Hindsight is Always 20/20

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Background

Karmanos Cancer Institute, an NCI-Designated Comprehensive Cancer Center, collaborates with Kresge Eye institute to assess clinical trial patients requiring protocol-mandated ophthalmology exams. To address inconsistencies in source data collection, we developed and implemented the Ophthalmology Exam Workflow and Source Document Template. This initiative ensures compliance with protocol requirements by providing clear guidelines for identifying required ophthalmology exams, standardizing data capture, and streamlining document distribution

Methods Implemented

A working group was established comprised of study coordinators and a clinical research nurse to ensure the process aligned with all operational needs. Together, we developed the workflow and a template document in accordance with institutional standards and research requirements. As part of the effort, we also created a standardized ophthalmology source document to be used when sponsor-provided materials are unavailable. The finalized workflow was completed and fully implemented on 28-May-2024.

Goals

The primary goals of this initiative were to standardize ophthalmology source documents and to create reference materials that clarify how specific exams should be collected and documented. By establishing these standards, the project aimed to reduce workload and enhance both efficiency and productivity.

Common Eye Exam Tests

- Schirmer Test
- Slit Lamp Examination
- Intraocular Pressure
- SD-OCT
- Fundoscopy
- Color Fundus Photographs
- Ocular Characteristics
- Biomicroscopy Anterior Segment
- Refractive Error
- Amsler Grid Test
- External Eye Examination

Outcomes

The workflow reduced the workload for study coordinators, clinical research nurses, and Kresge staff. Implementing a template source document and workflow led to fewer issues at the point of care, as these can now be addressed ahead of patient visits. It also streamlined the review and documentation of patient ophthalmological history per protocol. Study coordinators reported that creating source documents is now more efficient, thanks to the template's comprehensive list of assessments. Nurses noted the process has become noticeably smoother and more seamless since implementation. The initiative also strengthened the relationship with Kresge.

Lessons Learned & Future Direction

Standardizing source documentation for ophthalmology exams highlighted the need to create and standardize template source documents for other protocol-required testing, such as audiology exams, speech audiometry tests, ICANS/ICE assessments, Child-Pugh Score, and other non-standardized tests. The future objective is to centralize the location of ophthalmology testing results by uploading them to the electronic medical record.

Internal Study # / Sponsor Study # /
Lead SC name, email, phone number
OPHTHALMOLOGY EXAM

Patient Initials: _____ Date of Birth: _____ Date: _____

VISUAL ACUITY:

Is the patient using corrective vision? ☐ Yes ☐ No

Assessment Chart	Location	Results	Overall Interpretation	Comments (if applicable)
☐ EOTRS ☐ Tumbling E Chart ☐ Snellen Chart ☐ Other	Right Eye (OD)	Result: _____ Best corrected visual acuity: _____	☐ Normal ☐ Abnormal (NCS) ☐ Abnormal (CS) ☐ Not Done	
	Left Eye (OS)	Result: _____ Best corrected visual acuity: _____	☐ Normal ☐ Abnormal (NCS) ☐ Abnormal (CS) ☐ Not Done	

VISUAL FIELD EXAMINATION:

☐ Normal   ☐ Abnormal (NCS)   ☐ Abnormal (CS)   ☐ Not Done

Describe abnormal findings: _____

CORNEAL EVALUATION WITH FLUORESCEIN DYE ADMINISTERED:

Staining: ☐ Yes ☐ No

If yes, describe: _____

Other irregularities: ☐ Yes ☐ No

If yes, describe: _____

Conclusion

This project helped address some major gaps in how we document ophthalmology exams, improved operational efficiency and alleviated staff workload. It also strengthened our partnership with Kresge and set us up to expand standardization to other types of testing. Next, we're aiming to centralize ophthalmology results in the electronic medical record to make them easier to access for both clinical care and research.