

Partners in Progress: Cancer Patient Advocates and FDA

Sponsored by the Food and Drug Administration (FDA)

Oncology Center of Excellence (OCE)

Supported by: American Association for Cancer Research (AACR), American Society of Clinical Oncology (ASCO), & American Society of Hematology (ASH)

Location: Food and Drug Administration, 10903 New Hampshire Ave, Great Room 1503 A, B & C,
Silver Spring, MD 20993

Date: November 13, 2017 9am-4pm

Time	Topic	Speaker
9:00 AM-9:30 AM	Introductory Comments & Welcome	Paul Kluetz (OCE)
		Annie Ellis (Patient Advocate)
		Jon Retzlaff (AACR)
		Jeannine Salamone & Shimere Sherwood (ASCO)
		Suzanne M. Leous (ASH)
9:30 AM-10:20 AM	Role/Mission of FDA Centers	Moderator: Paul Kluetz Richard Pazdur (OCE) Peter Marks (CBER) Jeffrey Shuren (CDRH)
	Q&A	
10:20 AM-10:40 AM	BREAK	
10:40 AM-12:00 PM	FDA Myth Busters	Virginia Kwitkowski (DHP)
	Primer on Drug Development	Gideon Blumenthal (OCE)
	Organizations within FDA and How They Participate in Anti-Cancer Product Development	Deb Miller (OHCA) Kevin Wright (OPDP)
	Q&A	
12:00 PM-1:00 PM	LUNCH	
1:00 PM-2:00 PM	How Patients and Advocates are Crucial to Our Mission	Patty Spears (Patient Advocate) & Aviva Krauss (DHP)
	Current FDA Outreach Efforts (PFDD, Patient Experience data in labeling)	Paul Kluetz (OCE) Vishal Bhatnagar (DHP) Heather Benz (CDRH)
	Q&A	

2:00 PM-	Introductory Comments	Janet Woodcock (CDER)
3:00 PM	Expanded Access to Investigational Drugs	Joohee Sul (DOP2)
	Exploration of Real World Data	Carol Pamer (OSE)
	Q&A	
3:00 PM-	Updates from OCE Centers on Recent Cancer Product Approvals What's new and exciting?	Steven Lemery (DOP2)
3:30 PM		Tara Ryan (CDRH) Najat Bouchkouj (CBER)
3:30 PM-	Q&A Adjourn	Moderator: Paul Kluetz (OCE)
4:00 PM		

CBER=Center for Biologics Evaluation and Research; CDER=Center for Drug Evaluation and Research; CDRH=Center for Devices and Radiological Health; DHP=Division of Hematology Products; DOP2=Division of Oncology Products 2; OHCA=Office of Health and Constituent Affairs; OPDP= Office of Prescription Drug Promotion; OSE=Office of Surveillance and Epidemiology