

We Understand the Challenges of Researching Ophthalmic Disease



Thanks to an aging world population and increase in comorbid diseases, ophthalmic disorders are on the rise. Not only do they present a huge burden to society, the associated healthcare costs are significant. Which is why the search for new treatments is more important than ever. However, the very nature of ophthalmic diseases means that they are particularly difficult to research. The eye has a complex anatomy that can be affected by a wide range of disorders. For example, diabetes and some CNS conditions can affect ocular health, which means that patients' eligibility for trials may be compromised by contraindicated medications. Sight-threatening conditions are diagnosed and treated very quickly, so finding and recruiting treatment-naïve patients can be extremely difficult.

What's more, investigative sites for ophthalmology trials have to offer a wide range of specialized equipment (for example, OCT, fundus photography, fluorescein angiography, microperimetry, fundus autofluorescence and ETDRS BCVA assessment) as well as highly trained people to operate it. In addition, all imaging techniques and equipment has to be certified by central reading centers.

So what does this mean for companies looking to research new treatments for ophthalmic diseases? A patient population that's difficult to recruit, combined with increasingly focused inclusion/exclusion criteria and the need for in-depth ophthalmic expertise, means that you need a CRO with real therapeutic alignment, long-standing site relationships, disease-specific experience and appreciation of the logistical set-up and conduct of ophthalmology studies.

We're highly specialized and therapeutically aligned. Developing treatments for patients with ophthalmic diseases requires an unusually high level of disease-specific knowledge as each disorder has its own etiology.

At Syneos Health™, we've built our entire organization on therapeutic alignment. No matter which therapeutic area we work in, the teams we put in place are always specialized in that discipline. We are unique in that we have full-time ophthalmologists who act not only as subject-matter experts and consultants but also provide medical expertise across all our ophthalmology trials, which is rare within a CRO. Our Ophthalmology team focuses solely on this therapeutic area and has unrivaled trial experience. From the people on the ground to those running operational logistics, and right up to senior management, you will always be dealing with someone who knows your therapeutic area and exactly what you need.

Our Ophthalmology Trial Experience Since 2010

33 Phase I to IV studies completed, 1,441 investigative sites involved, over 11,000 patients recruited for Ophthalmology trials in:

- Ocular hypertension/glaucoma
- Neovascular age-related macular degeneration
- Geographic atrophy
- Cataracts
- Branch retinal vein occlusion
- Dry eye/ocular surface disease
- Ocular infection and inflammation
- Diabetic retinopathy
- Diabetic macular edema
- Contact lenses
- Ocular implants and prostheses
- Autoimmune disease (Sjögren's syndrome)
- Oxidative stress and inflammation
- NAION

We've Worked With the Sites You Need for Years

We've always fostered exceptionally close working relationships with our investigative sites, which means that we know investigators and site staff well enough to make sure they're all following your protocol consistently. This is especially important given that satisfying stringent inclusion/exclusion criteria and quantifying ophthalmic disorder status requires highly specialized input. Site feasibility is another vital aspect of researching ophthalmic disorders. Do sites have the right equipment? Is it up to date? Is staff regularly trained? By staying connected with sites and constantly updating our databases, we know precisely which sites are ready for your trials and so can greatly reduce the required amount of study feasibility work, reducing time and costs. Our Ophthalmology team provides regular CRA training, and if some of your sites need extra support, we'll provide it. Our Psychometric Review Team and our well-established investigator and site staff certification programs, tailored to your target indication, serve to ensure your protocols are implemented consistently everywhere.

At Syneos Health we understand the logistics of setting up ophthalmology studies. We have worked with the leading fundus photography reading centers in North America and Europe in the evaluation of 3- and 7-field fundus photography, fluorescein angiography, optical coherence tomography (anterior and posterior segment) and indocyanine green. We understand that the logistics of imaging and BCVA by ETDRS methodology certifications are essential components to ensure credibility of study endpoints. They also can be the rate limiting step to efficient study startup. We therefore aim to work with your investigators and the reading centers to ensure efficient and timely certification, by identifying the potential for "grandfathering" and motivation of photographers and BCVA technicians.

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We Find the Right Patients for Your Study

Recruiting patients whose biggest fears can be blindness or treatment side effects requires a unique skill-set. From rare genetic conditions, such as Stargardt disease or retinitis pigmentosa, to diseases with worldwide impact like AMD, diabetic retinopathy and glaucoma our full-time Patient Recruitment Team understands exactly how patients with ophthalmic diseases feel. We maintain a range of specialty population databases so that the patients your sites are enrolling exactly meet your inclusion/exclusion criteria. We use recruitment materials tailored specifically to people with poor vision. We know how to help sites find patients in situations where overt recruitment is not an option. And we've created a metrics-based toolbox that helps us look at the broader recruitment picture—for example, in many ophthalmic diseases we need to attract and recruit patients' caregivers, be they relatives or professional carers. Our Clinical Surveillance Team is focused purely on working closely with sites, and reviewing pre-randomized patient data and videos to ensure that only the right patients end up taking part in your studies.

For more information about Syneos Health's ophthalmic disease capabilities, please contact us on one of the telephone numbers below:

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About Syneos Health

Syneos Health™ (Nasdaq:SYNH) is the only fully integrated biopharmaceutical solutions organization. Our company, including a Contract Research Organization (CRO) and Contract Commercial Organization (CCO), is purpose-built to accelerate customer performance to address modern market realities. Created through the merger of two industry leading companies – INC Research and inVentiv Health – we bring together more than 21,000 clinical and commercial minds with the ability to support customers in more than 110 countries. Together we share insights, use the latest technologies and apply advanced business practices to speed our customers' delivery of important therapies to patients. To learn more about how we are shortening the distance from lab to life™ visit SyneosHealth.com.

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