U.S. FOOD & DRUG ADMINISTRATION

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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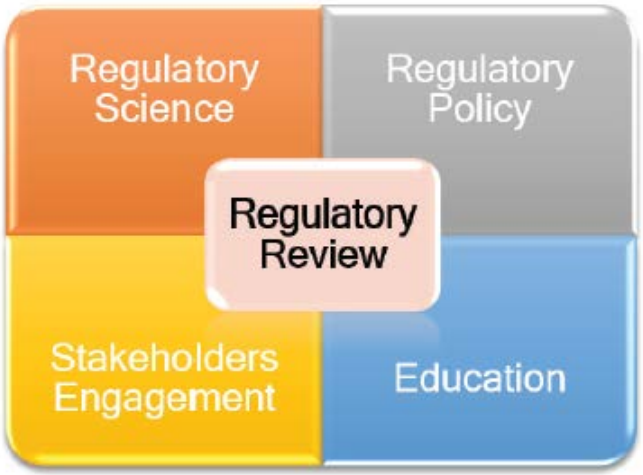
ABOUT THE ONCOLOGY CENTER OF EXCELLENCE

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

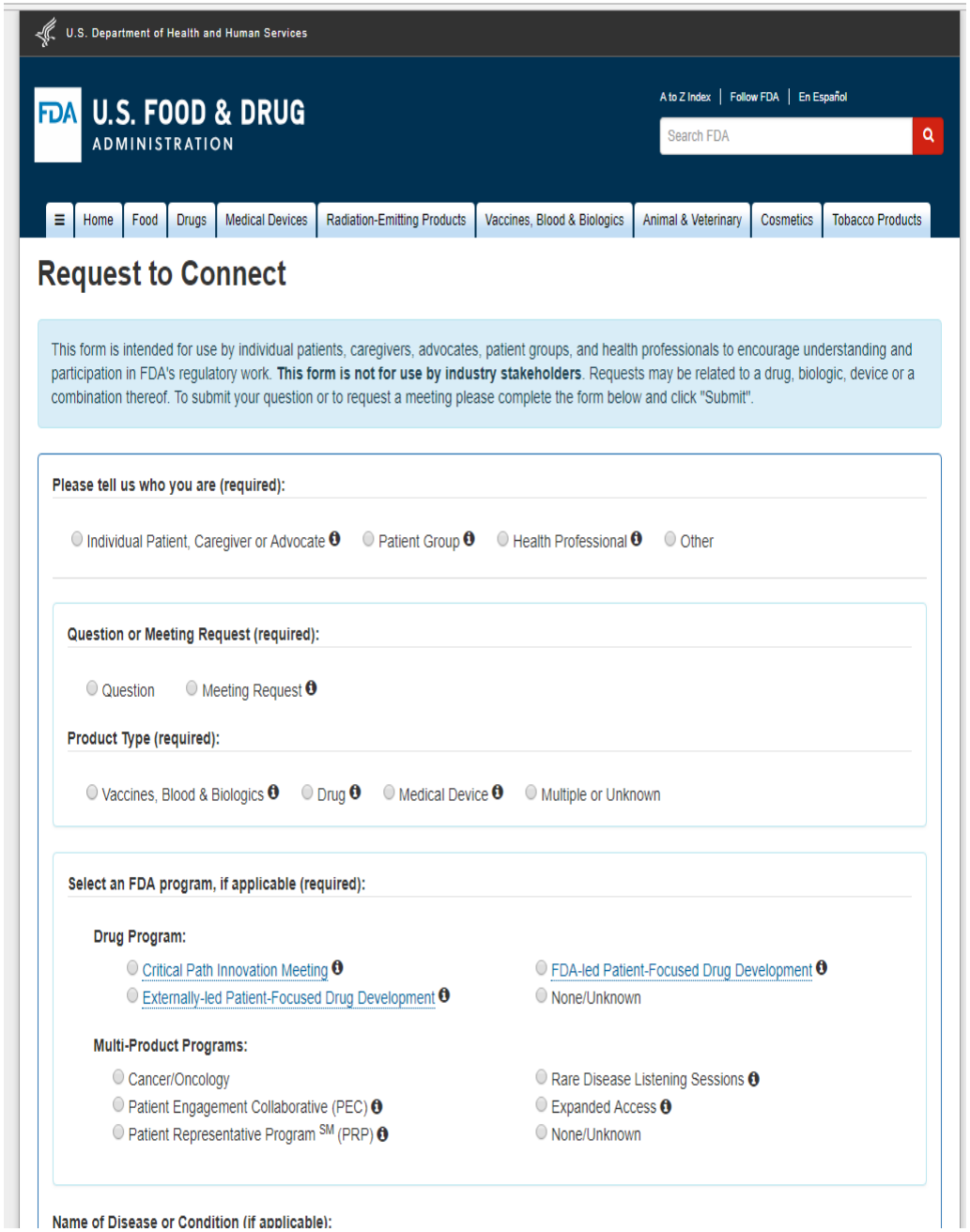
We seek to create a unified and collaborative scientific environment to advance the development and regulation of oncology products for patients with cancer.

A Central Entry Point for Patient Inquiries

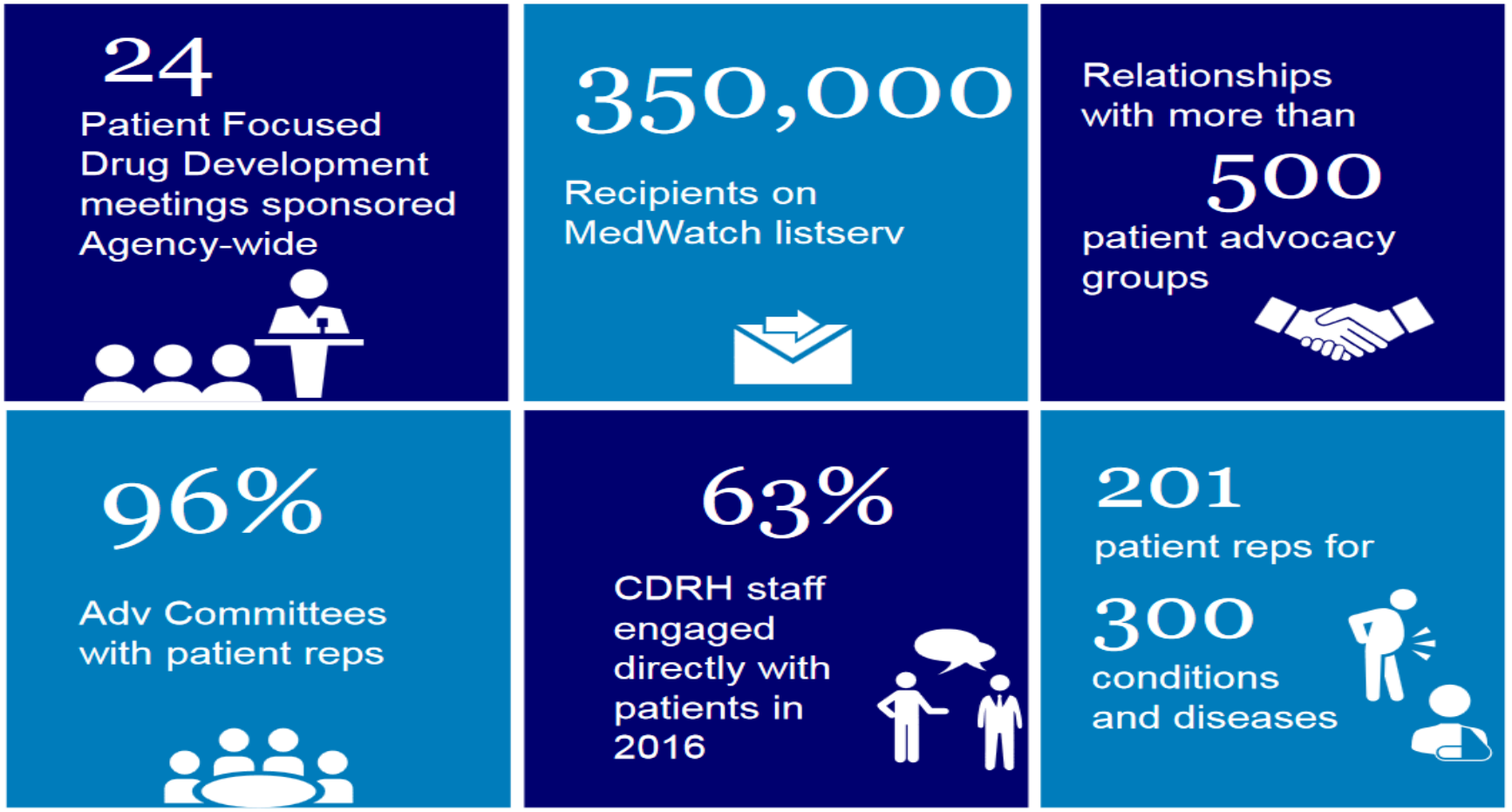
- www.Fda.gov/RequestToConnect
- A triage system to direct inquiries to appropriate center or office
  - Working closely with CBER, CDER, CDRH & other offices (e.g., OEA)
- Leveraging CDER's External Stakeholder Meeting Request (ESMR) System

START HERE

www.fda.gov/requesttoconnect



FDA Patient Engagement by the Numbers



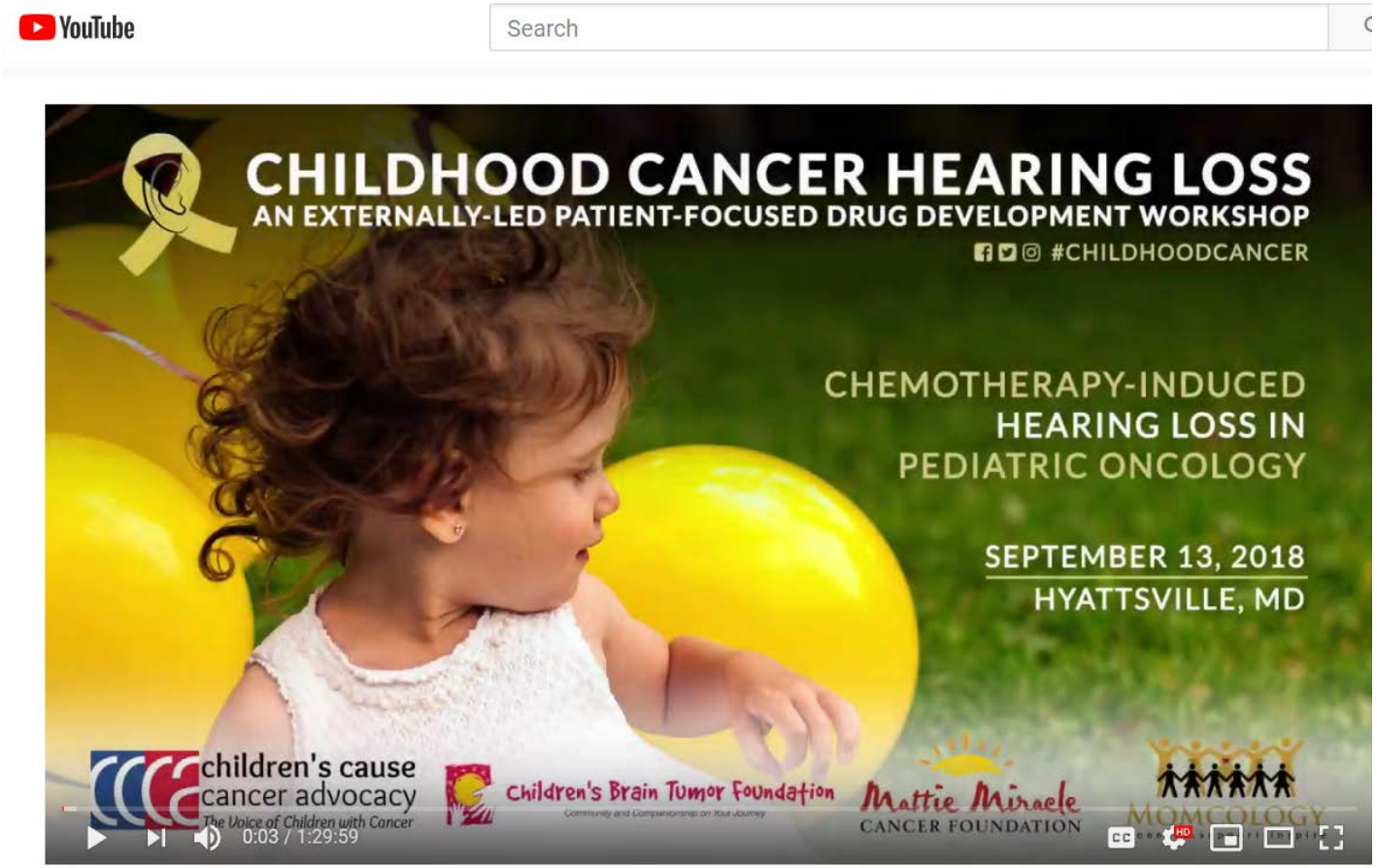
www.fda.gov Source: Client interviews, Center-provided data

FDA's Patient Focused Drug Development Meetings Staff Leads

Externally-led Patient Focused Drug Development Meetings

patientfocused@fda.hhs.gov

Externally-Led Patient Focused Drug Development Meetings

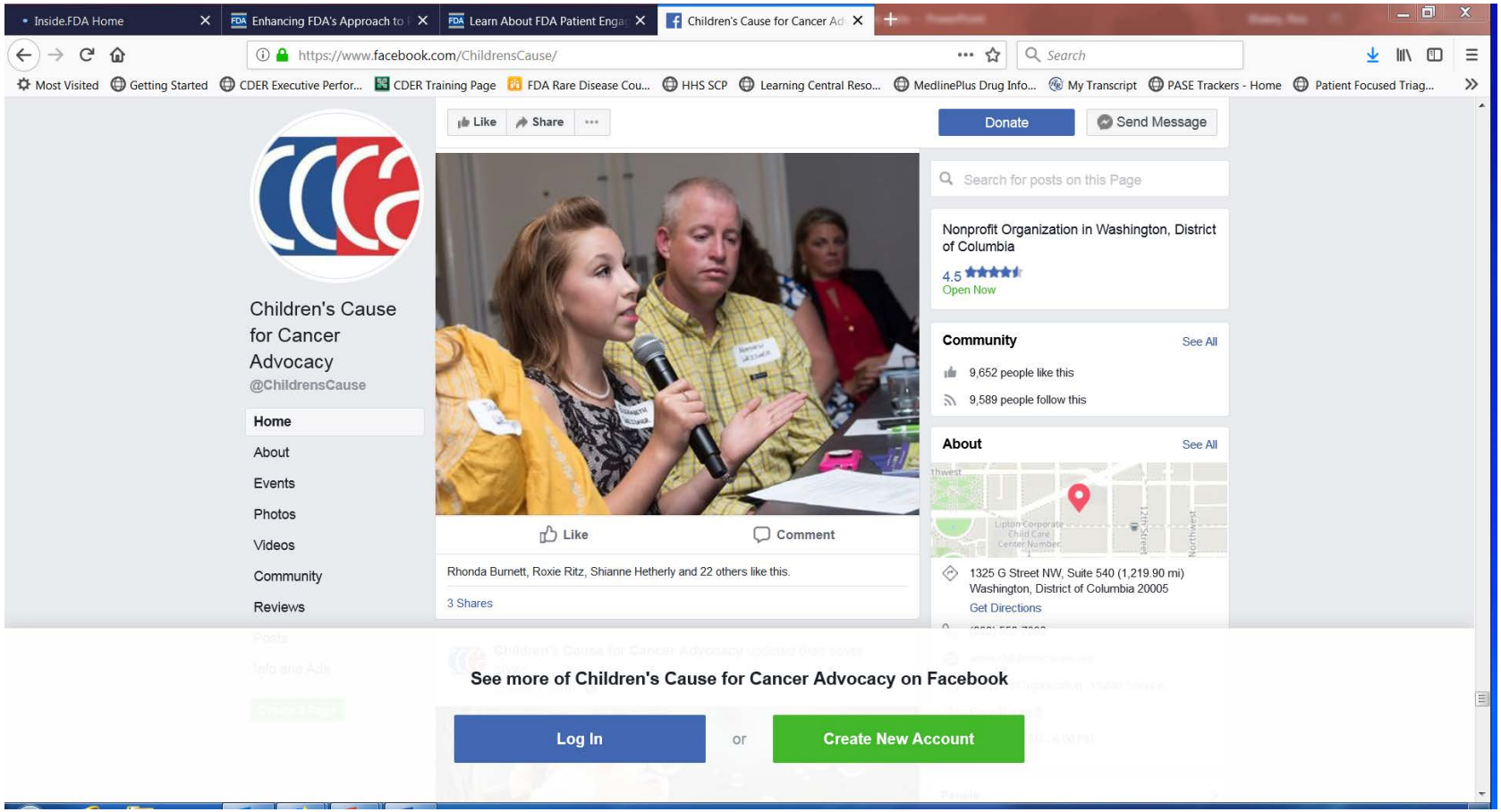


Panel 1: Living with Chemotherapy Induced Hearing Loss

Externally-led Patient Focused Drug Development Meetings

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



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

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 Asessment 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,*

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:

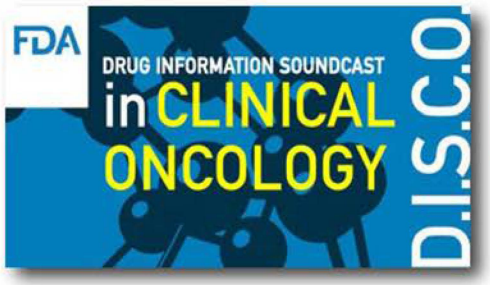
- Impact of Cancer on Patients and Caregivers
- War on Cancer: Progress and Challenges

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

- Gregory Reaman, MD: OCE Associate Director of Pediatric Oncology
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- 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

Request to Connect with FDA	**www.Fda.gov/RequestToConnect**
Oncology Center of Excellence "Project Community"	Rea.Blakey@fda.hhs.gov
CDER Externally-led Patient Focused Drug Development	patientfocused@fda.hhs.gov
Submissions to FDA Docket	www.regulations.gov
FDA Patient Representative Program	FDAPatientRepProgram@fda.hhs.gov
Oncology Drugs Advisory Committee	ODAC@fda.hhs.gov


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