

NCI-ISIGS-WMIS Workshop on Regulatory Pathways for Clinical Use of Optical Methods and Exogenous Targets for Cancer Detection

May 4, 2016
8:00 AM – 5:00 PM
Shady Grove Rockville MD

AGENDA

8:00 Welcome and Introduction Lalitha Shankar, MD, PhD

8:15 Clinical Need (15 minutes) Eben Rosenthal, MD

8:30 Precedence (60 minutes):
Quick overview of CDER and CDRH: Betsy Ballard
What parallels can be drawn from other approved procedures or agents? Paula Jacobs

Panel (30 mins): Neil Ogden, MS, Louis Marzella, MD, PhD, Bambi Reynolds, B.S. (LiCoR), John Fengler, M.A.Sc., (Novadaq), Paula Jacobs, PhD

Moderator: Mike Bouvet, MD

9:30 Development of Imaging Devices (60 minutes)

Overview of devices currently available (trial and market) – Bob Nordstrom, PhD (10 min)

Panel: John Frangioni, MD, PhD, Christopher Contag, PhD, Laura Marcu, PhD, Vasilis Ntziachristos, PhD, Ann Gillenwater, MD, Josh Pfefer, PhD, Betsy Ballard, MD, and Neil Ogden, MS, Robert Nordstrom, PhD

Moderator: Brian Pogue, PhD

10:30 Coffee Break (15 minutes)

10:45 Imaging Agents (105 minutes): Targeting and detection

Safety and toxicity assessment of agent - Adebayo Laniyonu, PhD (15 mins)

PK and PD issues - clinical pharmacology – Gene Williams, PhD (15 mins)

NCI Resources - Paula Jacobs, PhD (15 mins)

Panel: Jamey Wiechert, PhD, Steve Chen, MD, Philip Low, PhD, Michael Tweedle, PhD, Adebayo Laniyonu, PhD and Gene Williams, PhD, Pete Choyke, MD

Moderator: James Basilion, PhD

1:15 Clinical Trial Objectives and Endpoints (90 minutes)

Phase 1 and 2 (20 mins) – Carla Wiese, Phillip Davis, MD

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Efficacy endpoints for approval (qualitative, quantitative) – **Betsy Ballard, MD** (20 min)

How do endpoints change through the phases of clinical development: Histopathologic correlation, MOHs surgery– **Louis Marzella, MD, PhD** (20 mins)

Panel: Lalitha Shankar, MD, PhD, Jonathan Sorger, PhD, Thomas Wang, MD, PhD, Barbara Smith, MD, PhD, Merrill Biel, PhD, MD, Carla Wiese, Phillip Davis, MD, Louis Marzella, MD, PhD, Andrew Farb, MD, Betsy Ballard, MD

Moderator: Eben Rosenthal, MD

2:45 Break – 15 mins

3:00 Regulatory discussions: Development of combination products in optical imaging (75 minutes)
(Patricia Love, MD, Kristina Lauritsen, PhD and James Bertram, PhD from OCP) (20 min)

Question and answer session

Panel: Neil Ogden, MS, Louis Marzella, MD, PhD, Patricia Love, MD, Kristina Lauritsen, PhD, James Bertram, PhD. If additional panelists are needed, please add the following: Neil Ogden, MS, Louis Marzella, MD, PhD, Eben Rosenthal, MD, and James P. Babilion, PhD

Moderator: Paula Jacobs, PhD

5:00 Adjourn