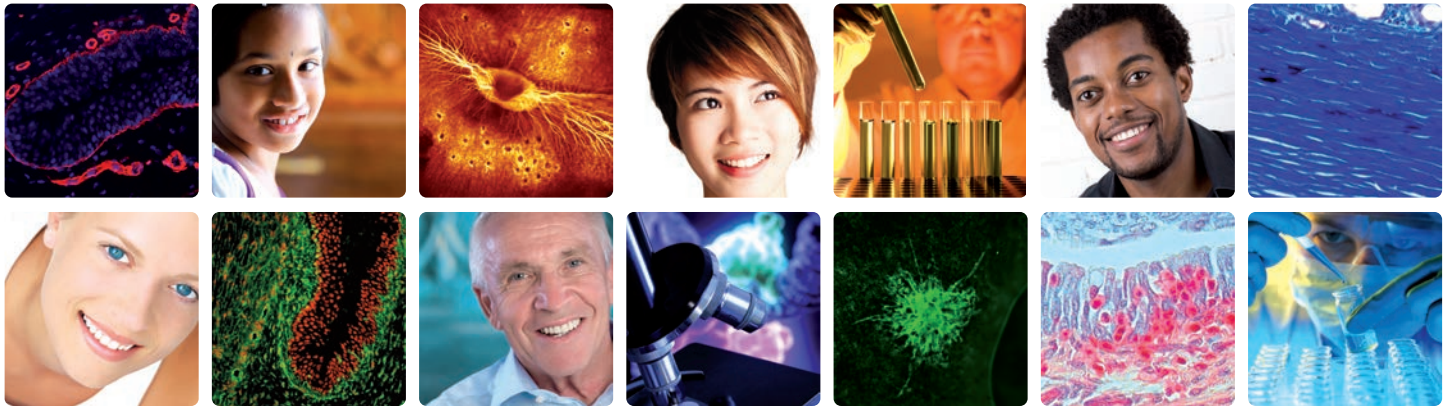


Preclinical & Clinical
Ophthalmology
Research Services Worldwide

iris PHARMA

A GLOBAL SERVICE PROVIDER OF PRECLINICAL AND CLINICAL RESEARCH IN OPHTHALMOLOGY

The Iris Pharma staff's cutting-edge knowledge in ophthalmology, 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

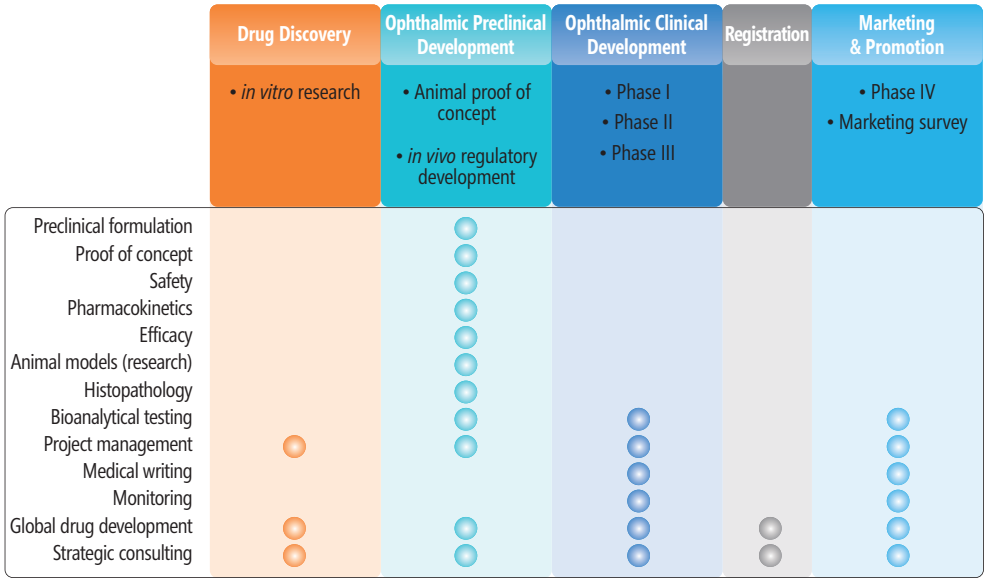
Iris Pharma

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 at Iris Pharma has been offering ophthalmologic drug and device development services to pharmaceutical and biotechnology companies worldwide, from newcomers to specialists in ophthalmology.



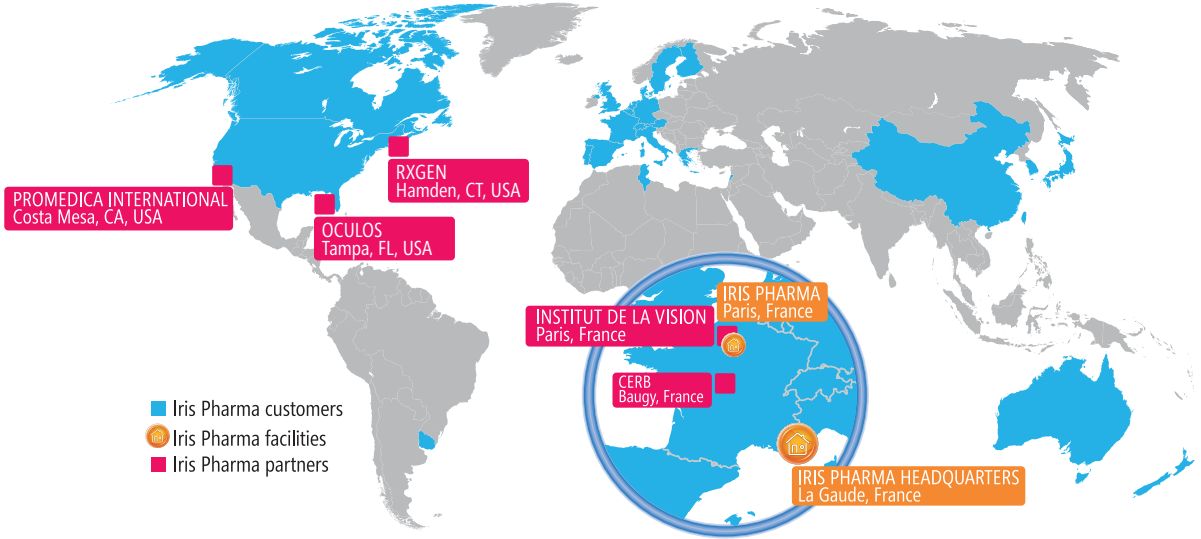
Stand-alone service or global support

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

Translation of more than 60 ocular drugs and medical devices from the laboratory to marketing approval in Europe, North America, and all around the world

A WORLD-CLASS COMPANY

Get the best research services in ophthalmology wherever you are



- **270+ 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."

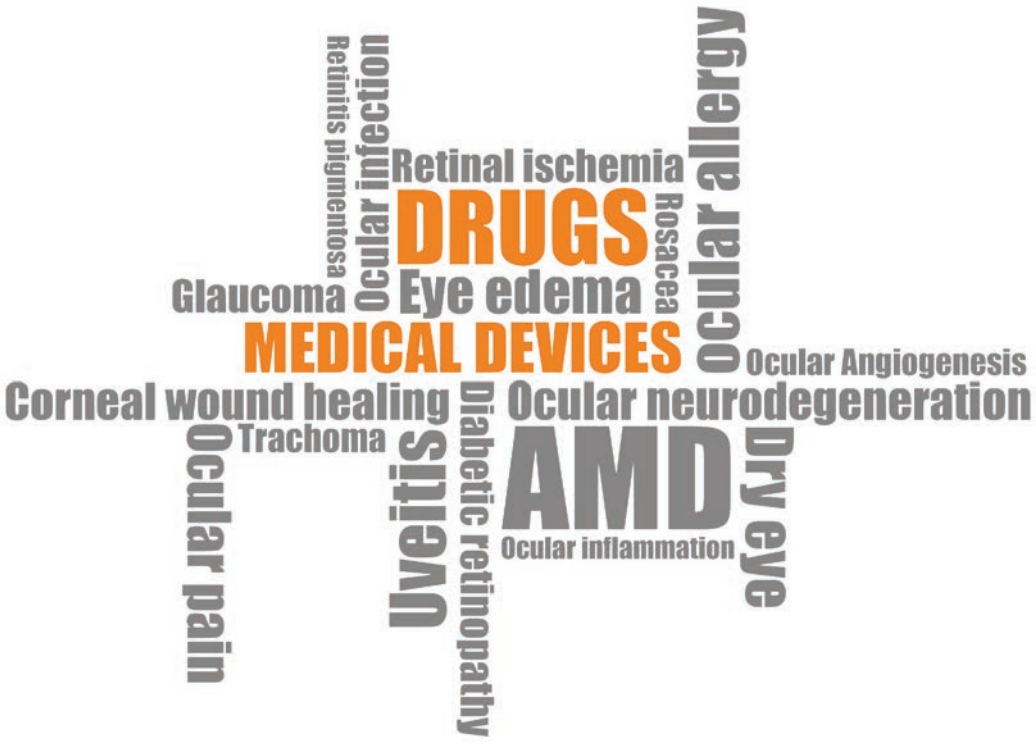
VP R&D – International Pharmaceutical Company Specialized in Ophthalmology

Iris Pharma

Comprehensive Ocular Expertise

Iris Pharma **Comprehensive Ocular Expertise**

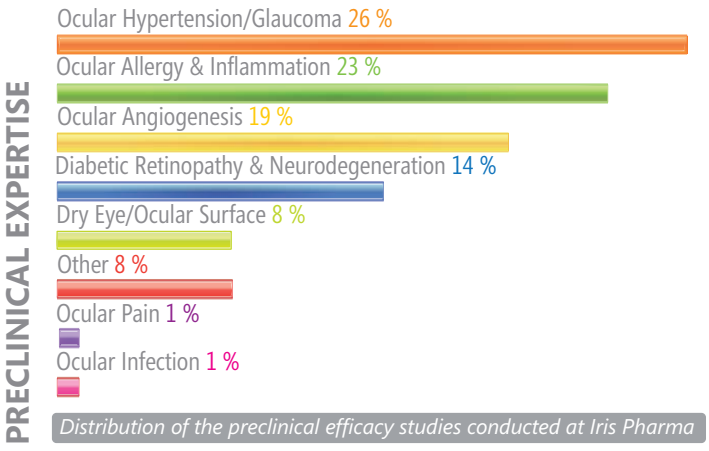
Since its founding in 1989, Iris Pharma has based the company on and expanded its expertise in the science of ophthalmology.



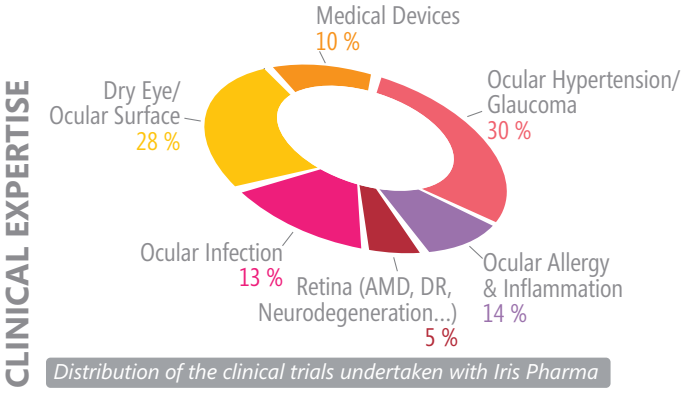
Therapeutic specialization: the solution for reducing time to market

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.



Distribution of the preclinical efficacy studies conducted at Iris Pharma



Distribution of the clinical trials undertaken with Iris Pharma

> *Their stellar study conduct and expert advice have been crucial to advancing our AMD program.*
>
> **Team Leader Preclinical Research** – German Biotechnology Company

Iris Pharma was instrumental to 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

- Phase I-IV clinical trials & medical marketing surveys
- Regulatory affairs
- Study monitoring & site management
- Project management
- Data management & biostatistics
- Medical writing
- Pharmacovigilance
- Investigational Medicinal Product (IMP) management
- Central laboratory services

CONSULTING SERVICES

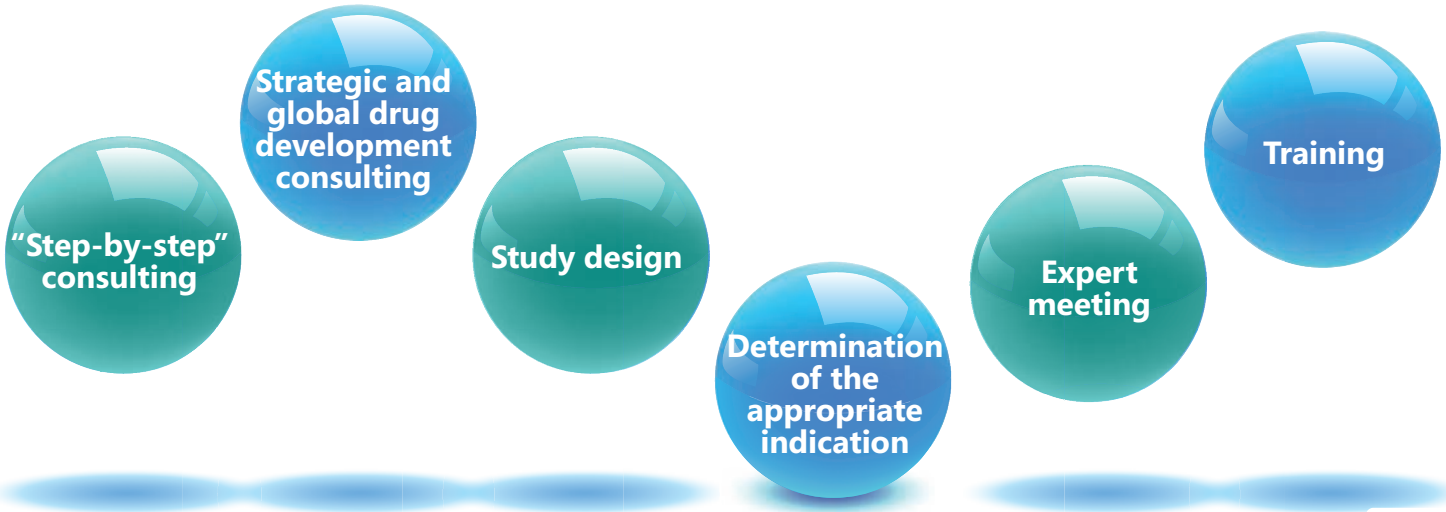
"Step-by-step" consulting, strategic & global drug development consulting, expert meeting, training

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.



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 at our own laboratories and animal houses.

• Proof of concept studies • Pilot studies • GLP regulatory studies: ocular pharmacokinetics and safety • Ocular efficacy models
• *In vivo* screening • Set-up of new animal models

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 human eye conditions for preclinical studies and *in vivo* screening

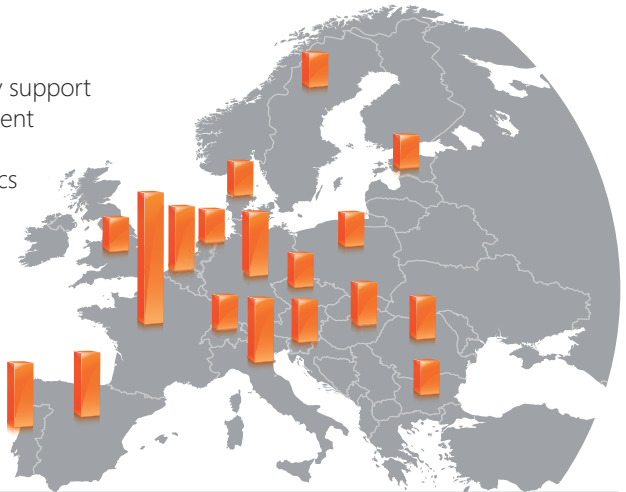
More than 2,500 ocular preclinical studies performed since 1989

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 and site management
- Project management
- Data management and statistics



*European distribution of the clinical trials: **3,900** clinical sites and **26,000** 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

- **More than 100 clinical trials conducted in Europe, North America and North Africa**
- **Phase I to phase IV clinical studies and marketing surveys**
- **All ophthalmology indications including pediatrics**
- **All administration modes: topical, systemic, via device**

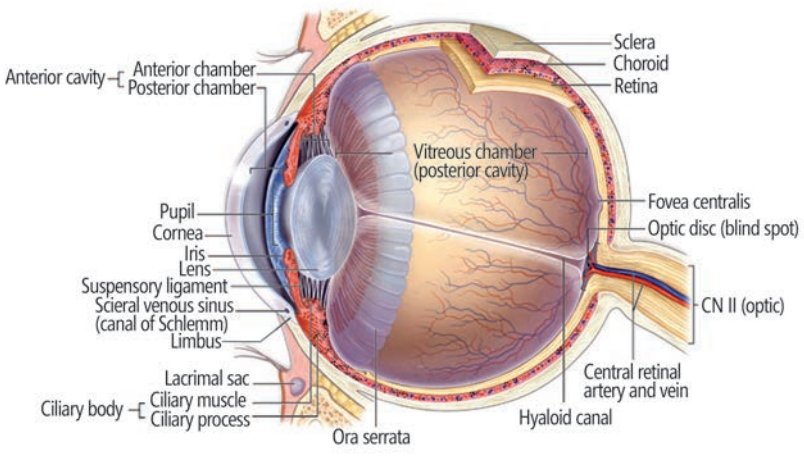
BIOANALYTICAL TESTING SERVICES

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

EXPERIMENTAL DESIGN:

- Quick Mini PK studies
- Non-radioactive PK studies: RRLC-MS/MS, HPLC-MS, HPLC-UV, Luminex, ELISA (methods development and validation are required)
- Radioactive PK studies: ^{14}C, ^{3}H, ^{125}I (beta-gamma counter, RIA)
- Autoradiography: macro & micro
- Regulatory safety GLP programs according to guidelines (OECD, FDA, competent French 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
Vitreous
Retina
Choroid
Sclera
Optic nerve
Plasma and blood

Main matrices available 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 nearly 70 ophthalmological drugs and medical devices to the American and European markets for glaucoma, allergy, infection, inflammation and dry eye.
Your compound could be next!
Pierre-Paul Elena – Iris Pharma CEO

Iris Pharma

Contact

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