iris
PHARMA

PRECLINICAL & CLINICAL OPHTHALMOLOGY
RESEARCH SERVICES WORLDWIDE

« Iris Pharma has helped bring more than 70 ocular drugs and medical devices to international markets for various diseases such as glaucoma, dry eye, ocular inflammation, infection and allergy .

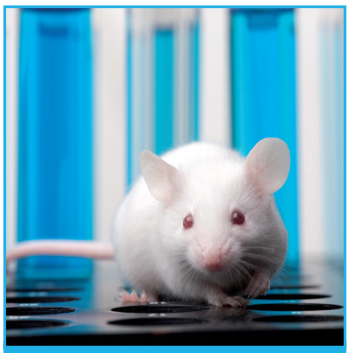
Your compound could be the next!»

Yann Quentric - Iris Pharma CEO

iris PHARMA

THE SPECIALIST FOR YOUR OCULAR DRUG & MEDICAL DEVICE DEVELOPMENT **SINCE 1989**

Iris Pharma is a worldwide Contract Research Organization (CRO) offering ophthalmologic drug and device development services. From animal proof of concept and *in vivo* regulatory development through to clinical trials and marketing surveys, our teams have excellent knowledge and expertise in each step of the drug development process.



Animal proof of concept

Preclinical Development

Clinical Development

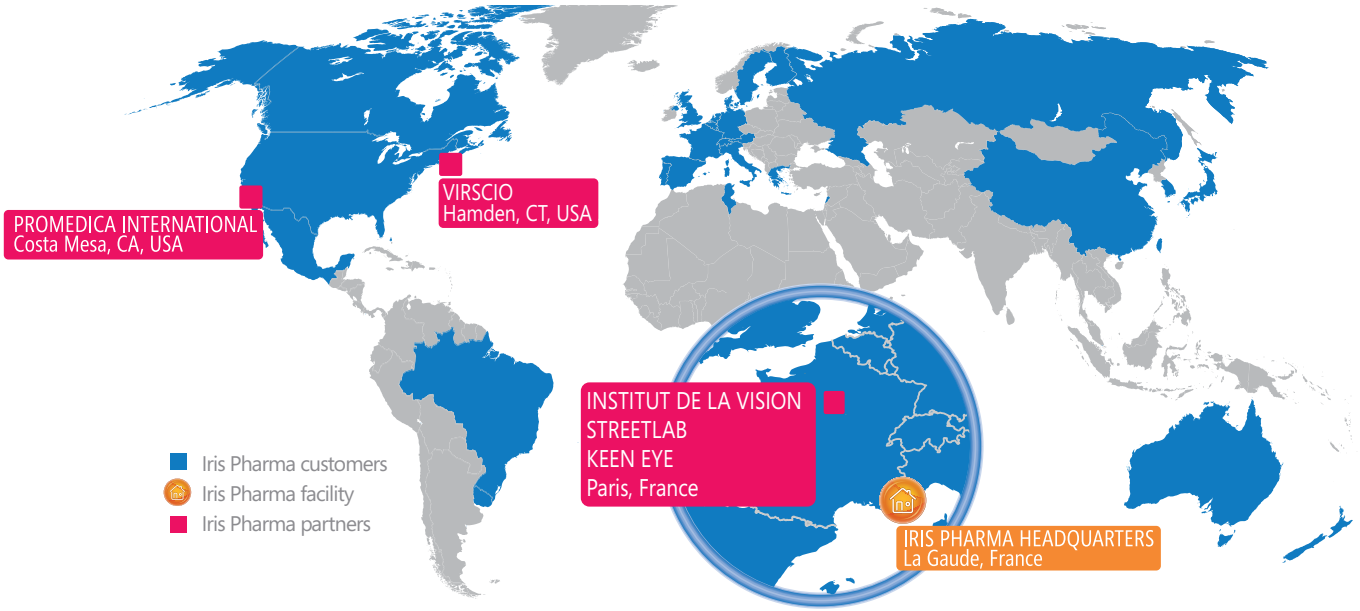
Post-marketing

WHEREVER YOU ARE

GET THE BEST RESEARCH SERVICES IN OPHTHALMOLOGY

A world-class company with 400 international customers including pharmaceutical and biotechnology companies, drug delivery platform companies, consultants and universities.

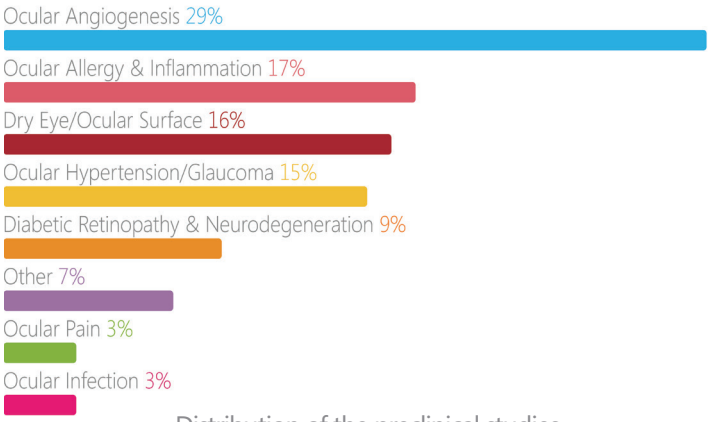
A network of experts and strong partnerships with research facilities, scientists, contract research organizations and digital health company around the world.



MASTERY OF ALL OCULAR PATHOLOGIES IN PRECLINICAL AND CLINICAL DEVELOPMENT

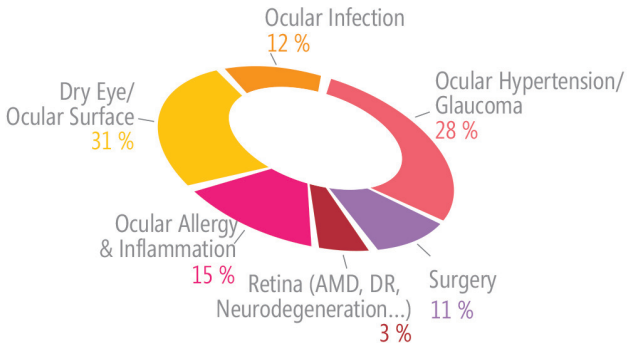
Iris Pharma helps you to develop your potential drugs and devices involving all areas of the eye, from the ocular surface to the posterior segment, and the main conditions affecting this organ, such as age-related macular degeneration, diabetic retinopathy, glaucoma and dry eye syndrome.

PRECLINICAL EXPERTISE



Distribution of the preclinical studies carried out at Iris Pharma

CLINICAL EXPERTISE



Distribution of the clinical trials conducted with Iris Pharma

THERAPEUTIC SPECIALIZATION

THE SOLUTION FOR REDUCING TIME TO MARKET

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 you receive high-quality services delivered by well-informed and experienced staff who will guide your drug or device to market in the most efficient manner possible.

CERTIFICATIONS & ACCREDITATIONS

- Statement of compliance with Good Laboratory Practices (GLP) and Good Clinical Laboratory Practices (GCLP)
- Adherence to all trial-related requirements (ICH-GCP)
- Authorization No. E06-065-9 for experiments on live animals
- French research tax credit accreditation (CIR)

« Their stellar study conduct and expert advice have been crucial to advancing our AMD program. »

Team Leader Preclinical Research
German Biotechnology Company

WHY IRIS PHARMA?

A Proven Track Record and Extensive Experience

We have facilitated the translation of more than 70 ocular drugs and medical devices from the laboratory to marketing approval.

Completely Dedicated to Ophthalmology

Our experts can guide you in making the best decisions to move your ocular products from the laboratory to humans as quickly, safely and effectively as possible.

A Global View of the Drug Development Process

Partnering with you to carry out preclinical and clinical studies: we are thinking of humans from the moment we begin testing on animals.

Comprehensive Ocular Expertise

Our scientists master all ocular pathologies, from the surface to the posterior segment of the eye, including dry eye, glaucoma, AMD and diabetic retinopathy.

A world-Class International Company

We carry out international submissions in compliance with GLP, GCLP and GCP requirements and international guidelines (FDA, OECD, EMA).

Our network of experts and partners extends around the world.

Working with You Now and in the Future

Since 1989, we have been a trustworthy, financially stable company committed to long-term collaborations with each of our customers.

As an independent CRO, we ensure impartial development of ocular drugs and devices.

Consistently Aiming for Scientific Excellence

Our staff is highly qualified and specialized in the field of ophthalmology.

We use state-of-the-art medical and scientific equipment for all of your projects.

We validated unique animal models designed for ophthalmology research.

YOUR CHALLENGES

Iris Pharma is an expert in helping you with every challenge from the moment you have a project involving the eye

DEMONSTRATION

«I'd like to assess the possible therapeutic value of my lead compound in ocular diseases»

POSITION FOR SUCCESS AND EFFECTIVENESS IN OPHTHALMOLOGY

ENTRUST IRIS PHARMA TO

- Get valuable information from cost effective studies to guide your future work
- Quickly and easily determine the efficacy, PK and safety profiles of your compounds
- View trends before moving forward

MAXIMIZATION

«My drug candidate or medical device shows promise in treating ocular diseases. Help me to achieve high added value!»

WITH YOU TO CREATE VALUE

- Demonstrate your product's value
- Bridge the gap between innovation and pharmaceutical products
- Capture investors' and venture capitalists' attention to secure development funding
- Prepare your product for the licensing process
- Start a collaboration with a partner

ASSURANCE

«I need a full preclinical package or clinical trials for my ocular drug or ophthalmic medical device»

PROCEED WITH CONFIDENCE FROM BENCH TO BEDSIDE

WHILE WORKING WITH IRIS PHARMA YOU WILL

- Master requirements: regulatory requirements, the right data to assemble and key studies
- Master the steps, milestones and deadlines

INVESTIGATION

«I need a step-by-step approach and "À la carte" studies»

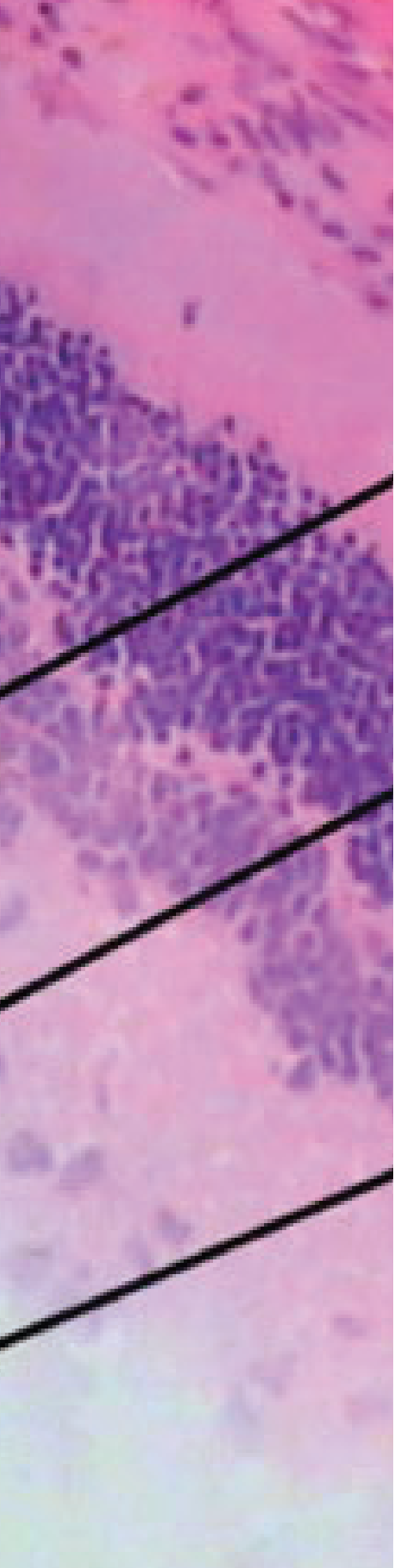
GET EXPERT SUPPORT AT ANY POINT IN YOUR DEVELOPMENT PROGRAM

CONTRACT WITH IRIS PHARMA TO

Immediately benefit from the unique know-how and resources of a renowned expert in ophthalmology able to understand your needs and intervene at any stage of your program

« 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



PRECLINICAL DEVELOPMENT SERVICES

Since 1989, the Iris Pharma team has provided services in the scientific and technical disciplines of preclinical development. We deliver high-quality, regulatory compliance work that helps you move faster from concept to clinical research.

A UNIQUE OCULAR BACKGROUND

- 2,900 preclinical ocular studies carried out at our labs
- 3,500 intravitreal injections performed on animals last year
- 180 posters & papers related to preclinical projects have been authored by our scientists
- Labs and animal husbandry dedicated 100% to ophthalmology

CUTTING-EDGE PRECLINICAL STUDIES

Iris Pharma offers:

- Pharmacological studies in animals to investigate the method of action and effects of a substance in the eye
- Good Laboratory Practice (GLP) studies to determine the ocular safety, tolerance, pharmacokinetics and toxicokinetics of test drugs and devices
- Pilot and proof of concept studies to help you determine the most effective direction for future studies

We can also guide you in your preclinical development programs while assisting you in:

- Selection of preclinical animal models according to the clinical features
- Study design and data interpretation
- Preclinical packages including budgets, timelines and regulatory requirements
- Transversal project management
- Strategic and global drug development consultancy

HIGHLY-QUALIFIED & EXPERIENCED STAFF

- Our collaborators understand and fulfil your needs and objectives
- Our staff includes ophthalmologist, veterinarians, histopathologist, pharmacists, pharmacologists, study directors, qualified laboratory animal personnel trained in ophthalmology
- We are fully compliant with FDA and EMA regulations

QUALITY

- Commitment to providing the best-in-class quality services (quality systems, quality initiatives, service assessment)
- Compliance with GLP principles since 1995

ETHICAL USE OF ANIMALS

- Ethical evaluation of projects
- Internal animal well-being structure
- Animals treated according to the ARVO statement for the use of animal in ophthalmic and vision research
- Implementation of the 3Rs principles

TECHNICAL SKILLS

- Optical Coherence Tomography (OCT)
- Electroretinography (ERG)
- Confocal microscopy
- Slit lamp examinations
- Anterior & posterior segment & fundus photography
- Fluorescein angiography (HRA), retina/choroid flatmount
- Anterior flare (laser flare meter), ocular fluorophotometry
- Esthesiometry, tonometry, pupilometry
- Immunology (e.g. Retinal Ganglion Cells (RGC) labeling, ELISA)
- Vitrectomy, photocoagulation (argon laser), phacoemulsification, microsurgery
- Histology, micro-dissection of ocular samples

OCULAR DOSE ROUTES

Topical, intravitreal, sub-retinal, sub-tenon, subconjunctival, suprachoroidal, intracameral, retrobulbar, intraperitoneal, intrascleral, intrastromal, periocular, oral, intravenous, subcutaneous, punctal plug, device implantation, iontophoresis...

SPECIES

- Rabbits, rats, mice, non human primates*

*via our partner

IN VIVO PHARMACOLOGY STUDIES AND ANIMAL EFFICACY MODELS

Benefit of validated animal models for the translation of drug and device findings from bench to bedside

Iris Pharma offers preclinical testing of drug in nearly 50 animal efficacy models to mimic the conditions of the human eye.

Iris Pharma can also develop new animal models as needed, according to our customers' specific requirements. Our expertise in preclinical research enables us to assess the compatibility of our animal models with your objectives and to customize the study design according to your needs.

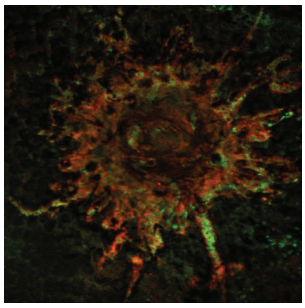
OUR EXPERIENCE

1,200+ ocular efficacy studies performed in animal models

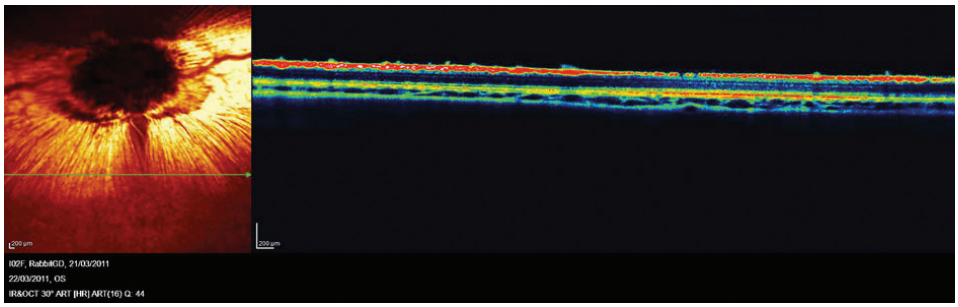
THERAPEUTIC EXPERTISE

- Age-related macular degeneration
- Conjunctivitis
- Corneal fibrosis syndromes
- Corneal graft
- Corneal wound healing
- Diabetic retinopathy
- Dry eye syndrome
- Glaucoma
- Inherited retinal degeneration
- Keratitis
- Orphan diseases
- Ocular irritation
- Optic neuropathies
- Ocular pain
- Ocular discomfort
- Ocular surgery
- Ocular inflammation
- Retinopathy of prematury
- Stromal ulceration
- Uveitis

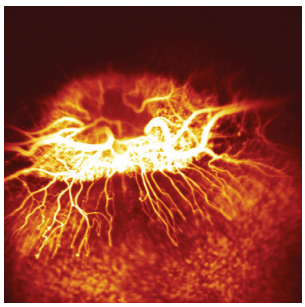
... and many other pathologies



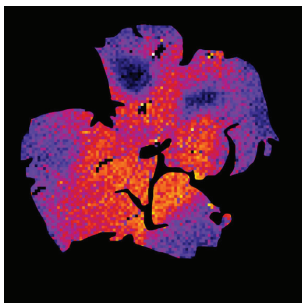
Choroidal neovacularization rat isolectin B4 and FITC dextran staining argon laser model



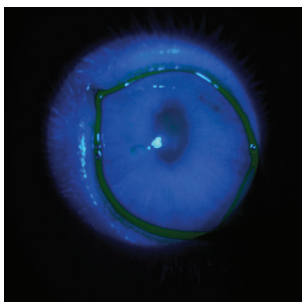
OCT image of normal retina of rabbit



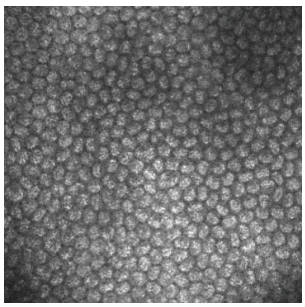
HRA rabbit fundus Fluorescein angiography



Retinal ganglion cells density in a rat HPIO model



Slit lamp corneal fluorescein staining rabbit normal Cornea



HRT-IVCM rabbit normal Corneal endothelium

CUSTOMIZABLE ANIMAL MODELS TO MIMIC HUMAN EYE CONDITIONS

		Disease & Pathologic feature		Induction	Rabbit	Rat	Mouse
OCULAR SURFACE	Corneal angiogenesis	Chemical injury, infection, inflammation		Corneal alkali burn	●	●	
				Corneal sutures	●		
	Inflammation	Non IgE-mediated conjunctivitis		Histamine		●	
				Compound 48/80		●	
		IgE-mediated conjunctivitis		Ragweed pollen			●
				Ovalbumin			●
		Dry eye syndrome		Scopolamine		●	
				Controlled environmental condition			●
				Scopolamine + controlled environmental conditions			●
				Lacrimal gland excision		●	●
		Meiboman gland dysfunction		Freund's Complete Adjuvant	●		
		Corneal Inflammation		LPS + scrapping		R&D	
	Corneal wound healing	Corneal epithelial defects		Epithelial abrasion	●		
		Keratectomy		Manual	●		
	Tear volume, tear quality	Dry eye syndrome		Lacrimal gland excision		●	●
	Ocular pain	Refractive surgery, DR, dry eye syndrome		Capsaicin	●		
ANTERIOR SEGMENT	Ocular hypertension	Chronic hypertension, glaucoma		Glucocorticoid (POAG model)		●	
		Acute hypertension, glaucoma		Water loading	●		
				Hypertonic saline	●		
		Normotensive, glaucoma		-	●	●	
	Inflammation	Anterior uveitis	Severe inflammation	Lipopolysaccharide (EIU model)	●	●	●
			Slight inflammation	Lipopolysaccharide (EIU model)	●		
		Panuveitis		Mycobacterium tuberculosis	●		
		Anterior inflammation		Aqueous humor paracentesis	●		
				Phacoemulsification	●		
POSTERIOR SEGMENT	Choroidal angiogenesis	Wet AMD		Argon laser		●	●
	Retinal angiogenesis	DR, ROP, wet AMD		Hypoxia (OIR model)		R&D	●
		DR, wet AMD, retinal occlusion		DL-AAA	●		
	Retinal vascular permeability	DR, macular edema		VEGF	●		
	Retinal degeneration	Retinal vein occlusion, glaucoma, DR		Acute elevated IOP (ischemia reperfusion model)		●	
				Optic nerve clamping (ischemia reperfusion model)		●	
				STZ		●	
				NMDA (excitoxic damage model)		●	
		Geographic atrophy, dry AMD		Blue light		●	
		Retinitis pigmentosa		MNU		●	●
		Geographic atrophy		Sodium iodate	R&D	●	●
	Retinal detachment	-		Sodium hyaluronate		R&D	
	Inflammation	Panuveitis		Mycobacterium tuberculosis	●		
		Posterior uveitis		S-antigen (EAU model)		●	
OTHERS	Sub-chronic toxic stress	Irritation		Benzalkonium chloride	●		
		Secondary open-angle glaucoma		Glucocorticoid		●	
		Corneal wound healing delay		Mechanical wound	●	●	
	Surgery	Phacoemulsification			●		
		Paracentesis			●		
		Device implantation			●		

AMD: Age related macular degeneration
DR: Diabetic retinopathy
DL-AAA: DL-alpha-aminoadipic acid
EAU: Experimental autoimmune uveitis
LPS: Lipopolysaccharide
MNU: N-methyl-N-nitrosourea
NMDA: N-methyl-D-aspartate
OIR: Oxygen-induced retinopathy
ROP: Retinopathy of prematurity
STZ: Streptozotocin
VEGF: Vascular endothelial growth factor

Last updated: April 12, 2024

OCULAR PHARMACOKINETICS

Entrust your ocular PK studies to a specialist

Iris Pharma offers complete ocular pharmacokinetic (PK) evaluation services in a GLP environment to obtain the reliable data required before first-in-human clinical studies of your product. Our skilled and experienced staff handles all administration routes as well as the microdissection and sampling of each eye structure.

OUREXPERIENCE

600+ ocular pharmacokinetic studies

EXPERIMENTAL DESIGN

- Pilot pharmacokinetic
- Pharmacokinetic
- Bioavailability
- Bioequivalence
- Tissue distribution
- Delivery optimization
- Single or repeated dose, ascending dose
- Toxicokinetic / Pharmacodynamic
- Regulatory GLP program according to guidelines (OECD, FDA, French competent Authority) or non-GLP evaluation

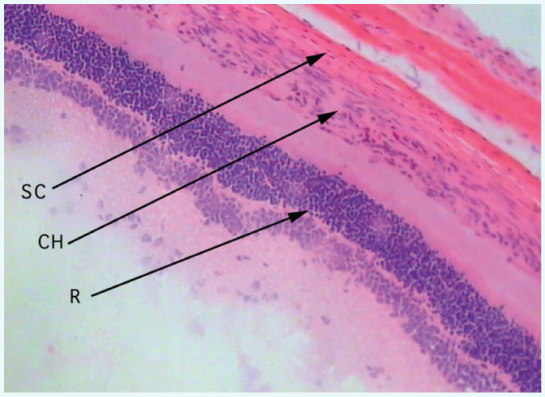
ADVANTAGES

- Animal experimentation and bioanalytical analysis in the same site
- Ocular sample dissection in rabbits, rats, mice
- Methods validated for all ocular matrices, including rare matrices
- Development of methods

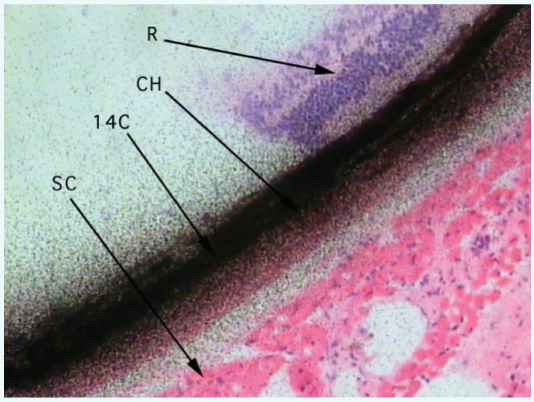
SAMPLING

- Ocular microdissection:
  - Tears
  - Eyelids
  - Palpebral or bulbar
  - Conjunctiva
  - Nictitating membrane
  - Extra ocular muscles
  - Lacrimal gland
  - Harderian gland
  - Nasolacrimal duct
  - Conjunctiva
  - Cornea
  - Aqueous humor
  - Iris
  - Ciliary body
  - Lens
  - Vitreous
  - Retina
  - Choroid
  - Sclera
  - Optic nerve
- Other sampling:
  Whole blood, plasma, organs, urine, feces

EFFECT OF EYE PIGMENTATION IN A PK STUDY
Posterior segment of the rat eye (sagittal section)



Albino rat (CH: choroid - R: retina - SC: sclera)



Pigmented rat (CH: choroid - R: retina - SC: sclera - 14C: carbon-14 labelling)

OCULAR TOLERANCE/SAFETY TESTING

Your GLP-certified CRO for consistency, reliability, reproducibility, quality and integrity in preclinical safety tests

Safety assessment or preclinical testing is the first major step toward regulatory approval. Iris Pharma offers the regulatory safety GLP program: acute tolerance, sub-chronic tolerance, corneal anesthesia and where applicable, pupillary diameter and lacrimation testing.

OUR EXPERIENCE

550+ ocular tolerance studies

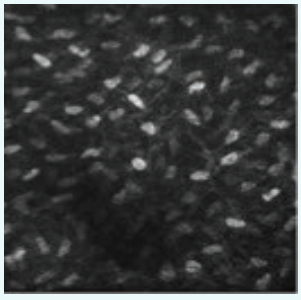
EXPERIMENTAL DESIGN

- Acute tolerance
- Sub-chronic tolerance (<3 months)
- Chronic tolerance (>3 months)
- Corneal anesthesia
- Pupillary diameter
- Lacrimation
- LLNA
- Toxicokinetic analyses
- Single or repeated dose, Maximum Tolerated Dose (MTD), dose selection, escalating
- Regulatory GLP program according to guidelines (OECD, FDA, French competent Authority) or non-GLP evaluation

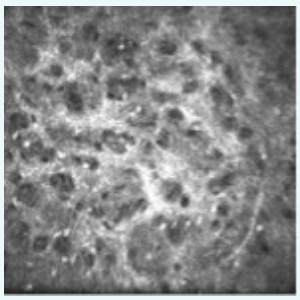
OCULAR TOLERANCE END-POINTS

- Ocular examinations
- Ocular histopathology
- General clinical observations
- Systemic (blood chemistry, hematology, organ histology...)
- Optional end-points (e.g. ERG, HRT-II)
- Draize, McDonald & Shadduck's, Kimura's, Nussenblatt's scoring
- Funduscopy

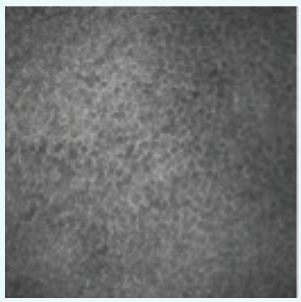
IN VIVO CORNEAL CONFOCAL MICROSCOPY EVALUATION (HRT-II)



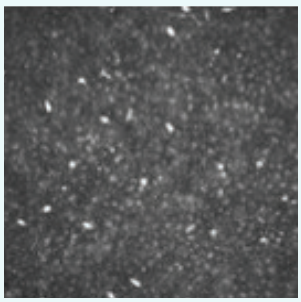
Heatly corneal stroma



Opacity in corneal stroma



Healthy corneal epithelium



Inflammation in corneal epithelium

« The responsiveness, flexibility and preclinical study advice we received from Iris Pharma helped us to reach proof of concept very quickly. »

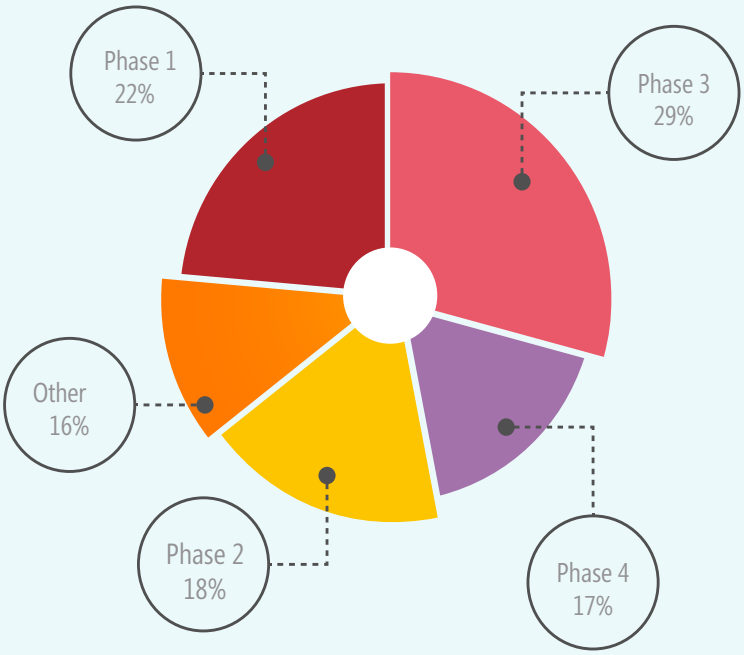
VP R&D – International Pharmaceutical Company Specialized in Ophthalmology

CLINICAL TRIAL SERVICES

At Iris Pharma, we have decades of experience in performing comprehensive clinical research and development in all areas of ophthalmology.

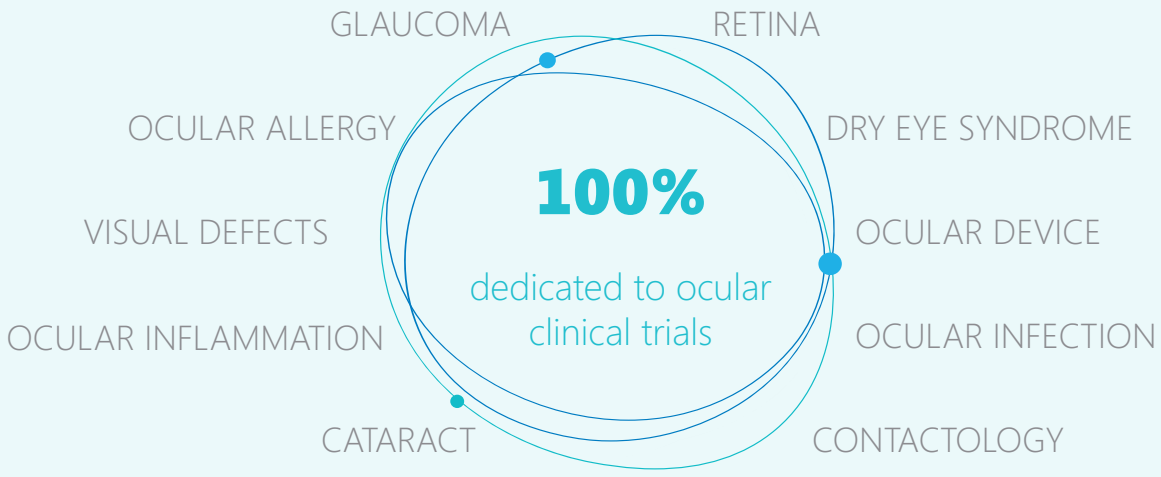
CLINICAL TRIAL PHASES

Our experts in clinical research are skilled in performing all phases of clinical trials (phases 1, phase 2a-2b and phase 3) to obtain marketing approval by the relevant authority, such as the European Medicines Agency (EMA) or the U.S. Food and Drug Administration (FDA).
They also effectively manage exploratory studies, clinical observational studies, post-marketing studies (e.g. phase 4 study and medico-marketing survey) and provide real life datas.



PROVEN EXPERTISE IN OPHTHALMOLOGY

We are skilled in performing clinical studies for a comprehensive variety of eye disorders.



Our therapeutic focus on ophthalmology allows you to benefit from our networks of experienced investigative sites and scientists in every eye disease and ensures the conditions supporting efficient patient recruitment.

« 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

OUR EXPERIENCE

130+ clinical studies and marketing surveys conducted in ophthalmology
5,000+ sites opened in 36 countries
43,000+ patients involved in clinical studies & marketing surveys

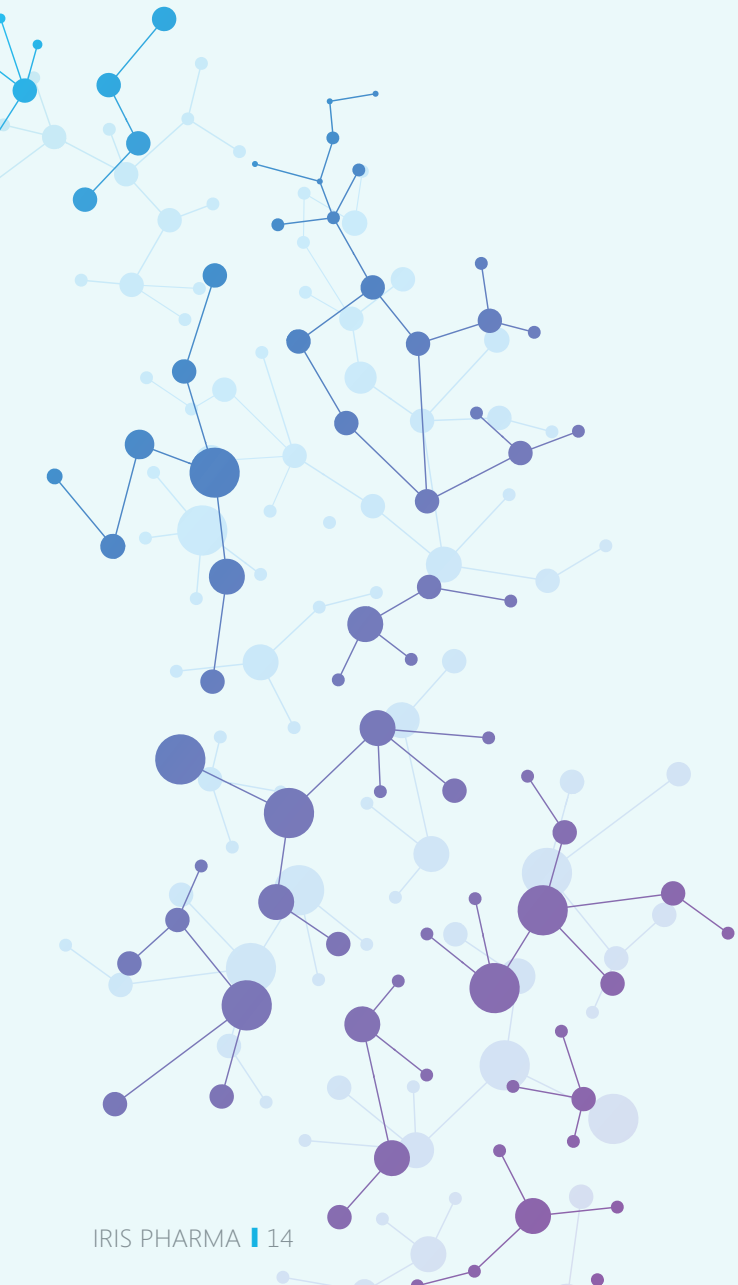
OUR SERVICES

We provide our customers with the high-quality services necessary for evaluating new drugs and devices on patients, respecting the regulatory authorities' requirements.

- Regulatory Affairs
- Study Monitoring and Site Management
- Project Management
- Data Management and Biostatistics*
- Medical Writing
- Pharmacovigilance*
- Investigational Medicinal Product (IMP) Management*
- Bioanalytical Testing Services
- Central laboratory services

* Via our partners

With Iris Pharma, you can mix-and-match stand-alone services or choose global support to test new ocular drugs and devices in humans during clinical development.



KEY RELATIONSHIPS & INTERNATIONAL NETWORK OF EXPERTS

- Privileged contacts with international opinion leaders and experts in ophthalmology and pharmacology
- A well-established network of internationally renowned ophthalmologists and investigative sites
- Expert partners in medical writing
- Membership in regulatory and quality assurance associations
- An international network of local regulatory consultants

HIGHLY QUALIFIED EXPERIENCED STAFF

- Our experienced staff understand and fulfil your expectations and objectives
- Our experts include ophthalmologists, pharmacists, pharmacologists...
- Iris Pharma's team is comprehensively and regularly trained and updated on GCP, study monitoring guidelines, local legislations and ophthalmologic pathologies
- More than 40 posters and papers related to clinical projects and development have been authored by our staff

BROAD INTERNATIONAL EXPERIENCE & PRESENCE

We have been performing clinical trials throughout Western and Eastern Europe and North Africa since 1994, and in North America since 2007.

Based on this extensive experience, our multicultural clinical operation teams are familiar with multinational submissions, international and local agency requirements and everything that will make your clinical trial a success.

In the United States, Iris Pharma has one experienced partner with solid expertise in ophthalmology clinical study management and monitoring.

Iris Pharma partner

Iris Pharma facility

COUNTRIES: Algeria - Armenia - Austria - Belgium - Bosnia - Bulgaria - Croatia - Czech Republic - Denmark - Estonia - France - Georgia - Germany - Greece - Hungary - India - Israel - Italy - Latvia - Lithuania - Morocco - The Netherlands - Norway - Poland - Portugal - Romania - Saudi Arabia - Serbia - Slovakia - Spain - Sweden - Switzerland - Tunisia - Turkey - United Kingdom - USA

INNOVATIVE TECHNOLOGY PLATFORM & TECHNIQUES

BIOANALYTICAL TESTING SERVICES

Cutting-edge bioanalytical services in ocular matrices

Iris Pharma develops, customizes, and validates assays of drug candidates and metabolites in a variety of ocular matrices to support preclinical, biopharmaceutical, and clinical pharmacology programs.

OUR EXPERIENCE

- 250+ bioanalytical studies
- GLP-compliant bioanalytical laboratory since 1995

EXPERIMENTAL DESIGN

- Ocular pharmacokinetic analysis
- Assay method development from scratch, optimization, validation and transfer
- Sample analysis technologies in multiple biological matrices and animal species
- Metabolite identification
- Expertise in proven, validated methods to quantitatively measure all types of compounds (small or large molecules) and expertise in immunoassay systems
- Feasibility assessments

TECHNICAL SKILLS

We are experts in processing samples using tools that are both fast and sensitive, such as:

- Mass spectrometry (RRLC-MS/MS)
- High-performance liquid chromatography coupled with different detectors (MS, RID, FLUO, UV)
- Hematology analyzer
- Immunoassays (Luminex, ELISA, EIA)
- Cell-based fluorescence assay (flow cytometry)
- Biochemistry analyzer (Piccolo Xpress)

EXAMPLES OF COMMERCIAL RRLC-MS/MS METHODS VALIDATED IN HOUSE (in rabbit)

- Diclofenac in vitreous
- Dexamethasone in vitreous, choroid and retina
- Timolol in aqueous humor
- Cyclosporin A in aqueous humor, cornea, ciliary body iris, conjunctiva and lacrymal gland
- Azitromycin in bulbar conjunctiva, cornea and aqueous humor

Animal ocular matrices

- Palpebral conjunctiva
- Bulbar conjunctiva
- Aqueous humor
- Cornea
- Lens
- Iris
- Iris-ciliary body
- Vitreous
- Retina
- Choroid
- Sclera
- Optic nerve
- Tears

INNOVATIVE TECHNOLOGY PLATFORM & TECHNIQUES

NON-GMP PRECLINICAL OCULAR FORMULATION

The benefits of the right preclinical ocular drug formulation to improve drug delivery and to provide maximal effectiveness in animal testing

The eye's natural barriers and elimination systems, the organ's complexity, the difficulty in reaching certain tissues or segments and overall the eye sensitivity are all challenges that Iris Pharma seeks to overcome. Formulation in the ophthalmology field is a particularly difficult subject that requires know-how and great experience in order for your ophthalmic compound to be used effectively in preclinical studies.

Iris Pharma offers adequate non-GMP preliminary formulation of your ocular drugs to be tested in preclinical studies, depending on the chemical properties of the compounds and the dosage form desired.

Iris Pharma can also evaluate and improve the solubility of your compounds, with or without preservatives.

OUR EXPERIENCE

- Development of several formulations, notably ophthalmic gels
- We have helped bring to the market leading eye gels such as Siccafluid®, NyoGel®, Geltim, Timosan®, Timogel...

DRUG SUBSTANCES

- Small organic and inorganic molecules
- Peptides and proteins including biologics
- Oligonucleotides, DNA and RNA

SPECIALIZED FORMULATION TARGETING PRECLINICAL RESEARCH (non-GMP)

- Solubility in pH buffers and in eye-compatible solvents
- Development of dosage form
- Delivery optimization
- Drug solubilizer screening
- Excipient compatibility
- Bioavailability enhancement
- Preclinical formulation development integrated with analytical development contract services
- Stability testing (short-term stability at +5°C and at ambiant temperature)

Addressing your formulation challenges

- Insoluble or unstable drugs
- Poor bioavailability
- Short residence time & poor penetration
- Intolerance, discomfort, irritation
- Inadequate PK profile
- Specific delivery either to the anterior segment or posterior segment of the eye
- Suspension

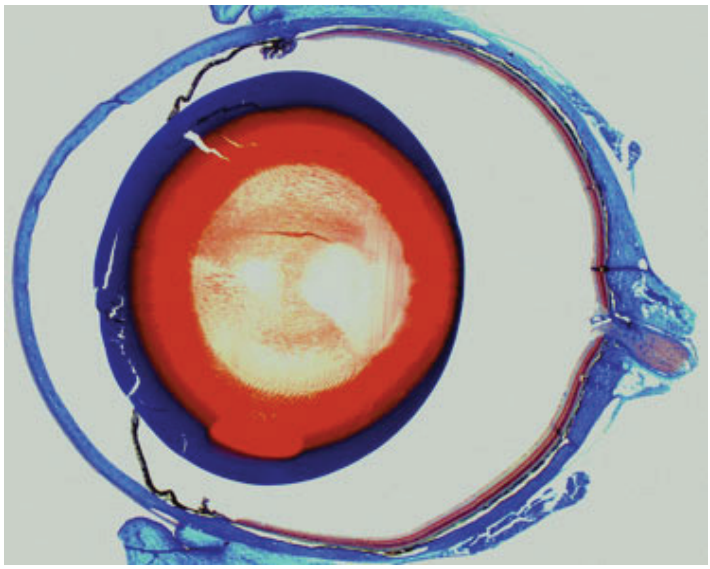
OCULAR HISTOLOGY

Ocular histology is a true craft, requiring highly trained, specialized staff. The difference in density from one ocular structure to another may go unnoticed by those who have little experience in this field.

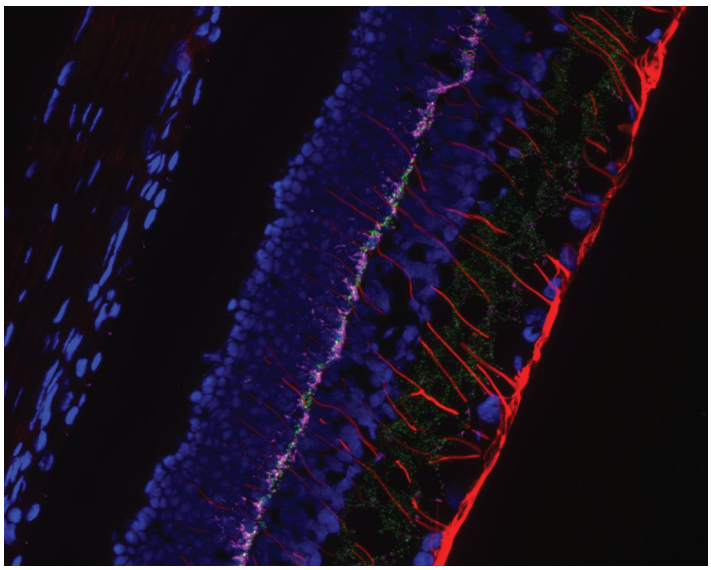
Iris Pharma's team has been working for more than three decades on detailing and analyzing every structure of the eye, even going so far as to observe inflammatory cells in the vitreous body and aqueous humor.

An advanced Artificial Intelligence (AI) technology could be available to optimize the performance of the bioimaging analysis.*

* Via our partner



Sagittal section of the eye (rat)



Quadruple immunohistochemical staining of a sagittal section of the retina (rat)

SPECIALIZED EVALUATIONS

Our skilled pathologists are able to use several techniques and perform specialized evaluations, including:

- Biopsies
- Histological sections
- Ophthalmic specimen slide preparation
- Microscopic examination of tissues
- Staining by immunohistochemistry
- Immunofluorescence

LEADING TECHNOLOGY

All histology equipment is available at our facilities (e.g. an ApoTome fluorescence microscope, a microtome with motorized stage capability (slide scanner), a cryocut and a fully automated staining, dehydrating and embedding system).

CELLULAR AND MOLECULAR BIOLOGY ASSAYS

Efficient ocular biomarker to be tested in preclinical and clinical research

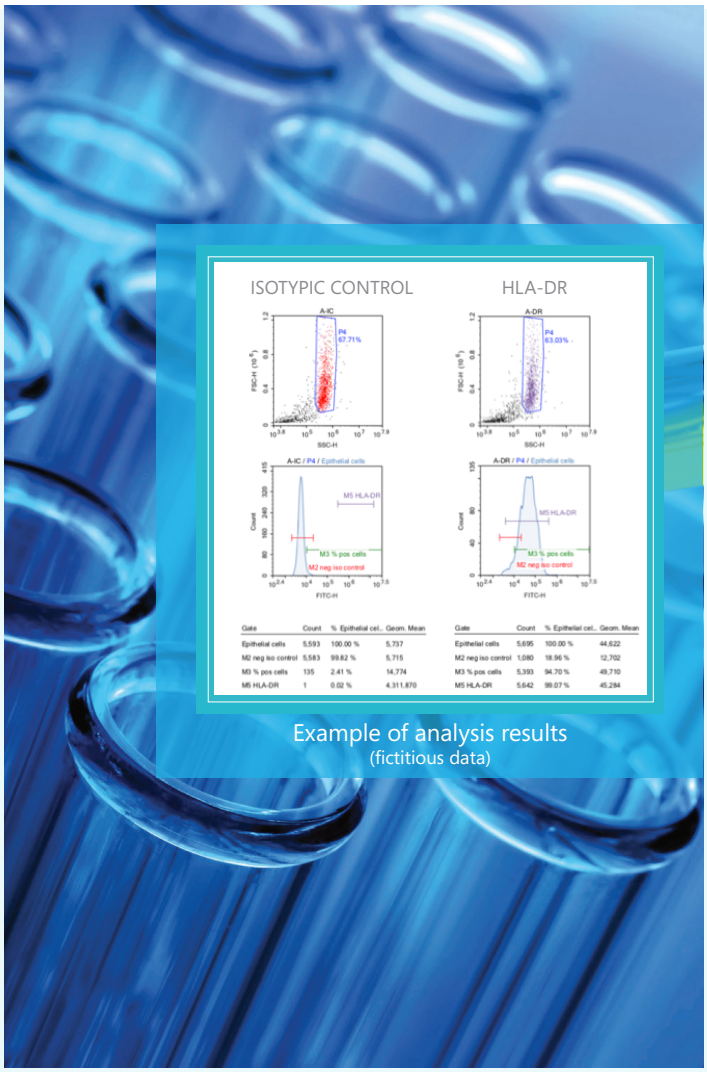
The expression of ocular biomarkers provides valuable information for predicting and investigating the efficacy of new ocular therapies during preclinical and clinical research.

FOLLOW PREDICTIVE BIOMARKERS IN ANIMAL MODELS

Our multidisciplinary team of scientists works with our customers to identify and quantify predictive ocular biomarkers – such as those involved in neovascularization and the inflammation - in many animal models.

INCORPORATE BIOMARKERS INTO THE CLINICAL TRIALS DESIGN

Dry eye syndrome is a multifactorial disease on the ocular surface, leading to conjunctival inflammation associated with expression of biomarkers such as HLA-DR (Human Leukocyte Antigen).
HLA-DR quantification is very interesting in clinical trials related to ocular surface diseases and is used in the US and EU as an ancillary parameter to be considered.
HLA-DR quantification by flow cytometry has been developed at Iris Pharma from the scientific publication: *Flow cytometry in impression cytology specimens. A new method for evaluation of conjunctival inflammation. Baudouin C, Brignole F, Becquet F, Pisella PJ, Goguel A. Invest Ophthalmol Vis Sci. 1997;38:1458-64.*



Example of analysis results
(fictitious data)

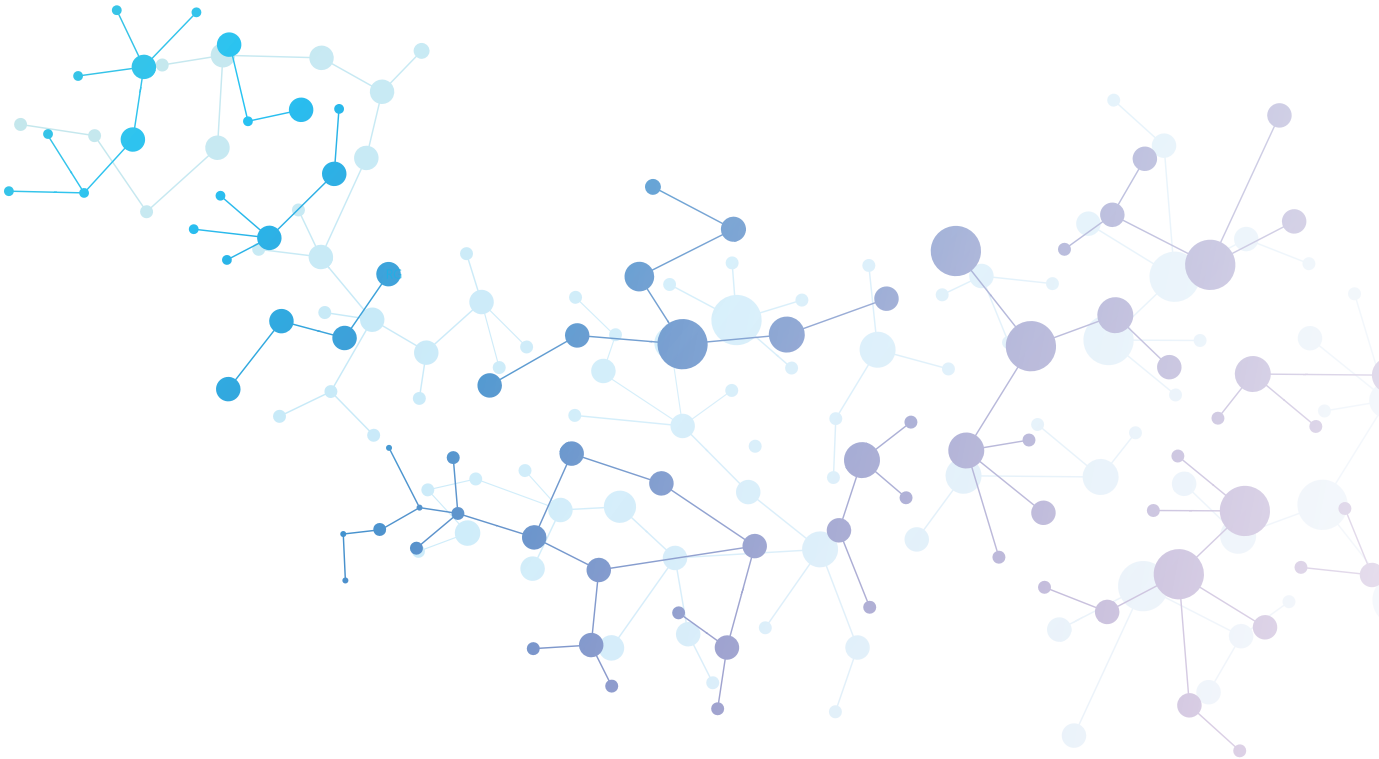
ADVANCED TECHNOLOGY

- **Flow cytometry (NovoCyte™)**
  This fast, reliable method characterizes cells individually thanks to the specific staining of targeted biomarker proteins.

- **RT-qPCR (LightCycler® 480)**
  This technology simultaneously amplifies, detects and quantifies targeted biomarker mRNA. From RNA extraction to the choice of primers and data analysis, every step is technically and scientifically supervised by Iris Pharma experts.

- **ELISA**
  The Enzyme-Linked Immunosorbent Assay (ELISA) is the standard for quantitative analysis of cytokines and other biomarkers.

- **Multiplex (Luminex® 200 system)**
  The microsphere-based liquid array used by Iris Pharma simultaneously measures a large number of analytes in a single cycle of the assay. With this system, biochemical quantifications and multiple simultaneous analyses can be carried out on low sample volumes. Iris Pharma can, for example, perform analyses of cytokines in animal models of inflammation, notably in an EIU (endotoxin-induced uveitis) model.



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