



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

Sponsored by the FDA Oncology Center of Excellence  
Supported by: LUNgevity, 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<br>9:00 AM  | <b>Registration and Continental Breakfast</b><br>Great Room Lobby   | <i>Food and beverages generously provided<br/>by Supporting Organizations</i>              |
| 9:00 AM<br>9:30 AM  | <b>Introductory Comments &amp; Welcome</b> <ul style="list-style-type: none"> <li>FDA Oncology Center of Excellence (OCE)</li> <li>LUNgevity</li> <li>Ovarian Cancer Research Alliance</li> <li>Pancreatic Cancer Action Network</li> </ul> | Paul Kluetz & Vishal Bhatnagar<br><br>Kristen Santiago<br>Vanessa Cramer<br>Victoria Manax |
| <b>Session 1: Introduction to the Role of FDA</b><br>Moderator: Rosanna Setse |   |  |
| 9:30 AM<br>10:45 AM   | <ul style="list-style-type: none"> <li>Primer on Drug Development</li> <li>Avoiding Pitfalls in Drug Development</li> <li>Q &amp; A</li> </ul>  | Preeti Narayan<br><br>Vishal Bhatnagar   |
| 10:45 AM<br>11:00 AM  | <b>Break</b>  |  |
| <b>Session 2: How Patients Engage</b><br>Moderator: Rea Blakey                |   |  |
| 11:00 AM<br>11:40 AM  | <ul style="list-style-type: none"> <li>How FDA Involves Patient Advocates</li> <li>How NCI Involves Patient Advocates</li> <li>How Patient Advocates Participate in Drug Development</li> <li>Q&amp;A</li> </ul>                            | Susan Chittooran<br>Amy Williams<br>Susan Leighton   |

| <b>Session 3: Oncology Center of Excellence's Outreach Efforts</b><br><b>Moderator: Paul Kluetz</b> |  |  |
|---|--|--|
| 11:40 AM<br>12:00 PM  | <b>OCE Patient-Focused Drug Development Update and Outreach Efforts</b> <ul style="list-style-type: none"> <li>• Q&amp;A</li> </ul>  | Paul Kluetz<br>Janice Kim  |
| 12:00 PM<br>1:15 PM   | <b>Networking Lunch</b><br><b>(Great Room)</b>   |  |
| <b>Session 4: Insights into Cancer Drug Development</b><br><b>Moderator: Vishal Bhatnagar</b>       |  |  |
| 1:15 PM<br>2:15 PM  | <ul style="list-style-type: none"> <li>• <b>Clinical Trial Study Population vs. Real World Patients: Narrowing the Divide</b></li> <li>• <b>Expanded Access to Investigational Drugs</b></li> <li>• <b>Project Facilitate</b></li> <li>• <b>Q&amp;A</b></li> </ul> | 'Lola Fashoyin-Aje<br>Virginia Kwitkowski<br>Natasha Kormanik                          |
| 2:15 PM<br>2:30 PM  | <b>Break</b>   |  |
| <b>Session 5: Patient-Focused Drug Development</b><br><b>Moderator: Bellinda Kallimanis</b>         |  |  |
| 2:30 PM<br>4:00PM   | <ul style="list-style-type: none"> <li>• <b>Project Patient Voice</b></li> <li>• <b>Update on Wearable study from Kaiser</b></li> <li>• <b>FDA Reviewer Perspective: How PROs are being used in the benefit:risk assessment</b></li> </ul>                         | Belinda Kallimanis<br>Paul Kluetz<br>Bindu Kanapuru                                    |
| <b>Session 6: Updates from FDA Centers</b><br><b>Moderator: Virginia Kwitkowski</b>                 |  |  |
| 4:00 PM<br>4:30 PM  | <b>Updates from FDA Centers</b><br><b>Recent Cancer Product Approvals---What's new and exciting!</b>   | <b>CDER:</b> Michael Menefee<br><b>CBER:</b> Poornima Sharma<br><b>CDRH:</b> Tara Ryan |
| 4:30 PM-<br>5:00 PM   | <b>Questions/Answers</b><br><b>ADJOURN</b>   |  |

| Program Committee   | Supporting Organizations   |
|---|--|
| Paul Kluetz<br>Virginia Kwitkowski<br>Rosanna Setse<br>Tara Ryan<br>Poornima Sharma<br>Najat Bouchkouj<br>Kirsten Goldberg<br>Rea Blakey<br>Vishal Bhatnagar<br>'Lola Fashoyin-Aje<br>Susan Chittooran<br>Jenny Gao<br>Belinda Kallimanis<br>Janice Kim<br>Danielle Krol<br>Candis Morrison<br>Preeti Narayan<br>Rosanna Setse<br>Michael Menefee<br>Ashley Lee<br>Tiara Watkins<br>Richard Krzysztofik<br>Tony Cossentino<br>Joan Todd | <p data-bbox="930 258 1057 285"><b>LUNGevity</b></p> <p data-bbox="930 294 1365 352">Kristen Santiago, Andrea Stern Ferris, Katie Brown</p> <p data-bbox="930 401 1330 428"><b>Ovarian Cancer Research Alliance</b></p> <p data-bbox="930 436 1370 495">Vanessa Cramer, Chad Ramsey, Sarah DeFeo</p> <p data-bbox="930 543 1341 571"><b>Pancreatic Cancer Action Network</b></p> <p data-bbox="930 579 1422 638">Victoria Manax, Donna DeDario Manross, Valerie Holzherr</p> |

### Thank you to our Supporting Organizations

#### **LUNGevity**

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](http://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>