

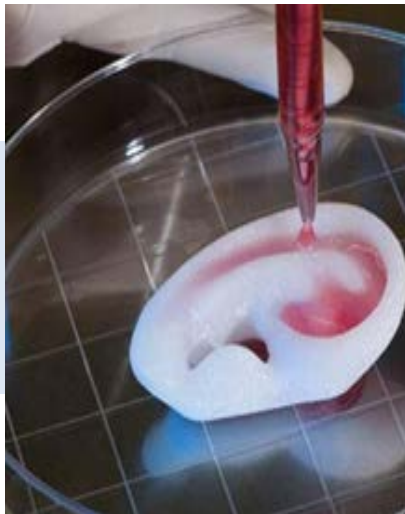
# Partnering with Patients

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

**Kathryn O'Callaghan**

CDRH Assistant Director for Strategic Programs  
FDA Center for Devices and Radiological Health

# 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”





# 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*



## 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

✓ **85%** CDRH  
Employee-  
Patient  
Interaction

Meaningful  
engagement

Making it  
easier for  
CDRH staff to  
obtain patient  
input

Partnership

✓ **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](mailto:Lisa.Miller@fda.hhs.gov)

**Patient Input**

**Patient  
Reported  
Outcomes**

**Patient  
Preference  
Information**

Direct from patient:

Symptoms

Function

Psychological well being

Quality of life

Patient perspective:

trade-offs between

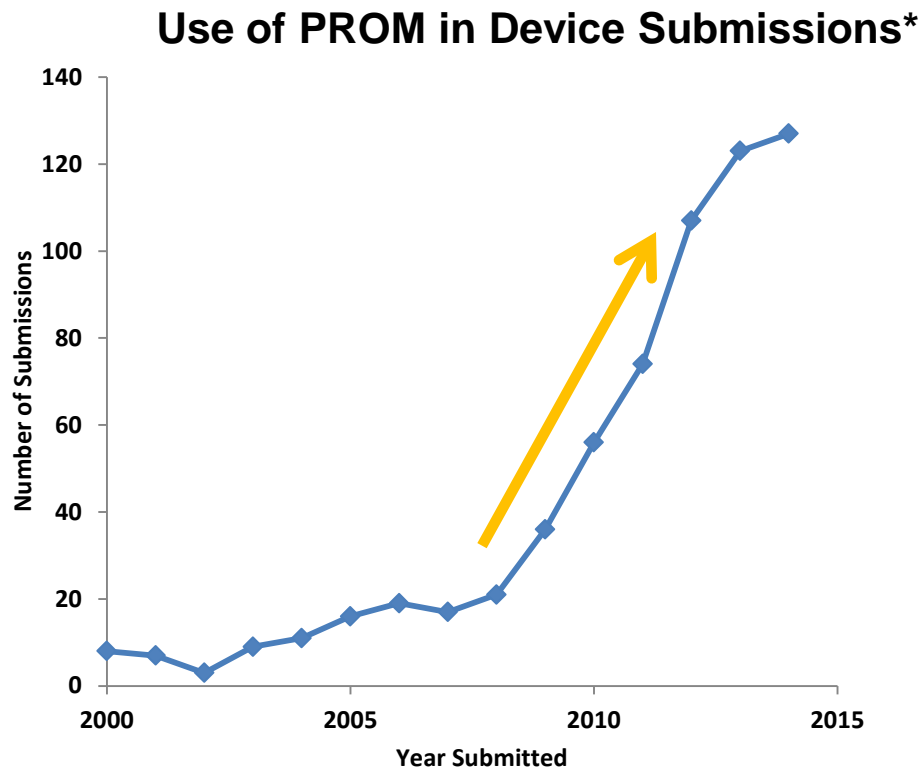
benefits and risks



# 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

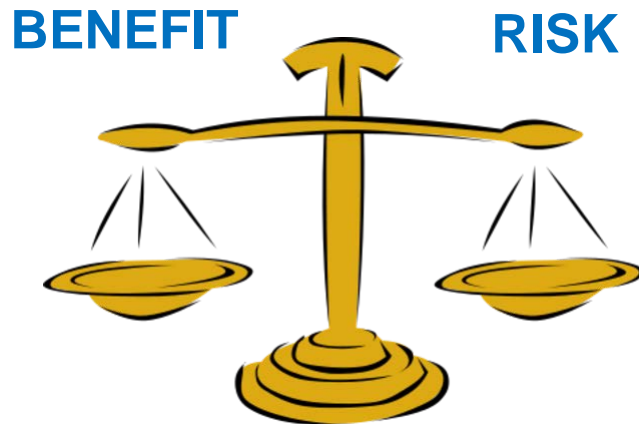
- PPI & PRO in Marketing Application Benefit-Risk

- 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.

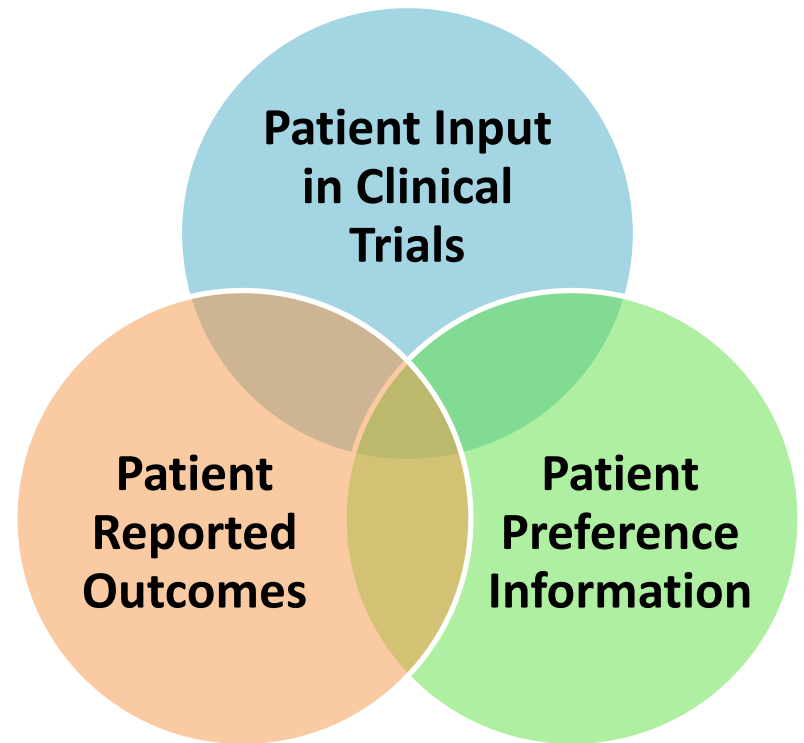


- **Weight loss**
  - Patient-informed trial design
  - PMA approval
- **At home dialysis**
  - Patient risk tolerance
  - Expanded indication for solo at home use
- **Diabetes care**
  - Risk management for pediatric population
- **Ongoing studies**
  - Neurology
  - Oncology
  - Ophthalmics
  - Prosthetics
  - Women’s health
  - Urology
  - Pediatrics

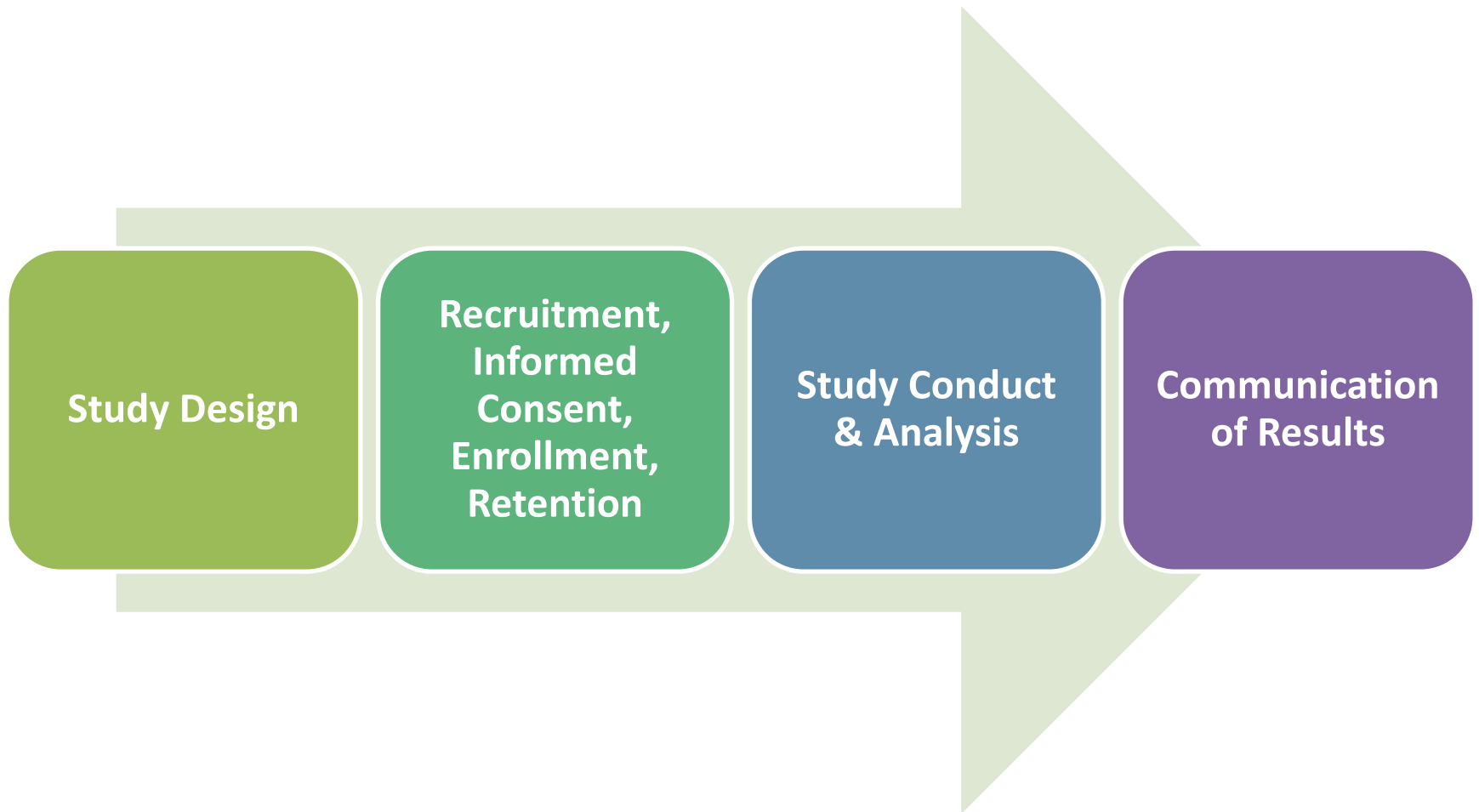
# Building on Progress Together



## MDUFA IV



# What clinical trials challenges can patient input help solve?





**Thank You**

**Katie O'Callaghan**

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