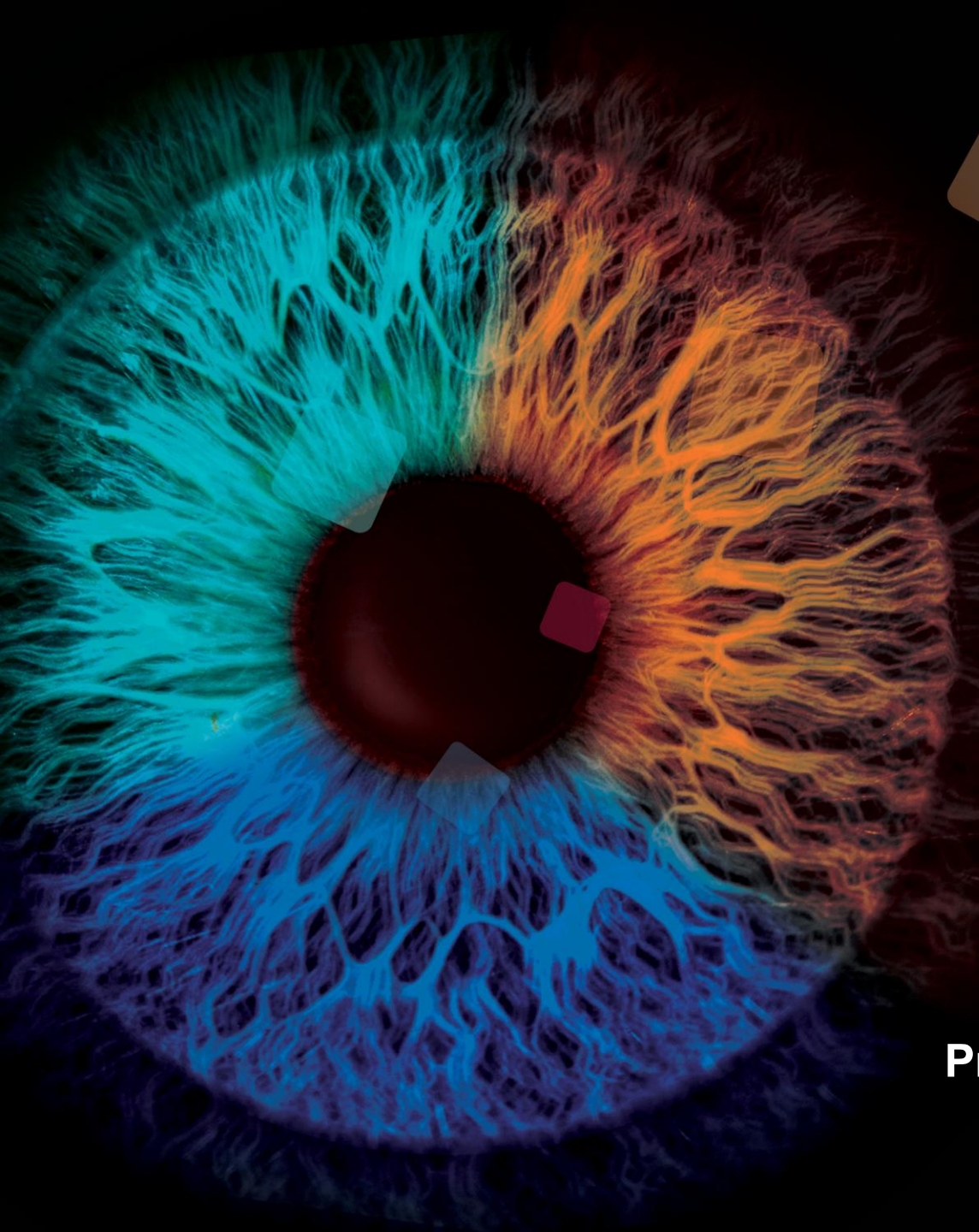




Iris Pharma
Capabilities Overview
July 2024

**Preclinical & Clinical Development
Services in Ophthalmology**



WHO WE ARE



Quick Facts & Figures

**A world leading CRO dedicated to
Preclinical & Clinical Research
in Ophthalmology**



Founded: 1989 by Pierre-Paul ELENA, PhD.

President: Yann QUENTRIC, M.Sc.

Headquarters: Nice, France

Ownership: Privately owned

Employees: 50+

A Mature Company



Partnership with Keen Eye

Acquisition of Eynostics
Partnership with Streetlab

Partnership with Virscio

Merger with Clirophtha
Partnership with Institut de la Vision
Strategic alliance with Promedica Int.

Foundation of Clirophtha

Foundation of Iris Pharma

2020

YEARS
OF EXCELLENCE IN
OCULAR DRUG DEVELOPMENT



2015

2010

2005



2000

1995



1990

Iris Pharma continues to be the worldwide leader in ocular drug and device development



Advanced bioimage analysis solutions (AI)



Ocular biomarker quantification service



Extended clinical assessment



NHP animal models



Preclinical ocular formulation service



Acceleration of the animal model validation



Clinical trials in ophthalmology



Bioanalytical testing service



Ocular histology service



Preclinical studies in ophthalmology



A Proven Experience since 1989



Products approved
glaucoma, dry eye, infection,
inflammation, allergy etc.



Preclinical studies



Animal models
developed & validated in house



Intravitreal injections
last year



Posters & papers



Clinical sites



Patients / Subjects



Clinical studies

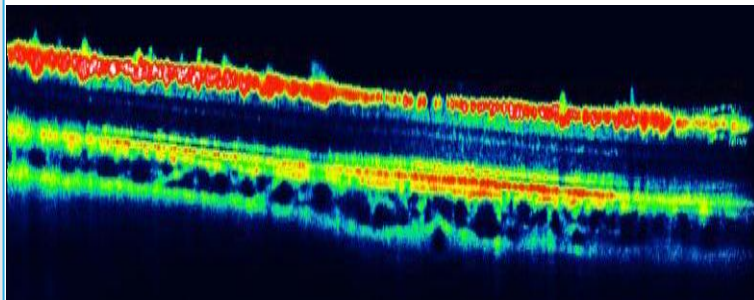


A Dynamic Company Looking into the Future

MATERIAL INVESTMENT

Our latest acquisitions:

- HRA-OCT (*Spectralis®*)
- RT-qPCR (*LightCycler® 480*)
- LC-MS/MS (*Agilent®*)
- Flow cytometry (*NovoCyte™*)
- Multiplex (*Luminex® 200*)



ADVANCED TECHNOLOGY

- AI technology to optimize the performance of bioimaging analysis
- Efficient ocular biomarker to be tested in preclinical and clinical research



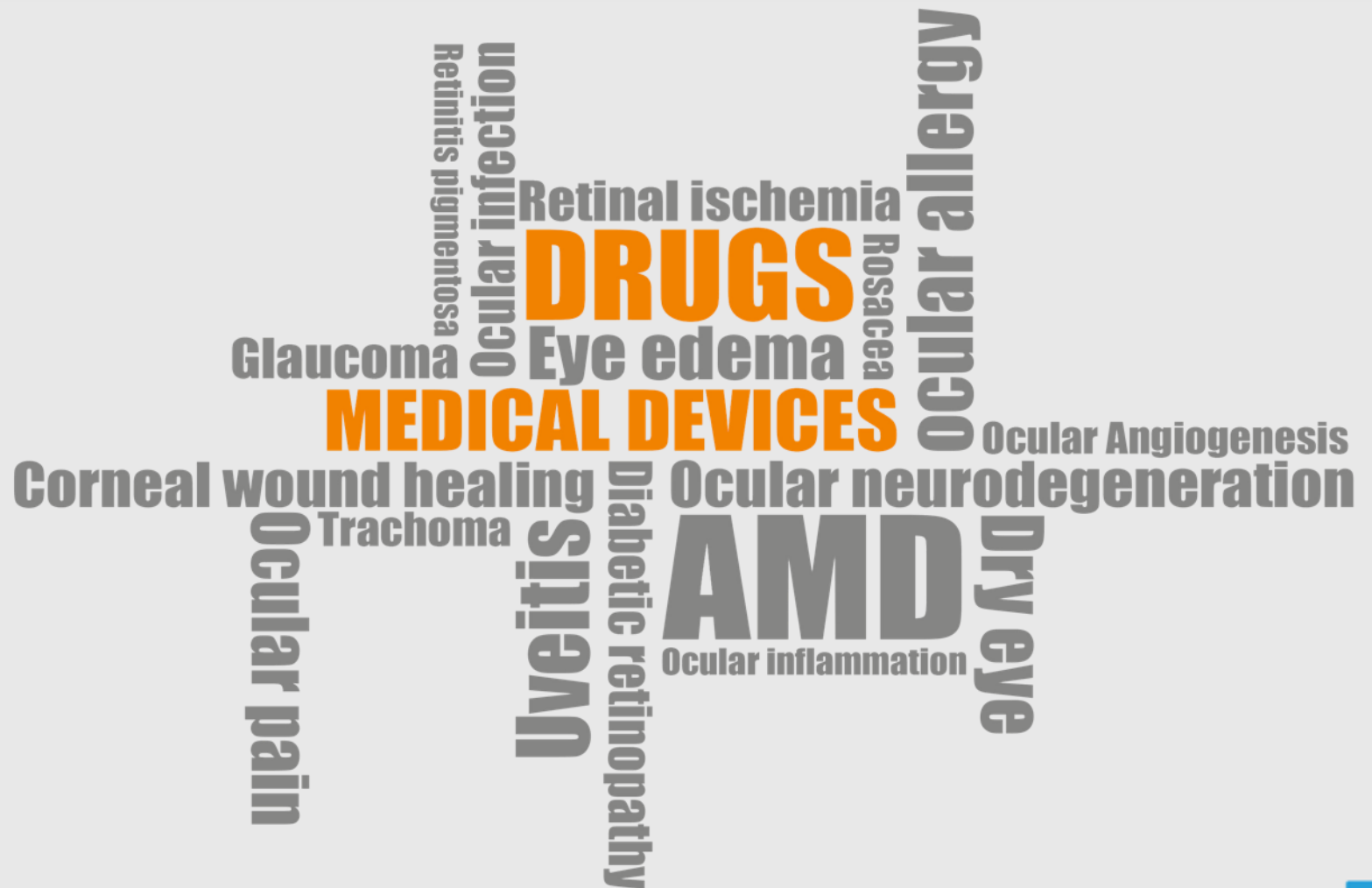


OUR SOLUTIONS



A Comprehensive Ocular Expertise

From the Surface to the Posterior Segment of the Eye





An Answer for Your Ocular Challenges

ON DEMAND
STUDIES

PRECLINICAL
PACKAGE
INCL. TOX

CLINICAL TRIALS

FULL
DEVELOPMENT
PROGRAM

REPURPOSING

CUSTOM
(R&D SUPPORT
SERVICES)

PROOF OF
CONCEPT

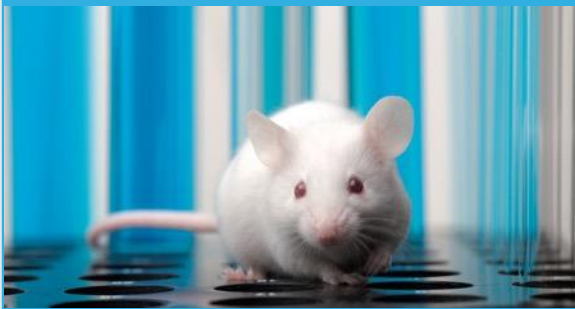
CONSULTING



Expert Services

PRECLINICAL SERVICES

- Animal models
- Preclinical ocular formulation (non-GMP)
- Ocular surgery
- Micro-dissection



CLINICAL SERVICES

- Project management
- Study monitoring
- Site management
- Data management, biostatistics
- Medical writing
- Pharmacovigilance
- IP management
- Regulatory affairs



INNOVATIVE TECHNOLOGY PLATFORM & TECHNIQUES

- Bioanalytical testing services
- Ocular histology
- Cellular & molecular biology assays (i.e. biomarker identification or quantification)
- Central laboratory services



CONSULTING SERVICES

"Step by step" consulting services, strategic & global drug development consulting services, experts meeting organization, training



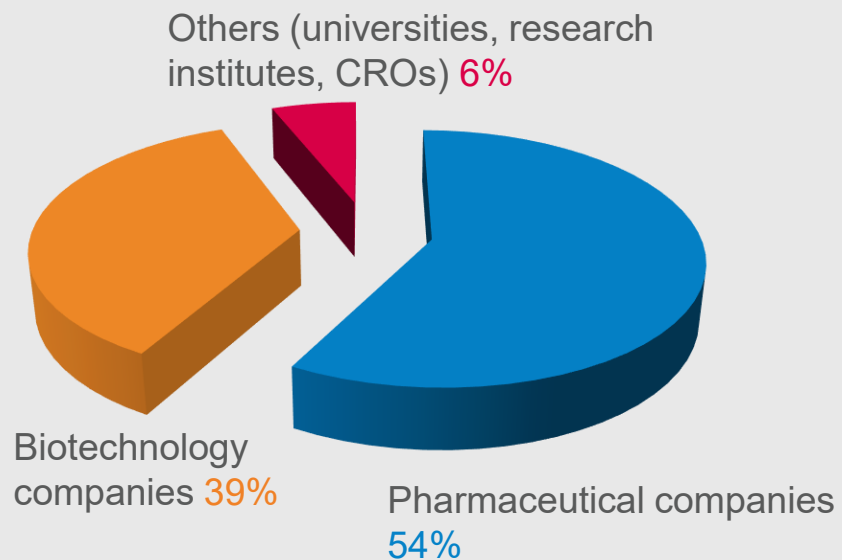
A World-Class Service Provider



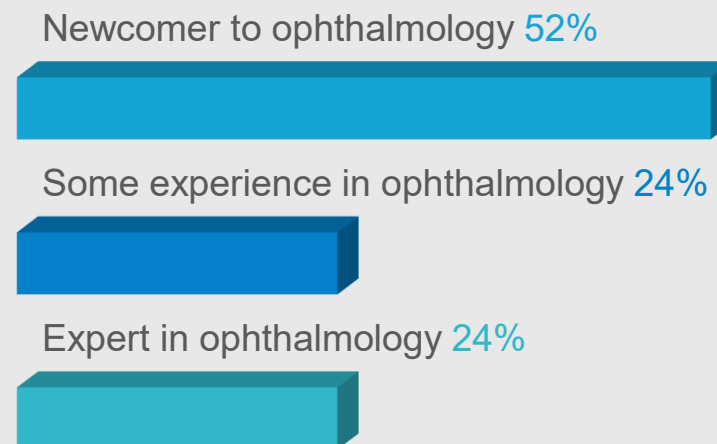


A Wide Array of Clients

COMPANIES BY SEGMENT



COMPANIES BY EXPERIENCE





OUR ASSETS

An Experienced & Dedicated Staff at your Service

Experts and
qualified staff
on board

Ophthalmologist, Pharmacist, Veterinarian, Histopathologist,
Pharmacologist, Ophthalmology Research Scientist

Experienced
team

A total experience of 400+ years in ophthalmology

Regular
training

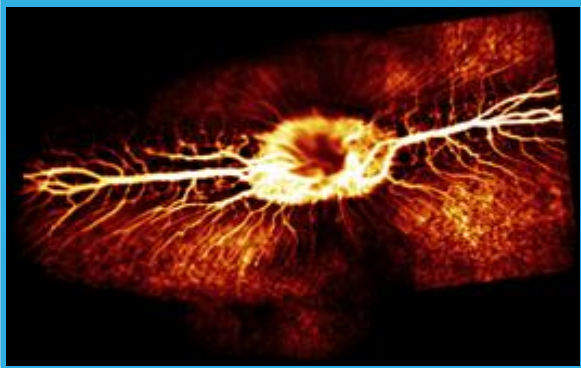
- GLP, GCP, GCLP
- Ocular microsurgery
- Ocular microdissection
- Medical training



On a Perpetual Quest for Scientific Excellence

LAB EQUIPMENT

- A unique small animal facility dedicated to ophthalmology
- A state-of-the-art ocular technology and scientific equipment



DEVELOPMENT

- An active department dedicated to animal model development
 - Very promising formulations developed in-house for application in animals



SCIENTIFIC EXCELLENCE

- Attendance to the most important ophthalmology meetings and training programs
 - Active member of prestigious associations (ARVO, AAO, SFO, EVER, etc.)
- Posters and papers in international ophthalmology meetings and journals



Key Relationships and International Network of Experts

A well-established network of internationally renowned ophthalmologists and investigative sites



Membership in regulatory and quality assurance associations (EUCROF, SOFAQ, GCP news...)



Privileged contacts with international opinion leaders and experts in ophthalmology and pharmacology



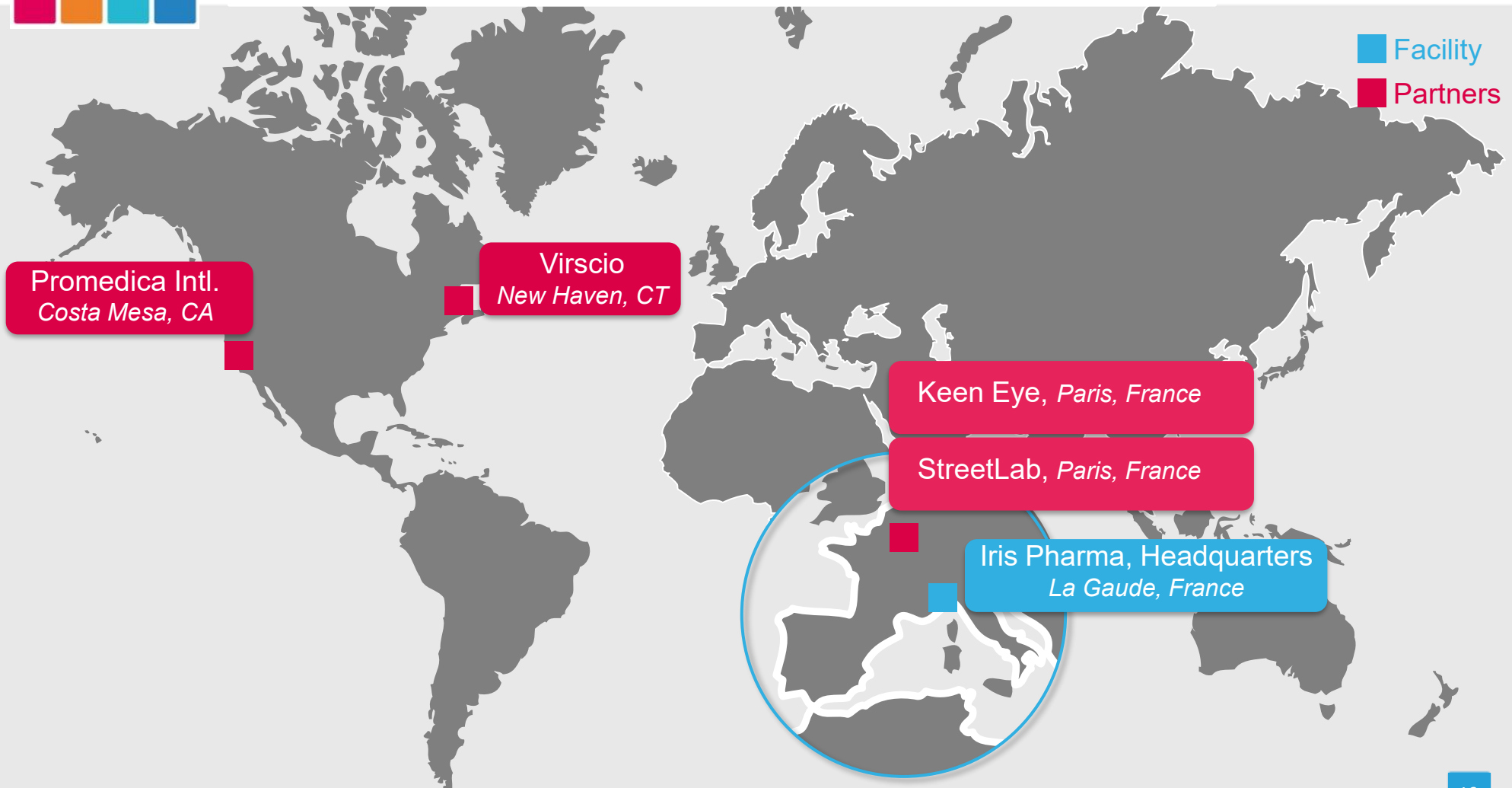
Expert partners in medical writing



An international network of local regulatory consultants



Well-Established Partnerships Worldwide





A Quality Policy Delivered Consistently and Successfully

- Studies conducted in accordance with GLP, GCLP and GCP
- Continued compliance with relevant regulatory requirements
- Robust internal audit program and management review process
- Routine inspections and renewal of certifications

	1995	1997	1999	2001	2002	2004	2006	2007	2008	2009	2010	2012	2014	2016	2019	2021	2022
Statement of compliance with GLP (ANSM or COFRAC inspections)	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•
Animal housing authorization (DSV or DDPP inspections)					•	•					•			•			•



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH



ansm
Agence nationale de sécurité du médicament
et des produits de santé





Committed to Continuous Improvement and Customer Satisfaction

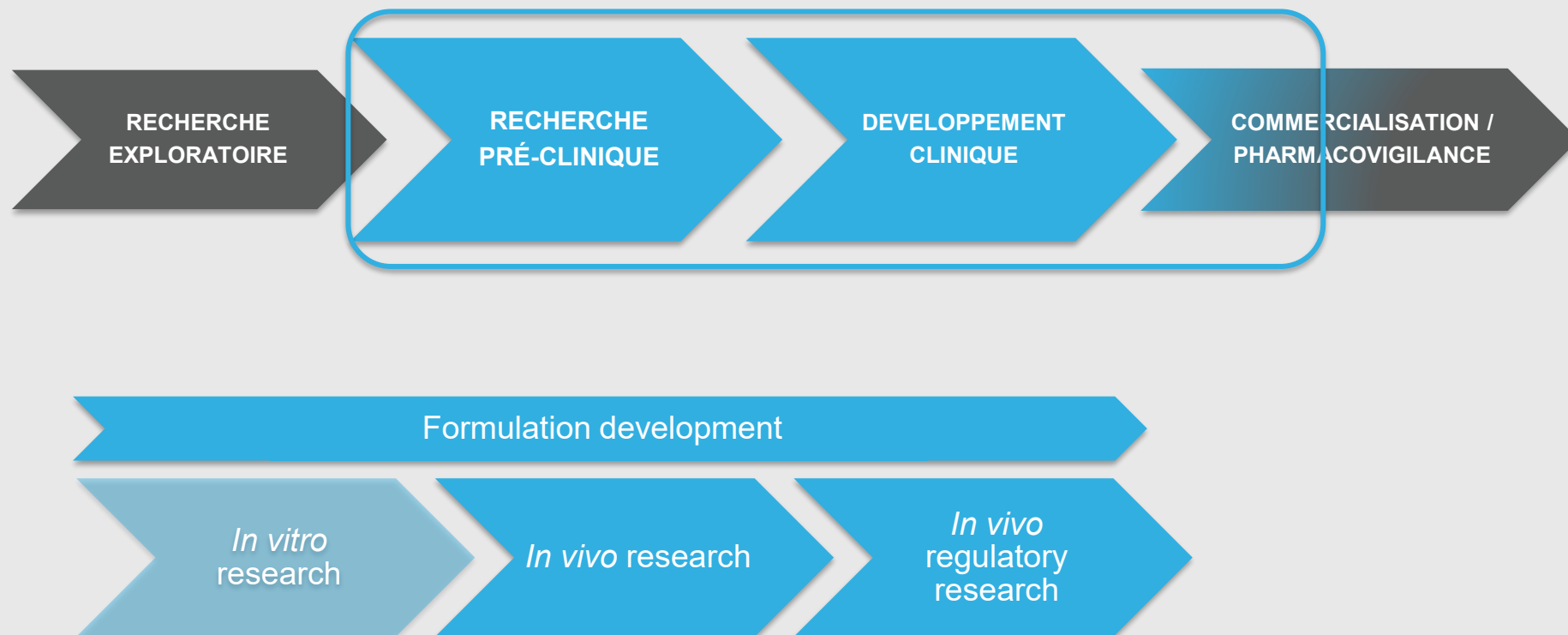




FOCUS ON PRECLINICAL SERVICES



Preclinical Services Overview



-  Services provided by Iris Pharma
-  Services not provided by Iris Pharma



BIOANALYTICAL TESTING

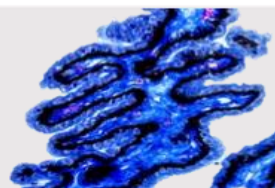
Bioanalytical method development & validation in a variety of ocular matrices

Main Kind of Preclinical Studies



PHARMACOKINETICS

Ocular Pharmacokinetics



SAFETY & TOLERANCE

Safety

- Corneal anesthesia
- Lacrimation
- Pupillary diameter

Ocular tolerance

- Acute tolerance
- [sub-] chronic tolerance



EFFICACY

Ocular hypertension
Ocular allergy
Ocular inflammation
Corneal wound healing
Retinal ischemia
Retinal degeneration
Diabetic retinopathy and related (DME...)
Angiogenesis
Dry eye syndrome
Ocular pain
Eye discomfort
Ocular irritation



A Broad Preclinical Experience

Ocular Efficacy



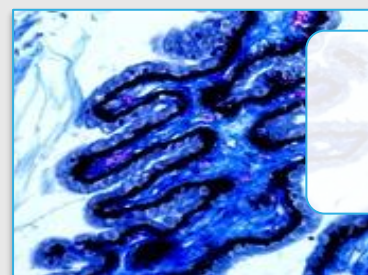
1,200+

Ocular Tolerance &
Safety Assessment



550+

Ocular
Pharmacokinetics



600+

Bioanalytical Testing
Services



250+

Non GMP Preclinical
Ocular Formulation



50+

Consulting &
Development Plan

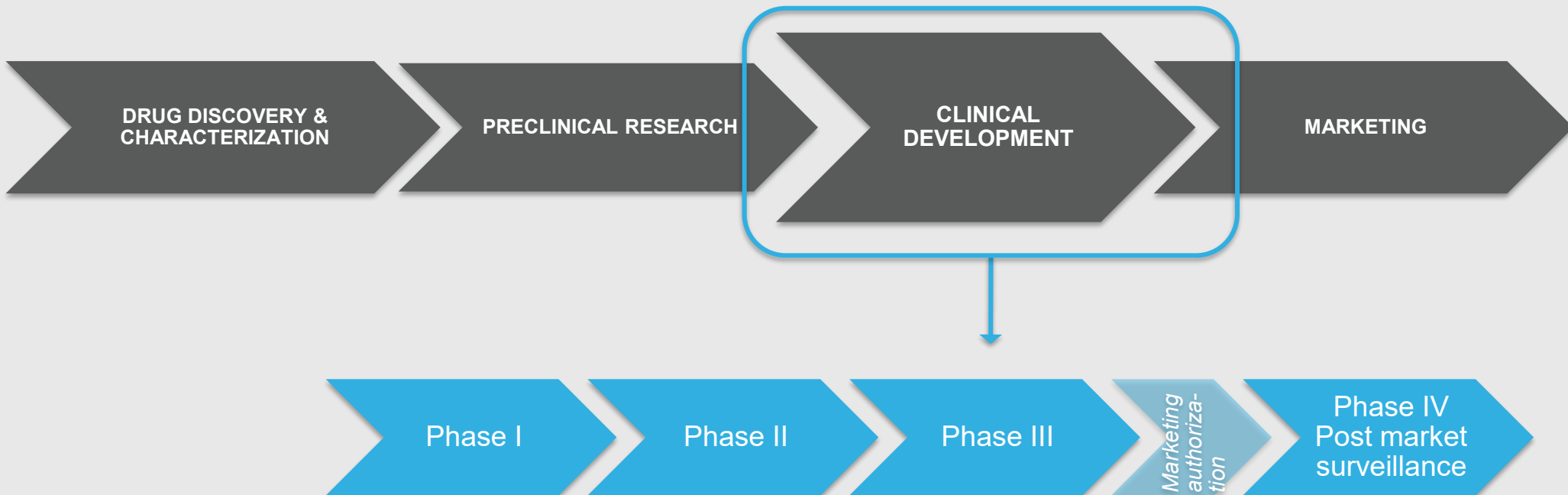




FOCUS ON CLINICAL SERVICES



Full Clinical Services



- Services provided by Iris Pharma
- Services not provided by Iris Pharma



Clinical Services Capabilities



Regulatory Affairs



Clinical Study Management



Project Management



Data Management & Biostatistics



Pharmacovigilance



Medical Writing



Central Laboratory Services



Consulting



A Documented Clinical Experience



PRODUCTS

Drugs	85
Medical devices	42
Others	3



KEY THERAPEUTIC AREAS

Dry eye syndrome	38
Glaucoma	37
Ocular inflammation	17
Ocular infection	15
Visual acuity/Cataract	13
Retinal disorders	5
Anesthesia	2
Ocular allergy	1
Uveitis	1
GVHD	1



CLINICAL TRIAL PHASES

Phase I	29
Phase II	22
Phase III	38
Phase IV	21
Medico-marketing	18
Investigator driven	2



COUNTRIES

Western Europe
Eastern Europe
North Africa
North America*

* partner

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