

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

Oncologic Drugs Advisory Committee (ODAC) Meeting
April 21, 2022

DRAFT 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)

Ranjana H. Advani, MD

Physician Leader, the Lymphoma Clinical Care
Program
Saul A. Rosenberg Professor of Lymphoma
Stanford University Medical Center
Stanford, California

Mark R. Conaway, PhD

Professor and Director of Translational Research
Division of Translational Research and Applied
Statistics
Department of Public Health Sciences
University of Virginia
Charlottesville, Virginia

Massimo Cristofanilli, MD, FACP

Chief of Breast Medical Oncology
Associate Director of Precision Medicine
Meyer Cancer Center (MCC)
Scientific Director of the Englander Institute of
Precision Medicine (EIPM)
Weill Cornell Medicine
Division of Hematology-Oncology
New York, New York

Jorge A. Garcia, MD

(Acting Chairperson)
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

Christopher H. Lieu, MD

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

Ravi A. Madan, MD

Clinical Director
Genitourinary Malignancies Branch
Center for Cancer Research
National Cancer Institute
National Institutes of Health
Bethesda, Maryland

David 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

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

Oncologic Drugs Advisory Committee (ODAC) Meeting

April 21, 2022

MEETING ROSTER (cont.)

Anthony D. Sung, MD

Associate Professor of Medicine
Duke University School of Medicine
Duke Adult Blood and Marrow Transplant Clinic
Durham, North Carolina

ONCOLOGIC DRUGS ADVISORY COMMITTEE MEMBER (Non-Voting)

Jonathan D. Cheng, MD

(Industry Representative)
Senior Vice President
Head of Oncology Development
Global Drug Development
Bristol-Myers Squibb
Lawrenceville, New Jersey

TEMPORARY MEMBERS (Voting)

Jessie Lai-Sim Au, PharmD, PhD

Director
Institute of Quantitative Systems Pharmacology
Carlsbad, California
Moser Endowed Chair of Pharmaceutical Sciences
University of Oklahoma Health Sciences
Oklahoma City, Oklahoma
Chief Scientific Officer
Optimum Therapeutics LLC
Carlsbad, California
Distinguished University Professor Emeritus
The Ohio State University
Columbus, Ohio

Andy I. Chen MD, PhD

Associate Professor
Knight Cancer Institute
Oregon Health & Science University
Portland, Oregon

Christopher S. Coffey, PhD

Professor, Department of Biostatistics
Director, Clinical Trials Statistical & Data
Management Center
University of Iowa
Iowa City, Iowa

Louis F. Diehl, MD

Professor of Medicine
Duke University
Durham, North Carolina

Kieron M. Dunleavy, MD

Director of Hematology
Lombardi Comprehensive Cancer Center
Medstar Georgetown University Hospital
Georgetown University
Washington, District of Columbia

Walter K. Kraft, MD

Professor of Pharmacology, Medicine & Surgery
Department of Pharmacology and Experimental
Therapeutics
Thomas Jefferson University
Philadelphia, Pennsylvania

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

Oncologic Drugs Advisory Committee (ODAC) Meeting
April 21, 2022

MEETING ROSTER (cont.)

Michele Nadeem

(Patient Representative)
Charlestown, Massachusetts

Gita Thanarajasingam, MD

Associate Professor, Division of Hematology
Department of Medicine
Mayo Clinic
Rochester, Minnesota

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

Marc R. Theoret, MD

Deputy Center Director, OCE
Supervisory Associate Director (Acting)
OOD, OND, CDER, FDA

Nicole Gormley, MD

Director
Division of Hematologic Malignancies II (DHM II)
OOD, OND, CDER, FDA

Nicholas Richardson, DO, MPH

Team Leader
DHM II, OOD, OND, CDER, FDA

Yvette Kasamon, MD

Team Leader
DHM II, OOD, OND, CDER, FDA

Thomas Gwise, PhD

Director
Division of Biometrics IX
Office of Biostatistics (OB)
Office of Translational Sciences (OTS), CDER, FDA

Brian Booth, PhD

Director
Division of Cancer Pharmacology I
Office of Clinical Pharmacology
OTS, CDER, FDA