

# Ophthalmology

Collaborate with our dedicated team of experts, offering strategic leadership and tailored support for your Ophthalmic disease clinical trials.

Emmes' Ophthalmology team harness more than 35 years of clinical development expertise, spanning work in both public and private sectors. We provide full-service support across all phases of clinical development, leveraging deep experience in age related diseases, rare and orphan diseases, as well as cellular and gene therapies.

Emmes has formed a strong ophthalmic network through long-standing relationships with many retina clinical trial sites and investigators. We decrease study start time and allow participants to receive potential therapeutics on an abbreviated timeline.

## Modernizing clinical research with tech & AI

At Emmes we are modernizing and automating clinical research across the full spectrum of clinical trial activities to operate faster, more efficiently, and with higher quality. We are the industry's first native digital and Al specialty CRO built on a proprietary technology and Al platform.

## **Services Offerings**

Protocol Development and Navigation

Clinical Trial Management

Site Management and Monitoring

Data Management

Quality Assurance

Pharmacovigilance

Biostatistics and Bioinformatics

Global Regulatory Affairs



Fact Sheet

## What sets us apart?

#### Benefits of our services

**35+ year history** - in ophthalmic research. Across both government clients, including the National Eye Institute (NEI) and beyond NEI-sponsored grants, with 30+ biopharma sponsors and 2 Al diagnostic clients.

**Breadth of experience -** involved in 150+ studies in the last 5 years across all major ophthalmic research areas including age-related macular degeneration, uveitis, diabetic retinopathy, glaucoma, dry eye and ophthalmic devices.

**Non-standard studies -** Emmes' ophthalmic research experience spans multiple types of interventions, including leading AI/ML capabilities in diagnostics, supporting innovative trial design and execution with small patient populations and trial rescue in stem cell.

**OptymEdge** - Emmes is the largest and longest-standing provider of certification and training for visual functions in the industry supported by OptymEdge, enabling optimal trial design, site setup and trial outcomes.

## **Highlights Include**

**NEI Partnership** - Emmes is a key partner for the NEI with 150 sponsored projects since 1987, providing statistical and clinical coordinating, alongside monitoring activities to maintain support for ongoing and upcoming research.

**Rescued suspended gene therapy program -** Emmes engaged for deep biostatistical ophthalmic expertise, applying advanced data visualizations for safety monitoring insights that allowed the sponsor to identify and address safety issues. As a result, the FDA lifted the clinical hold on the program.

First autonomous AI screening tool - Supported the first FDA DE Novo cleared autonomous AI system for diabetic retinopathy. Our partnership in this pivotal trial led to FDA marketing approval of IDx-DR (Now LumineticsCore) in 2018 – the first device authorized for marketing that does not require a clinician to interpret results.

**Innovative trial design -** Designed a statistical model that leveraged bilateral data, pre, and post-treatment while utilizing historical data as a control. This allowed for study continuation following an issue with placebo manufacturing.

**AREDS and ARED2** - Coordinating Center for these studies resulting in OTC AREDS vitamins and leading to 90+ co-authored peer-reviewed manuscripts and 119 Conference presentations.

For additional information on our Ophthalmology services, please visit www.emmes.com

## **Key Statistics**

150+

Studies over last 5 years

1400+

Patients enrolled to date

7

Pivotal trials

30+

Biopharma clients

140+

Active OptymEdge trials

