Preclinical & Clinical Ophthalmology Research Services Worldwide
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 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
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 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 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.
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

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

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