IRIS PHARMA FACT SHEET

A GLOBAL SERVICE PROVIDER OF PRECLINICAL AND CLINICAL RESEARCH IN OPHTHALMOLOGY

COMPANY OVERVIEW

WORK WITH A SPECIALIST

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.

Our focus on the eye allows us to be at the forefront of this field and to help our clients to move their product through the testing and regulatory process in a rapid and cost-effective manner allowing them to market their drugs and devices faster. We are proud to have partnered with clients to bring more than 60 ocular drugs and medical devices to international market in the past 27 years.

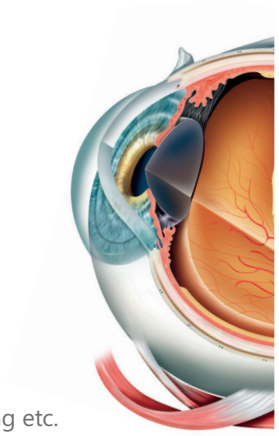
At Iris Pharma, quality is a state of mind. Our Quality Assurance program is designed to ensure that our client studies are performed in compliance with GLP and ICH-GCP requirements, guidelines (FDA, OECD, etc) and local regulatory laws and to maintain Iris Pharma's standard of excellence in our work.

KEY FACTS

Foundation: 1989 by Dr. Pierre-Paul ELENA
CEO: Yann QUENTRIC, M.Sc.
Company Type: Private
Offices: La Gaude, FR (Headquarters) - Paris, FR
Employees: 73
2015 Turnover: 7.8 M€
Clients: 280+ worldwide clients
FDA & EMA New Drug Approvals: 66

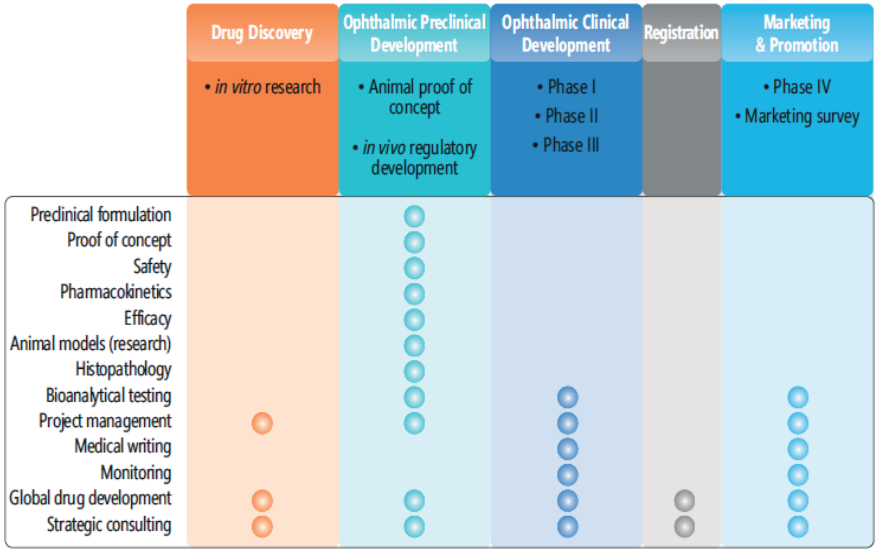
THERAPEUTIC EXPERTISE

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



IRIS PHARMA EXPERTISE

A COMPLETE RANGE OF OCULAR SERVICES



From animal proof of concept and *in vivo* regulatory development through to clinical trials and marketing surveys, our highly qualified staff - consisting of ophthalmologist, veterinarian, pharmacists and scientists - have an excellent knowledge and know-how of each step of the drug development as well as a global overview of the whole process. We are able to conduct studies that meet our clients' specific needs and objectives at every stage of their projects.

We also provide accurate strategic consulting services to help our clients to anticipate and plan for any issues which may arise during the drug development process.

SERVICES FOR OCULAR DRUGS & MEDICAL DEVICES DEVELOPMENT

Benefit from the unique experience and background of an expert in ophthalmology whatever the service required.

PRECLINICAL STUDIES AND SERVICES

We manage the complete animal ophthalmic development of drugs and devices using state of the art apparatus (Spectralis HRA-OCT, Luminex, Apotome, RRLC-MS/MS, laser flare meter...).

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

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

2,500+
preclinical studies completed

1,400
intravitreal injections/year

40+
customizable animal models

CLINICAL TRIALS

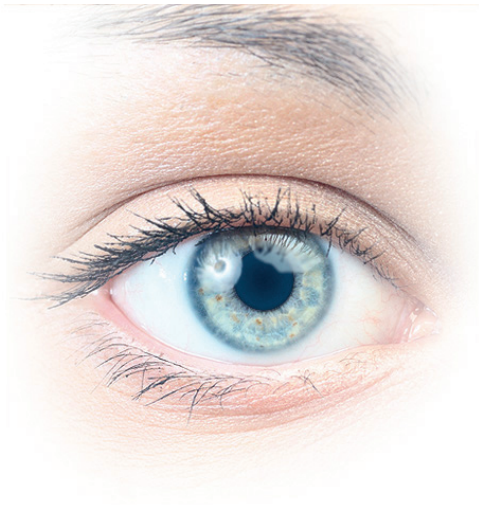
We have been performing phase I to IV clinical trials and medical marketing surveys throughout Europe, North Africa, and North America. We provide our clients with the high quality services necessary to evaluate new drugs and devices on patients respecting regulatory authority requirements.

- Medical writing and regulatory support
- Monitoring
- Project management
- Data management and biostatistics
- Pharmacovigilance

100+
clinical studies and surveys performed

40,000
patients involved in studies and surveys

5,200
sites opened for clinical trials & marketing surveys (Europe, North Africa and North America)



CONSULTING SERVICES

Iris Pharma supplies 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.

BIOANALYTICAL TESTING SERVICES

We develop, customize and validate assays for drugs and their metabolites used in preclinical and clinical studies, according to GLP standards or not. Analytical methodologies used include RRLC-MS/MS, HPLC-MS, Luminex, ELISA and radioactivity in preclinical and clinical samples.

PRECLINICAL FORMULATION

We develop and optimize ocular drug formulations to improve drug delivery which is essential for ophthalmic medications to be used effectively and to provide maximal benefit.

PARTNERING

- Institut de la Vision, one of the major eye disease research centers in Europe
- RxGen, a specialty preclinical CRO focused on the development and application of translational research models
- Promedica International, a US-based CRO providing clinical research services in North America
- Oculos Clinical Research, a full service ophthalmic CRO based in US, with the capability to manage all phases of human clinical trials
- CERB, a leading international CRO offering non ocular pharmacology and regulatory toxicology services

CERTIFICATIONS & ACCREDITATION

- Statement of compliance with Good Laboratory Practices (GLP)
- Adherence to all the trial related requirements (ICH-GCP)
- Authorization to store for future use, to use, import and export radionucleids, in sealed and unsealed sources n°2014-022762
- Experiment authorization on live animals n°D 06-065-9
- CIR (French Research Tax Credit) accreditation

iris PHARMA

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