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

FDA-ASCO Co-Sponsored Public Workshop

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

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July 12, 2019

Twitter: #OCEOOutcomes19
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

What impacts matter most to patients and how to measure them?

What aspects of clinical trials can be better tailored to meet the patients who (might) participate in the trial?

How to integrate PRO data into Benefit-Risk (BR) assessments?

How to best communicate the information to patients and prescribers?

Adapted from Dr. Theresa Mullin, FDA
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
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

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

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

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

ASCO's Mission Pillars
Research Education Quality

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 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

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

Modernizing Clinical Trial Eligibility Criteria: Recommendations of the American Society of Clinical Oncology—Friends of Cancer Research Organ Dysfunction, Prior or Concurrent Malignancy, and Comorbidities Working Group

Observational Research to Inform: American Society of Clinical Oncology

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” “health out comes researcher” “patient” “regulator” “academic” etc.
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Password: publicaccess
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