

**ADVISORY COUNCIL ON
BLOOD STEM CELL TRANSPLANTATION (ACBSCT)**
U.S. Department of Health and Human Services

AGENDA
Subject to Change

Virtual Meeting

Thursday, October 24, 2024

2:00 PM – 6:00 PM Eastern Time

2:00 PM – 2:05 PM

Welcome and Opening Remarks

Shelley Tims Grant, ACBSCT, Executive Secretary
Dr. Navneet Majhail, MD, MS, FASTCT, Chair, ACBSCT

2:05 PM – 2:25 PM

Update on Mis-matched Unrelated Donor Transplant Clinical Trial

Steven Devine, MD
Chief Medical Officer, NMDP
Senior Scientific Director, Center for International Blood and Marrow Transplant Research (CIBMTR)
Minneapolis, MN

2:25 PM – 2:45 PM

Overview of FDA’s Draft Graft Versus Host Disease Drug Development Guidance

Mona Elmacken, MD
Lead Physician, Malignant Hematology Branch Center for Biologics Evaluation and Research
U.S. Food and Drug Administration White Oak, MD

2:45 PM – 3:15 PM

Overview of Treatment Options, Including Gene Therapy, for Sickle Cell Disease

Lewis Hsu, MD, PhD
Professor of Pediatric Hematology
Director of Pediatric Sickle Cell
University of Illinois at Chicago
Chicago, IL

3:15 PM – 3:45 PM

Plan for Center for Medicare and Medicaid Innovation (CMMI) Cell and Gene Therapy Access Model

Aurelia Chaudhury, JD
CMMI Model Lead, Cell and Gene Therapy Access Model Division of Health Plan Innovation
Centers for Medicare and Medicaid Services Baltimore, MD

3:45 PM – 4:15 PM

Drug Approvals for Vertex and Bluebird Bio Products and Expectations for 15-year Long-Term Follow-up for Treated Patients

Megha Kaushal, MD, MSc
Branch Chief, Benign Hematology Branch
Division of Clinical Evaluation/Office of Therapeutic Products Center for Biologics Evaluation and Research
U.S. Food and Drug Administration White Oak, MD

4:15 PM – 4:30 PM

Overview of Cord Blood Searches from the Registry Perspective

Kelly Lazration
Manager, Clinical HLA Services NMDP
Minneapolis, MN

4:30 PM – 4:45 PM

Overview of Cord Blood Searches from the Clinician Perspective

Andromachi (Machi) Scaradavou, MD
Pediatric Hematologist-Oncologist and Bone Marrow Transplant Specialist
Memorial Sloan Kettering Cancer Center New York, NY

4:45 PM – 5:15 PM

Public Comments

5:15 PM – 5:45 PM

New Business and Discussions

6:00 PM

Adjourn