

MEETING

Virtual Public Meeting - Patient-Generated Health Data Throughout the Total Product Life Cycle of Medical Devices

MAY 4, 2021

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- Meeting Information

Date:

May 4, 2021

Time:

10:00 AM - 4:00 PM ET



The U.S. Food and Drug Administration (FDA) is announcing a virtual public meeting entitled "Patient-Generated Health Data Throughout the Total Product Life Cycle of Medical Devices". The purpose of this meeting is to discuss patient-generated health data (PGHD) and its potential

impact across the healthcare ecosystem.

BACKGROUND

As stated in the Office of the National Coordinator for Health Information Technology's webpage on Patient-Generated Health Data, PGHD includes health-related data that is created, recorded, or gathered by or from patients. Health and treatment history, biometric data, symptoms, and lifestyle habits can all be categorized as PGHD. The potential role of PGHD in the post-market surveillance of medical device safety was discussed during the FDA's Patient Engagement Advisory Committee (PEAC) meeting on November 15, 2018. The PEAC recommended additional discussions about the critical elements of this data and how it could be used across the medical device total product life cycle. To address those recommendations from the PEAC members, the FDA's Center for Devices and Radiological Health (CDRH) is hosting a meeting focusing on PGHD and its potential uses throughout the healthcare ecosystem. Sources of PGHD, data quality measures, interoperability, and potential impacts of the data in regulatory and healthcare settings will be discussed during this meeting.

The FDA invites stakeholders from the medical device industry, patient organizations, research organizations, healthcare professionals, payors, and other interested individuals to join this discussion and provide their individual opinions on the use of PGHD in medical device development, evaluation, and monitoring. The topic details are provided in the Preliminary Agenda below.

- Date and Time
- Webcast Meeting Link
- Preliminary Agenda
- Registration
- Contact
- Resources

DATE and TIME

This meeting will be held on **May 4, 2021**, from 10:00 a.m. to 4:00 p.m. (ET) by webcast only.

WEBCAST MEETING LINK

The virtual public meeting will be a live webcast and the link will be provided in your confirmation email. The link for the archived webcast will be posted to this web page for viewing after the meeting.

PRELIMINARY AGENDA

This agenda is preliminary and subject to change. More information will be made available as presenters are confirmed.

Time	Event
10:00 a.m.	Welcome
10:15 a.m.	Patient-Generated Health Data (PGHD) Basics
10:45 a.m.	Data Management
11:15 a.m.	Break
11:25 a.m.	Patient-Driven Registries
12:40 p.m.	Lunch
1:10 p.m.	Stakeholder Perspectives on Methods of PGHD Integration into the Healthcare Ecosystem
2:25 p.m.	Break
2:35 p.m.	Art and Science of Building Trust Among Stakeholders and Building Bridges Between Data Sources
3:50 p.m.	Closing Remarks
4:00 p.m.	Adjourn

REGISTRATION

If you wish to attend this virtual meeting, you must register by 4:00 p.m. on May 3, 2021. There is no fee to register for the meeting.

Title

Mr. Mrs. Ms. None

First Name *

Last Name *

Titles

Email Address *

Please enter Email again for verification.

Phone Number *

No dashes or spaces in phone numbers please.

Affiliation, Company or Organization ***Stakeholder Category**

Registrants will receive confirmation when requests for participation have been accepted, if applicable.

If you require special accommodations due to a disability or need additional information regarding registration, please contact Susan Monahan, Office of Communication and Education, Center for Devices and Radiological Health, U.S. Food and Drug Administration, 10903 New Hampshire Avenue, Bldg. 32, Silver Spring, MD 20993, 301-796-5661, Susan.Monahan@fda.hhs.gov (mailto: Susan.Monahan@fda.hhs.gov).

CONTACT

For questions regarding meeting content, please contact:

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RESOURCES

- Patient-generated health data information (<https://www.healthit.gov/topic/scientific-initiatives/patient-generated-health-data>)
- FDA Patient Engagement Advisory Committee (</advisory-committees/committees-and-meeting-materials/patient-engagement-advisory-committee>)
- 2018 PEAC Meeting Materials (</advisory-committees/patient-engagement-advisory-committee/2018-meeting-materials-patient-engagement-advisory-committee>)

 More Meetings,
Conferences, and
Workshops (</news-events/fda-meetings-conferences-and-workshops>)