Putting Patients First
FDA Patient Engagement Initiatives

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FDA OCE Conversations on Cancer

Award-winning OCE public panel discussion series examining cancer-related social issues with inclusive and diverse panel members from around the U.S. and within the FDA

https://www.fda.gov/about-fda/oncology-center-excellence/conversations-cancer

OCE Funded External Collaborations

Dr. Theresa Coles, PhD

Objective: Describe how cancer patients interpret questions and choose responses to patient-reported physical function measures with different recall periods or concepts

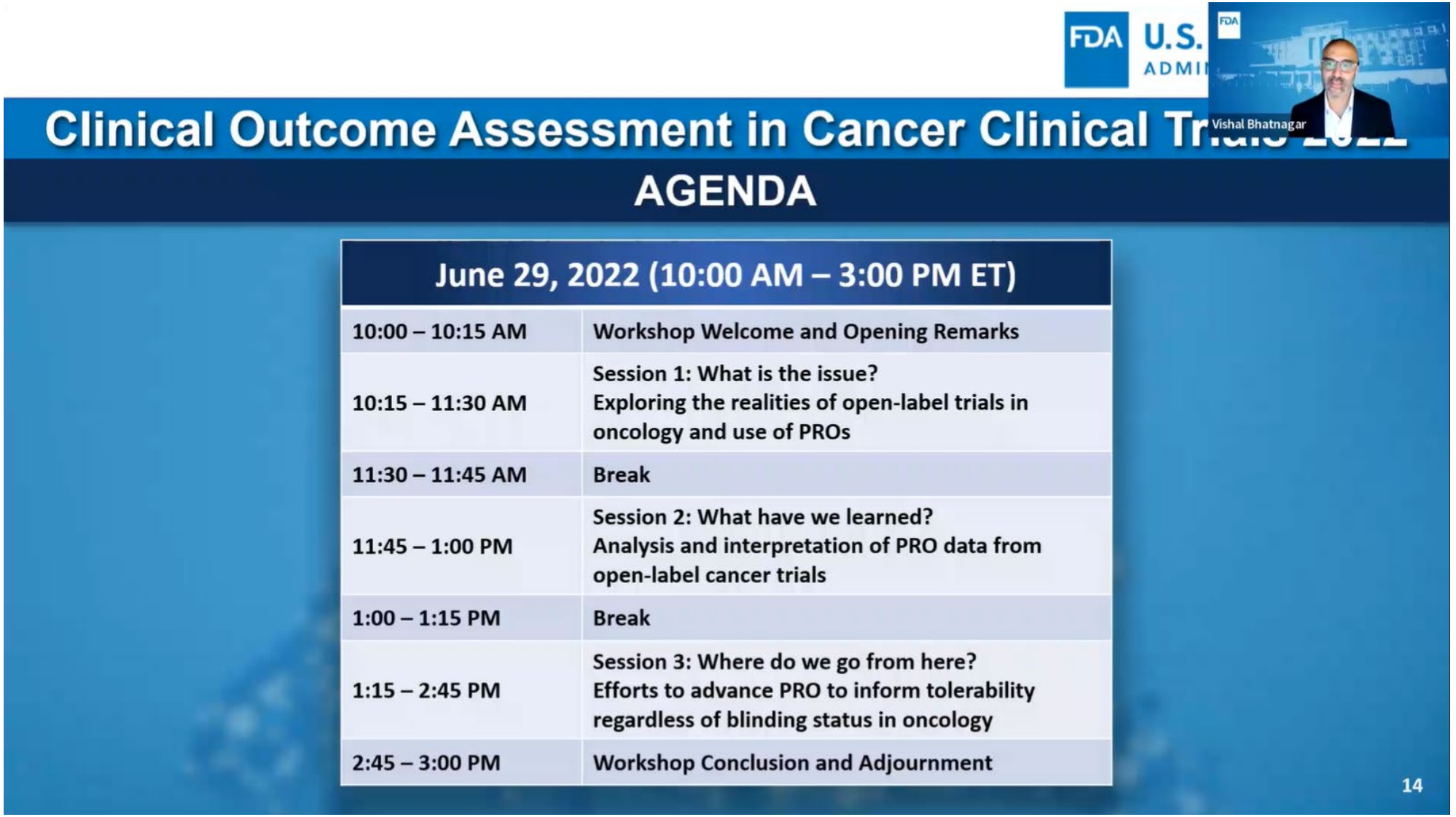
Dr. Gita Thanarajasingam, MD

Objective: Collect ClinRO, PRO, PerfO and wearable physical function data, and identify sensitivity to change/thresholds among these various sources

Improve the collection, analysis, interpretation and reporting of **physical function** data in oncology clinical trials

Clin Cancer Res. 2021 Oct 1; 27(19): 5161–5167.
doi: 10.1158/1078-0432.CCR-20-4429
https://www.fda.gov/about-fda/oncology-center-excellence/oce-scientific-collaborative

COA-CCT Annual Workshop



June 29, 2022 (10:00 AM – 3:00 PM ET)	
10:00 – 10:15 AM	Workshop Welcome and Opening Remarks
10:15 – 11:30 AM	Session 1: What is the issue? Exploring the realities of open-label trials in oncology and use of PROs
11:30 – 11:45 AM	Break
11:45 – 1:00 PM	Session 2: What have we learned? Analysis and interpretation of PRO data from open-label cancer trials
1:00 – 1:15 PM	Break
1:15 – 2:45 PM	Session 3: Where do we go from here? Efforts to advance PRO to inform tolerability regardless of blinding status in oncology
2:45 – 3:00 PM	Workshop Conclusion and Adjournment

https://www.fda.gov/news-events/fda-meetings-conferences-and-workshops/fda-workshop-7th-annual-clinical-outcome-assessment-cancer-clinical-trials-workshop-06292022

Patient Engagement Opportunities

https://www.fda.gov/patients/learn-about-fda-patient-engagement/fda-patient-engagement-opportunities

Patient Listening Sessions

The FDA hosts a series of Patient Listening Sessions that allow patients and caregivers to share their experiences living with a disease or condition and share the most urgent needs with FDA staff to help inform medical product development. This is a collaboration with the National Organization for Rare Disorders and the Reagan-Udall Foundation for the FDA.

Patient Engagement Collaborative (PEC)

The Patient Engagement Collaborative (PEC) is a patient group established by FDA and the Clinical Trials Transformation Initiative (CTTI). The PEC is composed of individuals and patient organization representatives who discuss topics focusing on enhancing patient engagement in medical product development and regulatory discussions at FDA.

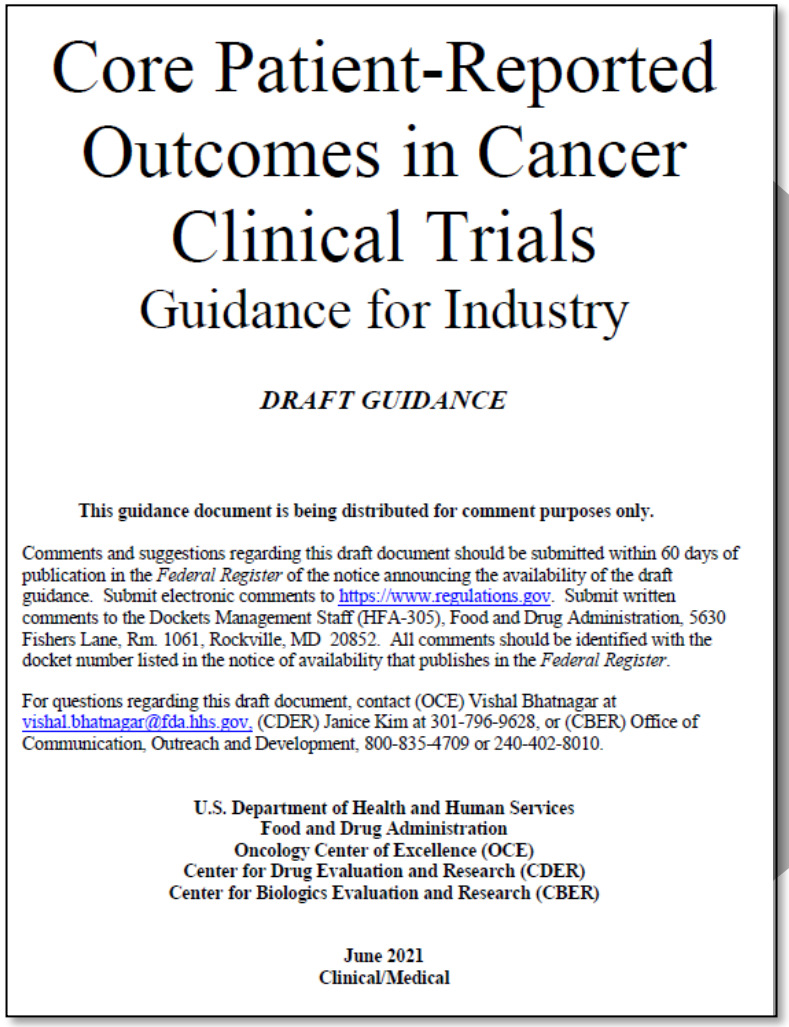
FDA Patient Representative Program

The FDA Patient Representative Program® is one of the agency's primary mechanisms for recruiting patients and caregivers who have experience with a disease, condition or medical device. FDA patient representatives are appointed as special government employees to participate in important agency directed assignments.

Patient-Focused Drug Development Initiative (PFDD)

Patient-focused drug development (PFDD) is a systematic approach to help ensure patients' experiences, perspectives, needs and priorities are captured and meaningfully incorporated into drug development and evaluation. Patients are uniquely positioned to inform the understanding of the therapeutic context for drug development

OCE Core Outcomes Guidance



Core Patient-Reported Outcomes in Cancer Clinical Trials

Guidance for Industry

DRAFT GUIDANCE

This guidance document is being distributed for comment purposes only.

Comments and suggestions regarding this draft document should be submitted within 60 days of publication in the *Federal Register* of the notice announcing the availability of the draft guidance. Submit electronic comments to https://www.regulations.gov. Submit written comments to the Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number listed in the notice of availability that publishes in the *Federal Register*.

For questions regarding this draft document, contact (OCE) Vishal Bhatnagar at vishal.bhatnagar@fda.hhs.gov, (CDER) Janice Kim at 301-796-9628, or (CBER) Office of Communication, Outreach and Development, 800-835-4709 or 240-402-8010.

U.S. Department of Health and Human Services
Food and Drug Administration
Oncology Center of Excellence (OCE)
Center for Drug Evaluation and Research (CDER)
Center for Biologics Evaluation and Research (CBER)

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Clinical/Medical

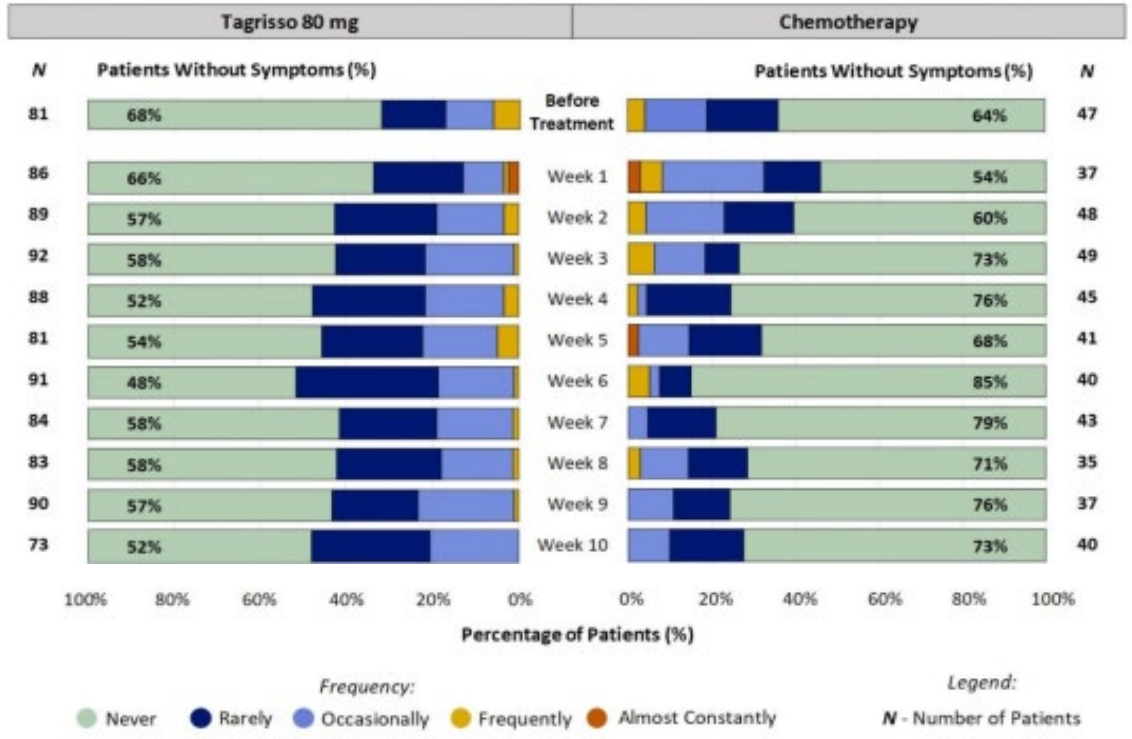
https://www.fda.gov/regulatory-information/search-fda-guidance-documents/core-patient-reported-outcomes-cancer-clinical-trials

Project Patient Voice

Patient-Reported Diarrhea During the First 24 Weeks on Treatment for Patients Who Completed a Questionnaire:

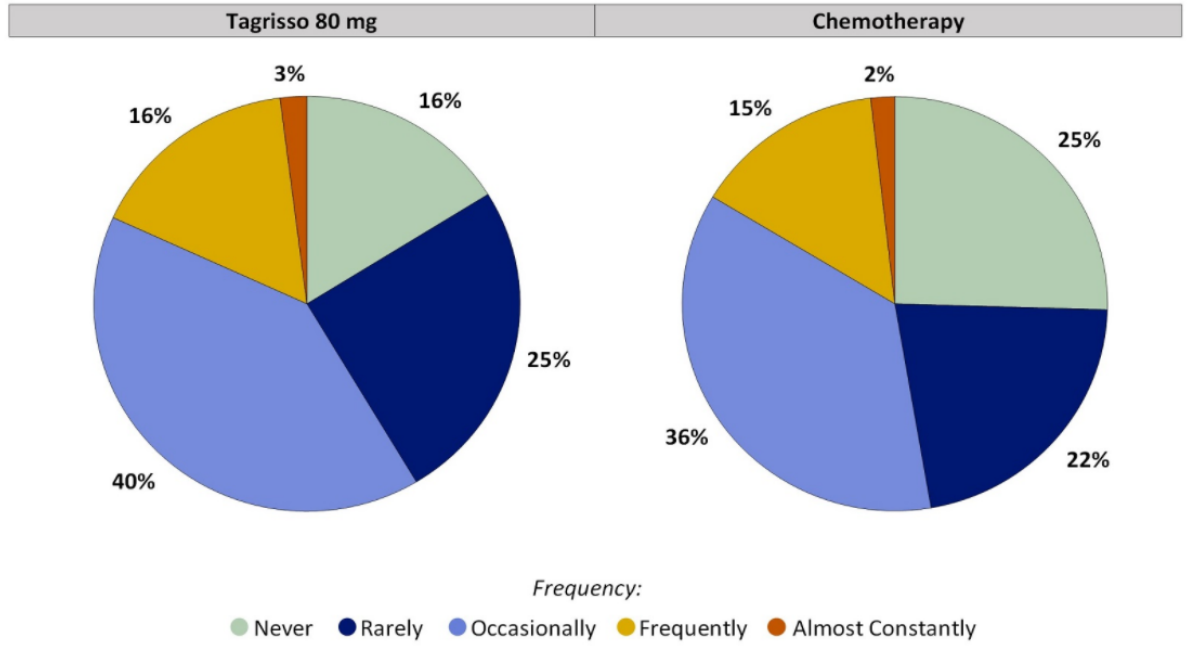
Figure 1 shows the percentage of patients reporting how often they had Diarrhea at each time point. For example, at week 2, 43% of patients taking Tagrisso reported Diarrhea (ranging from Rarely to Frequently). The range of patients who had any Diarrhea during the first 24 weeks of treatment with Tagrisso was between 34% - 53%. Click here for more information on how to read the graphs below.

Figure 1. Patient-Reported Diarrhea During the First 24 Weeks on Treatment



Worst Response Option for Diarrhea That Patients Reported During the First 24 Weeks on Treatment

Figure 2. Worst Patient-Reported Diarrhea During the First 24 Weeks on Treatment



https://www.fda.gov/about-fda/oncology-center-excellence/project-patient-voice

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Patients, Caregivers, and Advocates who participate in FDA initiatives