Preclinical & Clinical Ophthalmology Research Services Worldwide
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
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.

- **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
Since its founding in 1989, Iris Pharma has based the company on and expanded its expertise in the science of ophthalmology.
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 provides a one-stop solution for ophthalmology drug and device development, which brings significant advantages in terms of flexibility and efficiency.

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

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

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

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

- 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: $^{14}$C, $^{3}$H, $^{125}$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.
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