

Food and Drug Administration (FDA)
Center for Biologics Evaluation and Research (CBER)
Office of Therapeutic Products
76th Meeting of the Cellular, Tissue, and Gene Therapies Advisory Committee
October 31, 2023
Web Conference

Final Meeting Roster

MEMBERS

Tabassum (Taby) Ahsan, Ph.D.

(Acting Chairperson)

Expertise: Biomedical Engineering

Term: 05/17/2021-03/31/2024

Vice-President

Cell Therapy Operations

City of Hope

Duarte, California 91010

Marshall E. Bloom, M.D. +

Expertise: Virology Viral Vectors and Gene Therapies

Term: 04/01/2022-03/31/2026

Division of Intramural Research

Chief, Biology of Vector-Borne Viruses

Section

National Institutes of Health

Hamilton, Montana 59840

Christopher K. Breuer, M.D.

Expertise: General Surgery and Pediatric Surgery

Term: 04/01/2022-03/31/2026

Director of Tissue Engineering Program and Surgical Research

Director, Center for Regenerative Medicine

Nationwide Children's Hospital

Columbus, Ohio 43215

Eric Crombez, M.D. ***

Expertise: Industry Representative

Term: 09/19/2022-03/31/2024

Chief Medical Officer

Ultragenyx Gene Therapy

Cambridge, Massachusetts 02139

Donald B. Kohn, M.D. +

Expertise: Gene Therapies for Blood Diseases

Term: 08/23/2022-03/31/2025

Distinguished Professor

Departments of Microbiology, Immunology and Molecular Genetics, Pediatrics,

Molecular and Medical Pharmacology

David Geffen School of Medicine at UCLA

University of California, Los Angeles

Los Angeles, California 90095

Wendy B. London, Ph.D.

Expertise: Biostatistics, Clinical Trial Design Oncology

Term: 04/01/2023-03/31/2027

Associate Professor of Pediatrics

Boston Children's Hospital/Dana-Farber

Cancer Institute

Harvard Medical School

Boston, Massachusetts 02215

+ Not Attending

** Consumer Representative

*** Industry Representative

Food and Drug Administration (FDA)
Center for Biologics Evaluation and Research (CBER)
Office of Therapeutic Products
76th Meeting of the Cellular, Tissue, and Gene Therapies Advisory Committee
October 31, 2023
Web Conference

Final Meeting Roster

Sean J. Morrison, Ph.D. +

Expertise: Stem Cell Biology
Term: 04/01/2022-03/31/2026
Director
Children's Medical Center Research Institute
University of Texas Southwestern Medical
Center
Dallas, Texas 75390

Kathleen O'Sullivan-Fortin, Esq. **

Expertise: Consumer Representative
Term: 08/23/2022-03/31/2025
Founder, ALD Connect, Inc.
Middleton, Massachusetts 01949

Melanie Ott, M.D., Ph.D.

Expertise: Virology and Immunology
Term: 04/01/2022-03/31/2026
Gladstone Institute of Virology and
Immunology
University of California, San Francisco
San Francisco, California 94158

Nirali N. Shah M.D., M.H.Sc. +

Expertise: Hematology and Oncology
Term: 02/04/2022-03/31/2026
Head, Hematologic Malignancies Section
Pediatric Oncology Branch
Lasker Clinical Research Scholar
National Cancer Institute
Bethesda, Maryland 20892

Gil I. Wolfe, M.D. +

Expertise: Neurology
Term: 02/04/2022-03/31/2026
Professor and Chairman of Neurology
Irvin and Rosemary Smith Chair
University at Buffalo Distinguished Professor
Department of Neurology
Jacobs School of Medicine and Biomedical
Sciences, University at Buffalo/SUNY
Buffalo, New York 14202

Joseph Wu, M.D., Ph.D.

Expertise: Cardiology and Radiology
Term: 04/01/2023-03/31/2025
Director, Stanford Cardiovascular Institute
Professor of Medicine and Radiology
Stanford University
Stanford, California 94305

+ Not Attending

** Consumer Representative

*** Industry Representative

Food and Drug Administration (FDA)
Center for Biologics Evaluation and Research (CBER)
Office of Therapeutic Products
76th Meeting of the Cellular, Tissue, and Gene Therapies Advisory Committee
October 31, 2023
Web Conference

Final Meeting Roster

TEMPORARY VOTING MEMBERS (TVMs)

Robert A. Dracker, M.D.

Expertise: Sickle Cell Disease
Medical Director
Summerwood Pediatrics
Infusacare Medical Services
Liverpool, New York

Jasmine Hightower, M.S.W.

(Patient Representative)
Expertise: Sickle Cell Disease
Dothan, Alabama

Alexis C. Komor, Ph.D.

Expertise: Gene Editing
Assistant Professor
Department of Chemistry and Biochemistry
University of California, San Diego
La Jolla, California

Lisa Lee, Ph.D.

Expertise: Bioethics, Epidemiology
Associate Vice President for Research and
Innovation
Director, Scholarly Integrity and Research
Compliance
Virginia Polytechnic Institute and State
University
Blacksburg, Virginia

Amy Shapiro, M.D.

Expertise: Sickle Cell Disease
Medical Director, CEO
Indiana Hemophilia & Thrombosis Center
Indianapolis, Indiana
Adjunct Senior Investigator, Clinical Track
Versiti Blood Research Institute
Milwaukee, Wisconsin

John F. Tisdale, M.D.

Expertise: Stem Cells
Branch Chief, Cellular and Molecular
Therapeutics Branch
National Heart, Lung, and Blood Institute
National Institutes of Health
Bethesda, Maryland

Scot A. Wolfe, Ph.D.

Expertise: Genome Editing Systems
Professor
Department of Molecular, Cell, and Cancer
Biology
UMass Chan Medical School
Worcester, Massachusetts

+ Not Attending

** Consumer Representative

*** Industry Representative

Food and Drug Administration (FDA)
Center for Biologics Evaluation and Research (CBER)
Office of Therapeutic Products
76th Meeting of the Cellular, Tissue, and Gene Therapies Advisory Committee
October 31, 2023
Web Conference

Final Meeting Roster

GUEST SPEAKERS

Daniel E. Bauer, M.D., Ph.D.

Expertise: Off-Targets of Gene Editing
Principal Investigator and Staff Physician
Dana-Farber/Boston Children's Cancer and
Blood Disorders Center
Boston Children's Hospital
Boston, Massachusetts

Fyodor Urnov, Ph.D.

Expertise: Gene Editing
Professor, Department of Molecular and Cell
Biology
University of California, Berkeley
Director of Technology and Translation
Innovative Genomics Institute
Berkeley, California

FDA PARTICIPANTS

Nicole Verdun, M.D.

Director, Office of Therapeutic Products
(OTP), CBER, FDA

Leila P. Hann

Associate Director for Policy
OTP, CBER, FDA

Karl Kasamon, M.D.

Reviewer
Office of Clinical Evaluation, Division of
Hematology, Benign Hematology Branch
OTP, CBER, FDA

Komudi Singh, Ph.D.

Bioinformatics Reviewer
Office of Cellular Therapy and Human Tissue
OTP, CBER, FDA

FDA ADMINISTRATIVE STAFF

LCDR Cicely Reese, Pharm.D.

Designated Federal Officer (DFO)
Division of Scientific Advisors and
Consultants (DSAC)
Office of Management (OM), CBER, FDA
E-mail: CBERCTGTAC@fda.hhs.gov

Tonica Burke, B.S.

Committee Management Specialist
DSAC, OM, CBER, FDA

Joanne Lipkind, M.S.

Committee Management Officer
DSAC, OM, CBER, FDA

LaShawn Marks

Committee Management Officer
DSAC, OM, CBER, FDA

Prabhakara Atreya, Ph.D.

Director
DSAC, OM, CBER, FDA

+ Not Attending
** Consumer Representative
*** Industry Representative