Contact**

**Corporate Headquarters:** Iris Pharma - Les Nertières - Allée Hector Pintus - 06610 La Gaude - France  
Phone: +33 4 93 594 959 - Fax: +33 4 93 594 950 - Email: [info@iris-pharma.com](mailto:info@iris-pharma.com) - Web: [www.iris-pharma.com](http://www.iris-pharma.com)



[www.iris-pharma.com](http://www.iris-pharma.com)



A GLOBAL SERVICE PROVIDER OF PRECLINICAL AND CLINICAL RESEARCH IN OPHTHALMOLOGY

