12:00 p.m. ET  Welcome & Introduction

Edward Abrahams
President
Personalized Medicine Coalition

12:05 p.m. ET  Exploring the Potential Impact of a Transitional Coverage for Emerging Technologies (TCET) Pathway

• Steven Farmer, M.D., Ph.D.
  Chief Strategy Officer for Coverage and Senior Medical Officer
  Center for Clinical Standards and Quality
  Centers for Medicare and Medicaid Services

12:35 p.m. ET  Business Meeting

Daryl Pritchard, Ph.D.
Senior Vice President, Science Policy
Personalized Medicine Coalition

• Science Policy Updates
  o PMC’s Research Program for Advancing Personalized Medicine in 2022
    ▪ Study No. 8: “Addressing Practice Gaps in the Implementation of Personalized Medicine in Cancer Care”
    ▪ Study No. 9: “Addressing Disparities in Research Advancing Personalized Medicine”
o Working Group Updates

- Health Data Working Group
  - American Data Privacy and Protection Act (discussion draft with section-by-section summary)
- Pharmacogenetics Working Group

Cynthia A. Bens
Senior Vice President, Public Policy
Personalized Medicine Coalition

- Public Policy Updates
  - Congressional Activities
    - Congressional Personalized Medicine Caucus
    - User fee program reauthorization (House Energy and Commerce bill; Senate HELP bill with section-by-section summary)
      - PMC remarks during FDA’s Public Meeting on the Fifth Reauthorization of the Medical Device User Fee Act (April 21, 2022)
      - PMC remarks during FDA’s Public Workshop on the Seventh Reauthorization of the Prescription Drug User Fee Act (September 28, 2021)
    - FY 2023 appropriations for FDA and NIH
      - PMC outside witness testimonies (May 2022)
  - Regulation
    - FDA Draft Guidance on Use of Circulating Tumor Deoxyribonucleic Acid for Early-Stage Solid Tumor Drug Development
  - Coverage and Reimbursement
    - CMS’ Transitional Coverage for Emerging Technologies (TCET) pathway
    - CMS’ payments for CAR-T cell therapy under Inpatient Prospective Payment Systems (IPPS) proposed rule for FY 2023
    - CMS’ proposed discontinuation of ICD-10 "not otherwise specified" (NOS) codes for coverage of next-generation sequencing (NGS)-based genetic testing under National Coverage Determination (NCD) 90.2
      - PMC comment letter (May 5, 2022)
- Tracking PMC members’ policy issue expertise
- Working Group Updates
  - Pharmaceutical & Diagnostics Working Group
  - Patient Advocacy Organization Working Group

1:50 p.m. ET New Business

2:00 p.m. ET Conclusion