U.S. FOOD & DRUG ADMINISTRATION

FDA Oncology Center of Excellence BAA Day

11/14/24

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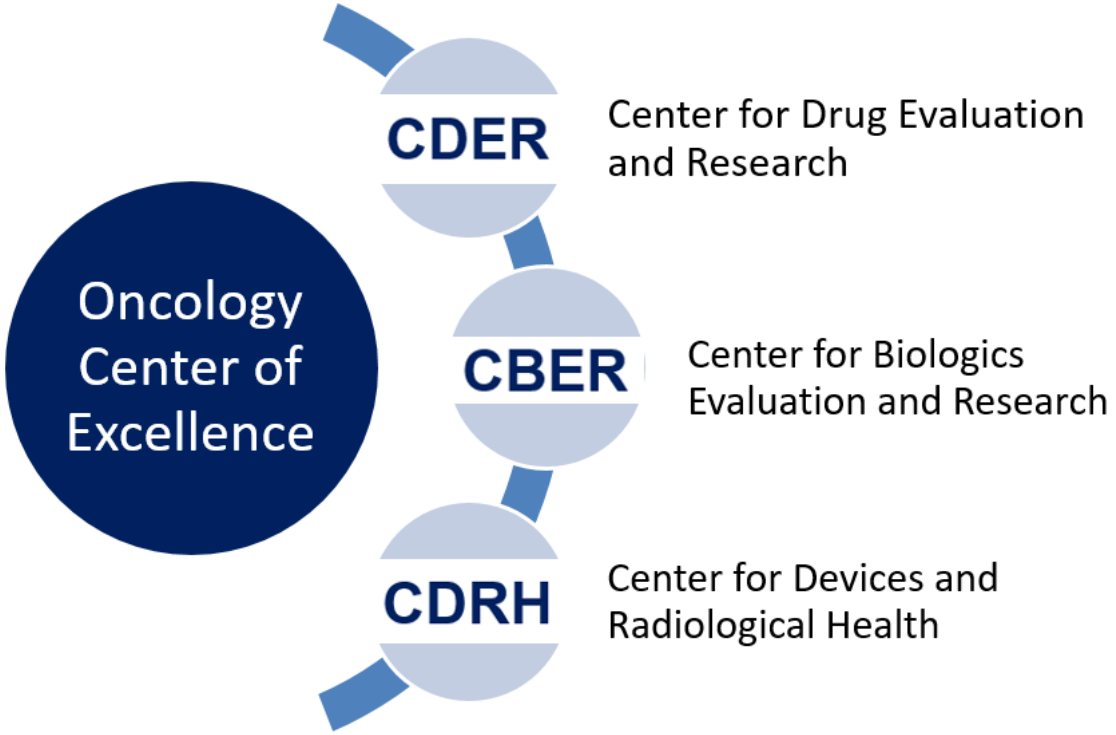
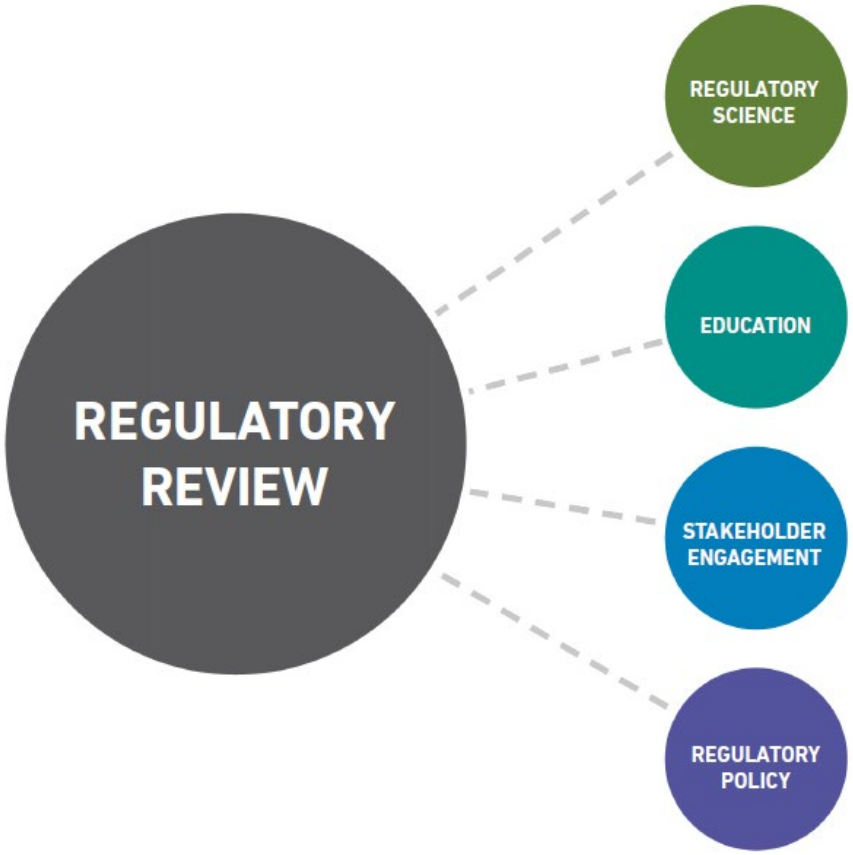
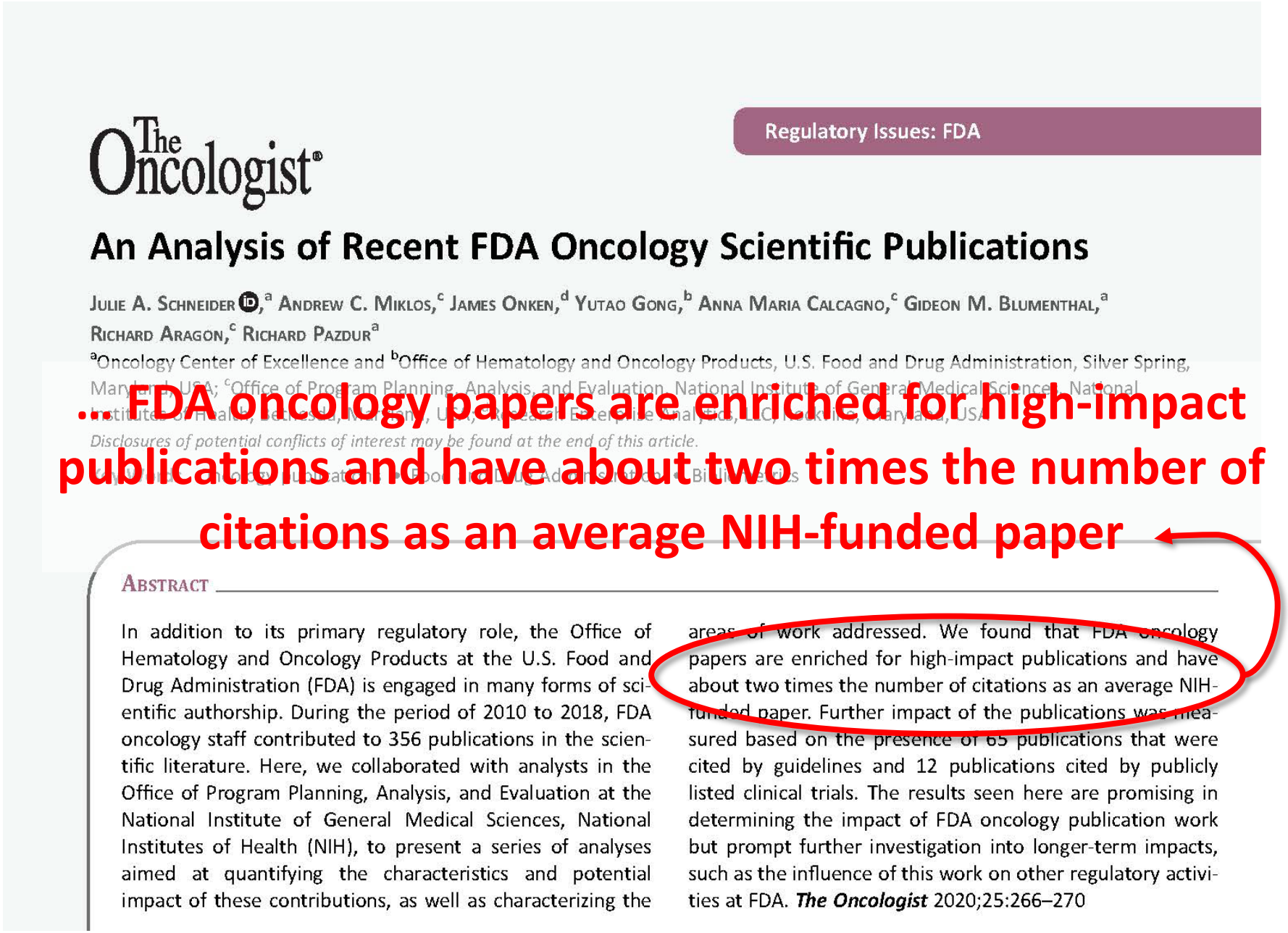
Introduction to the Oncology Center of Excellence

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



Introduction to the Oncology Center of Excellence





The Oncologist®

Regulatory Issues: FDA

An Analysis of Recent FDA Oncology Scientific Publications

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Disclosures of potential conflicts of interest may be found at the end of this article.

…FDA oncology papers are enriched for high-impact publications and have about two times the number of citations as an average NIH-funded paper

Abstract

In addition to its primary regulatory role, the Office of Hematology and Oncology Products at the U.S. Food and Drug Administration (FDA) is engaged in many forms of scientific authorship. During the period of 2010 to 2018, FDA oncology staff contributed to 356 publications in the scientific literature. Here, we collaborated with analysts in the Office of Program Planning, Analysis, and Evaluation at the National Institute of General Medical Sciences, National Institutes of Health (NIH), to present a series of analyses aimed at quantifying the characteristics and potential impact of these contributions, as well as characterizing the areas of work addressed. We found that FDA oncology papers are enriched for high-impact publications and have about two times the number of citations as an average NIH-funded paper. Further impact of the publications was measured based on the presence of 65 publications that were cited by guidelines and 12 publications cited by publicly listed clinical trials. The results seen here are promising in determining the impact of FDA oncology publication work but prompt further investigation into longer-term impacts, such as the influence of this work on other regulatory activities at FDA. ***The Oncologist*** 2020;25:266–270

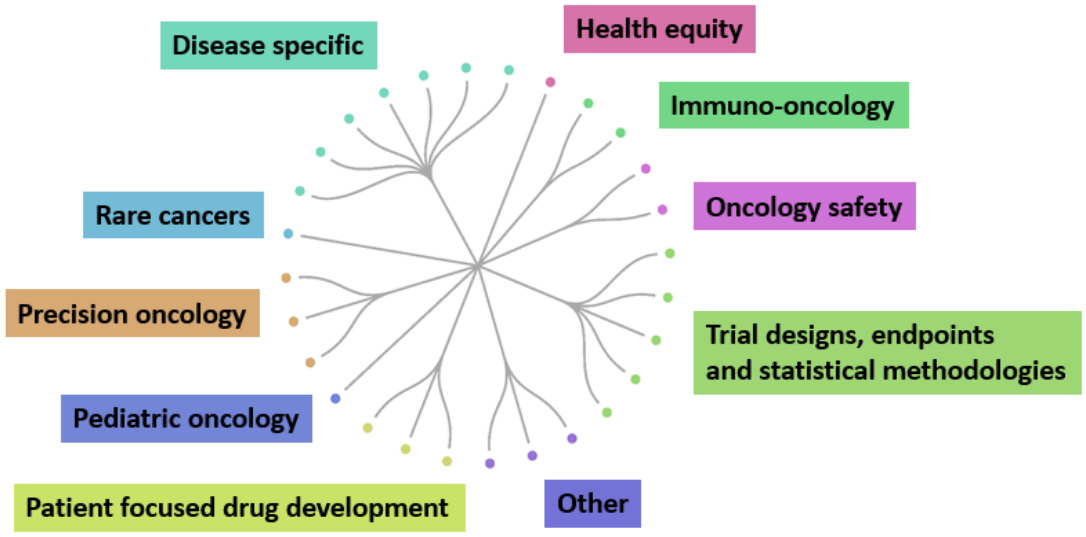
OCE Scientific Collaborative mission

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

Cell/gene and personalized neo-antigen-based therapies for cancer
Health equity and special populations in oncology drug development
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)

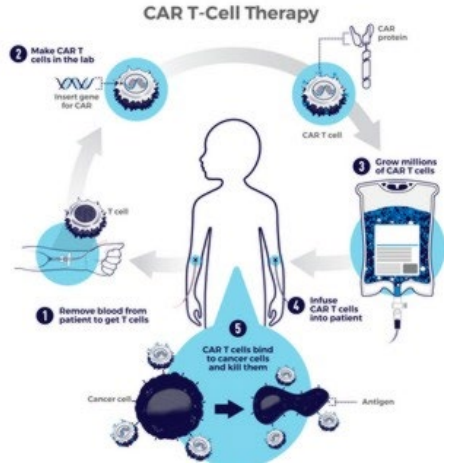


OCE Scientific Interest Areas | FDA

https://pubmed.ncbi.nlm.nih.gov/33910935/
Schneider et al. Clin Cancer Res 2021;27:5161-7

OCE scientific interest areas

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

Health equity and special populations in oncology drug development
Applied research to understand the factors that affect the safety and treatment response in demographic subgroups that have been historically underrepresented in oncology trials (e.g., racial/ethnic minorities, older adults, persons with disability, etc.).

NEW (I.J.)

- Study RWD to understand drug utilization and dosing patterns for oral therapies in older adults with cancer

OCE scientific interest areas

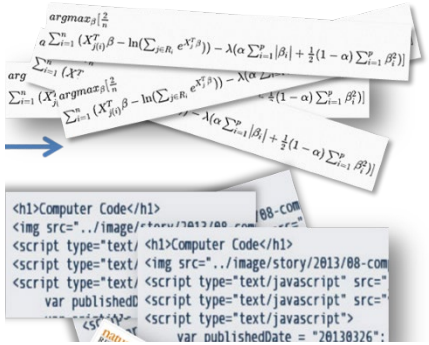
Immuno-oncology
Applied research to analyze clinical and scientific issues relevant to regulatory submissions of immuno-oncology products such as understanding unique side effects and atypical responses (e.g., delayed progression, pseudo-progression) to immune checkpoint inhibitors.

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

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.)

- Evaluate statistical methods for intercurrent events in oncology clinical trials, including but not limited to cross-over, treatment switch, treatment discontinuation, or other events that could induce informative censoring.

OCE scientific interest areas

Oncology therapeutic 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. Explore use of real-world data to inform post-marketing safety.

NEW (I.J.)

- Develop improved and standardized approaches to collect serious toxicities such as cytokine release syndrome and neurotoxicity across a drug class, e.g., bispecific T cell engagers

OCE scientific interest areas

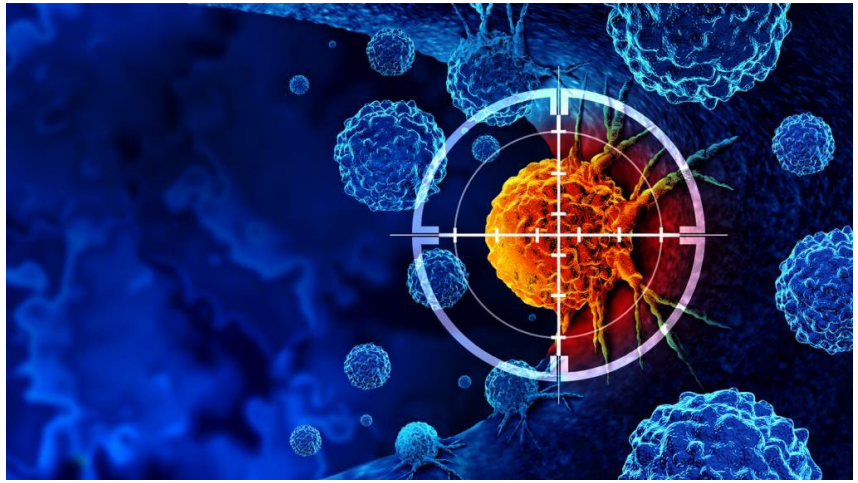
Pediatric oncology
Applied research to accelerate the development of oncology therapeutics for children and adolescents, for example through developing new preclinical models, novel trial designs, and use of real world data.

NEW (I.F.)

- Research to facilitate development of common-control designs in international pediatric clinical trials in oncology.
- Research to validate early efficacy endpoints for pediatric oncology trials.
- Research to investigate methods to recruit diverse populations of patients into pediatric oncology trials, such as through developing best practices for more patient and family/caregiver-friendly methods for informed consent and conveying information about clinical trial participation.

OCE scientific interest areas

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 and use of decentralized elements including telemedicine and incorporation of other pragmatic features into clinical trials.

NEW (I.F.)

- Development of the infrastructure for a coordination network and data repository for patient-level data across institutions and internationally to support drug development and regulatory decision-making for ultra-rare tumors

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. Innovative approaches such as clinical trials including pragmatic elements or other prospective designs are encouraged

NEW (I.J.)

Methods-focused research using artificial intelligence or machine learning approaches

- To analyze, assess and interpret the scientific literature or currently available evidence in a novel way
- To apply to RWD to enhance knowledge of novel study methods and understanding potential uses in regulatory science including evaluation of data quality, e.g., developing AI/ML approaches to process unstructured data (or in combination with structured data) or approaches to data transparency
- To understand approaches to improve introduction of pragmatic elements into clinical trials such as understanding clinical site selection or enhancement of representation to advance health equity

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For more information about active OCE-funded BAA projects visit

OCE-Funded Active Extramural Research Projects