FDA's Center for Devices and Radiological Health (CDRH), the Johns Hopkins University Center of Excellence for Regulatory Science & Innovation (CERSI), and the University of Maryland CERSI present:

IMPACT Bootcamp: Navigating the Journey from Digital Health Technologies to Meaningful Patient Outcomes

January 26, 2022
10:30 AM – 3:30 PM Eastern Time, Virtual (Zoom)

January 5, 2022 – January 25, 2021
Pre-Bootcamp Activities – *Flexible timing based on participants' own schedules*

Bootcamp participants will watch 4 pre-bootcamp videos (cumulative duration of approximately 65 minutes) and complete a quiz in advance of the January 26, 2022 live virtual bootcamp. Completing pre-bootcamp activities is required for participation on January 26.

January 26, 2022
Live Virtual Bootcamp - *All times are Eastern Daylight Time (EDT)*

10:30 – 10:35 AM	**Welcome** Allen Chen, PhD, Program Manager, Patient Science and Engagement Program, Center for Devices and Radiological Health (CDRH), U.S. Food and Drug Administration (FDA) William E. Bentley, PhD, Co-PI, University of Maryland (UMD) CERSI; Professor of Bioengineering, University of Maryland G. Caleb Alexander, MD, MS, PI, JHU CERSI, Professor of Epidemiology and Medicine, Johns Hopkins Bloomberg School of Public Health
10:35 – 10:55 AM	**Recap and Application of Concepts 1: You've Got a Digital Health Technology … What Do You Call It?** Bakul Patel, MSEE, MBA, Director, Digital Health Center of Excellence, CDRH, FDA • *Digital Health Technologies (DHTs)* • *An Introduction to Terminology, Concepts, and Regulation*
10:55 – 11:15 AM	**Recap and Application of Concepts 2: Patient Input and Clinical Outcome Assessments (COAs)** Michelle Tarver, MD, PhD, Deputy Director, Office of Strategic Partnerships and Technology Innovation; Director, Patient Science and Engagement Program; Program Director for Patient Science, Digital Health Center of Excellence, CDRH, FDA

	• *Patient Input in the DHT Development Lifecycle* • *DHTs and Clinical Trials: Introduction to Clinical Outcome Assessments (COAs) and their Development & Validation*
11:15 – 11:30 AM	Q & A
11:30 – 11:40 AM	**Break**
11:40 – 12:20 PM	**Hands-On Practice 1:** Patient Input to Support Your DHT Development
12:20 PM – 1:20 PM	**Lunch**
1:20 – 2:30 PM	**Hands-On Practice 2:** Developing Your DHT to be Used to Support Clinical Investigations • *If you plan for your product to be used as a COA, how will you define the Context of Use?* • *What evidence will you develop to support your intended use and context of use?* • *Given your product is digital, what other considerations are there when considering use in a clinical investigation?*
2:30 – 2:45 PM	**Break**
2:45 – 3:25 PM	**Hands-On Practice 3:** Developing Your DHT to be Used Outside of Clinical Investigations (i.e., to Diagnose, Treat, or Promote General Wellness) • *If you would like to market your product for use outside of a clinical trial, how will you determine whether it is a medical device?* • *How will you determine the regulatory requirements (if any) that apply?*
3:25 – 3:30 PM	**Concluding Remarks**