



**U.S. Food and Drug Administration (FDA)
Center for Devices and Radiological Health (CDRH)
Patient Engagement Advisory Committee (PEAC) Meeting
Hilton Washington DC North/Gaithersburg**

AGENDA

November 15, 2018

Thursday, November 15, 2018

8:00 AM – 5:00 PM

- 8:00 AM **Patient Engagement Advisory Committee (PEAC) Call to Order**
Paul T. Conway, Chairperson, PEAC
- 8:15 AM **Welcome and Opening Remarks**
Jeffrey Shuren, M.D., J.D., Director, CDRH, FDA
- 8:30 AM **Applications of Postmarket Regulatory Tools Supporting Use of Patient-Generated Health Data**
Thomas Gross, M.D., MPH, Director, Office of Surveillance and Biometrics, CDRH, FDA
- 8:45 AM **Real-World Evidence Guidance**
Owen Faris, Ph.D., Director, Office of Clinical Trials Program, CDRH, FDA
- 8:55 AM **Patient-driven Registries**
Shilpa Venkatachalam, Associate Director, Patient Centered Research, Global Healthy Living Foundation (GHLF)
- 9:05 AM **Challenges with Registries and Opportunities through NESTcc**
Rachel Rath, MPH, Deputy Director of NESTcc, MDIC
- 9:15 AM **Digital Health Technology**
Marisa Cruz, M.D., Senior Medical Advisor, Digital Health Unit, CDRH, FDA
- 9:25 AM **Industry Perspective on Digital Health Technology**
Paul Coplan, Sc.D., MBA, Vice President & Head of Medical Device Epidemiology, Johnson & Johnson



9:35 AM	Overview of Social Media <i>Jen Horonjeff, Ph.D., Founder/CEO, Savvy Cooperative</i>
9:45 AM	Social Media for Postmarket Monitoring <i>Hesha Duggirala, Ph.D., MPH, Chair, FDA Data Mining Council</i>
9:55 AM	Open Committee Discussion
10:30 AM	BREAK
10:45 AM	Open Public Hearing
12:15 PM	LUNCH
1:00 PM	Roundtable Discussions
1:45 PM	Roundtable Summations and Open Committee Discussion
2:45 PM	BREAK
3:00 PM	Committee Discussion of FDA Questions
4:50 PM	Closing Remarks
5:00 PM	Adjourn