

Hindsight is Always 20/20

J. Dominello, H. Cressman, C. Zuccaro, C. Galasso, E. Cunningham

Karmanos Cancer Institute, Wayne State University

1. Background

Karmanos Cancer Institute 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.

2. Goals

- Standardize ophthalmology source documents
- Create reference material for how specific exams are collected/documented.
- Decrease the workload and increase efficiency and productivity.

3. Solutions and Methods

- Established a working group comprising study coordinators and a clinical research nurse to ensure the process aligned with all operational needs.
- Developed the workflow and template document in accordance with institutional standards and research requirements.
- Created a standardized ophthalmology source document for use in the absence of sponsor provided materials.
- The workflow was completed and implemented on May 28, 2024

4. Outcomes

- Reduced the workload for study coordinators, clinical research nurses, and Kresge staff.
- The implementation of a template source document and workflow has led to a reduction in issues and questions that previously arose at the point of care, as they can now be addressed in advance of patient visits.
- Streamlined review and documentation of patient ophthalmological history as required per protocol.
- Study coordinators have reported that the source document creation process has been significantly streamlined due to the template's comprehensive list of assessments, including units of measurement.
- Nurses have noted that the process has become noticeably smoother and more seamless since the implementation of the workflow.
- Strengthened relationship with Kresge

5. Lessons Learned and Future Directions

- Standardizing source documentation for ophthalmology exams highlighted a need for the creation and standardization of template source documents for other protocol required testing. (i.e. audiology exams, speech audiometry tests, ICANS/ICE assessment, Child-Pugh Score, etc. or other non-standard tests)
- The future objective is to centralize the location of ophthalmology testing results by uploading them to the electronic medical record.