

# FDA's External Engagement and Patient Advocacy: A Dialogue to Better Inform FDA of Needs and Priorities

## Oncology Center of Excellence

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Oncology Center of Excellence

# ABOUT THE ONCOLOGY CENTER OF EXCELLENCE

The FDA Oncology Center of Excellence (OCE) is the agency's first Inter-center Institute.

## *Under the Cures Act,*

**the purpose of an Inter-center Institute** is to coordinate activities among FDA Centers applicable to the major disease area, including coordinating staff, streamlining review activities, promoting scientific programs, recruiting and developing staff, and facilitating collaborative relationships within the Department of Health and Human Services.



## Our Mission

The mission of the Oncology Center of Excellence is to achieve patient-centered regulatory decision-making through innovation and collaboration.

## Our Vision

We seek to create a unified and collaborative scientific environment to advance the development and regulation of oncology products for patients with cancer.

# A Central Entry Point for Patient Inquiries



- [www.Fda.gov/RequestToConnect](http://www.Fda.gov/RequestToConnect)
- A triage system to direct inquiries to appropriate center or office
  - Working closely with CBER, CDER, CDRH & other offices (e.g., OEA)
- Leveraging CDER's External Stakeholder Meeting Request (ESMR) System

# START HERE



# www.fda.gov /requestto connect

U.S. Department of Health and Human Services

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## Request to Connect

This form is intended for use by individual patients, caregivers, advocates, patient groups, and health professionals to encourage understanding and participation in FDA's regulatory work. **This form is not for use by industry stakeholders.** Requests may be related to a drug, biologic, device or a combination thereof. To submit your question or to request a meeting please complete the form below and click "Submit".

**Please tell us who you are (required):**

Individual Patient, Caregiver or Advocate ⓘ  Patient Group ⓘ  Health Professional ⓘ  Other

**Question or Meeting Request (required):**

Question  Meeting Request ⓘ

**Product Type (required):**

Vaccines, Blood & Biologics ⓘ  Drug ⓘ  Medical Device ⓘ  Multiple or Unknown

**Select an FDA program, if applicable (required):**

**Drug Program:**

[Critical Path Innovation Meeting](#) ⓘ  [FDA-led Patient-Focused Drug Development](#) ⓘ  
 [Externally-led Patient-Focused Drug Development](#) ⓘ  None/Unknown

**Multi-Product Programs:**

Cancer/Oncology  Rare Disease Listening Sessions ⓘ  
 Patient Engagement Collaborative (PEC) ⓘ  Expanded Access ⓘ  
 Patient Representative Program <sup>SM</sup> (PRP) ⓘ  None/Unknown

**Name of Disease or Condition (if applicable):**

# FDA Patient Engagement by the Numbers

**24**  
Patient Focused  
Drug Development  
meetings sponsored  
Agency-wide



**350,000**  
Recipients on  
MedWatch listserv




Relationships  
with more than  
**500**  
patient advocacy  
groups




**96%**  
Adv Committees  
with patient reps



**63%**  
CDRH staff  
engaged  
directly with  
patients in  
2016



**201**  
patient reps for  
**300**  
conditions  
and diseases





FDA's

Patient Focused Drug Development  
Meetings Staff Leads

Externally-led Patient Focused Drug  
Development Meetings

[patientfocused@fda.hhs.gov](mailto:patientfocused@fda.hhs.gov)

# Externally-Led Patient Focused Drug Development Meetings



Search

**CHILDHOOD CANCER HEARING LOSS**  
AN EXTERNALLY-LED PATIENT-FOCUSED DRUG DEVELOPMENT WORKSHOP

f t i #CHILDHOODCANCER

CHEMOTHERAPY-INDUCED  
HEARING LOSS IN  
PEDIATRIC ONCOLOGY

SEPTEMBER 13, 2018  
HYATTSVILLE, MD

children's cause cancer advocacy  
The Voice of Children with Cancer  
0:03 / 1:29:59

Children's Brain Tumor Foundation  
Community and Companionship on Your Journey

Mattie Mirale  
CANCER FOUNDATION

MOMCOLOGY

cc hd

Panel 1: Living with Chemotherapy Induced Hearing Loss

# Externally-led Patient Focused Drug Development Meetings



[patientfocused@fda.hhs.gov](mailto:patientfocused@fda.hhs.gov)

Chronic, symptomatic, or affects functioning and activities of daily living;

Aspects of the disease are not formally captured in clinical trials;

Currently no therapies or very few therapies, or the available therapies do not directly affect how a patient feels, functions, or survives;

Severe impact on identifiable subpopulations (such as children or the elderly).



# Externally-Led Patient Focused Drug Development Meetings



Inside.FDA Home | Enhancing FDA's Approach to | Learn About FDA Patient Engag | Children's Cause for Cancer Adv

https://www.facebook.com/ChildrensCause/

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Nonprofit Organization in Washington, District of Columbia

4.5 ★★★★★  
Open Now

Community See All

9,652 people like this  
9,589 people follow this

About See All

Lipton Corporate Child Care Center

1325 G Street NW, Suite 540 (1,219.90 mi)  
Washington, District of Columbia 20005  
Get Directions

Children's Cause for Cancer Advocacy

See more of Children's Cause for Cancer Advocacy on Facebook

Log In or Create New Account



# Informing FDA of Needs and Priorities

Comments can be submitted electronically through <http://www.regulations.gov> to any FDA docket

# Patient Representative Program



[FDAPatientRepProgram@fda.hhs.gov](mailto:FDAPatientRepProgram@fda.hhs.gov)

As a consultant for the review divisions (informing determinations of whether medical product's benefits outweigh the potential risks).

May offer patient or caregiver perspective, ask questions, and give comments to assist FDA Advisory Committee recommendations.

As presenters at FDA meetings and workshops on disease-specific or regulatory and health policy issues.



# Pediatric Subcommittee of the Oncology Drug Advisory Committee

ODAC Committee reviews and evaluates data concerning the safety and effectiveness of marketed and investigational human drug products for use in the treatment of cancer and makes appropriate recommendations to the Commissioner of Food and Drugs.

# Oncology Center of Excellence

## 2018 WORKSHOPS

In 2018, OCE held 18 workshops and 16 educational symposia.

Weighing the Evidence: Variant Classification and Interpretation in Precision Oncology	January 29, 2018
FDA-ISoP Public Workshop: Model Informed Drug Development (MIDD) for Oncology Products	February 19, 2018
Oncology Clinical Trials in the Presence of Non-Proportional Hazards	February 5, 2018
FDA-AACR-ASTRO Clinical Development of Drug-Radiotherapy Combinations	February 22-23, 2018
IASLC-FDA Lung Cancer Neoadjuvant Meeting 2018	March 1-2, 2018
Oncology Center of Excellence Listening Session	March 15, 2018
Accelerating Anticancer Agent Development and Validation Workshop 2018	May 2-4, 2018
FDA-AACR-SGO Workshop on Drug Development in Gynecologic Malignancies	June 14, 2018
FDA-ASCO Workshop: 2018 Clinical Outcome Assessments in Cancer Clinical Trials	June 22, 2018
FDA Public Workshop: Development of Treatments for Localized Prostate Cancer	July 11, 2018
FDA-PDS Symposium	August 8, 2018
FDA-AACR Workshop: Non-Clinical Models for Safety Assessment of Immuno-Oncology Products	September 6, 2018
FDA-HESI Public Workshop: Preclinical and Translational Safety Assessment of CD3 Bispecifics	October 1-2, 2018
FDA-ASH Public Workshop: Sickle Cell Disease Clinical Endpoints	October 17-18, 2018
FDA Public Workshop: Clinical Trials to Optimize Outcomes in Early Breast Cancer	October 29, 2018
FDA-SITC Public Workshop: Immune-modified Response Criteria in Cancer Immunotherapy Clinical Trials	November 8, 2018
ASCO Leadership Development Program	November 16, 2018
FDA Public Workshop: Partners in Progress 2018 - Cancer Patient Advocates and FDA	November 27, 2018
FDA Public Workshop: Product Development in Hemophilia	December 6, 2018

Networking lunch for cancer patient advocates and OCE oncologists at the Partners in Progress 2018 - Cancer Patient Advocates and FDA workshop.



# OCE Project Community

Expose community members across the US to the diverse doctors, scientists and health care providers who work as FDA oncology product reviewers while developing synergistic collaborations between reviewers and the community to:

- increase participation in clinical trials & improve the design of clinical trials,
- increase minority participation toward genetic database contributions,
- increase the number of effective cancer diagnostics and products, and
- facilitate access to cancer information for the high-risk individuals, underserved / underrepresented populations and the public.

Create mutually beneficial and enduring partnerships among communities, advocates and OCE cancer product reviewers.

# ENGAGEMENT/OUTREACH (Continued)

## Clinical Oncology for the Non-Oncologist

Successful review of cancer therapies requires a multi-disciplinary team of clinical and non-clinical scientists. The Oncology Center of Excellence (OCE) provides an educational series for the non-oncologist on the natural history and treatment of various cancers, and how this knowledge informs clinical trial design and endpoints.

In 2018, OCE held 5 sessions where experts presented on:

- Acute Lymphocytic Leukemia (ALL), Acute Myeloid Leukemia (AML), and emerging therapies
- Hepatocellular carcinoma (HCC)
- Cutaneous Melanoma
- Brain Tumors for Beginners
- Pancreatic Cancer

## Conversations on Cancer

### *Making Cancer Personal at the FDA*

The Oncology Center of Excellence (OCE) provides a forum to discuss specific cancer topics, including personal stories from employees, a discussion of disease management by our oncology experts, and recent advances in the field.

In 2018, OCE held 2 sessions:

- Impact of Cancer on Patients and Caregivers
- War on Cancer: Progress and Challenges



## OCE's communication outlets include:

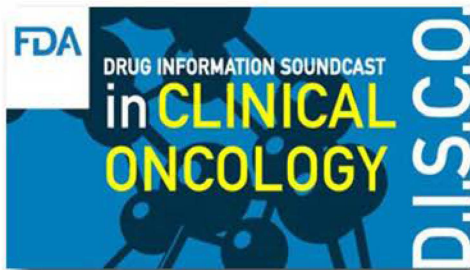
### OCE Oncology/Hematology Approval Announcements web page and listserv:

The OCE posted 63 approval announcements in 2018. These short articles are also sent via a free FDA listserv to over 90,000 email subscribers.



**@FDAOncology on Twitter:** The OCE Twitter account, begun in early 2017, had nearly 10,000 followers at the end of 2018.

**Scientific Journals:** In 2018, OCE and affiliated oncology/hematology staff in other FDA centers published approximately 84 articles in scientific journals.



**FDA Drug Information Soundcast in Clinical Oncology (D.I.S.C.O.)** Produced 9 podcasts in 2018 on drug approvals.

**The Week in Oncology:** A weekly internal email for OCE staff and affiliates across the FDA.





# Acknowledgements



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- Elleni Alebachew: OCE Reg. Project Mgr.
- FDA Patient Affairs Staff
- CDER, Office of the Center Director, PFDD Team
- FDA Advisory Committee Management Team
- FDA Patient Representative Program Team

# Patient Engagement with FDA

<b>Request to Connect with FDA</b>	<a href="http://www.Fda.gov/RequestToConnect">www.Fda.gov/RequestToConnect</a>
Oncology Center of Excellence “Project Community”	<a href="mailto:Rea.Blakey@fda.hhs.gov">Rea.Blakey@fda.hhs.gov</a>
CDER Externally-led Patient Focused Drug Development	<a href="mailto:patientfocused@fda.hhs.gov">patientfocused@fda.hhs.gov</a>
Submissions to FDA Docket	<a href="http://www.regulations.gov">www.regulations.gov</a>
FDA Patient Representative Program	<a href="mailto:FDAPatientRepProgram@fda.hhs.gov">FDAPatientRepProgram@fda.hhs.gov</a>
Oncology Drugs Advisory Committee	<a href="mailto:ODAC@fda.hhs.gov">ODAC@fda.hhs.gov</a>

