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COMMUNITY

PROJECT  
FACILITATE

PROJECT  
COUNTERPOINT

PROJECT  
ORBIS

ONCOLOGY CENTER OF EXCELLENCE  
PROJECT  
RENEWAL  
Evaluate. Collaborate. Educate.

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SOCRATES

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# ONCOLOGY CENTER OF EXCELLENCE

2019 ANNUAL REPORT



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## DIRECTOR'S MESSAGE



## ENVISIONING ONCOLOGY IN 2025

**Richard Pazdur, MD**

Director, Oncology Center of Excellence

This past year marked my 40th year as an oncologist and 20th year at the Food and Drug Administration. When I started out in oncology, there were about 30 approved drugs for treating patients with cancer. In the past 20 years, we approved 150 drugs for oncology and hematologic malignancies. But the major advances have occurred in our understanding of the mechanisms of disease. That has led to targeted therapies aimed at specific molecular targets on the cancer cells, as well as a greater understanding of the tumor and immunology of disease. We have a whole new class of drugs, the PD-1 drugs, as well as CAR-T therapies. Although the new therapies offer potentially better outcomes for patients, it is also clear to me that improvements can be made in the development of the next generation of these therapies to encourage collaboration among drug developers, reduce duplicative efforts, and enroll patients wisely on trials that will make a difference.

As we enter OCE's third year, we are embarking on Project 2025, an initiative to envision the next five years in cancer drug development and leverage our resources and talents to improve collaboration with stakeholders and move the field forward as quickly as possible. I have asked our Associate Directors and staff to propose bold initiatives that reflect this spirit. Some of those projects are outlined in this report. Two of these initiatives began in 2019. The Project Facilitate call center opened in May 2019 to assist oncology healthcare providers or regulatory professionals in requesting access to investigational therapies for patients with cancer. Project Facilitate is a single point of contact where FDA oncology staff will help physicians and their healthcare team through the process to submit an Expanded Access request for an individual patient with cancer. In September, we launched Project Orbis to provide a framework for concurrent submission and review of oncology products among international regulatory agencies. This collaboration may allow patients with cancer to receive earlier access to products in other countries and may benefit future drug development by encouraging greater uniformity in global standards of treatment. I traveled to Australia and Singapore to meet with the medical product regulatory agencies in both countries, as well as academic and practicing medical and hematologic oncologists, patient advocates, and industry representatives to discuss the first Project Orbis approval in conjunction with Australia's Therapeutic Goods Administration and Health Canada.

On this visit, I also met with physicians who I knew from my days as an oncology training director, and I saw for the first time a cancer center that years earlier I had recommended be built by the Singapore government. Australia and Singapore have well-established and high-quality healthcare systems that provide leadership for clinical trials and drug development in Southeast Asia. Project Orbis may help patients with cancer in those countries get access to new therapies earlier than they would without this effort.

Key to these efforts is the underlying strong regulatory work conducted in the FDA office that reviews drugs for treatment of cancer. When I first arrived at the FDA in 1999, the agency had 10 medical oncologists who each reviewed drugs for all types of cancer. We now have more than 100 medical and hematologic oncologists who specialize in specific cancers and develop deep expertise through their review work, professional development, and research interests. Every so often, reorganization is necessary to better meet the needs of the review work. In November 2019, the Office of Hematology and Oncology Products was reorganized and renamed the Office of Oncologic Diseases. Three divisions reviewing products for oncology and hematologic malignancies became five divisions. This created a flatter organization with smaller clinical divisions to enable more efficient drug review, allow for greater stakeholder engagement in various disease programs, as well as greater professional development opportunities for staff.

At the OCE, our vision is to create a unified and collaborative scientific environment to advance the development and regulation of products for patients with cancer. We hope you will enjoy reading about the work of the OCE and that it inspires you to consider joining us on this endeavor. Take part in our public workshops, tune in to our webinars, listen to talks that our staff give at conferences around the country and the world, read our publications, follow us on Twitter, ask us questions, offer advice, and let us know what's important to you.

## **Richard Pazdur, M.D.**

A handwritten signature in blue ink that reads "Richard Pazdur MD". The signature is written in a cursive, flowing style.

Director, Oncology Center of Excellence

## OCE ORGANIZATIONAL STRUCTURE

### Our Mission

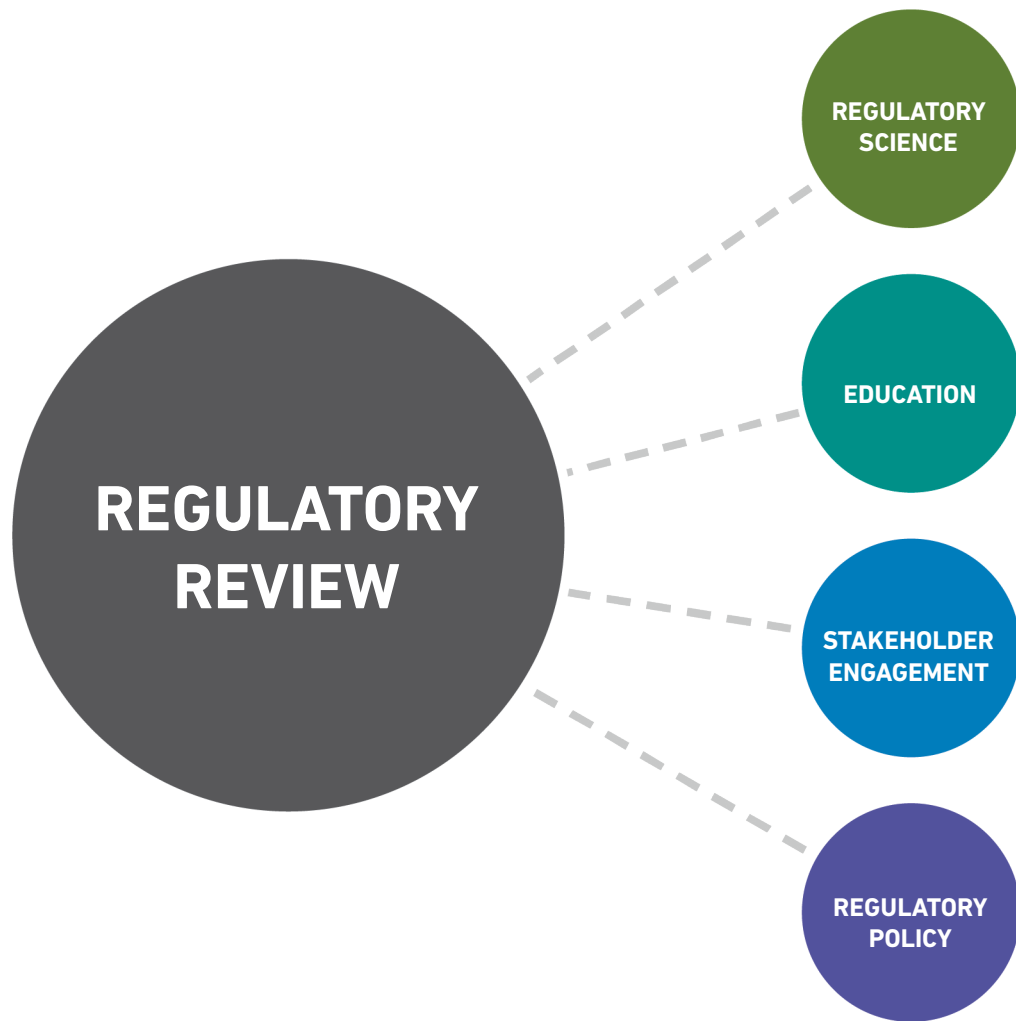
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The mission of the Oncology Center of Excellence is to achieve patient-centered regulatory decision-making through innovation and collaboration.

### Our Vision

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



## 2019 OCE LEADERSHIP

**CENTER DIRECTOR****Richard Pazdur, MD****Deputy Center Director:** Gideon Blumenthal, MD**Deputy Center Director:** Paul G. Kluetz, MD**AD For Immunotherapeutics (Acting):** Marc R. Theoret, MD**AD for Regulatory Affairs:** Tamy Kim, PharmD**AD for Pediatric Oncology:** Gregory Reaman, MD**AD for Medical Policy:** Patricia Keegan, MD**AD for Oncology Devices (Acting), also Chief Medical Officer,  
Office of Surgical and Infection Control Devices, CDRH:** Dorian M. Korz, MD**AD for Oncology In vitro Diagnostics (Acting), also Director of  
Personalized Medicine, CDRH:** Wendy Rubinstein, MD, PhD**AD for Cell and Gene Therapy, also Chief of Oncology Branch,  
CBER/OTAT):** Ke Liu, MD, PhD**AD for Neuro Oncology:** Joohee Sul, MD**AD for Research Strategy and Partnership:** Julie Schneider, PhD**AD for Global Regulatory Outreach:** Dianne Spillman, BS**AD for Communications:** Kirsten Goldberg, MA**AD for External Outreach and Engagement:** Rea Blakey, BS**AD for Education (Acting):** Jennifer Gao, MD**AD for Patient Outcomes (Acting):** Vishal Bhatnagar, MD

\*AD = Associate Director



## REGULATORY REVIEW

Authorized by the 21st Century Cures Act, the OCE was established in January 2017 to facilitate the development and clinical review of oncology products by uniting scientific experts across the FDA's product centers to conduct expedited review of drugs, biologics, and devices.

### In 2019, the FDA approved...

- 11 New molecular entities (NMEs) for oncology
- 27 Supplemental approvals for additional oncology indications or patient populations
- 3 Biosimilars
- 4 Premarket Approval Applications (PMA)
- 4 PMA Modifications

### Several novel review tools were used, including...

- 1 Approval using the [Real-Time Oncology Review \(RTOR\)](#)
- 7 Approvals using the [Assessment Aid](#)
- 12 Approvals using both initiatives

The RTOR, initiated in 2018, permits the FDA to access key data prior to the official submission of the application. The goal is to allow the review team to begin their review earlier and communicate with the applicant prior to the application's complete submission. RTOR has enabled the approval of applications only a few weeks following formal submission.

The Assessment Aid is a multidisciplinary review template divided into two parts: the applicant's position and FDA's assessment. The goal of this initiative is to focus the FDA's written review on critical thinking regarding the adequacy of the data and strength of results, reducing the time spent on recapitulation of information and administrative tasks such as formatting.

## HOW OCE REVIEW WORKS WITH FDA PRODUCT CENTERS:

Applicants submit applications to the product center they normally would, and those centers decide whether the product will be under an expedited program. For products selected, the OCE forms a Medical Oncology Review and Evaluation (MORE) team that includes a medical oncology specialist and specialists from the relevant product center.

### The MORE team:

- Provides a unified clinical review to promote development of safe and effective oncology products.
- Builds on cross-center collaboration by providing input to selected INDs that are under expedited program.
- Implements common decision-making standards for Breakthrough Therapy and Fast Track designation for all oncology therapeutic products.

The completed clinical review is sent to the product center, which makes the final application approval determination, taking into account both clinical and non-clinical information.

**2019 ONCOLOGY APPROVALS\***

PRODUCT	INDICATION	APPLICATION TYPE
<b>Acalabrutinib</b>	Chronic lymphocytic leukemia (CLL) or Small lymphocytic lymphoma (SLL)	Supplement
<b>Ado-trastuzumab emtansine</b>	Adjuvant treatment of patients with HER2-positive early breast cancer (EBC) who have residual invasive disease after neoadjuvant taxane and trastuzumab-based treatment	Supplement
<b>Alpelisib</b>	With fulvestrant for postmenopausal women and men with HR+, HER2 negative PIK3CA mutated, advanced or metastatic breast cancer	NME
<b>Apalatumide</b>	Metastatic castration-sensitive prostate cancer (mCSPC)	Supplement
<b>Atezolizumab</b>	In combination with paclitaxel protein-bound for unresectable locally advanced or metastatic triple-negative breast cancer whose tumors express PD-L1 as determined by an FDA approved test	Supplement
<b>Atezolizumab</b>	In combination with carboplatin and etoposide, for the first-line treatment of adult patients with extensive-stage small cell lung cancer (ES-SCLC)	Supplement
<b>Atezolizumab</b>	In combination with paclitaxel protein-bound and carboplatin for the first-line treatment of adult patients with metastatic non-squamous non-small cell lung cancer (NSCLC) with no EGFR or ALK genomic tumor aberrations	Supplement
<b>Avelumab</b>	In combination with axitinib for first-line treatment of patients with advanced renal cell carcinoma (RCC)	Supplement
<b>Bevacizumab-bvzr</b>	Biosimilar to bevacizumab	Biosimilar
<b>Cabozantinib</b>	Hepatocellular carcinoma previously treated with sorafenib	Supplement
<b>Darolutamide</b>	Non-metastatic castration-resistant prostate cancer (CRPC)	NME
<b>Daratumumab</b>	In combination with lenalidomide and dexamethasone for patients with newly diagnosed multiple myeloma who are ineligible for autologous stem cell transplant	Supplement
<b>Daratumumab</b>	Multiple myeloma in combination with bortezomib, thalidomide, and dexamethasone in newly diagnosed patients who are eligible for autologous stem cell transplant (ASCT)	Supplement
<b>Enfortumab vedotin-ejfv</b>	Locally advanced or metastatic urothelial cancer who have previously received a programmed death receptor-1 (PD-1) or programmed death-ligand 1 (PD-L1) inhibitor, and a platinum-containing chemotherapy in the neoadjuvant/adjuvant, locally advanced or metastatic setting	NME
<b>Entrectinib</b>	ROS1-positive NSCLC	NME
<b>Entrectinib</b>	Adult and pediatric patients with solid tumors with NTRK gene fusion	NME
<b>Enzalutamide</b>	Metastatic castration-sensitive prostate cancer (mCSPC)	Supplement
<b>Erdafitinib</b>	Locally advanced or metastatic urothelial carcinoma that has FGFR3 or FGFR2 alterations and progressed during or following at least 1 line of platinum-containing chemotherapy	NME
<b>Fam-trastuzumab deruxtecan-nxki</b>	Unresectable or metastatic HER2-positive breast cancer who have received two or more prior anti-HER2-based regimens in the metastatic setting	NME
<b>Ivosidenib</b>	Newly diagnosed acute myeloid leukemia (AML) in >75 years old or who have comorbidities that preclude the use of intensive induction chemotherapy	Supplement

\* Approval numbers reflect approvals from CBER, CDER and CDRH

PRODUCT	INDICATION	APPLICATION TYPE
<b>Lenalidomide</b>	With rituximab for previously treated follicular lymphoma (FL) and marginal zone lymphoma (MZL)	Supplement
<b>Niraparib</b>	Advanced ovarian, fallopian tube, or primary peritoneal cancer who have been treated with three or more prior chemotherapy regimens and are HRD positive	Supplement
<b>Olaparib</b>	Maintenance treatment of deleterious or suspected deleterious germline or somatic BRCA-mutated advanced epithelial ovarian, fallopian tube or primary peritoneal cancer who are in complete or partial response to 1st-line platinum-based chemotherapy	Supplement
<b>Olaparib</b>	Maintenance treatment for BRCA-mutated metastatic pancreatic cancer	Supplement
<b>Pembrolizumab</b>	Adjuvant melanoma with involvement of lymph nodes following resection	Supplement
<b>Pembrolizumab</b>	First line treatment of Stage III NSCLC who are not candidates for surgical resection or definitive chemoradiation or metastatic NSCLC, and whose tumors express PD-L1	Supplement
<b>Pembrolizumab</b>	Metastatic SCLC with disease progression on or after platinum-based chemotherapy and at least one other prior line of therapy	Supplement
<b>Pembrolizumab</b>	Recurrent locally advanced or metastatic squamous cell carcinoma of the esophagus whose tumor's express PD-L1	Supplement
<b>Pembrolizumab</b>	In combination with axitinib for the first-line treatment of patients with advanced renal cell carcinoma (RCC)	Supplement
<b>Pembrolizumab</b>	In combination with lenvatinib for advanced endometrial carcinoma that is not MSI-H or DMMR	Supplement
<b>Pembrolizumab</b>	First-line treatment of patients with metastatic or unresectable recurrent head and neck squamous cell carcinoma (HNSCC)	Supplement
<b>Pexidartinib</b>	Symptomatic tenosynovial giant cell tumor associated with severe morbidity or functional limitations and not amenable to improvement with surgery	NME
<b>Polatuzumab vedotin-piiq</b>	With bendamustine and rituximab for diffuse large B-cell lymphoma (DLBCL) after two prior therapies	NME
<b>Ramucirumab</b>	Hepatocellular carcinoma with AFP >400 ng/ml and have been treated with sorafenib	Supplement
<b>Rituximab-pvvr</b>	Biosimilar to Rituximab	Biosimilar
<b>Ruxolitinib</b>	Steroid refractory graft-versus-host disease (GVHD) in adult and pediatric patients 12 years and older	Supplement
<b>Selinexor</b>	With dexamethasone for relapsed/refractory multiple myeloma	NME
<b>Tipiracil hydrochloride and trifluridine</b>	Metastatic gastroesophageal junction (GEJ) adenocarcinoma previously treated with two prior lines of chemotherapy	Supplement
<b>Trastuzumab-pkrb</b>	Biosimilar to Trastuzumab	Biosimilar
<b>Venetoclax</b>	With obinutuzumab in untreated CLL or SLL	Supplement
<b>Zanubrutinib</b>	Mantle cell lymphoma after one prior therapy	NME
<b>Ventana PD-L1(SP142) CDX assay</b>	Expanding the indications to include triple negative breast cancer (TNBC)	PMA Modification

PRODUCT	INDICATION	APPLICATION TYPE
<b>Therascreen FGFR RGQ RT-PCR kit</b>	PCR test of RNA samples from FFPE urothelial tumor for urothelial cancer treatment with BALVERSA (erdafitinib)	PMA
<b>Therascreen PIK3CA RGQ PCR kit</b>	PCR test of gDNA samples from FFPE breast tumor for breast cancer treatment with PIQRAY (alpelisib) based on a PIK3CA mutation detected result	PMA
<b>Therascreen PIK3CA RGQ PCR kit</b>	PCR test of ctDNA sample from plasma for breast cancer treatment with PIQRAY (alpelisib) based on a PIK3CA mutation detected result	PMA
<b>FoundationOne CDX</b>	Expanding the indications to include olaparib as a therapeutic for ovarian cancer with BRCA1/2 alterations	PMA Modification
<b>FoundationOne CDX</b>	Expanding the indications to include Tagrisso (osimertinib) as a therapeutic for non-small cell lung cancer (NSCLC) with EGFR exon 19 deletions and EGFR exon 21 L858R alterations	PMA Modification
<b>PD-L1 IHC 22C3 PHARMDX</b>	Expanding the indications to include esophageal squamous cell cancers	PMA Modification
<b>Mychoice HRD CDX</b>	NGS test of DNA samples from FFPE ovarian tumor for ovarian cancer treatment with Zejula (niraparib) based on BRCA1/2 mutations and Genomic Instability Score (GIS) results	PMA

## 2019 SUBMISSIONS REVIEWED UNDER EXPEDITED PROGRAMS\*

	Granted	Denied	Withdrawn
<b>Fast Track</b>	<b>45</b>	<b>26</b>	<b>0</b>
<b>Breakthrough Designation</b>	<b>35</b>	<b>15</b>	<b>14</b>
<b>Regenerative Medicine Advanced Therapy</b>	<b>3</b>	<b>4</b>	<b>0</b>

\* Approval numbers reflect approvals from CBER and CDER. In 2019 CDRH has received 243 Breakthrough Device requests and 136 were granted Breakthrough Devices. Out of the 136 granted Breakthrough Devices, 19 were Oncology related.

2019 REGULATORY INITIATIVES



Our Project Facilitate staff helping oncology healthcare professionals with Expanded Access requests for patients with cancer.

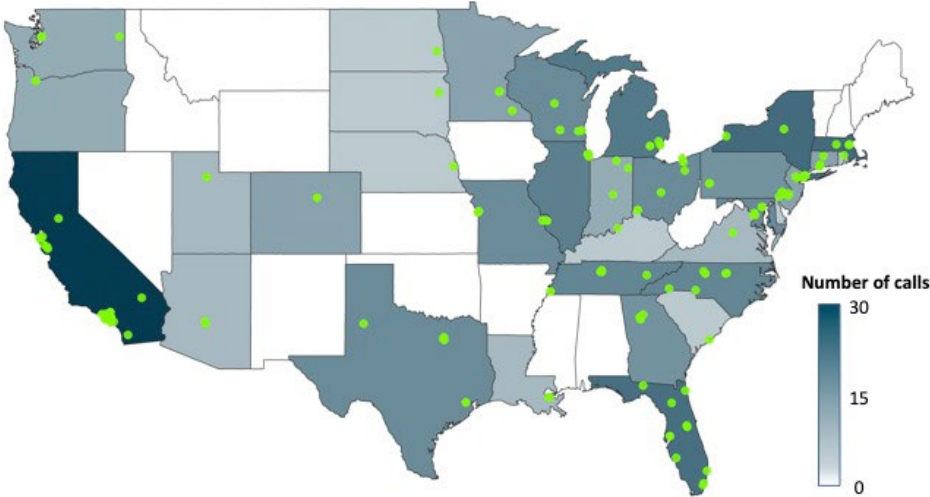
**Project Facilitate** is a pilot program to assist oncology healthcare professionals in requesting access to investigational therapies for patients with cancer. Project Facilitate is a single point of contact where FDA oncology staff will help physicians and their healthcare team through the process of submitting an Expanded Access request for an individual patient with cancer.

Project Facilitate staff can assist in locating IRB resources, finding the contact information for the drug manufacturer, and completing Form FDA 3926. FDA allows a vast majority of these requests to proceed, and Project Facilitate is here to guide oncology healthcare providers through the process. Project Facilitate staff will also follow up on requests to determine treatment outcomes and assist with follow-up reporting.

Healthcare providers or regulatory professionals may call Project Facilitate at (240) 402-0004 from 8 a.m. to 4:30 p.m. Eastern time, Monday through Friday.

Email: [OneProjectFacilitate@fda.hhs.gov](mailto:OneProjectFacilitate@fda.hhs.gov). For further information, refer to [Project Facilitate](#) webpage and [video link](#).

PROJECT FACILITATE - NUMBER OF CALLS FROM SITES





**Project Renewal** is a public health initiative that aims to update safety and efficacy information in the product labels for long-standing but critically important oncology drugs. The project is working to establish a set of repeatable processes to evaluate scientific evidence from available published literature to inform regulatory decisions for oncology product labeling updates, including potential new indications for use.

Project Renewal also provides the OCE with the opportunity to engage with the external oncology community and early career scientists to improve their understanding of the product labels and FDA regulatory review.

### KEY OBJECTIVES OF PROJECT RENEWAL



**Develop Repeatable Processes**

to evaluate scientific evidence and determine whether labeling updates are needed



**Use Published Data**

to research off-label uses and develop a method to update existing labels



**Engage with Oncology Community**

to increase transparency of FDA processes and encourage collaboration



**Foster Educational Experiences**

for Oncology Fellows to learn about the FDA’s mission and regulatory processes



Participating in the FDA Project Renewal process contributed more to my clinical practice than I realized that it would. My skills in literature review were sharpened, and it was gratifying to apply my clinical knowledge to help to make such a large impact while still in training. I’m very happy to have had this unique opportunity.



**Dr. Simran Elder,**

Oncology Fellow, University of Maryland, School of Medicine, Greenbaum Cancer Center



# PROJECT ORBIS



OCE Director Richard Pazdur, MD, met with representatives from cancer patient advocacy groups on his trip to Australia in 2019.



Dr. Pazdur and the OCE delegation met with staff from the Australia Therapeutic Goods Administration for productive discussion of collaborative reviews of oncology product applications and other issues in cancer drug development.

**Project Orbis** provides a framework for concurrent submission and review of oncology products among international regulators, which may allow patients with cancer to receive earlier access to products in countries where there may be significant delays in reviewing regulatory submissions, regardless of whether the product has received FDA approval.

Two Project Orbis actions took place in the fall of 2019, both in conjunction with the Australian Therapeutic Goods Administration and Health Canada.

Project Orbis is an outgrowth of teleconferences that the Office of Oncologic Diseases (OOD) has held since 2004 under a confidentiality agreement with other regulatory agencies to allow for exchange of information and collaboration on specific topics related to oncology applications under review. Currently, OOD holds a monthly teleconference with Australia's Therapeutic Goods Administration, Health Canada, the European Medicines Agency, Japan's Pharmaceuticals and Medical Devices Agency, and Switzerland's Swissmedic. Also, FDA and China's National Medical Products Administration have begun a quarterly meeting to discuss non-product specific regulatory issues facing worldwide drug development.

Pivotal clinical trials in oncology are commonly conducted internationally and these global trials are increasingly important for investigating the safety and effectiveness of cancer drugs for approval in the United States. Future drug development may benefit by establishing a greater uniformity of new global standards of treatment, leading to the optimal design of these important trials.

**Project Point/Counterpoint.** At a meeting of the Oncologic Drugs Advisory Committee on December 17-18, 2019, the OCE and the OOD tested a new version of the advisory committee briefing document. This pilot project combined the company’s position and the FDA’s position in one document, similar to the Assessment Aid.

The new briefing document increases the transparency of differences in viewpoints and is more concise to focus on salient data and facilitate the committee’s understanding of the critical issues for discussion.

**Project Protect** encompasses the OCE’s efforts to ensure the safety of drugs approved to treat patients with cancer.

Project Protect will also leverage the new requirement, under the Digital IND Safety Reporting Program, for IND safety reports to be submitted in a standard electronic format to allow for more effective review and tracking of this important safety information.

PROJECT PROTECT INCLUDES:

**A new centralized Safety Team**

that will foster consistent review, management, and communication of safety information across OOD Divisions and throughout the pre- and postmarket life-cycle of a drug and drugs within the same class.

**Data analysts to assist reviewers**

with regulatory and research initiatives using new analytic tools to maximize the efficiency of review of safety data from the IND stage, through application review, and after approval.

**Development of data standards,**

encouraging applicants to provide data in a consistent format to facilitate analysis of safety information in NDA and BLA applications.



## OCE PROGRAMS

### IMMUNO-ONCOLOGY

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The OCE Immuno-Oncology Therapeutics Program (IOTP) brings together expertise across the FDA and promotes development of immuno-oncology (IO) therapeutics to engage new, more efficacious treatment paradigms for patients with cancer.

#### HIGHLIGHTS OF THE **IOTP** IN 2019 INCLUDE:

**Approved new indications across several immune checkpoint inhibitors for patients with a variety of epithelial cancers, include the first IO approval for an aggressive form of breast cancer.**

**Supported internal and external regulatory science research efforts to advance IO therapeutics development, including the addition of IO research opportunities as a standalone portion of the FDA's Broad Agency Announcements.**

**Held several workshops and presentations on the unique features and pressing needs of IO therapeutics development, including a Friends of Cancer Research workshop on issues surrounding demonstration of contribution of effect for combinatorial drug development, as well as the FDA-Melanoma Research Alliance on development of neoadjuvant therapies for patients with melanoma.**

Looking forward to 2025, the IOTP will serve to address present and emerging challenges for development of IO products:

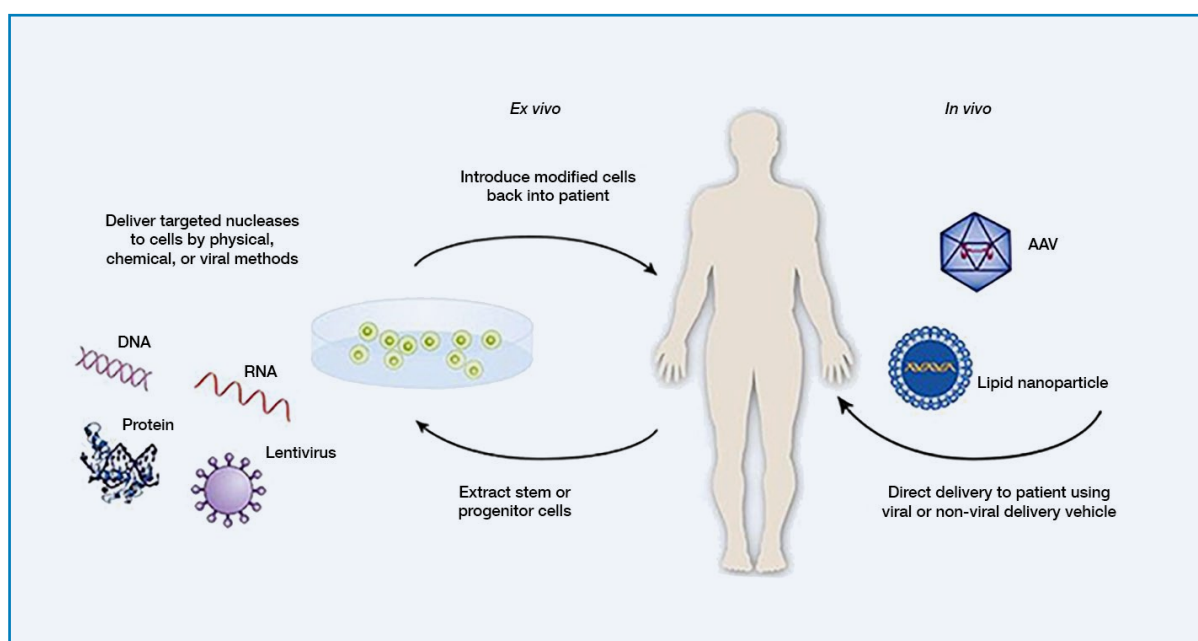
- **Foster** development of biomarkers that optimize the benefit-risk of cancer immunotherapeutics such as predictive biomarkers to identify patients more likely to respond, to develop a serious immune mediated toxicity, or require combinatorial approaches to address a potential resistance to a cancer immunotherapeutic.
- **Investigate** novel endpoints—using both existing and emerging technologies—that more fully characterize the clinical benefit of cancer immunotherapeutics.
- **Evaluate** novel drug development programs and pathways that disrupt the chemotherapeutic drug development paradigm and account for the unique aspects of cancer immunotherapeutics.
- **Develop** methodology and establish resources to interrogate the impact of novel regulatory actions or determinations—regulatory paths often forged by cancer immunotherapeutics, such as complementary diagnostics and tissue agnostic drug development.
- **Foster** collaborations with patient advocacy, scientific, and professional organizations with expertise in immuno-oncology to identify and address potential challenges for translating scientific advances at the bench to therapeutic advances for patients with cancer.

## ONCOLOGY CELL AND GENE THERAPY

The Oncology Cell and Gene Therapy program focuses on clinical evaluations for, and helps to expedite development of, cellular cancer therapies. Examples include T-cells modified with chimeric antigen receptors (CAR-Ts) or with T-cell receptors with redirected specificity (TCR-Ts), and developed using technologies including gene-editing, e.g., clustered regularly interspaced short palindromic repeats (CRISPR) or transcription activator-like effector nucleases (TALEN); novel strategies in hematopoietic stem cell transplantation (HSCT); dendritic cells; adoptive T-cell therapies; tumor neoantigen-based personalized medicine (vaccine or cell therapy); natural killer cells; oncolytic bacteria and viruses; therapeutic cancer vaccines; therapies that modulate the microbiome; and combinations of these therapeutics with hematopoietic stem cell transplantation, checkpoint inhibitors, chemotherapies, radiation and other agents.

To facilitate rapid research, development, and commercialization of CAR T-cell therapy so that more patients with cancer can benefit from it, OCE has worked with CBER to hold workshops with the Center for Medicare & Medicaid Services during its national coverage determinations.

In collaboration with the FDA Center for Biologics Evaluation and Research (CBER), OCE has also engaged with stakeholders in workshop discussions to facilitate development of novel cancer therapies—such as oncolytic viral therapy, cancer vaccines, and neoantigen-based therapy and microbiome therapy.



## ONCOLOGY DEVICES AND DIAGNOSTICS

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Oncology devices and diagnostics are reviewed and regulated by the Center for Devices and Radiological Health (CDRH) in partnership with OCE. In 2019, CDRH and OCE worked toward our common goal of patient-centered oncologic approaches and education through Project Personalized Medicine and Project Device Safety.

CDRH cleared fluorescence imaging devices using Indocyanine Green, for use in lymphatic mapping and tissue perfusion during and after resection of tissues, including renal tumors. The Cellvizio Confocal laser system and Nvision Optical Probe were cleared with indications to allow for imaging of the internal microstructure of tissues including esophageal and pancreatic-biliary systems.

Continuing our role of educating patients and health care providers about the benefits and risks of medical devices, CDRH updated the FDA website for medical device reports of breast implant-associated anaplastic large cell lymphoma (BIA-ALCL), a type of non-Hodgkin's lymphoma and a known risk from breast implants. A letter to health care providers was issued regarding identification, diagnosis, and treatment of BIA-ALCL. A public meeting in March 2019 discussed BIA-ALCL, the use of registries for breast implant surveillance, and best practices for informed consent discussion between patients and clinicians. FDA took significant action to protect women from BIA-ALCL by requesting that Allergan, the manufacturer of a specific type of textured breast implant, recall those implants due to the risk of BIA-ALCL.

In 2019, FDA approved several companion diagnostics including (1) a PCR-based test to detect PIK3CA mutations in FFPE tissue and plasma specimens from patients with breast cancer for treatment with PIQRAY (alpelisib) and (2) an NGS-based test for HRD-positive status determination in FFPE tissue from patients with ovarian cancer for treatment with Zejula (niraparib).

For a complete list of FDA-cleared or approved companion diagnostic devices, see: [\*\*List of Cleared or Approved Companion Diagnostic Devices \(In Vitro and Imaging Tools\).\*\*](#)



## ONCOLOGY REGULATORY AFFAIRS

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The focus of Oncology Regulatory Affairs is to develop and implement procedures that improve the regulatory review of oncology products across centers, interact with colleagues in CDRH, CDER, and CBER to allow for a more coordinated review of products undergoing review by OCE, facilitate OCE policy development, and provide a forum to exchange ideas and streamline regulatory review processes.

### **OCE Division Directors weekly meeting:**

The goal of these meetings is update OCE management on upcoming regulatory decisions or guidance and policy issues.

### **OCE Rounds:**

These meetings provide an open forum to discuss newly received NMEs, original BLAs, BTDs, RMATs, and notable supplements to elicit feedback from other disciplines such as biostatistics, clinical pharmacology, and product quality.

In 2019, Oncology Regulatory Affairs successfully launched Project Facilitate, provided regulatory advice and support for the RTOR, Assessment Aid, PFDD program, Pediatric Oncology Program, oncology guidance development and developed innovative regulatory automation and knowledge management tools. In general, Oncology Regulatory Affairs is a resource for FDA oncology when complex regulatory issues arise.

Looking toward 2025, this program hopes to further streamline and provide innovative ideas for internal and external regulatory processes to help expedite cancer drug development.



## PATIENT-FOCUSED DRUG DEVELOPMENT

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The OCE Patient-Focused Drug Development (PFDD) program fosters collaboration between FDA centers and external stakeholders involved in patient outcomes research in cancer populations. The goal is to identify rigorous methods to assess the patient experience that will complement existing survival and tumor information to better inform a cancer therapy's effect on the patient.

### IN 2019, THE PROGRAM ADVANCED ITS MISSION IN SEVERAL KEY AREAS

#### **Engaging with patients and advocacy groups.**

The program held its third annual Partners in Progress workshop, bringing advocates to the FDA to engage in dialogue and learn about regulatory science and policy. Another collaboration with advocacy groups sought to better understand patients' impression of visualization of clinical outcome assessments such as patient-reported outcomes (PRO) measures capturing symptomatic adverse events in cancer trials.

#### **Generating science-based recommendations for regulatory policy.**

The program co-sponsored its fourth annual Clinical Outcomes Assessment in Cancer Clinical Trials workshop with the American Society for Clinical Oncology. Over 500 international experts attended to hear discussions related to methods to rigorously assess physical function in cancer populations.

#### **Fostering research into measurement of the patient experience.**

The program published over 15 papers and abstracts on aspects of PRO analysis including missing data, effects of open label trials, and commonly used PRO tools in multiple peer-reviewed publications.

#### **Finding novel ways to communicate the patient experience.**

The program is advancing several initiatives to convey PRO data collected in cancer trials to patients and healthcare providers to better inform treatment decisions. This includes publications, public workshops, and web-based initiatives.



Looking toward 2025, the PFDD program will continue to advance patient-focused clinical research and assess and communicate rigorous patient experience data to inform FDA regulated products. Near-term goals include:

- **Continuing** our collaboration with patients, advocates, and drug developers on appropriate visualizations to communicate symptomatic adverse events and physical function data in a way that is clear and interpretable.
- **Communicating** patient-reported symptom and function data through publications and potential web-based solutions, with a goal to supplement existing data from the product label using standardized analytic methods and visualizations.
- **Fostering** development of technologies to collect data on symptoms and function for use in clinical trial and clinical care settings, including clarifying best practices for electronic capture using ePRO, wearable devices, and other sensor data.
- **Exploring** novel clinical endpoints, including composite or multi-component clinical and PRO data to complement a primary tumor-based or survival endpoint.
- **Advancing** clinical outcome assessment research through internal FDA research and collaborative efforts and engaging the scientific community through peer-reviewed literature and international conferences.



OCE Deputy Director Paul Kluetz, MD, opening the 2019 Clinical Outcomes Assessment in Cancer Clinical Trials workshop.

## PEDIATRIC ONCOLOGY

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The Pediatric Oncology Program is charged with assuring access to safe and effective cancer drugs and biologic products for children as expeditiously as possible. Because cancer drug development for children largely leverages drug development for cancers in adults, we focus on maximizing the regulatory authority available to the FDA.

Under the Best Pharmaceuticals for Children Act, we invite sponsors to present products earlier in the development timeline at the Pediatric Subcommittee of the ODAC. This allows us to expedite development and issue Written Requests for pediatric studies when appropriate. Recent amendments to the Pediatric Research Equity Act (PREA) enacted as Sec. 504 of FDA Reauthorization Act of 2017 (FDARA) provide an unprecedented opportunity to accelerate pediatric cancer drug development.

## EFFORTS TO SUCCESSFULLY IMPLEMENT THIS LEGISLATION INCLUDE:

Developing a **list of relevant molecular targets** vetted by external stakeholders in a series of public meetings to guide industry in developing possible pediatric development plans.

Sponsoring a public workshop to review two classes of targets with input from key thought leaders on pediatric application of immunotherapy and cell and gene therapy.

Taking part in meetings with BIO and PhRMA, industry-sponsored Pediatric Cancer Workshops, semi-annual Pediatric Liaison meetings, a Pediatric Cancer Advocacy Forum, and the Pediatric Cancer Working Group of the American Association for Cancer Research.

Collaborating with the FDA Office of Clinical Pharmacology to evaluate an AI (machine-learning) approach to refining the molecular targets list through a text-mining approach of published abstracts and publicly-available gene sequencing databases.

Developing a legislatively mandated draft guidance, **FDARA Implementation Guidance for Industry on Pediatric Studies of Molecularily Targeted Oncology Drugs.**

Providing sponsors with early advice on pediatric development, as mandated by Sec 503 of FDARA. Now designated as Type F meetings, these will assist sponsors in submitting initial Pediatric Study Plans (iPSPs).

Working with the U.S. National Cancer Institute, the Foundation for the NIH, industry, advocates, and academic investigators to develop a public-private partnership to broaden preclinical testing capabilities using pediatric tumor models of targeted drugs.

Collaborating with international regulators through regular teleconferences, which have resulted in the issuance of 5 Common Commentaries for industry.

Successful implementation of these amended provisions will dramatically change the landscape of pediatric cancer drug development into 2025 and provide the necessary environment and framework to accelerate early evaluation of novel drugs resulting in increased access to safe and effective cancer therapeutics for children and decreasing the timelines for development.

## PEDIATRIC ONCOLOGY APPROVAL FOR 2019

On August 15, 2019, the FDA granted accelerated approval to entrectinib (ROZLYTREK, Genentech Inc.) for adults and pediatric patients 12 years of age and older with solid tumors that have a neurotrophic tyrosine receptor kinase (NTRK) gene fusion without a known acquired resistance mutation, are metastatic or where surgical resection is likely to result in severe morbidity, and have progressed following treatment or have no satisfactory standard therapy. **More Information.**

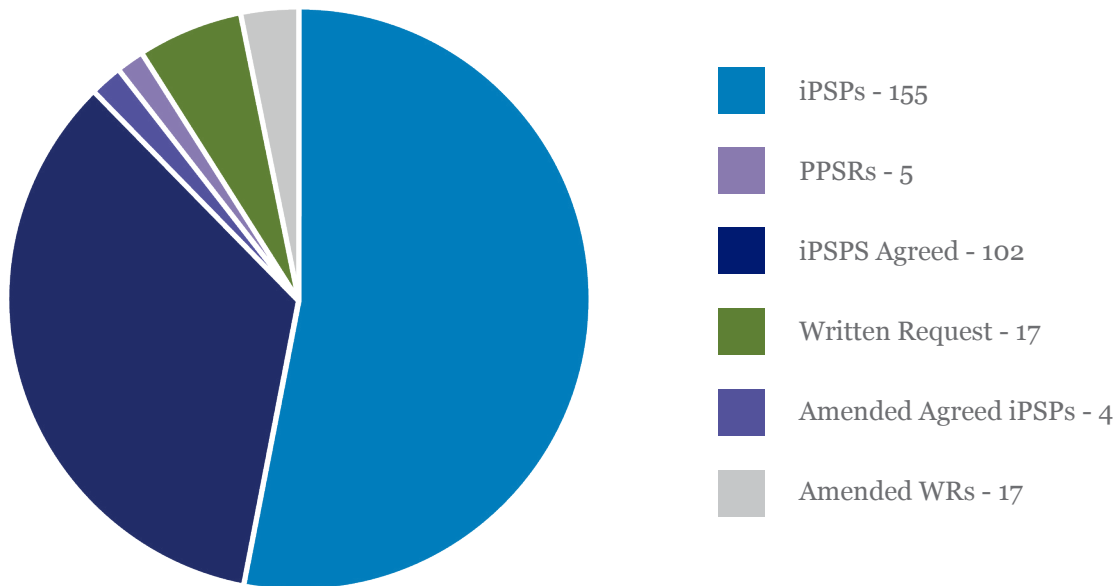
## ONCOLOGY SUBCOMMITTEE OF THE FDA'S PEDIATRIC REVIEW COMMITTEE (PERC)

An Oncology Subcommittee of the FDA's Pediatric Review Committee (PeRC) was established to provide pediatric cancer expertise in the review of initial Pediatric Study Plans (iPSPs), amended agreed iPSPs, Proposed Pediatric Study Requests (PPSRs), Written Requests (WRs), amended Written Requests (WRs) and marketing application pediatric plans.

**This past fiscal year the committee reviewed:**



### OCE PeRC TYPES OF REVIEWS





## PRECISION ONCOLOGY

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Precision oncology leads to customization of healthcare, with medical decisions, practices and products being tailored to each individual patient with cancer. In oncology drug, biologic, and device development, more precise targeting of a product to an individual's genomic, proteomic, or metabolomic make-up will likely lead to more effective and less toxic anti-cancer therapies.

Highlights of the Precision Oncology Program in 2019 include multiple workshops, including the FDA OCE, American Society of Clinical Oncology (ASCO) and Friends of Cancer Research (FOCR) workshop on development of tissue-agnostic, biomarker-based indications, held at FDA in April. A number of notable precision oncology approvals took place in 2019, including the second new molecular entity approved for a tissue-agnostic indication. In addition, the second solid tumor circulating tumor DNA test was approved, to detect PI3K mutations in patients with certain forms of advanced breast cancer.

Looking ahead toward 2025, the Precision Oncology Program hopes to ensure further development of biomarker-based drug development, including furthering policy on tissue-agnostic drug development, novel clinical trial designs incorporating blood-based biomarkers such as circulating tumor DNA, and novel imaging modalities. The program also will work with patient advocacy groups to ensure that the language around genomics and precision oncology is patient-friendly and easy to understand.



RESEARCH

PROJECT .....  
NextGen  
... RESEARCH

**Project NextGen Research.** FDA’s own translational research laboratory continues to interface with academic oncology centers, NIH, industry, and cooperative groups to collaborate on projects with regulatory implications. Abstracts on predicting immune related events based on germline signatures, and T cell repertoire in multiple myeloma were presented at prestigious national meetings with publications in press. Upcoming projects involve developing biomarkers to predict response in IDH mutated AML, using blockchain to transmit genomic data rapidly and securely, and understanding capabilities for detection of ctDNA in patients with lung cancer.



Project NextGen Research team members

## GUIDANCES

The OCE has led or participated in the development of 12 oncology-specific guidances in the past year.

TITLE	TYPE	DATE POSTED
<a href="#">FDARA Implementation Guidance for Pediatric Studies of Molecularly Targeted Oncology Drugs: Amendments to Sec. 505B of the FD&amp;C Act</a>	Draft	December 2019
<a href="#">Investigational In Vitro Diagnostics in Oncology Trials: Streamlined Submission Process for Study Risk Determination</a>	Final	October 2019
<a href="#">Placebos and Blinding in Randomized Controlled Cancer Clinical Trials for Drug and Biological Products</a>	Final	August 2019
<a href="#">Oncology Therapeutic Radiopharmaceuticals: Nonclinical Studies and Labeling Recommendations</a>	Final	August 2019
<a href="#">Male Breast Cancer: Developing Drugs for Treatment</a>	Draft	August 2019
<a href="#">Advanced Prostate Cancer: Developing Gonadotropin-Releasing Hormone Analogues</a>	Draft	July 2019
<a href="#">Oncology Pharmaceuticals: Reproductive Toxicity Testing and Labeling Recommendations</a>	Final	May 2019
<a href="#">Cancer Clinical Trial Eligibility Criteria: Brain Metastases</a>	Draft	March 2019
<a href="#">Cancer Clinical Trial Eligibility Criteria: Minimum Age for Pediatric Patients</a>	Draft	March 2019
<a href="#">Cancer Clinical Trial Eligibility Criteria: Patients with HIV, Hepatitis B Virus, or Hepatitis C Virus Infections</a>	Draft	March 2019
<a href="#">Cancer Clinical Trial Eligibility Criteria: Patients with Organ Dysfunction or Prior or Concurrent Malignancies</a>	Draft	March 2019
<a href="#">Considerations for the Inclusion of Adolescent Patients in Adult Oncology Clinical Trials</a>	Final	March 2019

ENGAGEMENT/OUTREACH



**Project Community.** A first of its kind at the FDA, OCE’s Project Community is a national community-based initiative focusing on introducing the work of FDA oncology experts to people in the community. The primary audience includes cancer survivors, patients, advocates, families and others in low-resource settings, underserved/under-represented communities or who live with heightened cancer risk. The mission is to extend cancer awareness and education of cancer drug development beyond the immediate Washington, DC, metropolitan area.



OCE Associate Director for External Outreach and Engagement Rea Blakey moderated a Q-and-A session at the American Association for Cancer Research Annual Meeting for patient advocates to talk with OCE leadership.



Project Community’s 2019 bi-coastal external outreach included leading a community-based town hall conversation entitled “The Benefits of Genetic Research” at the Allen Temple Baptist Church in Oakland, CA where the audience members seemed intent on capturing every word.

“

Thank you for your presence and your wonderfully informative presentation...I know that the participants benefited from the information that you shared, and I learned a lot from you as well!

”

**Marvella Ford, PhD.**

Medical University of South Carolina and South Carolina State University



ALONG WITH SEEKING COMMUNITY INPUT FOR PROJECT COMMUNITY GOALS THROUGH THE YEAR 2025, THE OBJECTIVES ARE:

**Expose FDA oncology product reviewers to the key concerns of cancer survivors, patients, advocates and families. Healthcare providers including oncology practitioners in low-resource settings, underserved/under-represented communities or who live with heightened cancer risk are also an important audience for the initiative.**

**Expose the US public (community members) to the diverse doctors, scientists and healthcare providers who work at OCE analyzing the scientific data that helps accelerate cancer product development.**

**Develop synergistic cooperation among FDA oncology reviewers and the public to increase scientific drug development knowledge including but not limited to:**

- **Increasing** participation in clinical trials,
- **Improving** the design of clinical trials,
- **Increasing** knowledge of and participation in genetic databases,
- **Facilitating** access to cancer information for high-risk communities, patients/advocates and others in minority and underserved, low-resource settings.

**Provide FDA oncology reviewers the opportunity to gain a more personal understanding of the enormous impact of cancer on patients and their loved ones.**

**Project Socrates: The Collaborative - FDA-NCI Clinical Investigator Program.** The FDA and the National Cancer Institute of the National Institutes of Health share a commitment to advancing medical research and developing new or more effective therapeutic agents to treat patients with cancer. The FDA-NCI Clinical Investigator Program is envisioned as one mechanism of interagency collaboration.

The FDA-NCI Clinical Investigator is a clinician-scientist who divides their time between clinical and regulatory duties. They hold a joint appointment in the NCI intramural program serving as an independent, tenure-track, Principal Investigator who develop and conduct cutting-edge clinical trials supported by the NIH Clinical Center and intramural NCI infrastructure. At the FDA, the physician functions as a Medical Officer and conducts regulatory review work and regulatory science in the Oncology Center of Excellence and the Office of Oncologic Diseases. They develop expertise in U.S. drug and biologic regulation, including novel and transformative therapies. Their clinical trial experience and expertise serve the FDA as “in house” disease specific experts. At the NCI, their regulatory and drug development experience serve the investigator community, IRB and protocol support office, and academic clinical fellowship program.

For additional information, contact [FDAOncology@fda.hhs.gov](mailto:FDAOncology@fda.hhs.gov).



## PUBLIC WORKSHOPS

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OCE Provides a platform for internal and external engagement to facilitate reciprocal exchange of science and ideas. In 2019, OCE held 15 workshops and 17 educational symposia.

1. FDA Oncology Center of Excellence - ASCO Fellows Day – March 8, 2019
2. FDA Oncology Center of Excellence Public Workshop: Childhood Cancer Advocacy Forum – March 15, 2019
3. FDA-NBTS Public Workshop: Product Development for Central Nervous System (CNS) Metastases – March 22, 2019
4. FDA-PDS (Project Data Sphere) Symposium – April 17, 2019
5. FDA-ASCO-FOCR Workshop on Development of Tissue-Agnostic, Biomarker-Based Indications – April 26, 2019
6. FDA-Duke Global Regulatory Pre-Workshop (in conjunction w/ AAADV) – May 7, 2019
7. Accelerating Anticancer Agent Development and Validation Workshop (AAADV) – May 8-10, 2019
8. FDA Oncology Center of Excellence-Reagan-Udall Foundation Public Workshop: Project Facilitate & EA Navigator: Working Together to Enable Patient Access to Investigational Oncology Drugs – May 16, 2019
9. FDA Oncology Center of Excellence-ASCO Fellows Day Public Workshop – May 31, 2019
10. FDA-ASCO Public Workshop: 2019 Clinical Outcome Assessments in Cancer Clinical Trials – July 12, 2019
11. FDA-AACR Regulatory Science and Policy Workshop: Real-World Evidence – July 19, 2019
12. August 8, 2019: FDA-BCAN Workshop: Endpoints for the Development of Neoadjuvant Systemic Therapy Regimens for Muscle-Invasive Bladder Cancer – August 8, 2019
13. Partners in Progress 2019 - Cancer Patient Advocates and FDA – October 8, 2019
14. FDA Oncology Center of Excellence-ASCO Fellows Day – November 5, 2019
15. FDA-MRA Approaches to Neoadjuvant Treatment in Melanoma – November 6, 2019



**EDUCATION**



**Project Socrates.** Project Socrates is an OCE initiative to build an educational network bridging oncology drug development and regulatory policy and science from the FDA to the public. By partnering with professional societies, the OCE hopes to extend the breadth of its educational outreach.

In 2019, Project Socrates introduced a regulatory column titled OCE Insights with The ASCO Post. The joint FDA-ASCO Fellows’ Day continued in its third year, with two one-day meetings at the FDA White Oak Campus and an additional

half day added prior to the 2019 ASCO Annual Meeting. The third class of high school students from the greater Washington, D.C. region spent six weeks at the FDA learning about careers in health care as part of the OCE Summer Scholars Program. The OCE Scientific Exchange, which offers medical hematology and/or oncology fellows currently in training a chance to receive in-depth mentoring and hands-on learning on various aspects of oncology drug development and regulatory science, continued in its third year and was expanded to include radiation oncology residents and pediatric hematology/oncology fellows. The Interagency Oncology Task Force (IOTF) Fellowship, a partnership between the National Cancer Institute, National Institutes of Health, the Department of Health and Human Services, and the FDA, welcomed two clinical fellows for a year-long curriculum. And on November 1, 2019, the FDA launched its first annual Oncology 3D educational session, a 1-day workshop at the FDA focused on translational oncology drug development, with topics spanning pharmacology, toxicology, clinical pharmacology, statistics, clinical trial design, companion diagnostics, and many others.

Looking ahead to 2025, Project Socrates plans on introducing many new initiatives, including establishing new regulatory fellowships, integrating international regulators and patient advocates into the 2020 AAADV Workshop, and leveraging the oncology expertise within the OCE to write a publication on oncology drug development, which will eventually be paired with an online case-based learning curriculum.



OCE and Office of Oncologic Diseases staff members (front, at railing) Jennifer Gao, MD, Gideon Blumenthal, MD, and Kelly Norsworthy, MD, led the OCE’s first Oncology 3D educational session.



**CONVERSATIONS ON CANCER**

“Conversations on Cancer – Making Cancer Personal at the FDA” is an educational lecture series for FDA employees. In 2019, OCE held two sessions.

**The Way It Was,  
The Way It Is,  
The Way It Should Be  
FEBRUARY 27, 2019**

This was OCE’s inaugural Black History Month “Conversations on Cancer” panel discussion. It was a robust look at the unfortunate events which helped to shape medical distrust among many members of the African American community which result in limited cancer clinical trial participation. Panelists Otis Brawley, MD (Johns Hopkins University), Doris Browne, MD, MPH (National Medical Association) and Lucile Adams-Campbell, PhD (Georgetown University) spoke candidly about current CT barriers for minority groups and efforts to gain cancer trial equity.

**The Patient Perspective on  
Cancer Clinical Trials:  
The Good, The Bad, and  
The Indifferent**

**SEPTEMBER 26, 2019**

A patient-focused, frank panel discussion about participating in a cancer clinical trial, including fiercely advocating to be placed on one. Our guests were cancer survivors and patient advocates Celinda Pena, Karen Peterson, and Desiree Walker.

Also rounding out the conversation were Christina Annunziata, MD, PhD – Investigator, NIH; Michael Diaz, MD – Community Oncology Alliance; and Victoria Manax, MD – PanCAN



Conversations on Cancer panelists Doris Browne, MD, Otis Brawley, MD, and Lucile Adam-Campbell, PhD, at OCE’s first Black History Month discussion.

## OCE SUMMER SCHOLARS

In 2019, 17 high school students were accepted to the six-week program that focuses on exposing students to cancer drug development, including basic science research, clinical trials, and regulatory review and approval.

### OBJECTIVES OF THE PROGRAM:

- Comprehensive exposure to the drug development process in oncology.
- Offer students an introduction to pivotal stakeholders and advocacy groups.
- Offer students an introduction to principles of translational and clinical research.
- End-of-program student presentation on a topic of interest.
- Optional assignment to assist oncology reviewers in writing approval summary manuscripts submitted to peer-reviewed journals. Three students took part in manuscript development this year following the six-week program.



Former FDA Commissioner Dr. Ned Sharpless meeting with the next generation of cancer researchers—OCE Summer Scholars.



OCE's 2019 Summer Scholars learning to identify sections of oncology drug labels and find important information for healthcare providers and patients.

## COMMUNICATIONS

The OCE Communications Program works with communications offices across the FDA and with external stakeholders at professional societies, the trade press, and patient advocacy organizations, to ensure accurate and appropriate external and internal communications regarding the center's programs and activities.

The program supports the OCE Director, Deputy Directors, and Associate Directors in their communications activities, including web pages, articles, talks, guidance documents, and other internal and external communications as needed.

The program also provides editorial support for medical and hematologic oncology reviewers writing articles for scientific journals, as well as research abstracts and presentations at scientific conferences and other external events.

In addition to leveraging other communications where possible, the OCE makes use of its own communications outlets, including:

### **OCE WEBSITE ON FDA.GOV:**

<http://www.fda.gov/OCE>

### **OCE APPROVAL ANNOUNCEMENTS:**

The OCE posted more than

**40 ANNOUNCEMENTS**

in 2019 on the OCE Oncology/Hematology Approval and Safety Announcements [web page](#).

These short articles are also sent via a free FDA listserv to more than

**90,000 EMAIL SUBSCRIBERS.**

### **SOCIAL MEDIA:**

The OCE Twitter account,

[@FDAONCOLOGY](#),

begun in early 2017, has more than

**15,000 FOLLOWERS**

at the end of 2019.

### **PUBLICATIONS:**

In 2019, OCE and affiliated oncology/hematology staff in other FDA centers

**PUBLISHED 73 ARTICLES**

in scientific journals.

### **THE WEEK IN ONCOLOGY:**

A weekly internal email for OCE staff and affiliates across the FDA.

## PUBLICATIONS

OCE recently conducted an analysis of 321 scientific publications by FDA Oncology staff from 2010-2018 (Schneider et al 2019). Most publications were produced in the area of clinical medicine, and include regulatory approval summaries, commentaries, review papers, editorials and original research. FDA Oncology publications are enriched for high impact papers and demonstrate about two times the number of citations as an average NIH-funded publication. Twelve percent of FDA Oncology publications were among the top 1% most cited papers in the field to which they were assigned based on journal of publication. This work highlights FDA Oncology staff engagement in high-quality scientific authorship in addition to completing regulatory review work.

### FOLLOWING IS A LIST OF OCE PUBLICATIONS IN 2019:

1. [Application of the Lung Immune Prognostic Index From Research to Clinical Practice-Reply](#). Kazandjian D, Gong Y, Blumenthal GM. JAMA Oncol. 2019 Nov 27. doi: 10.1001/jamaoncol.2019.5157.
2. [An Analysis of Recent FDA Oncology Scientific Publications](#). Schneider JA, Miklos AC, Onken J, Gong Y, Calcagno AM, Blumenthal GM, Aragon R, Pazdur R. Oncologist. 2019 Nov 26. pii: theoncologist.2019-0503. doi: 10.1634/theoncologist.2019-0503.
3. [Eligibility and Radiologic Assessment for Adjuvant Clinical Trials in Kidney Cancer](#). Agrawal S, Haas NB, Bagheri M, Lane BR, Coleman J, Hammers H, Bratslavsky G, Chauhan C, Kim L, Krishnasamy VP, Marko J, Maher VE, Ibrahim A, Cross F Jr, Liu K, Beaver JA, Pazdur R, Blumenthal GM, Singh H, Plimack ER, Choueiri TK, Uzzo R, Apolo AB. JAMA Oncol. 2019 Nov 21. doi: 10.1001/jamaoncol.2019.4117.
4. [An FDA analysis of clinical hold deficiencies affecting investigational new drug applications for oncology products](#). Manning ML, Thompson MD, Saber H, Maher VE, Crich JZ, Leighton JK. Regul Toxicol Pharmacol. 2019 Oct 31;110:104511. doi: 10.1016/j.yrtph.2019.104511.
5. [Reply to H. McLeod et al](#). Weinstock C, Fernandes LL, Theoret M, Tang S, Sridhara R, Beaver JA, Pazdur R. J Clin Oncol. 2019 Nov 1;JCO1902429. doi: 10.1200/JCO.19.02429.
6. [Pivotal Considerations for Optimal Deployment of Healthy Volunteers in Oncology Drug Development](#). Ahmed MA, Patel C, Drezner N, Helms W, Tan W, Stypinski D. Clin Transl Sci. 2019 Oct 31. doi: 10.1111/cts.12703. Review.
7. [Eligibility and Radiologic Assessment in Adjuvant Clinical Trials in Bladder Cancer](#). Apolo AB, Milowsky MI, Kim L, Inman BA, Kamat AM, Steinberg G, Bagheri M, Krishnasamy VP, Marko J, Dinney CP, Bangs R, Sweis RF, Maher VE, Ibrahim A, Liu K, Werntz R, Cross F, Beaver JA, Singh H, Pazdur R, Blumenthal GM, Lerner SP, Bajorin DF, Rosenberg JE, Agrawal S. JAMA Oncol. 2019 Oct 31:1-9. doi: 10.1001/jamaoncol.2019.4114.
8. [FDA Approval Summary: Palbociclib for Male Patients with Metastatic Breast Cancer](#). Wedam S, Fashoyin-Aje L, Bloomquist E, Tang S, Sridhara R, Goldberg KB, Theoret MR, Amiri-Kordestani L, Pazdur R, Beaver JA. Clin Cancer Res. 2019 Oct 24. pii: clincanres.2580.2019. doi: 10.1158/1078-0432.CCR-19-2580.
9. [Assessing an ASCO Decision Aid for Improving the Accuracy and Attribution of Serious Adverse Event Reporting From Investigators to Sponsors](#). Mileham KF, Schenkel C, Chuk MK, Buchmeier A, Perez RP, Hurley P, Levit LA, Garrett-Mayer E, Davis C, Bruinooge SS, Vose J. J Oncol Pract. 2019 Oct 24;JOP1900366. doi: 10.1200/JOP.19.00366.

10. [FDA Approval Summary: Ruxolitinib for Treatment of Steroid-Refractory Acute Graft-Versus-Host Disease.](#) Przepiorka D, Luo L, Subramaniam S, Qiu J, Gudi R, Cunningham LC, Nie L, Leong R, Ma L, Sheth C, Deisseroth A, Goldberg KB, Blumenthal GM, Pazdur R. *Oncologist*. 2019 Oct 22. pii: theoncologist.2019-0627. doi: 10.1634/theoncologist.2019-0627.
11. [Senna Occidentalis Poisoning: An Uncommon Cause of Liver Failure.](#) Ish P, Rathi S, Singh H, Anuradha S. *ACG Case Rep J*. 2019 Apr 8;6(4):e00035. doi: 10.14309/crj.000000000000035. eCollection 2019 Apr.
12. [Fatal neutropenic enterocolitis associated with docetaxel use: A review of cases reported to the United States Food and Drug Administration Adverse Event Reporting System.](#) Singh P, Nayernama A, Christopher Jones S, Amiri Kordestani L, Fedenko K, Prowell T, Bersoff-Matcha SJ. *J Oncol Pharm Pract*. 2019 Oct 8:1078155219879494. doi: 10.1177/1078155219879494.
13. [US Food and Drug Administration review of statistical analysis of patient-reported outcomes in lung cancer clinical trials approved between January, 2008, and December, 2017.](#) Fiero MH, Roydhouse JK, Vallejo J, King-Kallimanis BL, Kluetz PG, Sridhara R. *Lancet Oncol*. 2019 Oct;20(10):e582-e589. doi: 10.1016/S1470-2045(19)30335-3. Epub 2019 Sep 30. Review.
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15. [Public-private partnerships in transplant drug development.](#) Albrecht R, Papadopoulos EJ, Campbell M, Daniels S, Kluetz PG, Parekh A, Wang Y. *Am J Transplant*. 2019 Sep 25. doi: 10.1111/ajt.15604.
16. [Association Between FDA Label Restriction and Immunotherapy and Chemotherapy Use in Bladder Cancer.](#) Parikh RB, Adamson BJS, Khozin S, Galsky MD, Baxi SS, Cohen A, Mamtani R. *JAMA*. 2019 Sep 24;322(12):1209-1211. doi: 10.1001/jama.2019.10650.
17. [FDA Approval Summary: Tagraxofusp-erzs For Treatment of Blastic Plasmacytoid Dendritic Cell Neoplasm.](#) Jen EY, Gao X, Li L, Zhuang L, Simpson NE, Aryal B, Wang R, Przepiorka D, Shen YL, Leong R, Liu C, Sheth CM, Bowen S, Goldberg KB, Farrell AT, Blumenthal GM, Pazdur R. *Clin Cancer Res*. 2019 Sep 23. doi: 10.1158/1078-0432.CCR-19-2329.
18. [Cytokine Effects on the Entry of Filovirus Envelope Pseudotyped Virus-Like Particles into Primary Human Macrophages.](#) Stantchev TS, Zack-Taylor A, Mattson N, Strebel K, Broder CC, Clouse KA. *Viruses*. 2019 Sep 23;11(10). pii: E889. doi: 10.3390/v11100889.
19. [Machine-Learning and Stochastic Tumor Growth Models for Predicting Outcomes in Patients With Advanced Non-Small-Cell Lung Cancer.](#) Siah KW, Khozin S, Wong CH, Lo AW. *JCO Clin Cancer Inform*. 2019 Sep;3:1-11. doi: 10.1200/CCI.19.00046.
20. [Recent drug approvals for acute myeloid leukemia.](#) Lai C, Doucette K, Norsworthy K. *J Hematol Oncol*. 2019 Sep 18;12(1):100. doi: 10.1186/s13045-019-0774-x. Review.
21. [Exposure to TNF antagonist therapies induces variations of the gut microbiota in an in vivo model using healthy mice.](#) Gabay O, Vicenty J, Zack-Taylor A, Tiffany L, Wunderlin G, Smith D, Reyes-Munoz L, Edwards V, Wu WW, Phue JN, Santana-Quintero L, Lam PV, Clouse KA. *Joint Bone Spine*. 2019 Sep 9. pii: S1297-319X(19)30119-8. doi: 10.1016/j.jbspin.2019.08.001.



22. [Global Variation in Opioid Use in Prostate Cancer Trials](#). Roydhouse JK, Suzman DL, Menapace LA, Mishra-Kalyani PS, Sridhara R, Blumenthal GM, Beaver JA, Pazdur R, Kluetz PG. JAMA Oncol. 2019 Sep 12:e192971. doi: 10.1001/jamaoncol.2019.2971.
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