



**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 “Augmented Reality and Virtual Reality Medical Devices”

AGENDA

July 12 and 13, 2022

DAY 1 – July 12, 2022

- 10:00 AM **Patient Engagement Advisory Committee (PEAC) Call to Order**
Paul T. Conway, Chairperson, PEAC
- 10:20 AM **Conflict of Interest Statement**
Letise Williams, Designated Federal Official, CDRH, FDA
- 10:30 AM **Welcome and Opening Remarks**
Jeffrey Shuren, MD, JD, CDRH Director, FDA
- 10:40 AM **Augmented Reality and Virtual Reality Medical Devices – Overview**
Leeda Rashid, MD, MPH, ABFM, Physician, Digital Health Center of Excellence, Office of Strategic Partnerships and Technology Innovation, CDRH, FDA
- 10:50 AM **General Overview-AR/VR in healthcare –What is it? How is it used? What’s the difference?**
Walter Greenleaf, PhD, Neuroscientist, Virtual Reality, and Digital Health Expert, Stanford University
- 11:00 AM **Industry perspective: Developing AR medical devices for the surgical field**
Jennifer N Avari Silva, MD, CCEP-PC, FHRS, FAHA, FACC, Co-Founder & Co-Inventor Sentiar, Co-Founder & Co-Inventor Excera
- 11:10 AM **BREAK**
- 11:20 AM **Industry perspective: Designing Immersive Therapeutics (ITx) for Self-Directed, At-Home Use**
Josh Sackman, Co-Founder and President, AppliedVR



- 11:30 AM **Healthcare Provider perspective: Pediatric user as special populations for VR consideration**
Jeffrey I. Gold, PhD, Professor of Anesthesiology, Pediatrics, and Psychiatry & Behavioral Sciences, Keck School of Medicine, University of Southern California
Juan Espinoza, MD, FAAP, Assistant Professor of Clinical Pediatrics, Children's Hospital Los Angeles, Keck School of Medicine, University of Southern California
- 11:40 AM **Health Researcher perspective: The use of VR in other vulnerable populations and health equity considerations**
Courtney Lyles, PhD, Associate Professor, Center for Vulnerable Populations, University of California, San Francisco
- 11:50 AM **Patient perspective: The experience of using VR in a healthcare journey**
Sharif Razzaque, Vision Therapy Patient
- 12:00 PM **Open Committee Discussion**
- 12:20 PM **BREAK (Webcast Closes)**
- 12:30 PM **Virtual Breakout Session Begins (*separate meeting link*)**
(if registered for this session, please join using breakout session link at 12:25pm)
- 1:00 PM **LUNCH**
- 1:25 PM **Webcast Reopens**
- 1:30 PM **Virtual Breakout Summations**
FDA moderators
- 2:30 PM **Open Public Hearing**
- 3:30 PM **Open Committee Discussion**
- 3:55 PM **Day 1 Closing Remarks**
Paul T. Conway, Chairperson, PEAC
- 4:00 PM **Adjourn**



DAY 2 – July 13, 2022

- 10:00 AM **Patient Engagement Advisory Committee (PEAC) Call to Order**
Paul T. Conway, Chairperson, PEAC
- 10:20 AM **Conflict of Interest Statement**
Letise Williams, Designated Federal Official, CDRH, FDA
- 10:25 AM **Recap of Meeting Day 1**
Anindita Saha, Assistant Director, Digital Health Center of Excellence, Office of Strategic Partnerships and Technology Innovation, CDRH, FDA
- 10:40 AM **Committee Discussion of FDA Questions**
- 12:00 PM **LUNCH**
- 12:30 PM **Committee Discussion of FDA Questions**
- 1:55 PM **Closing Remarks**
Paul T. Conway, Chairperson, PEAC
- 2:00 PM **Adjourn**