

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

Gastrointestinal Drugs Advisory Committee (GIDAC) Meeting
September 13, 2024

MEETING ROSTER

DESIGNATED FEDERAL OFFICER (Non-Voting)

Jessica Seo, PharmD, MPH

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

GASTROINTESTINAL DRUGS ADVISORY COMMITTEE MEMBERS (Voting)

Christopher S. Coffey, PhD, MS

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

Theo Heller, MD

Chief, Translational Hepatology Section
Senior Investigator, Liver Diseases Branch
National Institute of Diabetes and Digestive Kidney
Diseases
National Institutes of Health
Bethesda, Maryland

Benjamin Lebwohl, MD, MS

(Chairperson)
Professor of Medicine and Epidemiology
Associate Clinical Chief, Division of Digestive and
Liver Diseases
Director of Clinical Research, The Celiac Disease
Center
Columbia University College of Physicians &
Surgeons
New York, New York

Brian P. Lee, MD, MAS

Associate Professor of Medicine
Division of Gastrointestinal and Liver Diseases
Keck School of Medicine
University of Southern California
Los Angeles, California

Joy M. McVey

(Consumer Representative)
Program Manager, Volunteer Services
Emory Healthcare
Principal Consultant
Simply Joy, LLC
Atlanta, Georgia

ACTING INDUSTRY REPRESENTATIVE TO THE COMMITTEE (Non-Voting)

Marek J. Honczarenko, MD, PhD

(Acting Industry Representative)
Senior Vice President
Head of Development
SUN Pharmaceutical Industries, Inc.
Princeton, New Jersey

FOOD AND DRUG ADMINISTRATION (FDA)

Center for Drug Evaluation and Research (CDER)

Gastrointestinal Drugs Advisory Committee (GIDAC) Meeting

September 13, 2024

MEETING ROSTER (cont.)

TEMPORARY MEMBERS (Voting)

Danielle Alstat, BAHM, RRT, CPFT

(Patient Representative)
Fairview Heights, Illinois

Daniel L. Gillen, PhD

Chancellor's Professor and Chair
Department of Statistics
University of California, Irvine
Irvine, California

Patrick S. Kamath, MD *(via video conferencing platform)*

Professor of Medicine
Consultant in Gastroenterology, Hepatology and
Liver Transplantation
Mayo Clinic College of Medicine
Rochester Minnesota

Pamela Shaw, PhD, MS

Senior Investigator
Biostatistics Division
Kaiser Permanente Washington Health Research
Institute
Seattle, Washington

Almut G. Winterstein, RPh, PhD, FISPE *(via video conferencing platform)*

Distinguished Professor
Department of Pharmaceutical Outcomes and
Policy
Dr. Robert and Barbara Crisafi Chair for
Medication Safety
College of Pharmacy
Director, Center for Drug Evaluation and Safety
(CoDES)
University of Florida
Gainesville, Florida

Therese Bittermann, MD, MSCE

Assistant Professor, Medicine and Epidemiology
University of Pennsylvania Perelman School of
Medicine
Philadelphia, Pennsylvania

David Goldberg, MD, MSCE

Associate Professor of Medicine
Associate Professor of Public Health Sciences
University of Miami Miller School of Medicine
Miami, Florida

Vincent Lo Re, MD, MSCE

Associate Professor of Medicine and Epidemiology
Division of Infectious Diseases, Department of
Medicine
Division of Epidemiology, Department of
Biostatistics, Epidemiology, and Informatics
Center for Clinical Epidemiology and Biostatistics
Perelman School of Medicine
University of Pennsylvania
Philadelphia, Pennsylvania

Til Stürmer, MD, MPH, PhD *(via video conferencing platform)*

Nancy A. Dreyer Distinguished Professor
Department of Epidemiology
University of North Carolina Gillings School of
Global Public Health
University of North Carolina at Chapel Hill
Chapel Hill, North Carolina

FOOD AND DRUG ADMINISTRATION (FDA)

Center for Drug Evaluation and Research (CDER)

Gastrointestinal Drugs Advisory Committee (GIDAC) Meeting

September 13, 2024

MEETING ROSTER (cont.)

FDA PARTICIPANTS (Non-Voting)

Frank A. Anania, MD, FACP, AGAF, FAASLD

Director (Acting)
Division of Hepatology and Nutrition (DHN)
Office of Immunology and Inflammation (OII)
Office of New Drugs (OND)
CDER, FDA

Tram Tran, MD, FAASLD, FACC

Medical Officer
DHN, OII, OND, CDER, FDA

Eugenio Andraca-Carrera, PhD

Biostatistics Team Leader
Division of Biometrics-VII (DB-VII)
OB, OTS, CDER, FDA

Ruby Mehta, MD

Cross-Discipline Team Leader
DHN, OII, OND, CDER, FDA

Yura Kim, PhD

Statistics Reviewer
Division of Biometrics-III (DB-III)
Office of Biostatistics (OB)
Office of Translational Science (OTS)
CDER, FDA

Joel L. Weissfeld, MD, MPH

Senior Medical Officer
Division of Epidemiology (DEPI)
Office of Pharmacovigilance and Epidemiology
(OPE)
Office of Surveillance and Epidemiology (OSE)
CDER, FDA