FDA's Oncology Center of Excellence and IVDs.

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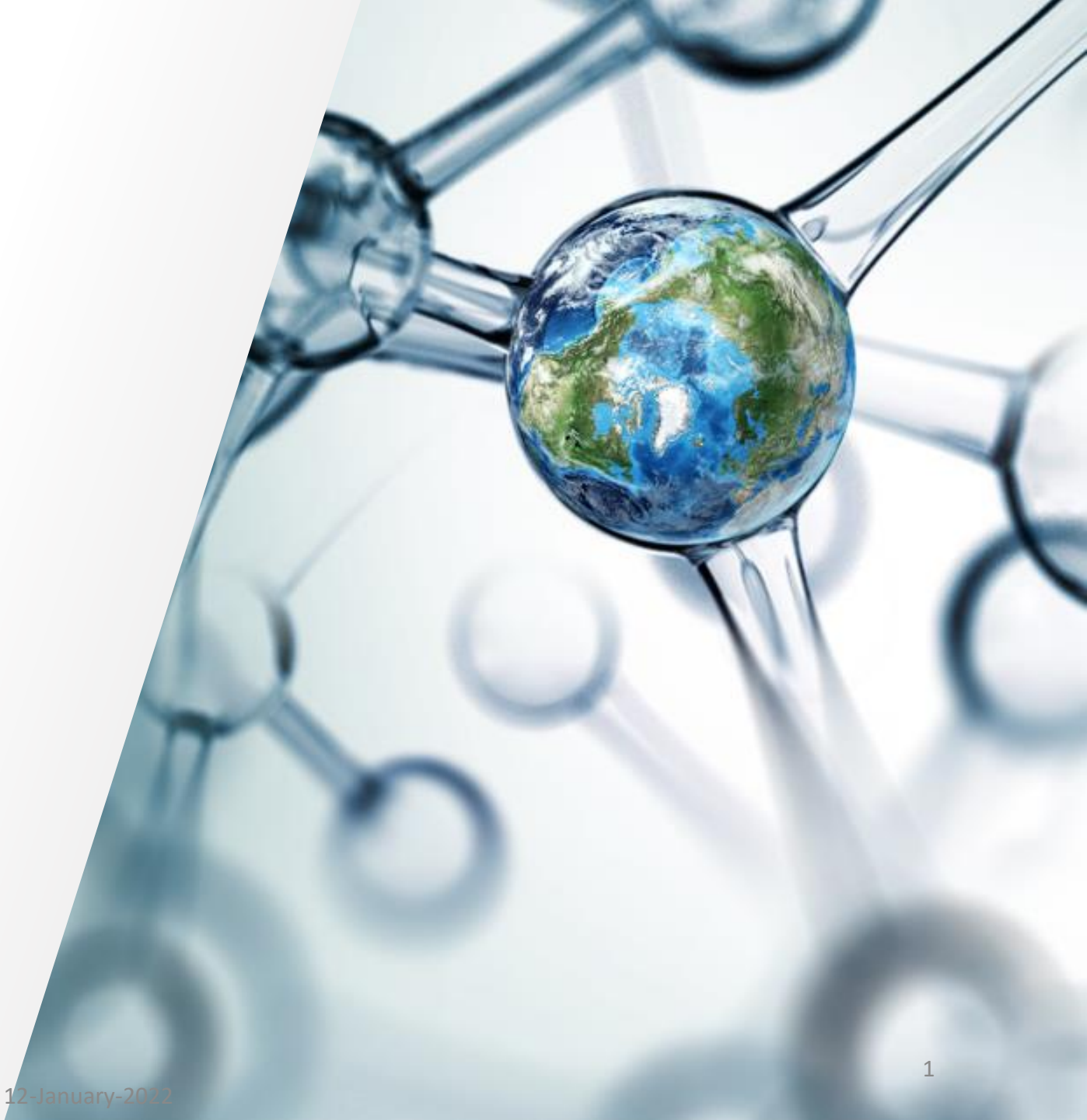

The world leader in serving science

FDA’s Oncology Center of Excellence

- The Oncology Center of Excellence (OCE) was authorized by the 21st Century Cures Act of 2016 and established on January 19, 2017.

- The Center unites experts across the FDA to conduct expedited review of medical products for oncologic and hematologic malignancies.

- The OCE also leads a variety of research and educational outreach projects and programs to advance the development and regulation of medical products for patients with cancer.

Oncology Center of Excellence (OCE) Leadership

- Center Director: Richard Pazdur, MD
- Deputy Center Director: Paul G. Kluetz, MD
- Deputy Center Director: Marc R. Theoret, MD
- Chief of Medical Oncology: Julia Beaver, MD
- Director for Regulatory Affairs and Regulatory Policy: Tamy Kim, PharmD
- Director, Oncology Program Operations: Sherwin Sapasap, MS, MBA, MHA
- Clinical Director Project Renewal (Acting): Sundeep Agrawal, MD

FDA Product Centers Working With OCE

- CDER
- CDER Office of Oncologic Devices
- Office of Oncologic Devices Immediate Office
  - Division of Oncology 1,2,3
  - Division of Hematologic Malignancies 1,2
  - Division of Hematology Oncology and Toxicology
- Center for Devices and Radiologic Health
- Center for Biologics Evaluation and Research
- Cellular and Gene Therapy
- Vaccines

Associate Directors

- Biomarkers and Precision Oncology: Reena Philip, PhD
- Cell and Gene Therapy (Acting): Adnan Jaigirdar, MD
- Communications: Kirsten Goldberg, MA
- Education: Jennifer Gao, MD
- External Outreach and Engagement: Rea Blakey, BS
- Global Clinical Sciences (Acting): Angelo de Claro, MD
- Global Regulatory Outreach: Dianne Spillman, BS
- Oncology Devices (Acting): Dorian M. Korz, MD
- Oncology Labeling: William Pierce, PharmD, MPH, BCPS
- Oncology In vitro Diagnostics: Wendy Rubinstein, MD, PhD
- Oncology in Older Adults and Special Populations (Acting): Harpreet Singh, MD
- Patient Outcomes: Vishal Bhatnagar, MD
- Pediatric Oncology: Gregory Reaman, MD
- Pediatric and Rare Cancer Drug Development (Acting): Martha Donoghue, MD
- Pharmacoepidemiology and Oncology RWE: Donna Rivera, PharmD, MS
- Safety (Acting): Abhilasha Nair, MD
- Science & Policy to Address Disparities (Acting): Lola Fashoyin-Aje, MD, MPH
- Strategy and Partnership: Julie Schneider, PhD
- Tissue Agnostic Drug Development (Acting): Steven Lemery, MD

OCE 2021 accomplishments related to IVDs

- The Center for Devices and Radiological Health (CDRH) reviews and regulates oncology devices and diagnostics in partnership with OCE. During 2021, CDRH and OCE authorized 16 oncology-related in vitro diagnostic devices (IVDs) including 12 companion |diagnostic approvals.

- Eight companion diagnostic devices were approved in areas of **unmet need** such as for:
  - CDx for IDH1 cholangiocarcinoma - **Oncomine Dx Target Test**
  - KRAS G12C variants in patients with non-small cell lung cancer - **Guardant360 CDx & therascreen KRAS RGQ PCR Kit**
  - The first tumor agnostic immunohistochemistry companion diagnostic was authorized for the identification of patients with solid tumors that are DNA mismatch repair deficiency - **Ventana MMR RxDx Panel**
  - A second group labeling claim was approved, for patients with unresectable or metastatic melanoma to detect specific BRAF variants for the selection of BRAF inhibitors or BRAF/MEK inhibitor combinations - **FoundationOne CDx**

- Both manufacturers of distributable kits and laboratory single sites continue to submit and obtain approvals for CDx products.

Timelines

- Understanding the Drug partners timeline is key to a smooth CDx submission and approva**l.**
- OCE works with CDER/CBER and CDRH as all parties work toward approval

For new indications:

- Aim for contemporaneous submission
- If this cannot occur, obtain FDA feedback as to how much space between the drug and Dx submission they would agree to
- Obtain the partner's drug review designation and then PDUFA date once it is available
- The drug review time will drive the CDx review when ever possible

Follow on CDx

- Std device approval times apply

Drug development paradigms/review designations/timelines that can be applied to targeted therapies:

- Fast Track - The review of drugs to treat serious conditions and fill an unmet medical need. These are eligibility for Accelerated Approval and Priority Review; therefore ~6 mos due to priority feature.
- Breakthrough- Intended to treat a serious condition and preliminary clinical evidence indicates that the drug may demonstrate substantial improvement over available therapy on a clinically significant endpoint(s). All Fast Track designation features apply therefore ~6 mos review due to inclusion of priority feature.
- Priority - A Priority Review designation means FDA's goal is to take action on an application within 6 months.
- Accelerated - Drugs for serious conditions that filled an unmet medical need to be approved based on a surrogate endpoint. No date associated with this. A quick glance at the accelerated approvals for targeted therapies shows a range of approx. 4.8 to 14.8. Most were below 10. Quite a few at 6.
- Standard Review - ~10 mos

OCE meetings and workshops

- One of the missions of OCE is that of educational focus and OCE holds many meetings and workshops each year

- At the following link you will find information about current and past events; obtain information, videos and webcasts.

  https://www.fda.gov/about-fda/oncology-center-excellence/oce-meetings-and-workshops

- The most recent workshop was held Sept 14 titled ***"FDA Oncology Center of Excellence Conversations on Cancer: Cancer Moonshot in Action: Launching the Next Generation of Cancer Leaders"***

Examples of prior workshops related to IVDs

- April 26, 2019: FDA-ASCO-FOCR Workshop on Development of Tissue-Agnostic, Biomarker-Based Indications. Meeting Information; #FDATissueAgnostic19
- Jan. 29, 2018: Weighing the Evidence - Variant Classification and Interpretation in Precision Oncology. Meeting Information; #FDACancerVariantExternal Link Disclaimer
- October 10, 2017: FDA-AACR Liquid Biopsies in Oncology Drug and Device Development Part II. Meeting Information