Partnering with Patients

Patient Engagement Advisory Committee (PEAC) Inaugural Meeting
October 11-12, 2017

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Patients are at the Heart of All We Do

CDRH Vision:
Patients in the U.S. have access to high-quality, safe, and effective medical devices of public health importance, first in the world.
Safe & effective medical device use increasingly depends on effective patient engagement

Patients today:

• More involved in shared decision-making and disease management

• Increasingly use devices at home

• Communicate and connect to share information with other “real-world patients”
“...the FDA is working to give patients a greater voice in medical product development and evaluation. This kind of active involvement is an essential component of the President’s Precision Medicine Initiative. [...] Success in these efforts could lead to tremendous advances in the understanding of health, disease, diagnosis, treatment, and recovery, ultimately transforming patients' experience of health care by enabling physicians to tailor care to an individual's specific needs and preferences.”

Hunter NL, O’Callaghan KM, Califf RM. JAMA 2015
Partner with Patients

Goal 1 – Promote a culture of meaningful patient engagement by facilitating CDRH interaction with patients

Goal 2 – Increase use and transparency of patient input as evidence in our decision-making
Culture of Patient Engagement

Interaction

Meaningful engagement

Partnership

✓ 85% CDRH Employee-Patient Interaction

Making it easier for CDRH staff to obtain patient input

✓ Inaugural PEAC meeting
CDRH Patient Organization Awareness Day

FDA White Oak Campus
November 15, 2017
11:00 am to 1:00 pm

Contact: Lisa.Miller@fda.hhs.gov
Patient Input

Patient Reported Outcomes
- Direct from patient:
  - Symptoms
  - Function
  - Psychological well being
  - Quality of life

Patient Preference Information
- Patient perspective: trade-offs between benefits and risks
Significant Increase in Patient Perspective Studies

- **>500% increase submissions with PROs** (2009-2015)

- **80% increase patient perspective studies overall** (FY15-FY17 to date)

*Submitted to CDRH as of FY2015*
Patient Input as Evidence

- Final Guidance
- Hiring & training staff
- Access to SMEs
- Expanding collaborative networks

- PPI in IDE Benefit-Risk
- PROs & Outcomes that Matter Most to Patients

- PPI & PRO in Marketing Application Benefit-Risk

- PPI in Compliance Benefit-Risk
- PPI & PRO for new uses
How Patient Preferences Contribute to Regulatory Decisions for Medical Devices

Posted on September 25, 2017 by FDA Voice

By: Jeffrey Shuren, M.D., J.D., Anindita Saha and Martin Ho, M.S.

- **Weight loss**
  - Patient-informed trial design
  - PMA approval

- **At home dialysis**
  - Patient risk tolerance
  - Expanded indication for solo at home use

- **Diabetes care**
  - Risk management for pediatric population

- **Ongoing studies**
  - Neurology
  - Oncology
  - Ophthalmics
  - Pediatrics
  - Women’s health
  - Urology
  - Prosthetics
Building on Progress Together

MDUFA IV

Patient Input in Clinical Trials

Patient Reported Outcomes

Patient Preference Information
What clinical trials challenges can patient input help solve?

- Study Design
- Recruitment, Informed Consent, Enrollment, Retention
- Study Conduct & Analysis
- Communication of Results
Thank You

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