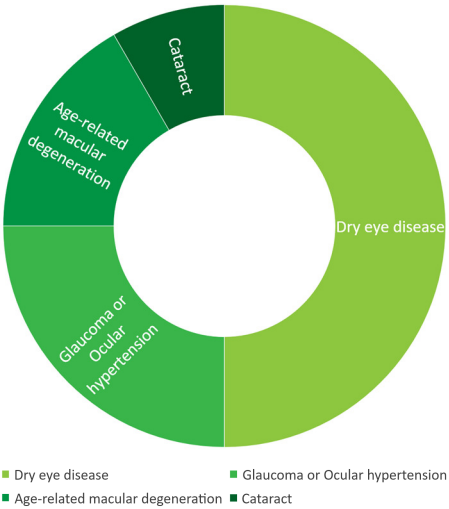
Ophthalmology
Clinical Trial Solutions in Europe

Pharmnet expertise

Ophthalmology is an area of strong competence for the Pharmnet team having completed 12 studies in this therapeutic area. This includes phase II, III and IV clinical trials as well as clinical investigation of medical device and medical writing. Over 600 screened subjects participated in these studies which comprised a variety of indications as outlined below.



Through ongoing relationships with Key Opinion Leaders in the Central European region (mainly, but not limited to, the Czech Republic, Slovakia, and Hungary), we have excellent connections to the sites and the community. We can also provide access to sites throughout Europe. Central and Eastern Europe have robust national patient databases. This, combined with the region's excellent medical infrastructure, makes it ideal for an ophthalmology study. Depending on the indication and severity of the disease, patients with ophthalmology diseases are managed at various levels of medical facilities (patients are treated in local private ophthalmology ambulances, large private ophthalmology clinics, and specialized centers within hospitals). We can propose the most efficient allocation of clinical sites across countries for a given protocol design because we have access to these sites and patients, as well as detailed knowledge of patient management standards. This ensures that patient recruitment is efficient and successful.

Why conduct a clinical trial with us?

We have intimate knowledge of the local regulatory requirements. We are experts in organizing ethics committee / IRB reviews, handling standard-of-care variations, navigating site contract requirements, and bridging language differences.

We can provide all necessary safety support, including safety data visualization, and clinical safety monitoring and reporting.

To further strengthen our offering, we have partnered with DP Clinical, a US-based full service CRO partner with extensive ophthalmology experience, both in-house and through KOLs, and access to U.S. sites if needed.

If your protocol requires uniformity of measurements (e.g., visual acuity assessed by ETDRS) and consistency across clinical trial sites (e.g., fluorescein angiography imaging, optical coherence tomography (OCT), OCT angiography), Pharmnet can arrange specific certification as well as central imaging reading through established providers.

We maintain a diagnosis-oriented approach in doing a top-line feasibility for selected countries. We present an executive summary of results for a specific pathology/protocol and propose scenarios to help our clients choose an optimal study solution in terms of study realization speed and cost. Some examples of basic characteristics for a few selected diagnoses follow. The Pharmnet team would be delighted to provide you with a more in-depth analysis of the pathology that is the focus of your next clinical development program.

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Key figures in ophthalmology in Europe

Since many eye diseases are age-related, the number of patients with reduced vision and blindness is expected to rise in European countries as a result of the current increase in life expectancy. It is estimated that 1.28 million blind people in the EU are more than 50 years old, with a further 10 million living with reduced vision. Four-fifths of cases of blindness can be prevented or cured. Age-related macular degeneration (AMD), glaucoma, cataract, and diabetic retinopathy are the most frequent causes of blindness in Europe. Furthermore, there are other ocular diseases, such as dry eye disease (DED), that are very common, have a very negative impact on patients' quality of life and are associated with an economic burden.

AMD is a progressive degenerative disease of the retina. There are currently 67 million people in the EU affected by AMD, with this figure expected to rise by 15% by 2050. AMD is classified into three stages: early, intermediate, and late. Late AMD is subdivided into two types: a more common wet form, which is characterized by choroidal neovascularization, and a dry form which is characterized by geographic atrophy of the retinal pigment epithelium. Only the wet form can be treated with anti-vascular endothelial growth factor agents. An anti-VEGF drug is injected directly into the vitreous body of the eye in this type of treatment. Patients with AMD are referred to specialized private ophthalmology clinics or hospital centers for diagnosis confirmation and treatment. Treatment with intravitreal injection of anti-VEGF agent is the standard treatment in European countries but it is also costly and associated with significant complications. Patients must meet specific entry criteria in order for the treatment to be covered by the public health system. As a result, many patients are ineligible for treatment, or they must pay for it themselves.

Glaucoma is a multifactorial optic neuropathy that is the leading cause of blindness. Glaucoma affects approximately 76 million people, with that figure expected to nearly double by 2040. In Europe, the prevalence of glaucoma is 2.93% among persons aged 40 to 80 years. The treatment includes topical drugs to lower the intraocular pressure, laser therapy, and glaucoma surgery. Patients with early-stage glaucoma are often cared for by local ophthalmologists. Patients with more complex forms of glaucoma or with advanced changes in visual functions are treated in specialized centers within hospitals.

Cataract, a dense, cloudy area that forms in the lens of the eye, is a multifactorial disease associated with age, female sex, genetic predisposition, smoking and other factors. Although cataract is almost always curable by surgery, it is still the leading cause of visual impairment worldwide. In Europe, the number of cataract surgeries per 100,000 population ranges from 1,725 in Latvia to 268 in Ireland.

DED is caused by decreased tear production, excessive tear evaporation, or both of these processes and it can lead to damage to the cornea and conjunctiva. The symptoms such as irritation, burning and visual disturbance have negative impact on the patient's quality of life. The prevalence rate ranges from 5% to 33%, with women being the most affected. Patients with mild to moderate disease are often managed by local ophthalmologists, whereas patients with moderate to severe DED are referred to specialized centers within hospitals. Artificial tears are typically used to treat patients with mild DED. For patients with moderate to severe DED, treatment options include topical anti-inflammatory drugs (such as cyclosporine), oral or topical antibiotics, autologous serum eye drops, punctal occlusion, and scleral contact lenses.