

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

Oncologic Drugs Advisory Committee (ODAC) Meeting

June 24, 2021

MEETING ROSTER

DESIGNATED FEDERAL OFFICER (Non-Voting)

She-Chia Chen, PharmD

Division of Advisory Committee and Consultant Management
Office of Executive Programs, CDER, FDA

ONCOLOGIC DRUGS ADVISORY COMMITTEE MEMBERS (Voting)

Massimo Cristofanilli, MD, FACP

Associate Director of Translational Research and
Precision Medicine
Robert H. Lurie Comprehensive Cancer Center
Chicago, Illinois

Jorge A. Garcia, MD, FACP

Chair, Division of Solid Tumor Oncology
George and Edith Richman Distinguished Scientist
Chair
Director, GU Oncology Program
University Hospitals Seidman Cancer Center
Case Comprehensive Cancer Center
Case Western Reserve University
Cleveland, Ohio

Susan Halabi, PhD

Professor of Biostatistics and Bioinformatics
Duke University Medical Center
Durham, North Carolina

Philip C. Hoffman, MD

(Chairperson)
Professor of Medicine
The University of Chicago
Section of Hematology/Oncology
Department of Medicine
Chicago, Illinois

Christopher H. Lieu, MD

Associate Professor of Medicine
Associate Director for Clinical Research
Director, Gastrointestinal Medical Oncology Program
University of Colorado
Aurora, Colorado

David E. Mitchell

(Consumer Representative)
Founder, Patients for Affordable Drugs
Bethesda, Maryland

Jorge J. Nieva, MD

Associate Professor of Clinical Medicine
Section Head, Solid Tumors
University of Southern California (USC) Norris
Comprehensive Cancer Center
Keck School of Medicine of USC
Los Angeles, California

Ashley Rosko, MD

Associate Professor
Division of Hematology
Department of Internal Medicine
Medical Director, Oncogeriatric Program
James Comprehensive Cancer Center
The Ohio State University
Columbus, Ohio

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MEETING ROSTER (cont.)

ACTING INDUSTRY REPRESENTATIVE TO THE COMMITTEE (Non-Voting)

Albert L. Kraus, PhD

(Acting Industry Representative)

Global Regulatory Portfolio Lead, Oncology
Pfizer, Inc.
Guilford, Connecticut

TEMPORARY MEMBERS (Voting)

Neil Berlin

(Patient Representative)

Owings Mills, Maryland

Marcia Cruz-Correa, MD, PhD, AGAF, FASGE

Professor, Medicine & Biochemistry
Executive Director, University of Puerto Rico (UPR)
Comprehensive Cancer Center
UPR Medical Sciences Campus
Puerto Rico Medical Center
San Juan, Puerto Rico

Pamela L. Kunz, MD

Associate Professor
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Yale University School of Medicine
New Haven, Connecticut

Mark A. Lewis, MD

Director, Gastrointestinal Medical Oncology
Intermountain Healthcare
Murray, Utah

Kathryn A. Lurain, MD

Assistant Research Physician
HIV and AIDS Malignancy Branch
Center for Cancer Research
National Cancer Institute
National Institutes of Health
Bethesda, Maryland

Diane Reidy-Lagunes, MD

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New York, New York

Kim Reiss Binder, MD

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Abramson Cancer Center
University of Pennsylvania
Perelman Center of Medicine
Philadelphia, Pennsylvania

Hanna K. Sanoff, MD, MPH

Associate Professor, Division of Oncology
Vice Chair for Clinical Operations
Division of Oncology
University of North Carolina
Chapel Hill, North Carolina

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MEETING ROSTER (cont.)

TEMPORARY MEMBERS (Voting) (cont.)

Colin D. Weekes, MD, PhD, FASCO

Associate Professor of Medicine
Harvard Medical School
Director, Medical Oncology Research for
Pancreatic Cancer
The Tucker Gosnell Center for
Gastrointestinal Cancers
Massachusetts General Hospital
Boston, Massachusetts

FDA PARTICIPANTS (Non-Voting)

Richard Pazdur, MD

Director, Oncology Center of Excellence (OCE)
Director (Acting)
Office of Oncologic Diseases (OOD)
Office of New Drugs (OND), CDER, FDA

Paul Kluetz, MD

Deputy Director, OCE
Supervisory Associate Director for Clinical
Oncology (Acting)
OOD, OND, CDER, FDA

Lola Fashoyin-Aje, MD, MPH

Associate Director for Science & Policy to
Address Disparities (Acting), OCE
Deputy Director (Acting)
DO3, OOD, OND, CDER, FDA

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Clinical Reviewer
DO3, OOD, OND, CDER, FDA

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OND, CDER, FDA

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DO3, OOD, OND, CDER, FDA

Sandra Casak, MD

Team Leader (Acting)
Division of Oncology 3 (DO3)
OOD, OND, CDER, FDA