Oncology Center for Excellence (OCE)

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Oncology Center of Excellence (OCE)

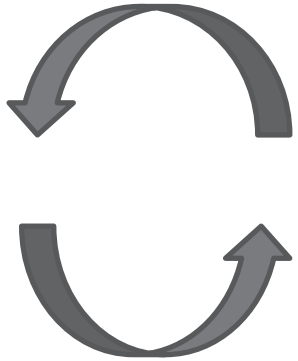
- Established in January 2017 as a part of 21st Century CURES Act
- Mission: *To achieve patient-centered regulatory decision-making through innovation and collaboration*

Oncology Center of Excellence & Interaction with Centers

Oncology Center of Excellence (OCE)

– **Director**

- Deputy Director
- AD Oncology Cell & Gene Therapies
- AD Oncology Medical Devices
- AD Oncology In Vitro Diagnostics
- AD Pediatric Oncology
- AD Oncology Regulatory Science & Informatics (INFORMED)
- AD Oncology Patient Outcomes
- AD Immuno-Oncology
- AD Oncology Regulatory Affairs
- AD Research Strategy & Partnerships



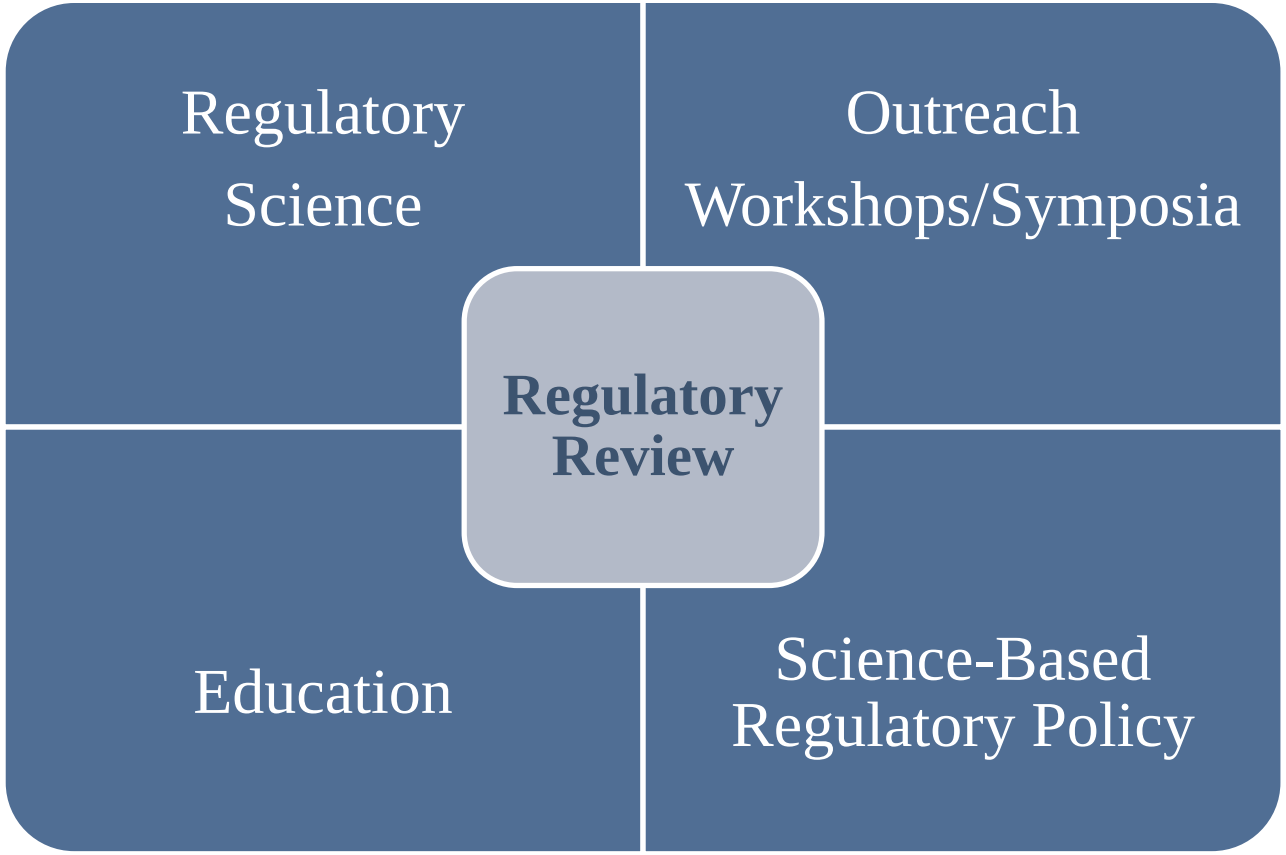
Center for Devices & Radiological Health (CDRH)

Center for Biologic Evaluation & Research (CBER)

Center for Drug Evaluation & Research (CDER)

AD = Associate Director

OCE Initiatives



OCE Regulatory Review

- Provide clinical review via Medical Oncology Review (MORE) Team
- Regulatory authority for marketing authorization remains in home Centers (CDER, CBER, CDRH)
- MORE teams required for products under expedited programs (Breakthrough, Fast Track, Regenerative Medicine, Priority Review, Accelerated Approval)
- MORE teams may be requested for any other regulatory submission at the discretion of the home Center

OCE MORE team

- Team makeup:
  - Primary clinical reviewer
  - Clinical team leader
  - Division Director (CDER)/Branch Chief (CBER)
  - OCE Director or designee
- Goal: provide both disease expertise and regulatory expertise within each MORE team
- May be made up of reviewers from multiple Centers to provide needed breadth of expertise

2017 OCE Accomplishments

- Took part in review and approvals of cancer products across the 3 centers that review drugs, biologics and devices
  - Clinical review conducted for:
    - 12 new drugs and biologics for treatment of cancer
    - 1 medical device (i.e., PMA) to diagnose or identify a patient for treatment
  - Provided subject matter and regulatory expertise on over:
    - a dozen submissions for breakthrough designation
    - 100 key development meetings
- Created cross-center forum: OCE clinical rounds include reviewers from all 3 centers (CDER, CBER and CDRH)

2017 OCE Accomplishments, cont'd

- Interaction with NIH/National Cancer Institute (NCI)/ Cancer Therapy Evaluation Program (CTEP)
  - Quarterly meetings with CTEP
  - FDA Liaison to NCI's Cooperative groups
  - Inclusion of NCI/CTEP on workshops
- Outreach with patient advocacy groups and oncology organizations
  - 9 Workshops and over 20 symposia
  - OCE approval bursts, podcasts, Twitter account, webpage

OCE Regulatory Review: 2017 Approvals in Cancer

*Drugs in red are for "New molecular entities"

Cancer type	Drugs
Breast	abemaciclib, palbociclib, ribociclib, pertuzumab, neratinib
Bladder	pembrolizumab, avelumab, durvalumab, nivolumab
Gastric	pembrolizumab, nivolumab, regorafenib
Kidney	cabozantinib, sunitinib
Lung	alectinib, dabrafenib and trametinib, ceritinib, pembrolizumab, brigatinib, osimertinib
Melanoma	nivolumab
Merkel Cell	avelumab
Ovarian	olaparib, niraparib
Tissue agnostic	pembrolizumab
Leukemia	gemtuzumab ozogamicin, liposome-encapsulated daunorubicin and cytarabine, enasidenib, **tisagenlecleucel**, inotuzumab ozogamicin, blinatumomab, midostaurin, bosutinib, dasatinib
Lymphoma	acalabrutinib, **axicabtagene ciloleucel**, pembrolizumab, brentuximab vedotin, copanlisib, obinutuzumab, rituximab and hyaluronidase
Multiple Myeloma	lenalidomide
Biosimilars	Ogivri (trastuzumab-dkst), Mvasi (bevacizumab-awwb)

OCE Community Outreach

- Community oncologists
- Patient groups
- Under represented groups (trial disparities project)
- Internship programs for summer high school students

OCE Regulatory Science

- New regulatory approaches to expedite oncology product development:
  - Facilitate efficient testing of novel drug combinations (e.g., master protocols in dose-finding and activity-estimating trials)
  - Streamline regulatory review processes for breakthrough products

- Methods to incorporate patients along the drug development continuum (Patient-Focused Drug Development)
  - Foster rigorous patient outcome measurement in cancer clinical trials and decision making

- Real world evidence in oncology product development

OCE Workshops

Events in 2017

- December 1, 2017: Assessment of Cardiovascular Toxicities in Immuno-Oncology Trials.
- November 28, 2017: Defining Disease Recurrence and Harmonizing Conduct in Adjuvant Bladder and Kidney Cancer Trials.
- November 13, 2017: Partners in Progress: Cancer Patient Advocates and FDA.
- November 6, 2017: FDA-ASCO Public Workshop: Geriatric Oncology Workshop.
- October 10, 2017: FDA-AACR Liquid Biopsies in Oncology Drug and Device Development Part II.
- July 20, 2017: FDA-AACR Oncology Dose Finding Workshop
- May 3-5, 2017: Accelerating Anticancer Agent Development and Validation Workshop
- April 25, 2017: FDA/C-Path Consortium Second Annual Workshop on Clinical Outcomes Assessments in Cancer Clinical Trials.
- Feb 23, 2017: FDA-ASCO: Hematology and Oncology Fellows Day Workshop

OCE: 2018 and beyond

Strengths and challenges of the current operating model:

- FDA colleagues value the oncology expertise that OCE delivers through its education and professional development programs and direct engagement with Centers on regulatory reviews
- External partners value the increased cohesiveness, responsiveness, and expertise that OCE brings
- FDA colleagues' challenges with OCE derive from inconsistencies in review decision criteria and differing capabilities and cultures across OCE and Centers and process inefficiencies in joint reviews

OCE: 2018 and beyond

Strategic mandate in near term:

- Develop an integrated and cohesive strategic agenda for oncology policy, regulatory science research, and external engagement.
- Serve as “One FDA” voice in oncology and as a first point of contact in oncology for external partners
- Provide bespoke support to clinical oncology reviews including priority, fast-track (FT), breakthrough (BT) and accelerated approval applications and jointly selected INDs and pre-INDs

OCE: 2018 and beyond

- Mandate would be best achieved in next 2-3 years by maintaining the current construct with OCE in Office of the Commissioner
  - dedicated funding for staff and programs
  - comprised primarily of Associate Directors and RPMs
- This near-term construct as transition to potential end-state structures

Thank you!