

13th Annual
4th Annual
4th Annual

Clinical Outcome Assessments in Cancer Clinical Trials (COA-CCT)

FDA-ASCO Co-Sponsored Public Workshop

FDA U.S. FOOD & DRUG
ADMINISTRATION
ONCOLOGY CENTER OF EXCELLENCE

ASCO[®]

AMERICAN SOCIETY OF CLINICAL ONCOLOGY

July 12, 2019

9:00 AM to 4:30 PM

FDA Campus - Silver Spring, MD



#OCEOutcomes19

@FDAOncology

Exploring measurement of physical function to inform cancer drug development

FDA Campus – Silver Spring, MD
July 12, 2019

Twitter: [#OCEOutcomes19](https://twitter.com/OCEOutcomes19)

The Co-Chairs Welcome You!



- **U.S. Food and Drug Administration**
 - **Paul Kluetz, M.D.**
Deputy Director, Oncology Center of Excellence, FDA

- **American Society of Clinical Oncology**
 - **Heidi Klepin, M.D., M.S.**
Chair, Cancer Research Committee, ASCO
 - **Stacy W. Gray, M.D., A.M.**
Cancer Research Committee, ASCO

Oncology Center of Excellence

Patient Focused Drug Development Program

<https://www.fda.gov/about-fda/oncology-center-excellence/patient-focused-drug-development>

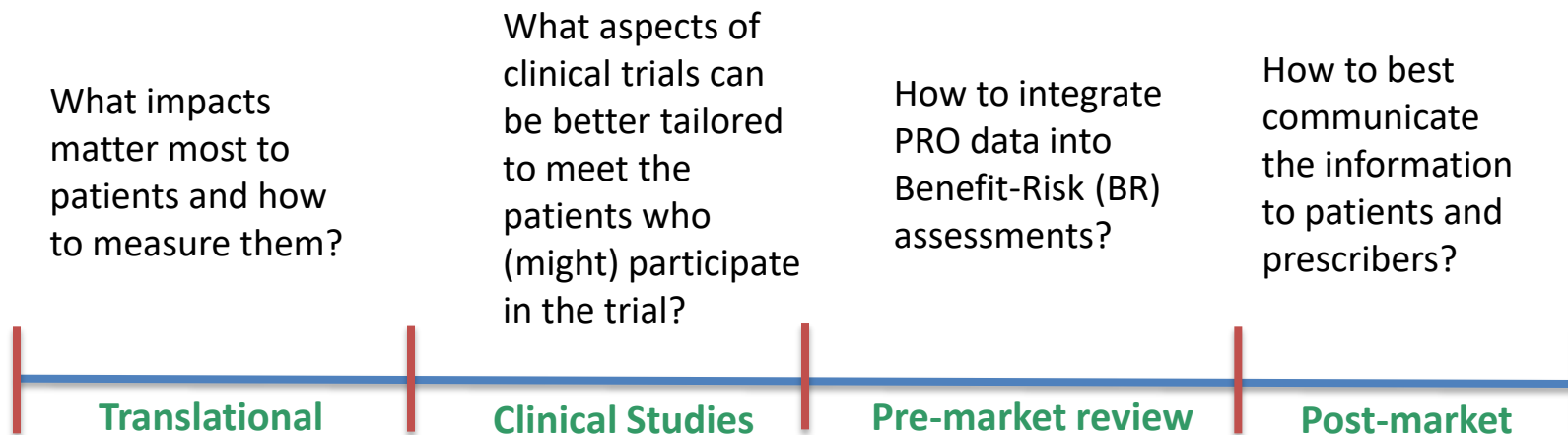
The OCE PFDD Team:

- **Vishal Bhatnagar, M.D.**
Associate Director of
Patient Outcomes (Acting)
- **Bellinda King-Kallimanis, Ph.D.**
Senior Staff Fellow- PFDD Science
- **Janice Kim, PharmD, M.S.**
Regulatory Project Manager- PFDD Policy

Priority areas in 2019:

- ✓ Consistent PRO regulatory review
- ✓ Applied cancer research
- ✓ Guidance development
- ✓ Data Visualization “Project PatientVoice”
- ✓ International Collaboration on Standards

Patient-Focused Drug Development is More than just Measuring Symptoms and Function



There are many other aspects of drug development that can be patient-focused

- Efficient FDA Review
- Expanded Eligibility Criteria
- Decentralized Trials
- Digital Health Technology
- Improving Access to Investigational Drugs



PROJECT FACILITATE

Assisting healthcare providers with requests for access to investigational oncology products

**DO YOU NEED HELP SUBMITTING A SINGLE PATIENT IND EXPANDED ACCESS (EA) REQUEST
(ALSO KNOWN AS COMPASSIONATE USE) FOR A PATIENT WITH CANCER?**

...FDA's Oncology Center of Excellence (OCE) can help:

- Locate IRB resources
- Find an EA contact for a drug/biotech company
- Complete Form FDA 3926

9:00 AM - 5:00 PM Eastern Time (M-F)

Phone: (240) 402-0004

Email: OncProjectFacilitate@fda.hhs.gov



www.fda.gov/oce

Patients: Talk to your healthcare provider to discuss whether expanded access is an appropriate option.

Where do clinical outcome assessments fit within ASCO's strategic priorities?

ASCO 2019-2023 Strategic Plan



Mission

Conquering cancer through research, education, and promotion of the highest quality patient care.

Vision

A world where cancer is prevented or cured, and every survivor is healthy.

Core Values

Evidence Care Impact

Five-Year Outcome Statement: Progress Toward Our Vision by 2023

ASCO leads the delivery of information and diverse expertise needed by the global oncology community to reduce the burden of cancer.

Five-Year Goal 1

Meet the Needs of Our Members and Others

Five-Year Goal 2

Increase Quality of Care

Five-Year Goal 3

Steward Our Resources

Five-Year Goal 4

Make a Global Impact

Goal Descriptors

Redefine the needs of ASCO's members and key constituents and deliver better support for the modern oncology professional

Ensuring the evidence, tools, research, and advocacy are available and useful to the practices and professionals delivering care

Smartly allocating ASCO's resources to maximize sustainability, efficiency, and ability to provide superior member experience

Supporting global delivery of quality care through bi-directional networks, quality tools, and research

ASCO's Mission Pillars

Research

Education

Quality

ASCO Cancer Research Committee Purpose

- Promote and support cancer research careers
- Advance clinical trial design and implementation
- Develop policy positions/statements regarding cancer research
- Analyze research-related policy and regulatory activities
- Promote clinical research conduct and address infrastructure needs
- Develop research-related educational content for ASCO programs and enduring materials

Examples of ASCO Cancer Research Committee Activities

VOLUME 33 · NUMBER 32 · NOVEMBER 10 2015

JOURNAL OF CLINICAL ONCOLOGY

ASCO SPECIAL ARTICLE

VOLUME 35 · NUMBER 16 · JUNE 1, 2017

JOURNAL OF CLINICAL ONCOLOGY

ASCO SPECIAL ARTICLE

Improving
With Cancer
Oncology

Arti Hurria, Lauren
Allison Magnuson
Michael A. Postow

ASCO special article

Clinical Cancer Advances 2019: Annual Report on Progress Against Cancer From the American Society of Clinical Oncology

Sumanta K. Pal, MD¹; Michael J. Miller, MS, MPH²; Neeraj Agarwal, MD³; Susan Marina Chang, MD⁴; Mariana Chavez-MacGregor, MD⁵; Ezra Cohen, MD⁶; Suzanne Cole, MD⁷; William Dale, MD, PhD⁸; Catherine S. Magid Diefenbach, MD⁹; Mary L. Disis, MD¹⁰; Robert Dreicer, MD¹¹; David L. Graham, MD¹²; N. Lynn Henry, MD, PhD¹³; Joshua Jones, MD¹³; Vicki Keedy, MD¹⁴; Heidi D. Klepin, MD¹⁵; Merry Jennifer Markham, MD¹⁶; Elizabeth A. Mittendorf, MD, PhD¹⁷; Carlos Rodriguez-Galindo, MD¹⁸; Michael S. Sabel, MD¹⁹; Richard L. Schilsky, MD²⁰; Mario Sznol, MD²¹; William D. Tap, MD²²; Shannon Neville Westin, MD²; and Bruce E. Johnson, MD¹⁷

Observational Research to Inform
Management

Arti Hurria, Clifford A. Hudis, Sandra Wong, Amylou Dueck, and

VOLUME 35 · NUMBER 33 · NOVEMBER 10 2017

JOURNAL OF CLINICAL ONCOLOGY

J Clin Oncol (2018) 36(11):1699-1711

DOI: 10.1200/JCO.2017.36.1699
Published online October 17, 2018
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Modernizing Clinical Trial Eligibility Criteria:
Recommendations of the American Society of Clinical
Oncology—Friends of Cancer Research Organ Dysfunction,
Prior or Concurrent Maligancy, and Comorbidities
Working Group

Stuart M. Lichtman, R. Donald Harvey, Marie-Anne Damiette Smit, Atiqur Rahman, Michael A. Thompson,
Nancy Roach, Caroline Schenkel, Suanna S. Bruinooge, Patricia Cortazar, Dana Walker, and Louis Fehrenbacher

COMMENTARY

Expanding the Evidence Base in Geriatric Oncology: Action
Items From an FDA-ASCO Workshop

Laura A. Levit, Harpreet Singh, Heidi D. Klepin, Arti Hurria

Moving forward

- Stakeholder engagement
- Education/dissemination
- Implementation
- Evaluation of impact

Overview of the Day

- Session 1: #PRO in Learning Healthcare
- Session 2: Estimands- What is your question?
- Session 3: Estimands- Developing physical function endpoints
- Session 4: How can physical function inform drug development?

Workshop Goal:

- Open Forum for discussion to advance measurement and analysis of clinical outcome data (including PRO)
- NOT guidance or endorsement of individual measurement tools or analytic methods

Word Cloud Test!

- How would you describe your background?
 - “clinician” “statistician” “healthoutcomes researcher” “patient” “regulator” “academic” etc.

Audience Poll - Word Cloud

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Password: publicaccess

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#6044



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