

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

Sponsored by the FDA Oncology Center of Excellence
Supported by: Cancer Support Community; Leukemia and Lymphoma Society; and Susan G. Komen

Food and Drug Administration,
10903 New Hampshire Ave, Great Room
Silver Spring, MD 20993
November 27, 2018 8:30am-4pm

Conference Hashtag: [#OCEPIP18](https://twitter.com/OCEPIP18)

	Topic	Speaker
8:30 AM-9:00 AM	Registration and Continental Breakfast Great Room Lobby	<i>Food and beverages provided by Cancer Support Community, Leukemia and Lymphoma Society, and Susan G. Komen</i>
9:00 AM-9:30 AM	Introductory Comments & Welcome <ul style="list-style-type: none"> • Assoc. Director of Clinical Science (OCE) • Cancer Support Community • Leukemia and Lymphoma Society • Susan G. Komen 	Paul Kluetz Elizabeth Franklin Liza Holder Patty Spears
9:30 AM-10:30 AM	Introduction to the Role of FDA <ul style="list-style-type: none"> • FDA Mythbusters • Primer on Drug Development • Q&A 	Virginia Kwitkowski Rosanna Setse
10:30 AM-10:45 AM	Break	
10:45 AM-11:25 AM	Patient Engagement in Product Development <ul style="list-style-type: none"> • OHCA Patient Representative Program • How Patient Advocates Participate in Drug Development • Q&A 	Moderator: Andrea Furia-Helms Salina Miller Patty Spears
11:25 AM-11:45 AM	Current FDA Outreach Efforts	Paul Kluetz
11:45 PM-12:45 PM	Lunch	

12:45 PM-1:45 PM	Insights into Drug Development <ul style="list-style-type: none"> • Avoiding Pitfalls in Drug Development • Expanded Access to Investigational Drugs • Q&A 	Nick Richardson Aviva Krauss
1:45 PM-2:00 PM	Break	
2:00 PM-3:15 PM	A Patient-Centered Approach to Efficacy Outcomes <ul style="list-style-type: none"> • Introduction and Framework • Discussion of Efficacy Outcomes <ul style="list-style-type: none"> ○ Overall Survival ○ Progression Free Survival ○ Event Free Survival ○ Disease Free Survival ○ Overall Response Rate • Outreach and Education 	Jennifer Gao and Mary Lou Smith Panelists: Kevin Wright LaShawn Griffiths Kristen Booze
3:15 PM-3:45 PM	Updates from OCE Centers on Recent Cancer Product Approvals---What's new and exciting?	CDER Vishal Bhatnagar CBER Najat Bouchkouj CDRH Tara Ryan
3:45 PM-4:00 PM	Questions/Answers Adjourn	