

11th Annual Clinical Outcome Assessment in Cancer Clinical Trials (COA-CCT) Workshop

“Measuring What Matters: The Patient Voice in Cancer Clinical Trials”

October 15, 2026 • 1:00 – 4:00 PM ET • Virtual

1:00 – 1:10 PM | 10 min Welcome & Opening Remarks

Presenter Vishal Bhatnagar — Associate Director for Patient Outcomes, Oncology Center of Excellence, FDA

1:10 – 2:25 PM | 1 hr 15 min Session 1: Progress and Gaps: Rethinking Core Outcomes for a New Era of Cancer Care

Moderator Vishal Bhatnagar — FDA

Panelists

- Yelak Biru — Patient Advocate
- Sydney BARNED — Physician & Patient Advocate
- Bárbara Segarra-Vázquez — Patient Advocate
- Valarie Traynham — Patient Advocate

Objectives

1. Examine how novel cancer therapies — including CAR-T, bispecific antibodies, and ADCs — have created gaps in existing PRO frameworks that patients experience but current measures do not capture.
2. Explore what patients living with cancer as a chronic condition need measured beyond the acute treatment window, and how survivorship outcomes can be better integrated into trial design.
3. Discuss the gap between PRO data collection and real-time clinical utility, and what closing that loop would mean for patients in trials.
4. Consider the evidence and feasibility for high frequency PRO assessment during the first treatment cycle as a meaningful extension of current FDA guidance recommendations.

2:25 – 2:35 PM | 10 min Break

2:35 – 3:50 PM | 1 hr 15 min Session 2: From Gaps to Goals: What Meaningful Progress Looks Like for Patients

Moderator Vishal Bhatnagar — FDA

Panelists

- Wenora Johnson — Patient Advocate
- Jan Geissler — Patient Advocate, Patvocates
- Julia Maües — Patient Advocate, GRASP Co-Founder

Objectives

1. Envision what genuine patient co-design of cancer clinical trials looks like in practice, and identify concrete steps sponsors can take to move from consultation to true partnership.
2. Explore how emerging technologies — ePRO platforms, wearables, AI-assisted monitoring — can be designed and deployed in ways that serve patients first, including through more frequent and meaningful data collection.
3. Articulate a patient-centered vision for what the next decade of PRO science should achieve, with specific, actionable milestones that sponsors, regulators, and the research community can work toward together.

3:50 – 4:00 PM | 10 min**Workshop Conclusion & Adjourn****Presenter**

Vishal Bhatnagar — Associate Director for Patient Outcomes, Oncology Center of Excellence, FDA