Ophthalmology

Emmes' ophthalmic experience spans to over 150 clinical studies, over half of which were in phases 1 or 2. Driven with purpose to conduct clinical research impacting human health and public policy, our ophthalmic team has provided full scope clinical trial support of retinal ophthalmic research studies and contributed to the testing of innovative therapeutic solutions for over 35 years.

This support has spanned trials for age-related diseases, rare and orphan diseases, and cellular and gene therapies. Emmes' heritage, focused on ophthalmic public health, means that our clinical research professionals often join our clients with a desire to make a difference for participants, by advancing research that may provide new therapeutics to those suffering from ophthalmic diseases.

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

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Highlights Include:

Serving as the Statistical and Data Coordinating Center (SDCC) and the Contract Research Organization of record for investigator-initiated trials at the National Eye Institute (NEI) for over 25 years.

Served as the full scope Coordinating Center for the SCORE and SCORE2 studies, as well as the AREDS and AREDS2 studies - resulting in AREDS vitamins.

Emmes provided and continues to provide full-service support to the Macular Telangiectasis (MacTel) project. The project has included support for a natural history observation registry, as well as Phase 1 and Phase 2 studies for a potential treatment for MacTel. Additionally, the project has started two additional protocols, funded by a biotechnology company, and a BLA submission is expected in 2022.

Since 2010, Emmes has been the full-service provider for a first-in-human gene transfer study in AMD for a biotechnology company. Additionally, since 2014, Emmes has been the full-service provider for two first-in-human gene transfer studies in Stargardt's Disease and Usher's Syndrome for a large biopharma company.

Recently, Emmes was awarded a contract with a biotechnology company to provide full-service support for a first-in-human RPESC-derived RPE Transplantation as potential therapy for dry AMD.

Full scope support includes:

- Protocol Development and Navigation
- Statistical Design and Analysis Support
- Site Management and Monitoring
- Regulatory Support
- Data Management
- Pharmacovigilance
- Electronic Trial Master File Support
- Data Safety and Monitoring Board (DSMB)

Key Facts:

Execution of over 100 contract officer approvals for over 50 subcontractors, consultants and ophthalmic equipment and supply vendors, specifically consultants and equipment for the ophthalmic studies.

Coordination of several first-in-human and rare disease protocols for over 10 small and large biopharma companies.

Co-authored more than 85 peer-reviewed manuscripts and more than 120 conference presentations to disseminate study findings to the scientific community for the AREDS studies.

Co-authored more than 40 peer-reviewed manuscripts and more than 60 conference presentations to disseminate study findings to the scientific community for the SCORE studies.

For additional information on our Ophthalmic Therapeutic Research Unit, please visit:
www.emmes.com/ophthalmology

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