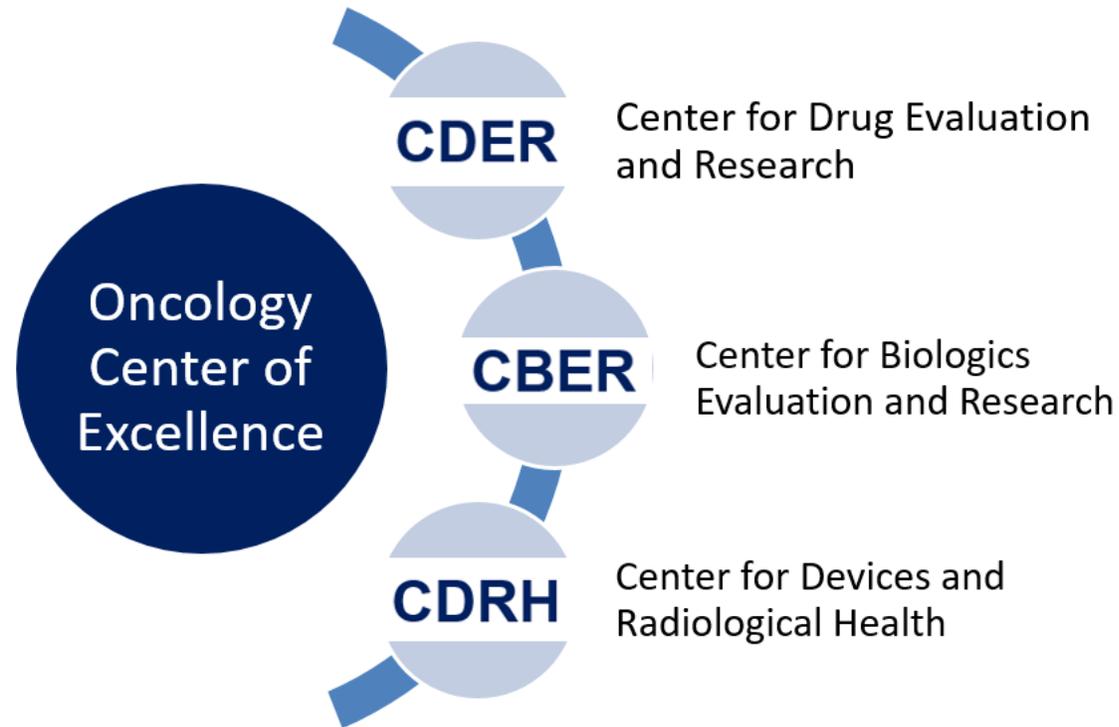# FDA Oncology Center of Excellence BAA Day
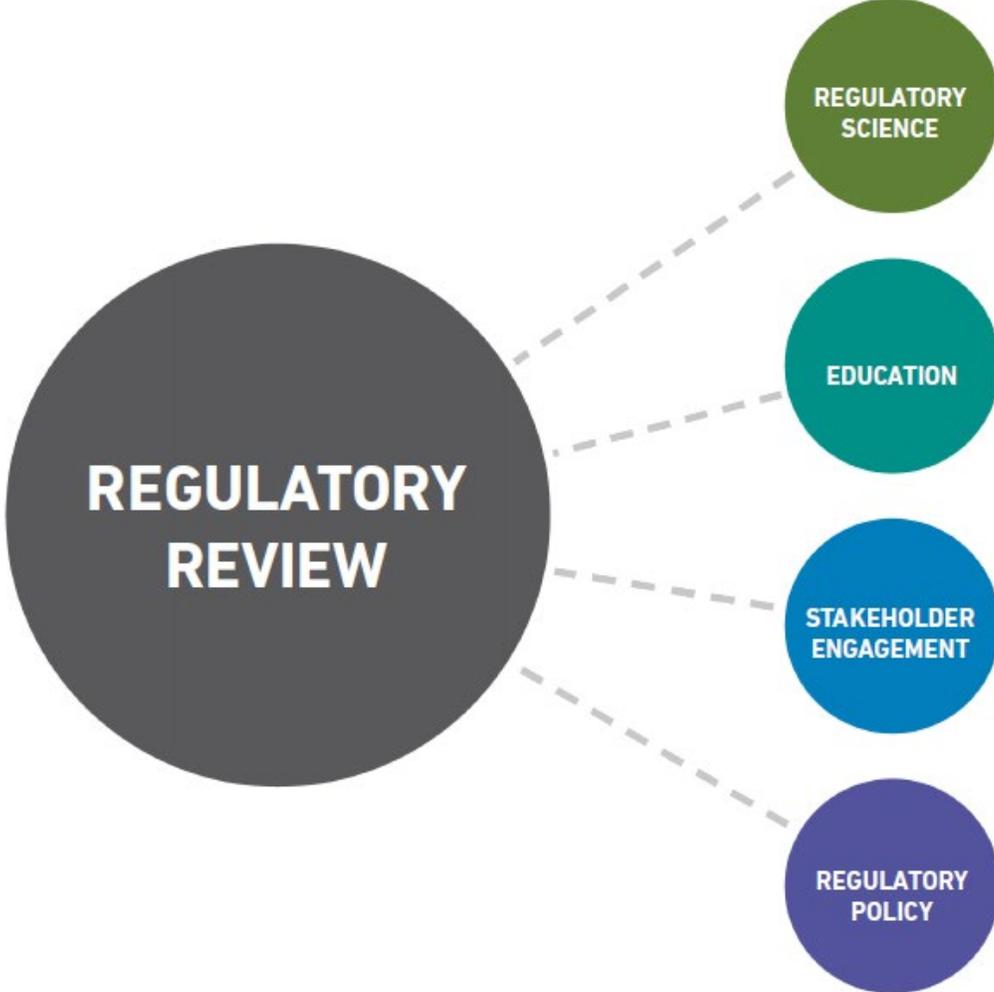## 1/20/26

Rebekah Zinn, Ph.D.
Senior Advisor, Research Strategy and External Partnerships, OCE

Introduction to the Oncology Center of Excellence

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

CDER Center for Drug Evaluation and Research

CBER Center for Biologics Evaluation and Research

CDRH Center for Devices and Radiological Health

Oncology Center of Excellence

Introduction to the Oncology Center of Excellence

REGULATORY SCIENCE

EDUCATION

STAKEHOLDER ENGAGEMENT

REGULATORY POLICY

REGULATORY REVIEW

OCE Scientific Collaborative mission

Support FDA scientific staff to plan and conduct high quality applied research that addresses challenges identified during regulatory review of oncology therapeutics

OCE Scientific Collaborative | FDA

OCE scientific interest areas

FDA

Cell/gene and personalized neo-antigen-based therapies for cancer

Immuno-oncology

Oncology patient-focused drug development

Oncology trial designs, endpoints and statistical methodologies

Oncology safety

Pediatric oncology

Precision oncology

Rare cancers

Oncology real world data utilization (cross-cutting)

OCE Scientific Interest Areas | FDA

Cell/gene and personalized neo-antigen-based therapies for cancer

Applied research related to clinical development, safety evaluation, manufacturing, and quality control of innovative approaches such as gene editing-based technology (e.g., CRISPR-Cas9), cell therapy (e.g., TIL, TCR-T, CAR-T) for solid and hematologic malignancies, and neo-antigen-based cancer therapy.

OCE scientific interest areas
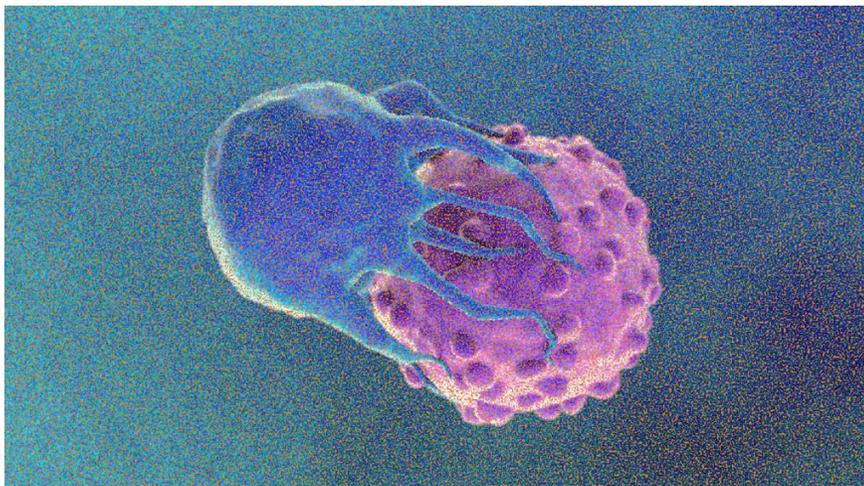
Immuno-oncology

Applied research to analyze clinical and scientific issues relevant to regulatory submissions of immuno-oncology products such as understanding treatment response/ resistance to immune checkpoint inhibitors (ICIs)


Oncology Center of Excellence

NEW (I.C.)
- Understanding tumor biomarkers (e.g., spatialomics, transcriptomic, proteomic analyses) that would predict subsequent radiologic and clinical outcomes (e.g., prolonged stability/ subsequent response vs. continued progression) in patients who have radiologic progression without signs of clinical progression that allows for discretionary continuation of current immune-checkpoint inhibitor therapy (BAA Charge I.C.1.)
- Further characterization of molecular mechanisms of immunologically cold tumors that could potentially translate into therapeutic interventions (BAA Charge I.C.1.)

OCE scientific interest areas

Oncology patient-focused drug development
Applied research to promote scientifically rigorous use of clinical outcome measures to quantify symptoms and function in oncology. Develop and create standard clinical endpoints, analytic and visualization methods, and use of digital health technology to further characterize a product's safety and efficacy.

OCE scientific interest areas

FDA
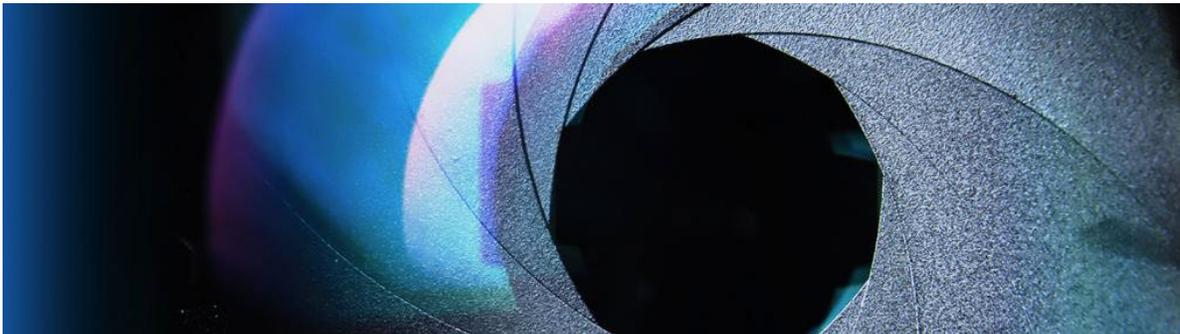
| **Oncology trial designs, endpoints and statistical methodologies** |
| --- |
| Innovative approaches for statistical analyses of oncology clinical trials. Identify, develop or refine endpoints using data sources other than information collected during traditional clinical trials that could be used in clinical studies to inform regulatory submissions. |

NEW (I.F.)
- Develop statistical methods for quantitative bias assessment when RWD is used in estimating treatment effect

Oncology safety

New approaches to allow for consistent and rigorous analysis of safety signals throughout the lifecycle of oncology therapeutics and to improve understanding of toxicity from oncology therapeutics in the patient population

OCE scientific interest areas
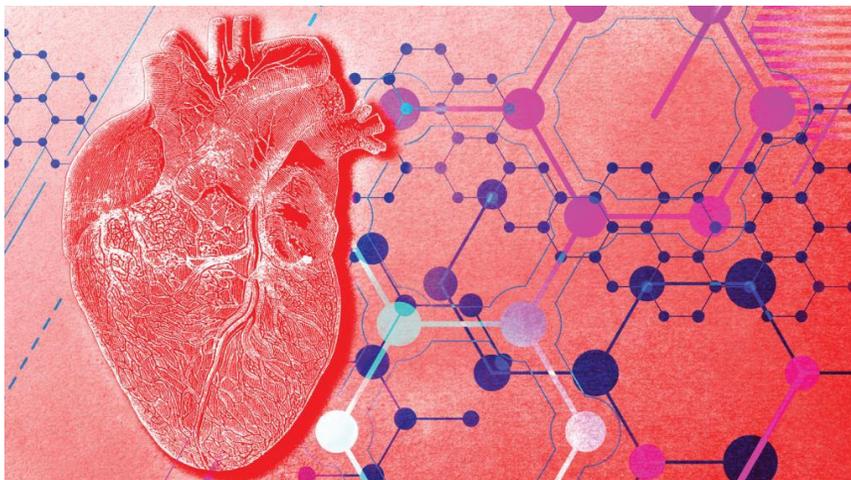
Pediatric oncology

Applied research to accelerate the development of oncology therapeutics for children and adolescents, for example through developing new preclinical models, novel trial designs, and use of real world data.


NEW

- Research to identify opportunities to improve adoption and use of pragmatic elements in clinical trials intended to support development of new products for pediatric cancers (e.g., novel collaboration approaches supported by workshops to engage interested parties (I.F.).
- Develop and implement a collaborative multistakeholder effort to support generation and use of real world data leveraging a registry framework for use in development of new therapies for pediatric patients with diffuse midline glioma (DMG) (including diffuse intrinsic pontine glioma, DIPG) and other high-grade gliomas. This may include identification and publication of best practices for generation of high quality real world data from patient registries; and creation and publication of a list of common data elements for registries in DMG/DIPG to promote standardized data collection. Modern technology applications or other advanced methods and novel collaboration approaches supported by workshops to engage interested parties may be used (I.J.).

OCE scientific interest areas

FDA

Precision oncology
Applied research to develop and deploy biomarkers (e.g., molecular, imaging) to accelerate and improve regulatory review of oncology therapeutics.

OCE scientific interest areas
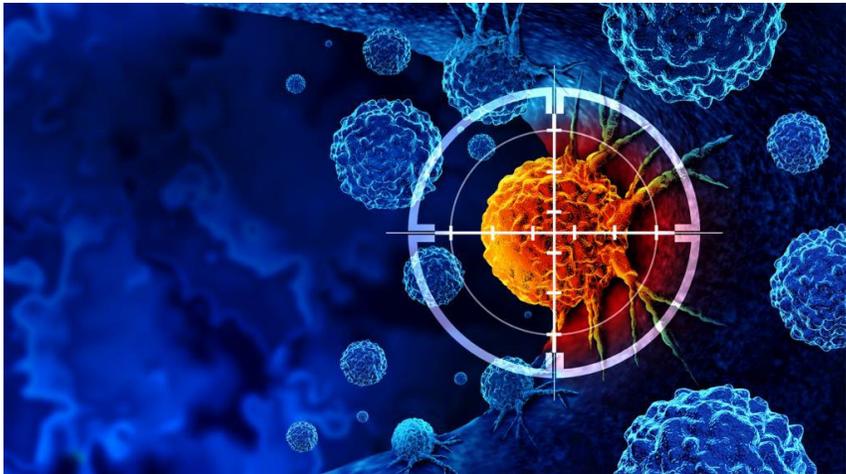
Rare cancers
Applied research to develop new approaches to support drug development in rare cancers such as drug repurposing, targeted therapy/ delivery strategies, novel endpoint development, and use of decentralized elements in clinical trials.

NEW

- Development of nanoparticle-based delivery approaches for therapeutic nucleic acids targeting onco-fusion transcription factors in metastatic tumor animal models of rare cancers using targeted bioPROTAC degradation or genomic editing strategies. Successful efforts should demonstrate effective delivery and expression in-vivo to tumor cells, and downregulation of the target transcription factor protein while minimizing off-target effects and limiting sequestration of the nanoparticle by the liver, spleen, and lungs (1.B.)
- Research to develop novel approaches to preserve the availability of drugs for which commercial developers have discontinued adult development that have strong potential in rare cancers but lack financial incentives for commercial development (1.F.)

OCE scientific interest areas

Oncology real world data utilization (cross-cutting)
Approaches to evaluate, integrate, and facilitate the use of oncology real world data (e.g., electronic health records, administrative health claims, drug or disease registries, patient reported or generated health data) to generate high quality real world evidence.

More information about active OCE-funded BAA projects

[OCE-Funded Active Extramural Research Projects](#)