FOOD AND DRUG ADMINISTRATION (FDA)
Center for Drug Evaluation and Research (CDER)

Pediatric Oncology Subcommittee of the
Oncologic Drugs Advisory Committee (pedsODAC) Meeting
May 22, 2024

AGENDA

Amendments made by Section 504 of the 2017 FDA Reauthorization Act (FDARA) to section 505B of the Food, Drug, and Cosmetic Act required, for original applications submitted on or after August 18, 2020, pediatric investigations of certain targeted cancer drugs with new active ingredients, based on molecular mechanism of action rather than clinical indication. The Subcommittee will discuss perspectives relating to implementation of this legislation and its impact on pediatric cancer drug development.

10:00 a.m.	Call to Order	**Alberto S. Pappo, MD** Chairperson, pedsODAC
10:05 a.m.	Introduction of Subcommittee and Conflict of Interest Statement	**Jessica Seo, PharmD, MPH** Acting Designated Federal Officer, pedsODAC
10:10 a.m.	Introductory Remarks	**Nicole Drezner, MD** Deputy Director Division of Oncology 2 (DO2) Office of Oncologic Diseases (OOD) Office of New Drugs (OND), CDER, FDA
10:15 a.m.	**FDA PRESENTATIONS**	
	FDA Reauthorization Act (FDARA) Amendments to the Pediatric Research Equity Act: FDA Perspectives and Updates on Implementation	**Marjilla Seddiq, MD** Medical Officer DO2, OOD, OND, CDER, FDA **Ramjay Vatsan, PhD** Associate Director for Policy Office of Gene Therapy (OGT) Office of Therapeutic Products (OTP) Center for Biologics Evaluation and Research (CBER) FDA
10:50 a.m.	**GUEST SPEAKER PRESENTATIONS**	
	European Perspective on Complementary US and EU Regulations in Support of Global Development	**Dominik Karres, MD** Senior Scientific Officer Paediatric Medicines Office Scientific Evidence Generation Department Human Medicines Division European Medicines Agency (EMA) **Maria Sheean, PhD** Scientific Officer Paediatric Medicines Office Scientific Evidence Generation Department Human Medicines Division, EMA

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AGENDA (cont.)

11:10 a.m.	Clarifying Questions	
11:30 a.m.	**GUEST SPEAKER PRESENTATIONS (cont.)**	
	Impact of RACE Act: COG Perspective	**Brenda J. Weigel, MSc, MD** Professor and Division Director Pediatric Hematology/Oncology University of Minnesota Chair, Developmental Therapeutics COG
11:50 a.m.	Research to Accelerate Cures and Equity (RACE) for Children ACT - Implementation and Impact Industry Perspective	**Ruchi Gupta, MS** Program Director, Regulatory Affairs Genentech, Inc.
12:10 p.m.	European academic perspectives on international trial collaboration in paediatric oncology	**Pamela Kearns, MBChB, BSc (Hons), PhD, FRCPCH** Chair of Clinical Paediatric Oncology Director, Institute of Cancer and Genomic Sciences University of Birmingham President of ITCC
12:30 p.m.	Clarifying questions	
12:45 p.m.	**LUNCH**	
1:30 p.m.	**OPEN PUBLIC HEARING**	
2:30 p.m.	Questions to the Subcommittee and Subcommittee Discussion	
3:30 p.m.	Closing Remarks	**Martha Donoghue, MD** Associate Director for Pediatric Oncology and Rare Cancers Oncology Center of Excellence (OCE) Office of the Commissioner (OC) Associate Director, Pediatric Oncology (Acting) OOD, OND, CDER, FDA
3:45 p.m.	**ADJOURNMENT**	