

IRIS PHARMA FACT SHEET

A GLOBAL SERVICE PROVIDER OF PRECLINICAL AND CLINICAL RESEARCH IN OPHTHALMOLOGY

COMPANY OVERVIEW

Iris Pharma is a worldwide Contract Research Organization (CRO), dedicated to preclinical and clinical research in ophthalmology.

We take a global approach to the ophthalmology drug and device development process, and support clients ranging from small start-ups to large pharmaceutical companies in moving forward products that directly or indirectly affect eye health.

DRUG DISCOVERY		PRECLINICAL DEVELOPMENT		CLINICAL DEVELOPMENT			POST-MARKETING	
Therapeutic target identification	High speed screening Lead compound optimization	Early Testing	Preclinical Development	Phase I	Phase II	Phase III	Phase IV	Mktg Survey
Iris Pharma Services								

Since its founding in 1989, Iris Pharma has been based on the science of ophthalmology and has expanded its expertise in the field. Our unique, specialized knowledge ensures that our clients receive high-quality services delivered by well-informed and experienced staff who will guide their drugs or devices to market in the most efficient manner possible. We are proud to have partnered with clients to bring nearly 70 ocular drugs and medical devices to international market in the past 30 years.

SOLUTIONS FOR ANY OCULAR CHALLENGES

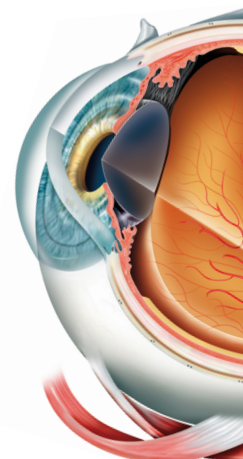


KEY FACTS

Founded: 1989 by Pierre-Paul ELENA, PhD.
President: Yann QUENTRIC, M.Sc.
State of ownership: Private
Headquarters: Nice, France
Employees: 80
2017 Turnover: 8.6 M€
Clients: 350 international customers
FDA & EMA New Drug Approvals: 70

THERAPEUTIC EXPERTISE

Age-Related Macular Degeneration
 Diabetic Retinopathy
 Neurodegeneration
 Retinal Ischemia
 Glaucoma
 Dry Eye Syndrome
 Corneal Wound Healing
 Ocular Infection
 Ocular Inflammation
 Conjunctivitis
 Ocular Allergy
 Ocular Pain
 Ocular Surgery
 Orphan Diseases
 Cataract
 Etc.



CERTIFICATIONS & ACCREDITATIONS

- Statement of compliance with GLP, GCLP and adherence to all trial-related requirements (ICH-GCP)
- Authorization No.2014-022762 to store for future use, to use, to import and to export radio-nuclides in sealed and unsealed sources
- Authorization No.D 06-065-9 for experiments on live animals
- French research tax credit accreditation (CIR)

QUALITY

At Iris Pharma, quality is a state of mind. Our quality assurance program is designed to ensure compliance with GLP, ICH-GCP and GCLP requirements, guidelines (FDA, OECD, etc.) and local regulatory laws and to maintain Iris Pharma's standard of excellence in our work.

Benefit from the unique experience and background of an expert in ophthalmology

PRECLINICAL DEVELOPMENT SERVICES

We manage the complete animal ophthalmic development of drugs and devices using state of the art apparatus (Spectralis® HRA+OCT, tomography, confocal microscopy, electroretinography, laser flare meter, etc.).

- Early testing (proof of concept and pilot studies)
- *In vivo* pharmacology studies and animal efficacy models
- GLP regulatory studies: ocular pharmacokinetics, safety and tolerability
- Applied research (set up and validation of new and existing models and methods)

All studies are performed in-house by our technicians who have been trained to perform microsurgery of the eye and experimental procedure.

CLINICAL DEVELOPMENT SERVICES

We have been performing phase I to IV clinical trials and medical marketing surveys throughout Europe, North Africa, and North America. We provide our customers with the high-quality services necessary for evaluating new drugs and devices on patients, respecting regulatory authorities' requirements.

- Regulatory support
- Study monitoring
- Site management
- Project management
- Data management and biostatistics
- Medical writing
- Investigational medicinal product (IMP) management*
- Pharmacovigilance*
- Bioanalytical testing services
- Central laboratory services

* Via our partners

BIOANALYTICAL TESTING SERVICES

We develop, customize and validate assays of drug candidates and metabolites in a variety of ocular matrices to support preclinical, biopharmaceutical, and clinical pharmacology programs.

Analytical methodologies used include mass spectrometry, high-performance liquid chromatography coupled with different detectors, hematology analyzer, immunoassays (Luminex, ELISA, EIA and RIA), cell-based fluorescence assay (flow cytometry).

PRECLINICAL FORMULATION

We offer adequate non-GMP formulation of ocular drugs to be tested in preclinical studies, depending on the chemical properties of the compounds and the dosage form desired. We can also evaluate and improve the solubility of the compounds, with or without preservatives.

HISTOLOGY

We have been working for three decades on detailing and analyzing every structure of the eye, even going so far as to observe inflammatory cells in the vitreous body and aqueous humor.

CELLULAR AND MOLECULAR BIOLOGY ASSAYS

We work with our customers to identify and qualify predictive ocular biomarkers in many animal models - such as those involved in neovascularization. We also incorporate biomarkers quantification into clinical trials design such as HLA-DR (human leukocyte antigen) for ocular surface disease studies.

STRATEGIC CONSULTING SERVICES

We supply the necessary understanding and experience to guide new ophthalmic products through the development process. As a partner we help to direct preclinical and clinical drug development, to anticipate and plan for any issues which may arise, to design and manage drug and device development programs, or to provide strategic study design.

PARTNERING

- **Institut de la Vision** (a research center for eye diseases) to strengthen the bond between industry and academic research
- **RxGen** (a specialty preclinical CRO) to offer fully integrated "bench-to bedside" ophthalmology research services
- **Promedica International** (a US-based CRO) to provide clinical research services in North America
- **StreetLab** (an innovative company for people with disabilities) to integrate quality of life in the clinical assessment of new products for use by the visually impaired
- **Keen Eye** (an image analysis specialist for the life sciences) to improve ophthalmology studies with artificial intelligence

3,000+
preclinical ocular studies completed

3,500
intravitreal injections/year

40+
animal efficacy models to mimic the conditions of the human eye

100%
labs and animal husbandry dedicated to ophthalmology

110+
clinical studies and surveys conducted

40,000
patients involved in clinical studies and surveys

4,800
sites opened in 36 countries (Europe, North Africa and North America)

