FDA CDRH Partnering with Patients

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VIEWPOINT

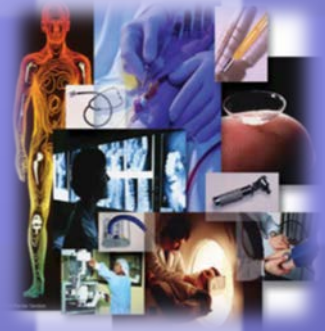
JAMA

Engaging Patients Across the Spectrum of Medical Product Development
View From the US Food and Drug Administration

"...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

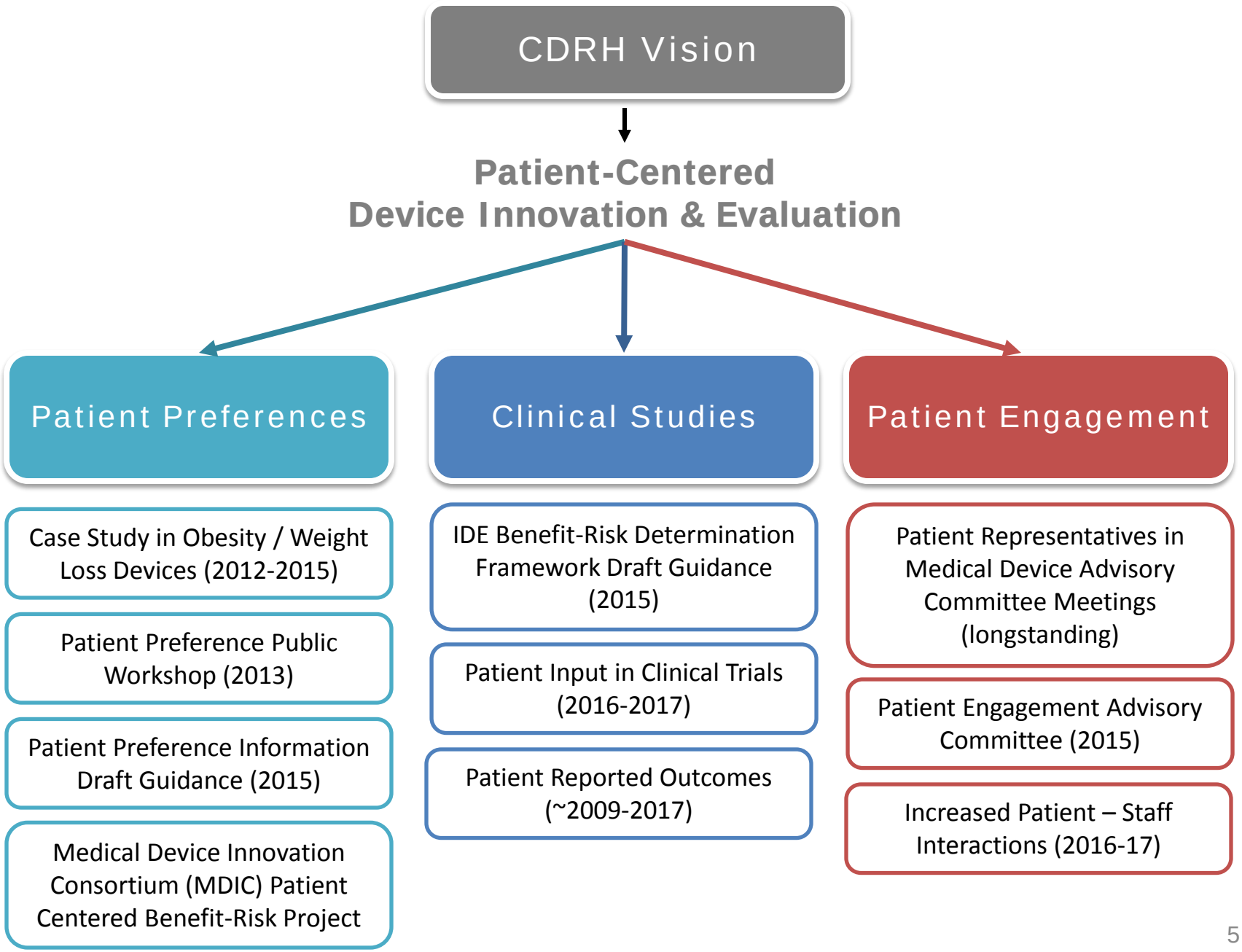


Patients are at the Heart of What We Do

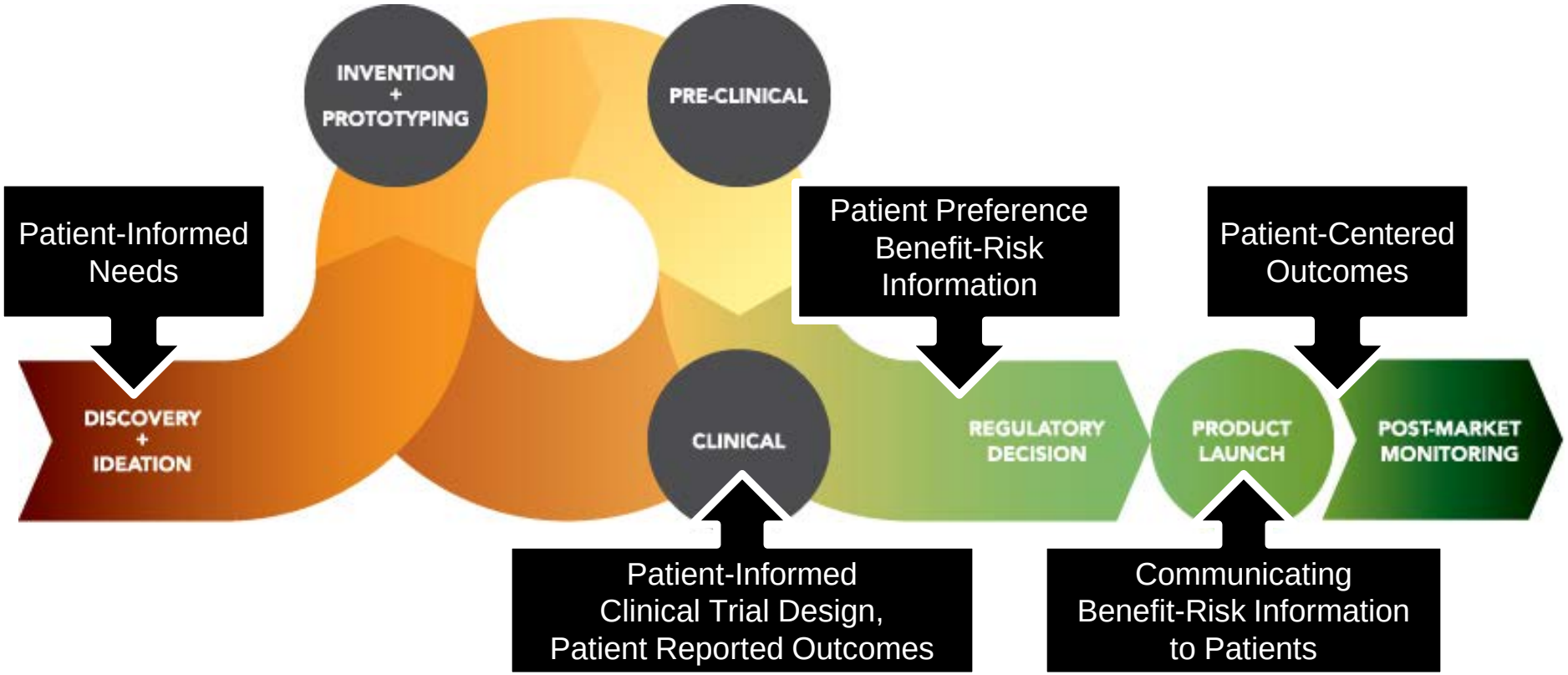
CDRH Vision: Patients in the U.S. have access to high-quality, safe, and effective medical devices of public health importance first in the world

FDA CDRH Strategic Priority: Partner with Patients

- *"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."*


CDRH Vision
Patient-Centered
Device Innovation & Evaluation
Patient Preferences
Clinical Studies
Patient Engagement
Case Study in Obesity / Weight Loss Devices (2012-2015)
Patient Preference Public Workshop (2013)
Patient Preference Information Draft Guidance (2015)
Medical Device Innovation Consortium (MDIC) Patient Centered Benefit-Risk Project
IDE Benefit-Risk Determination Framework Draft Guidance (2015)
Patient Input in Clinical Trials (2016-2017)
Patient Reported Outcomes (~2009-2017)
Patient Representatives in Medical Device Advisory Committee Meetings (longstanding)
Patient Engagement Advisory Committee (2015)
Increased Patient – Staff Interactions (2016-17)

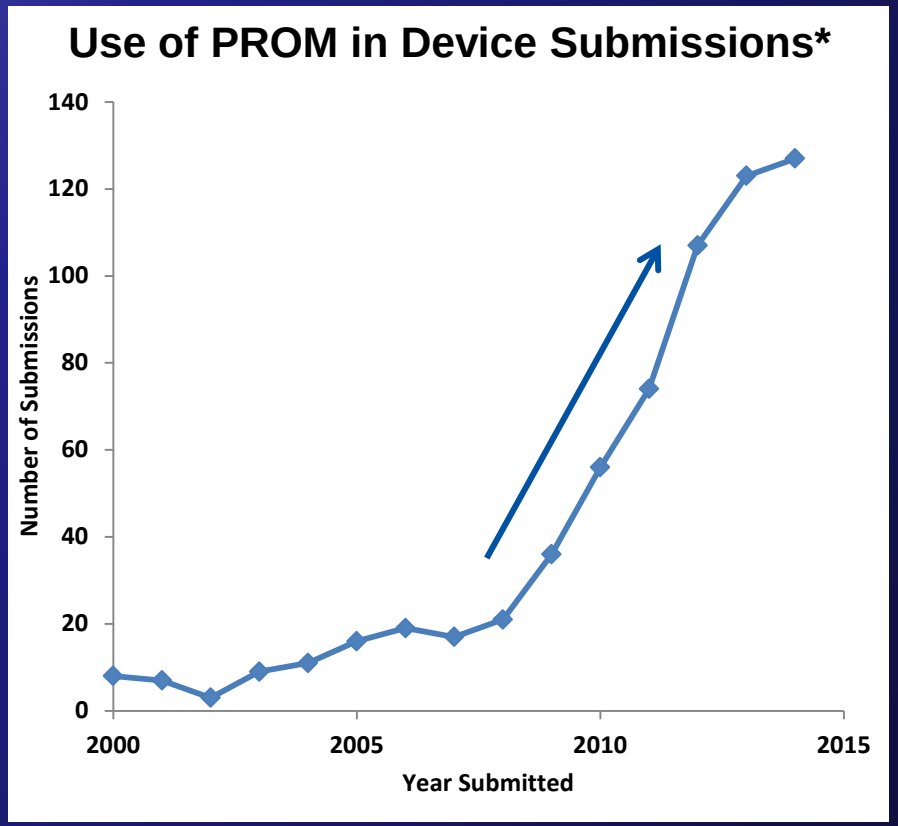
Where can patient perspectives inform medical device development and evaluation?



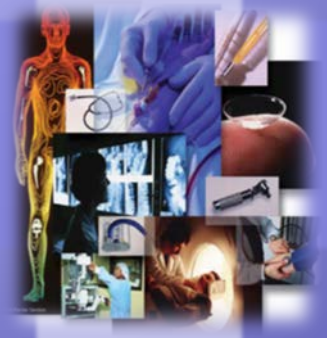
Increase in Patient Perspective Data

Submitted to CDRH as of FY2015

- 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** = **Patient-Centric Healthcare**

Patient Reported Outcomes (PRO)

- Endpoints in Regulatory studies
- Outcomes to monitor postmarket
- Interest to payers, providers, patients

Patient Preference Information (PPI)

- Inform endpoints or effect size for Regulatory studies
- Inform subgroup considerations
- Labeling changes / expanded indications

It's About the Patients

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