



**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 “Artificial Intelligence and Machine Learning in Medical Devices.”**

**AGENDA**

**October 22, 2020**

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**Thursday, October 22, 2020**

**10:00 AM – 5:00 PM**

- 10:00 AM      **Patient Engagement Advisory Committee (PEAC) Call to Order**  
*Paul T. Conway, Chairperson, PEAC*
- 10:10 AM      **Conflict of Interest Statement**  
*Letise Williams, Designated Federal Official, CDRH, FDA*
- 10:15 AM      **Welcome and Opening Remarks**  
*Jeffrey Shuren, M.D., J.D., CDRH Director, FDA*
- 10:25 AM      **Artificial Intelligence-Machine Learning Validation**  
*Bakul Patel, M.S.E.E., M.B.A., Director, Digital Health Center of Excellence, FDA*
- 10:35 AM      **Artificial Intelligence-Machine Learning Communication**  
*Pat Baird, Head of Global Software Standards, Philips*
- 10:50 AM      **Representation of Diverse Groups in Test Sets**  
*CAPT Terri Cornelison, M.D., Ph.D., F.A.C.O.G, Director, Health of Women, CDRH, FDA*
- 11:00 AM      **Cognitive Human Factors**  
*Kimberly Kontson, Ph.D., Biomedical Engineer, Division of Biomedical Physics, CDRH, FDA*
- 11:10 AM      **Open Committee Discussion**



11:30 AM	<b>BREAK</b>
11:35 AM	<b>Webcast Closes</b>
11:40 AM	<b>Virtual Breakout Session</b> <i>Confirmed Virtual Participants</i>
12:10 PM	<b>LUNCH</b>
12:30 PM	<b>Webcast Reopens</b>
12:40 PM	<b>Virtual Breakout Summations</b> <i>FDA moderators</i>
1:30 PM	<b>Open Public Hearing</b>
2:30 PM	<b>Open Committee Discussion</b>
3:00 PM	<b>BREAK</b>
3:10 PM	<b>Committee Discussion of FDA Questions</b>
4:40 PM	<b>Closing Remarks</b> <i>Paul T. Conway, Chairperson, PEAC</i>
5:00 PM	<b>Adjourn</b>