“...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
Patients are at the Heart of What 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.
We believe that if CDRH is to successfully achieve a mission and vision in the service of patients, we must interact with patients as partners, and work together to advance the development and evaluation of innovative devices, and monitor the performance of marketed devices.
Where can patient perspectives inform medical device development and evaluation?

Patient-Informed Needs

Invention + Prototyping

Patient Preference Benefit-Risk Information

Pre-Clinical

Patient-Centered Outcomes

Discovery + Ideation

Patient-Informed Clinical Trial Design, Patient Reported Outcomes

Clinical

Communicating Benefit-Risk Information to Patients

Regulatory Decision

Post-Market Monitoring

Product Launch
50% of PMAs received in FY15 contain PROs

Observed a >500% increase in premarket submissions with PRO endpoints since 2008

Identified over 600+ premarket submissions containing PROs from CY2000-2014*

* Based on search for PROs in CDRH’s historical submission archives
Goal is to improve patient health by better understanding experiences and preferences

- **Patient Engagement**
- **Science of Patient Input**
  - Endpoints in Regulatory studies
  - Outcomes to monitor postmarket
  - Interest to payers, providers, patients
- **Patient Centric Healthcare**
  - Inform endpoints or effect size for Regulatory studies
  - Inform subgroup considerations
  - Labeling changes / expanded indications

**Patient Reported Outcomes (PRO)**
- Inform endpoints or effect size for Regulatory studies
- Outcomes to monitor postmarket
- Interest to payers, providers, patients

**Patient Preference Information (PPI)**
It’s About the Patients

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