

Translational Pathways for Optical Drugs and Devices for Cancer Imaging

Friday, September 28, 2018, 8:30 am - 4:30 pm

**The Hotel at the University of Maryland,
7777 Baltimore Avenue, College Park, MD 20740**

AGENDA

Registration and Welcome Breakfast 7:30 am - 8:30 am

I. Introductory Addresses 8:30 am – 9:10 am

8:30 - 8:40 am	Welcome; workshop objectives	Nushin Todd
8:40 - 8:50 am	NCI overview of resources for optical imaging	Paula Jacobs
8:50 - 9:10 am	Unmet medical needs and scientific gaps	Sunil Singhal

II. Drug and Device Development 9:10 am – 10:30 am

9:10 - 9:20 am	Chemistry, manufacturing and controls considerations	Chris Galliford
9:20 - 9:30 am	Preclinical safety assessments	Jonathan Cohen
9:30 - 9:45 am	Preclinical assessments of devices	J. Mavadia-Shukla
9:45 - 10:00 am	Scientific standards for device development	Brian Pogue
10:00 - 10:30 am	<u>Panel Discussion</u> Moderator: Nushin Todd Panelists: Ravi Kasliwal, Adebayo Laniyonu, Colin Chen, Jessica Mavadia-Shukla, Brian Pogue	

Break (10 minutes)

III. Clarifying Regulatory Pathways 10:40 am – 12:00 pm

10:40 - 10:55 am	Pathways for clinical development for drugs & devices	Joshua Chetta & Phillip Davis
10:55 - 11:15 am	Drug-device combination products: request for designation; co-packaging and cross-labeling	James Bertram & Kristina Lauritsen
11:15 - 11:30 am	Implications of new legislation – FDARA 706	Robert Ochs
11:30 - 12:00 pm	<u>Panel Discussion</u> Moderator: Neil Ogden Panelists: Alex Gorovets, Jennifer Stevenson, Kristina Lauritsen, James Bertram, Robert Ochs, Robert Berlin	

Lunch (12:00 pm - 1:00 pm)

IV. Clinical Trial Design in Optical Imaging 1:00 pm - 2:40 pm

1:00 - 1:10 pm	Patient focused drug development	David Arons
1:10 - 1:20 pm	Imaging-specific endpoints	Phillip Davis
1:20 - 1:40 pm	Clinical study design considerations	B. Ballard & S. Nagel
1:40 - 1:55 pm	Evidentiary considerations	Sue-Jane Wang
1:55 - 2:10 pm	Study design issues: clinician's perspective	Eben Rosenthal
2:10 - 2:40 pm	<u>Panel Discussion</u> Moderator: Lalitha Shankar Panelists: Alex Gorovets, Binita Ashar, Sue-Jane Wang, Robert Nordstrom, David Arons, Sunil Singhal, Eben Rosenthal	

Break (10 minutes)

V. Industry Perspectives on Optical Imaging 2:50 pm - 3:50 pm

Presentations by industry

2:50 - 3:50 pm	Lumicell	Jorge Ferrar
	Stryker	John Fengler
	On Target	Tim Biro
	Intuitive Surgical, Inc.	Ian McDowall

3:50 - 4:20 pm

Panel Discussion

Moderator: James Basilion

Panelists: Jorge Ferrer, John Fengler, Tim Biro, Ian McDowall,
Janet Eary, Binita Ashar, Louis Marzella

VI. Closing Remarks 4:20 pm - 4:30 pm

4:20 - 4:30 pm	Workshop summary; future developments	Paula Jacobs, Neil Ogden, Louis Marzella
----------------	---------------------------------------	---

Adjourn