



**U.S. Food and Drug Administration (FDA)
Center for Devices and Radiological Health (CDRH)
Patient Engagement Advisory Committee (PEAC) Meeting
FDA Virtual Meeting**

**Discuss and make recommendations on the topic
“Advancing Health Equity in Medical Devices”**

AGENDA

**September 6, 2023
10:00 AM – 5:20 PM**

- 10:00 AM **Patient Engagement Advisory Committee (PEAC) Call to Order**
Paul T. Conway, Chairperson, PEAC
- 10:15 AM **Welcome from FDA Commissioner**
Robert M. Califf, M.D., Commissioner, FDA
- 10:30 AM **Conflict of Interest Statement**
Letise Williams, Designated Federal Official, CDRH, FDA
- 10:40 AM **Opening Remarks**
Jeffrey Shuren, M.D., J.D., CDRH Director, FDA
- 10:50 AM **FDA Perspective – Advancing Health Equity in Medical Devices**
Michelle Tarver, M.D., Ph.D., Deputy Center Director, CDRH, FDA
- 11:10 AM **BREAK**
- 11:20 AM **Stakeholder perspective – A Patient’s Health Journey**
Patrick O. Gee, Sr., Ph.D., Former Peritoneal/Hemodialysis Patient, Kidney Transplant Recipient
- 11:30 AM **Stakeholder perspective – Medical Devices as Drivers of Health Equity in Women’s Health in Rural and Underserved Communities**
Roseanne Gichuru, D.O., M.B.A., FACOOG, CPE, Obstetrics & Gynecology Specialist
- 11:40 AM **Stakeholder perspective – Advancing Equity In Medical Devices Innovation**



Jennifer Jones-McMeans, Ph.D., Divisional Vice President of Global Clinical Affairs, Abbott Vascular

- 11:50 AM **Stakeholder perspective – Designing with the end user in mind**
Jennifer Goldsack, M.Chem., M.A., M.B.A., OLY, Chief Executive Officer, Digital Medicine Society (DiMe)
- 12:00 PM **Open Committee Discussion**
- 12:25 PM **LUNCH**
- 1:00 PM **Stakeholder perspective – Understanding Health Equity in Clinical Trials**
Tesheia Johnson, M.B.A., M.H.S., Deputy Director and Chief Operating Officer of YCCI and the Director for Clinical Research, Yale School of Medicine
- 1:10 PM **Stakeholder perspective – Advancing Health Equity in Medical Devices: Health Literacy and Community Outreach**
Behtash Bahador, M.S., Director of Health Literacy, Center for Information & Study on Clinical Research Participation (CISCRP)
- 1:20 PM **Stakeholder perspective – The NIH All of Us Research Program: Accelerating Health Research Through Community Engagement**
Karriem S. Watson, D.H.Sc, M.S., M.P.H., Chief Engagement Officer of All of Us Research Program, National Institutes of Health
- 1:30 PM **Open Committee Discussion**
- 2:05 PM **BREAK**
- 2:15 PM **Open Public Hearing**
- 3:15 PM **Open Committee Discussion**
- 3:25 PM **BREAK**
- 3:35 PM **Committee Discussion of the FDA’s Questions**
- 5:15 PM **Closing Remarks**
Paul T. Conway, Chairperson, PEAC
- 5:20 PM **Adjourn**