CLINICAL TRIAL REMIX: UPDATE FOR NIH DATA MANAGEMENT PLAN 2023

DATA TYPE

Types and amount of scientific data expected to be generated in the project:
Method: Randomized patients will receive monthly ocular injections into the back of the eye of antiVEGF or Ozurdex. After each injection, patients will return 29 days later for visual acuity measurements. Visual acuity improvement or decrease will be determined using a Snellen chart. Number of letters of improvement or decline from previous study visit will be recorded in the EDC (electronic data capture) system. We will export data from the Electronic Data Capture system into SPSS for further analysis. The raw data will be transformed by statistical analysis and the subsequent processed datasets will be used for statistical analysis. To protect research participant identities, aggregated data will be made available for sharing.

Scientific data that will be preserved and shared, and the rationale for doing so:
Data will be collected using an Electronic Data Capture (EDC) system. Data will then be extracted from EDC into Excel to conduct analysis with SPSS. Data will be transformed into a comma separated value (.csv) format and stored in repository.

A brief listing of the metadata, other relevant data, and any associated documentation (e.g., study protocols and data collection instruments) that will be made accessible to facilitate interpretation of the scientific data.
File inventory: NWPalaceTR.WRL
File format: NCT
Necessary software: excel, csv
Variables: patient ID, date, sex, age, treatment, score, Ozurdex, antiVEGF

RELATED TOOLS, SOFTWARE AND/OR CODE

State whether specialized tools, software, and/or code are needed to access or manipulate shared scientific data, and if so, provide the name(s) of the needed tool(s) and software and specify how they can be accessed
Numerical data will be made available in csv format and will not require the use of specialized tools to be accessed or manipulated.

If applicable, specify how needed tools can be accessed, (e.g., open source and freely available, generally available for a fee in the marketplace, available only from the research team) and, if known, whether such tools are likely to remain available for as long as the scientific data remain available.
CSV is open-source and freely available. Excel is part of the Microsoft Suite and is provided by my university to all researchers.

STANDARDS

State what common data standards will be applied to the scientific data and associated metadata to enable interoperability of datasets and resources, and provide the name(s) of the data standards that will be applied and describe how these data standards will be applied to the scientific data generated by the research proposed in this project. If applicable, indicate that no consensus standards exist
Whenever possible, we will use common data elements to structure and organize our data. Our data will be structured and described using the standards set by EyeGENE, which is an NIH-supported repository sponsored by the National Eye Institute, and which has been widely adopted in the opthalmology community.

DATA PRESERVATION, ACCESS, AND ASSOCIATED TIMELINES

Repository where scientific data and metadata will be archived:
Dataset(s) resulting from this research will be shared via the EyeGENE repository. The National Ophthalmic Disease Genotyping and Phenotyping Network (eyeGENE®) is a genomic medicine initiative created by the National Eye Institute (NEI), part of the National Institutes of Health (NIH), in partnership with clinics and laboratories across the vision research community. The core mission of eyeGENE® is to facilitate research into the causes and mechanisms of rare inherited eye diseases and accelerate pathways to treatments. eyeGENE® was designed to achieve this goal through clinical and molecular diagnosis coupled with granting controlled access to clinical and genetic information in a data repository, to DNA in a biorepository, and to individuals consented to participate in research and clinical trials. The eyeGENE® Network currently includes a Coordinating Center at the NEI, CLIA-approved molecular genetic testing laboratories around the Nation, a patient registry, controlled-access centralized biorepository for DNA, and a curated de-identified genotype / phenotype database.

How scientific data will be findable and identifiable:
EyeGENE provides metadata, persistent identifiers in the form of DOIs, and long-term access. The eyeGENE® Network currently includes a Coordinating Center at the NEI, CLIA-approved molecular genetic testing laboratories around the Nation, a patient registry, controlled-access centralized biorepository for DNA, and a curated de-identified genotype / phenotype database.

When and how long the scientific data will be made available:
Data will be made available as soon as possible or at the time of associated publication. Data will be available through EyeGENE for five years after the end of the award cycle.

ACCESS, DISTRIBUTION, OR REUSE CONSIDERATIONS

Factors affecting subsequent access, distribution, or reuse of scientific data:
Patient names will be de-identified in order to protect patient confidentiality. HIPPA security and access requirements will be observed, including anonymizing data, using secure and limited access data servers, and creating controlled access measures as needed to comply with HIPPA requirements. Data security will be observed at all times. Requests for data will follow the protocols established by HIPPA.

To protect participant and family member privacy and confidentiality, shared data will be de-identified according to all federal and state guidelines and following the safe-harbor method. That method specifies that many identifiers are removed from data to be considered de-identified, including, but not limited to: names, all geographic subdivisions smaller than state, dates (except year), ages over 89 (listed as 90+ in all datasets), identifiable electronic numbers, biometric identifiers, various ID numbers (SSN, etc), and other possible identifiers. Only the minimum of PHI will be collected for the purposes of the study, and all team members are HIPAA trained.

Whether access to scientific data will be controlled:
Access to scientific data will not be controlled.

Protections for privacy, rights, and confidentiality of human research participants:
In order to ensure participant consent for data sharing, IRB paperwork and informed consent documents will include language describing plans for data management and sharing data, describing the motivation for sharing, and explaining that personal identifying information will be removed.

To protect participant privacy and confidentiality, shared data will be de-identified using the masking method. HIPPA security and access requirements will be observed, including anonymizing data, using secure and limited access data servers, and creating controlled access measures as needed to comply with HIPPA requirements. Data security will be observed at all times. Requests for data will follow the protocols established by HIPPA

OVERSIGHT OF DATA MANAGEMENT AND SHARING

Describe how compliance with this Plan will be monitored and managed, frequency of oversight, and by whom at your institution (e.g., titles, roles).
The following individuals will be responsible for data collection, management, storage, retention, and dissemination of project data, including updating and revising the Data Management and Sharing Plan when necessary.

- Lab Manager, Data Manager, UNMC, ORCID, lmanager@unmc.edu

PLANNED RESEARCH OUTPUTS

Title	Type	Anticipated release date	Initial access level	Intended repository(ies)	Anticipated file size	License	Metadata standard(s)	May contain sensitive data?	May contain PII?
numeric results	Dataset	2028-01-24	Open	EyeGENE	2 GB	CCA Non Commercial Share Alike 4.0 International	Darwin Core	Yes	No