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Special Advertising Report: CROs

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Iris Pharma: An Ophthalmology-focused CRO

In 1989, as the market for contract research organizations (CROs) was beginning to expand, a new player entered the field: Iris Pharma. Founder and CEO Pierre-Paul Elena, PhD, launched the company near Nice, France, offering preclinical studies in ophthalmology throughout Europe.

Elena himself had begun working in ophthalmology years earlier as a research officer at Laboratoires Dulcis-Allergan, a company producing ophthalmic prescription drugs. His research involved looking for receptors in the eye, and in this role, he saw a need for helping companies develop compounds and medical devices.

Iris Pharma's CEO Pierre-Paul Elena, PhD

When founding his own CRO, Elena chose to continue his work in this niche market, recognizing the importance of specialization. "My feeling is that you cannot offer all things to all companies," he explains. "I prefer to be focused on the eye because our employees know the eye very well. We have based the company from the beginning on the science and the services in ophthalmology."

Today, Iris Pharma has grown to 60 employees that have assisted customers in carrying out nearly 2,100 preclinical studies and 95 clinical trials and marketing surveys in ophthalmology in the past two decades. Iris Pharma works with clients from in vivo research through clinical testing, in addition to offering bioanalytical testing, preclinical formulation, ocular histopathology and consulting services.

"I think that Iris is probably the only CRO dedicated to ophthalmology from the first application in the laboratory to a Phase IV clinical trial in humans," Elena says. All services are in support of the company's mission to advance ocular health and ultimately benefit the lives of patients.

Iris Pharma, which refers to its customers as "partners," aims to help them move as efficiently and effectively as possible from the laboratory to the market, all while maintaining their values of service, quality, innovation and integrity. The CRO now works with more than 230 biotechnology and pharmaceutical companies from around the world, including Australia, New Zealand, Japan and China, as well as countries in North America.

Partners — which range from small start-ups to industry-leading pharmaceutical companies — include three types: those that have devoted

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Trends for the future

The clinical research environment has been changing over the past five years. Most drug developers are finding that by teaming with contract research organizations (CROs), they can more effectively and efficiently maintain the type of development strategy required to stay competitive.

Recent market studies and industry leadership panels have indicated:

- The number of research centers conducting clinical studies is declining. Among the 60 most active investigative sites in the US and Canada, the average number of new clinical studies initiated dropped 85% in the last five years. (CenterWatch, January 2012)
- 80% of large pharmaceutical companies are in the process of restructuring or have already restructured to outsource more clinical research to CROs. (William Blair, 2011)
- More than $100 billion is spent worldwide on global pharmaceutical R&D outsourcing, which is more than five times the figure that financial analysts have estimated. (Tufts Center for the Study of Drug Development R&D Management Report, October 2012)
- Increasingly, pharmaceutical companies are favoring – and CROs are carrying out – adaptive clinical trials, in which early findings result in changes to a study to decrease development time and costs, as well as improve the usefulness of the data gathered. (*Tufts CSDD R&D Management Report*, February 2012) ■

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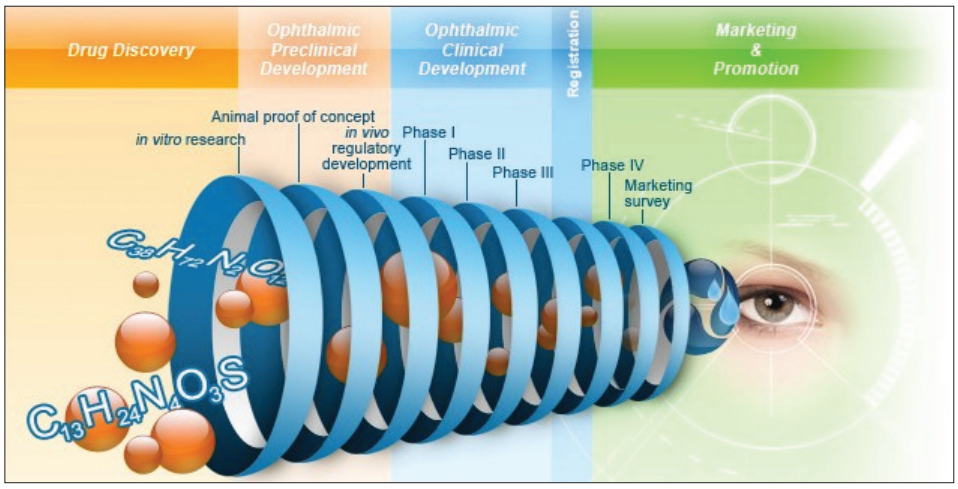
decades to work in ophthalmology; those that are newly interested in tackling the challenges of an aging population and an increasing prevalence of diabetes; and those in outside fields, such as oncology, who are looking to apply their work in areas such as neovascularization to ophthalmology.

"Our services are customized to the needs of a particular partner," Elena explains. "We are quite flexible."

Iris Pharma's areas of ocular expertise include:

- Age-related macular degeneration
- Diabetic retinopathy
- Neurodegeneration
- Retinal ischemia
- Glaucoma
- Dry eye
- Conjunctivitis
- Uveitis
- Ocular infection, inflammation and allergy
- Ocular pain and surgery
- Corneal wound healing
- Cataract



The CRO often works with partners who have ideas for drugs or devices, but are lacking the resources to bring these concepts to fruition. "We help them move from an idea to proof of concept, and then on to the development phase," Elena explains.

To date, Iris Pharma has developed more than 40 customizable animal models to test medical devices and drugs. For clinical studies, more than 24,000 patients and 3,700 clinical sites have been involved throughout Europe, North Africa, India and North America.

"We have been in this field for a long time, so we have the ability to think about humans when we are testing compounds in the laboratory," Elena says. "This is important because we're not here to end with laboratory studies – we're here to help our partners move as quickly as possible into patients. More and more people are coming to work with us for this global strategy and global development." ■

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