# Registries in ophthalmic diseases: Their development and use in research

# Course organizers

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# Presentations

Presenters and presentations may change.

| **Time** | **Topic** | **Speaker** |
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| 1-1:20pm | Tools for setting up a registry in age-related macular degeneration | **Organizer and Speaker: Anne Lynch MB, BCH, BAO, MSPH**  Professor of Ophthalmology  Director Division of Ophthalmic Epidemiology  Department of Ophthalmology  University of Colorado School of Medicine  Secondary appointment: Colorado School of Public Health  <https://medschool.cuanschutz.edu/ophthalmology/research/ophthalmic-epidemiology> |
| In this presentation, the key steps of how to set up a registry/database will be reviewed. The presentation will also discuss how to conduct quality research from an existing registry/database and the challenges associated with the use of an existing database/registry. An overview of the use of longitudinal and biomarker data will be discussed and also our experience of how to add modules to a registry in order to continue to build and advance the utility of the registry. | | |
| 1:20- 1:40pm | Building out research questions using a registry | **Organizer and Speaker: Jennifer Patnaik, PhD**  Assistant Professor of Ophthalmology  Lead Epidemiologist, Division of Ophthalmic Epidemiology  Department of Ophthalmology  University of Colorado School of Medicine  Secondary appointment: Colorado School of Public Health  <https://medschool.cuanschutz.edu/ophthalmology/research/ophthalmic-epidemiology> |
| Dr. Patnaik will share experience and tips on utilizing an existing registry and surveillance databases for research. In addition, she will focus on building upon existing registry data, with the primary focus on expanding research possibilities. Various options of how to expand registry databases will be discussed, in addition to key strategies of how to best create additional databases. She will address challenges and pitfalls experienced thus far and how to best prepare for and problem-solve potential issues. | | |
| 1:40-2:00pm | Registry database design and considerations: a statistician’s perspective | **Brandie Wagner, PhD**  Associate Professor of Biostatistics and Informatics  Lead Statistician, Division of Ophthalmic Epidemiology  Department of Ophthalmology  University of Colorado School of Public Health  <https://medschool.cuanschutz.edu/ophthalmology/research/ophthalmic-epidemiology> |
| This talk will cover best practices for designing registry databases and will include variable types, naming conventions, capturing longitudinal information and linking ancillary data. These topics will be covered from the perspective of aiding future analyses, tracking changes to the registry and to allow for flexibility in changes in clinical practice and disease definitions over time. | | |
| 2:00-2:20pm | Save Sight Registries | **Mark Gillies,**MB BS, PhD  Professor  Faculty of Medicine and Health  Clinical Ophthalmology and Eye Health  Save Sight Institute  <https://www.sydney.edu.au/AcademicProfiles/profile/resource?urlid=mark.gillies&type=cv> |
| In my presentation I will discuss the development of the Save Sight Registries, which provide uniquely high quality data by tracking internationally agreed minimum, patient-centered treatment outcome sets with mandatory fields. The flagship module, Fight Retinal Blindness!, has tracked outcomes of intravitreal injections for 15 years. Issues we have addressed include privacy, user engagement and issues associated with analysis of ophthalmic real world data. Greater global consensus on the standard minimum data to collect for treatment outcomes of ophthalmic diseases would add value to analyses. Development in this field will include interoperability with other clinical and imaging datasets for seamless transfer of high quality clinical data for analysis and AI-driven insights from these large datasets. | | |
| 2:20-2:35pm | Panel discussion |  |
| Open discussion with the previous speakers. | | |
| 2:35- 2:50pm | Break (15 minutes) |  |
| 2:50-3:10pm | Registries in retinopathy of prematurity and other pediatric eye diseases | **Emily McCourt, MD**  Associate Professor of Ophthalmology  University of Colorado School of Medicine  The Ponzio Family Chair for Pediatric Ophthalmology  Chief of Pediatric Ophthalmology, Children's Hospital Colorado  <https://som.ucdenver.edu/Profiles/Faculty/Profile/19817> |
| I will discuss the benefit of registries in retinopathy of prematurity and other pediatric eye diseases. I will review the clinical and research benefits of having robust pediatric databases in your practice. I will review some examples of how having pediatric eye disease databases have helped strengthen our clinical and research programs. | | |
| 3:10- 3:30 pm | The Pearls and Perils of Investigating Rare Neuro-Ophthalmic Diseases of Childhood | **Robert Avery, DO, MSCE**  Associate Professor of Ophthalmology and Neurology  Perelman School of Medicine  University of Pennsylvania and  Division of Ophthalmology  Children's Hospital of Philadelphia  [My Bibliography - NCBI (nih.gov)](https://www.ncbi.nlm.nih.gov/sites/myncbi/1NA2J8AQCJl5J/bibliography/41750946/public/?sort=date&direction=ascending) |
| Natural history studies and registries are an efficient way to improve the management of relatively rare conditions. Two recent prospective longitudinal studies highlight the challenges and successes of executing multi-center registries of rare pediatric neuro-ophthalmologic diseases. We will discuss how factors including sponsor support, sub-contracts, IRB approval, enrollment criteria, data complexity, site engagement, subject confidentiality, and inter-department collaboration all impact study outcomes. Specific examples of downstream benefits from registries and natural history studies (i.e., improved clinical care; historical controls for future trials) will be provided. Lessons learned and recommendations for optimizing study success will be discussed. | | |
| 3:30-3:50pm | Linking of imaging and biomarker data from the University of Colorado AMD registry | **Talisa de Carlo Forest, MD**  Assistant Professor of Ophthalmology  Director of Imaging  Department of Ophthalmology  University of Colorado School of Medicine  <https://som.ucdenver.edu/Profiles/Faculty/Profile/30446> |
| We will discuss the creation of the University of Colorado AMD Registry to correlate imaging biomarkers of disease progression with systemic markers of inflammation in patients with intermediate and advanced non-neovascular AMD. Systemic markers collected by multiplex immunoassay included cytokines, chemokines, complement, CRP, and RANTES. Qualitative and quantitative imaging biomarkers were reviewed by two trained graders, with a third grader for adjudication. We endeavor to uncover novel therapeutic targets for patients with non-neovascular AMD. | | |
| 3:50-4:10pm | The use of registries in international multi-center, prospective, longitudinal natural history studies in inherited retinal diseases | **Allison Ayala MS**  Director, FFB Consortium Coordinating Center  Director, CALEC Coordinating Center  Jaeb Center for Health Research |
| This talk will introduce the importance of natural history studies in clinical trial design, challenges of natural history studies in rare disease, and how to address those challenges. The talk will review a registry model developed by the Foundation Fighting Blindness Consortium to advance research in rare inherited retinal disease. This registry model includes the ability to (1) establish genetically and clinically well-characterized cohorts of patients across hundreds of rare genetic variants associated with retinal dystrophy, (2) provide international, multi-center, prospective, standardized cross-sectional data on phenotype-genotype associations, and (3) serve as a standing platform for accelerating subsequent natural history studies. | | |
| 4:10- 4:30 pm | Sight Outcomes Research Collaborative (SOURCE) | **Joshua D. Stein, MD, MS**  Edward T. and Ellen K. Dryer Career Development Professor in Ophthalmology and Visual Sciences  PI, Sight Outcomes Research Collaborative (SOURCE) registry  Associate Professor, Ophthalmology and Visual Sciences  University of Michigan Medicine  Department of Ophthalmology & Visual Sciences  Department of Health Management & Policy |
| I plan to provide a general overview of the Sight Outcomes Research Collaborative (SOURCE) Ophthalmology Big Data consortium. Topics I plan to cover include the ophthalmology departments who are actively participating in SOURCE, the sorts of data elements that are available to researchers, linking clinical data in SOURCE with other pots of data such as social determinants of health data, how one can gain access to SOURCE data for research or quality improvement projects. Information on the numbers of patients in SOURCE and the sociodemographic characteristics of these patients will be covered. In addition, I will cover some of the challenges with creating multi-institution registries like SOURCE. Finally, I will provide a few examples of research projects that are making use of this resource. | | |
| 4:30- 5:00pm | Panel discussion |  |
| Open discussion with the previous speakers. | | |
| 5pm | Adjourn |  |