

Updates from the CDRH Patient Science & Engagement Program

Inspired by Patients and Driven by Science

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FDA/CDRH/OST/DARSS

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Building Capacity—New Team Members

- *Program Manager— Alan Chen, Ph.D.*
 - *Manages research portfolio*
 - *Tracks accomplishments of the program*
- *Psychometrician— Fraser Bocell, Ph.D.*
 - *Expert in development and analysis of patient-reported outcomes*
- *Health Economist— David Gebben, Ph.D.*
 - *Expert in design, conduct, and analysis of patient preference studies (health preference research)*





ENGAGEMENT ACTIVITIES

CDRH Patient & Caregiver Connection*: Goals

To provide CDRH staff with access to **patients & caregivers** who are willing to share their individual experiences regarding:



Medical devices used for diagnosis, treatment, or management of their disease



Living with their specific disease



Current issues or trends related to medical devices

Provides FDA **timely** access to **aggregate patients' voices**

*FDA is not seeking, nor will patients or caregivers formally or informally provide group opinions, advice, or recommendations to CDRH. This is a pilot program.

Current Patient & Caregiver Connection Partners



CDRH Community Town Hall: Patient & Caregiver Connection

June 18, 2019

PEAC Recommendation—Support Data Sharing

U.S. Food and Drug Administration Supports Principles of Open Sharing of Data

- Shared a letter of support for the principles of openly sharing non-proprietary data collected by medical devices
- Encourage the empowerment of patients in the development and evaluation of medical devices & become active members in monitoring of devices
- Help enrich the understanding of benefits and risks of technology



Patient Safety
MOVEMENT

PEAC Recommendation—Framework for Patient Engagement in Clinical Trials



- *CDRH fully intends to publish draft guidance on patient engagement in medical device clinical investigations in FY 2019*
 - *Demystify barriers to engaging with patients as advisors in the design and conduct of clinical trials*



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