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# **FDA-NEI Workshop: Patient-Reported Outcomes and Vision-Related Quality of Life Questionnaires**

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# Patients are at the Heart of All We Do

*Inspired by Patients, Driven by Science*



## **CDRH Vision:**

Patients in the U.S. have access to high-quality, safe, and effective medical devices of public health importance, first in the world.

# CDRH Division of Patient-Centered Development

*Inspired by Patients, Driven by Science*

Understand the patients' perspectives and proactively incorporate them into all our decisions and regulatory activities where appropriate

Consistent  
Regulatory  
Review

Patient  
Engagement

Optimize  
Research  
Roadmap



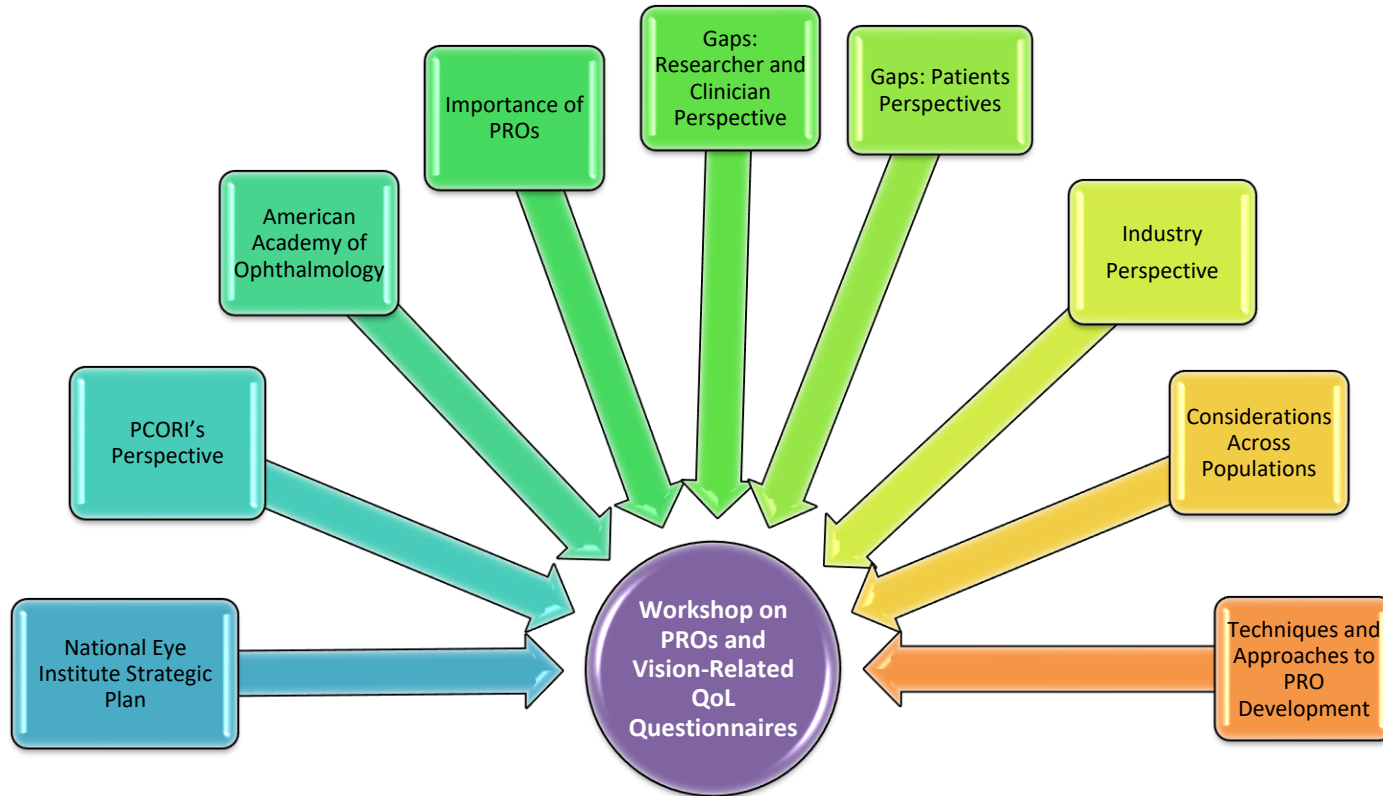
# Virtual Public Workshop – Patient-Reported Outcomes and Vision Related Quality of Life Questionnaires, September 29, 2023

SEPTEMBER 29, 2023

**Purpose:** Highlight the importance of patients' perspectives, patient-reported outcomes ("PROs"), and questionnaires to measure visual function and vision-related quality of life ("VFQs") in vision research and clinical care.

**Goal:** Identify future steps in the development of PROs and VFQs for a variety of ocular conditions and varying degrees of visual impairment.

# Virtual Public Workshop: Overview



# Patients' Perspectives



The focus of the session was on understanding gaps in clinical studies concerning visual challenges, emphasizing diverse perspectives, including those of children and adults at various stages of their vision impairment journey.

# Patients' Perspectives

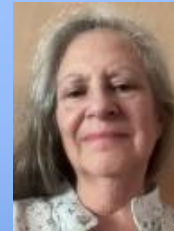
- Session: What are the gaps? Patients' Perspectives
- The patients shared experience living with a variety of conditions:
  - Cataracts
  - Adverse events due due to LASIK
  - Retinitis Pigmentosa
  - AMD
  - Glaucoma



S. Robert Levine



Alessio, Andrea,  
& Fabio



Barbara



Jaime



John



Judy

# Conclusions

- The workshop represented an initial step to (re-)visiting PRO measures for eye and vision conditions
- Patients participated in the planning and conduct of the meeting, reflecting the importance and value of their perspectives
- PRO measures can be an important step towards incorporating patients' perspectives and experiences in all aspects of health care



# Future Directions

- NEI, FDA, clinicians, industry and patient representatives are mapping out next steps.
- NEI's Strategic Plan envisions opportunities to “empower individuals living with visual impairments as partners in research”.
- CDRH's Guidance, “Patient Engagement in the Design and Conduct of Medical Device Clinical Studies” highlights potential for involvement of patient advisors to inform the design and conduct of medical device clinical studies as well as the tools used to collect outcomes.



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