



Partners in Progress: Cancer Patient Advocates and FDA Public Workshop III

Sponsored by the FDA Oncology Center of Excellence
Supported by: LUNgevity Foundation, Ovarian Cancer Research Alliance &
Pancreatic Cancer Action Network

Food and Drug Administration
10903 New Hampshire Ave, Great Room
Silver Spring, MD 20993

October 8, 2019 8:30am - 5:00 pm

Conference Hashtag: #OCEPIP19

Time	Topic	Speaker
8:30 AM 9:00 AM	Registration and Continental Breakfast Great Room Lobby	<i>Food and beverages generously provided by Supporting Organizations</i>
9:00 AM 9:30 AM	Introductory Comments & Welcome <ul style="list-style-type: none"> • FDA Oncology Center of Excellence (OCE) • LUNgevity Foundation • Ovarian Cancer Research Alliance • Pancreatic Cancer Action Network 	Virginia Kwitkowski Paul Kluetz Kristen Santiago Vanessa Cramer Victoria Manax
Session 1: Introduction to the Role of FDA Moderator: Rosanna Setse		
9:30 AM 10:45 AM	<ul style="list-style-type: none"> • Primer on Drug Development • Avoiding Pitfalls in Drug Development • Q & A 	Preeti Narayan Vishal Bhatnagar
10:45 AM 11:00 AM	Break	
Session 2: How Patients Engage Moderator: Rea Blakey		
11:00 AM 12:00 PM	<ul style="list-style-type: none"> • How FDA Involves Patient Advocates • How NCI Involves Research Advocates • How Patient Advocates Participate in Drug Development • Q&A 	Susan Chittooran Amy Williams Susan Leighton

Session 3: Oncology Center of Excellence's Outreach Efforts		
12:00 PM 12:20 PM	OCE Patient-Focused Drug Development Update and Outreach Efforts <ul style="list-style-type: none"> • Q&A 	Paul Kluetz Janice Kim
12:20 PM 1:30 PM	Networking Lunch (Great Room)	
Session 4: Insights into Cancer Drug Development Moderator: Bindu Kanapuru		
1:30 PM 2:30 PM	<ul style="list-style-type: none"> • Clinical Trial Study Population vs. Real World Patients: Narrowing the Divide • Expanded Access to Investigational Drugs • Project Facilitate • Q&A 	'Lola Fashoyin-Aje Virginia Kwitkowski Natasha Kormanik
2:30 PM 2:45 PM	Break	
Session 5: Patient-Focused Drug Development Moderator: Vishal Bhatnagar		
2:45 PM 3:45 PM	<ul style="list-style-type: none"> • FDA Reviewer Perspective: PROs in the Benefit:Risk Assessment • Assessing Physical Function in Cancer Patients • Project Patient Voice • Q & A 	Bindu Kanapuru Paul Kluetz Janice Kim & Vishal Bhatnagar
Session 6: Updates from FDA Centers Moderator: Virginia Kwitkowski		
3:45 PM 4:30 PM	Updates from FDA Centers Recent Cancer Product Approvals---What's New and Exciting!	CDER: Michael Menefee CBER: Poornima Sharma CDRH: Tara Ryan
4:30 PM- 5:00 PM	Questions/Answers ADJOURN	

Program Committee	Supporting Organizations
Paul Kluetz Virginia Kwitkowski Rosanna Setse Tara Ryan Poornima Sharma Najat Bouchkouj Kirsten Goldberg Rea Blakey Vishal Bhatnagar 'Lola Fashoyin-Aje Susan Chittooran Jenny Gao Belinda Kallimanis Janice Kim Danielle Krol Candis Morrison Preeti Narayan Rosanna Setse Michael Menefee Ashley Lee Tiara Watkins Richard Krzysztofik Tony Cossentino Joan Todd	<p data-bbox="930 258 1203 285">LUNgevity Foundation</p> <p data-bbox="930 294 1365 352">Kristen Santiago, Andrea Stern Ferris, Katie Brown</p> <p data-bbox="930 401 1333 428">Ovarian Cancer Research Alliance</p> <p data-bbox="930 436 1370 495">Vanessa Cramer, Chad Ramsey, Sarah DeFeo</p> <p data-bbox="930 543 1341 571">Pancreatic Cancer Action Network</p> <p data-bbox="930 579 1422 638">Victoria Manax, Donna DeDario Manross, Valerie Holzherr</p>

Thank you to our Supporting Organizations

LUNgevity Foundation

LUNgevity Foundation’s mission is to improve outcomes for people diagnosed with lung cancer. Our goals are three-fold: (1) to accelerate research to patients that is meaningful to them; (2) to empower patients to be active participants in their care and care decisions; and (3) to help remove barriers to access to high quality care.

LUNgevity Foundation has the largest lung cancer survivor network in the country and actively engage with them to identify, understand, and address unmet patient needs. We also have a world class Scientific Advisory Board that guides the programs and initiatives of the organization. For more information, please visit our website: www.lungevity.org.

Ovarian Cancer Research Alliance

Ovarian Cancer Research Alliance (OCRA) is the leading organization in the world fighting ovarian cancer from all fronts, including in the lab and on Capitol Hill, while supporting women and their families. There are three cornerstones of our mission:

1) Funding Reach: OCRA's ongoing investment in the most promising scientific research is funding discoveries, creating new treatments, and hastening desperately needed breakthroughs. 2) Advocating for Patients: We are THE voice for the ovarian cancer community, working with legislators to ensure federal ovarian cancer research and education funding, patient safety, and access to high-quality care are protected on Capitol Hill. 3) Supporting Survivors: Our programs help women navigate an overwhelming diagnosis, supporting patients and their families when and where they need it most. Website: <https://ocrahope.org>

Pancreatic Cancer Action Network

The Pancreatic Cancer Action Network (PanCAN) is dedicated to fighting the world's toughest cancer. In our urgent mission to save lives, we attack pancreatic cancer on all fronts: research, clinical initiatives, patient services and advocacy.

Our effort is amplified by a nationwide network of grassroots support. We are determined to dramatically improve patient outcomes. Website: <https://www.pancan.org>