



Involving Patients in Assuring Safe & Effective Medical Device Use

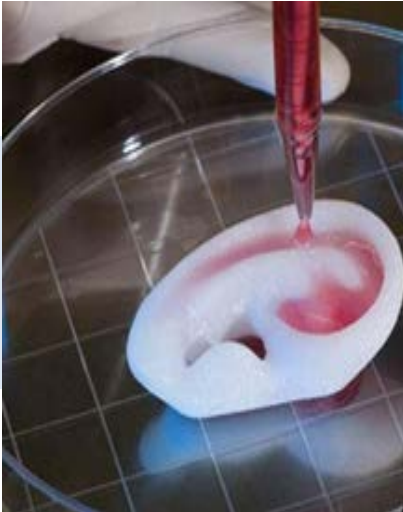
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Ophthalmology Advisory Committee, 3/17/2017

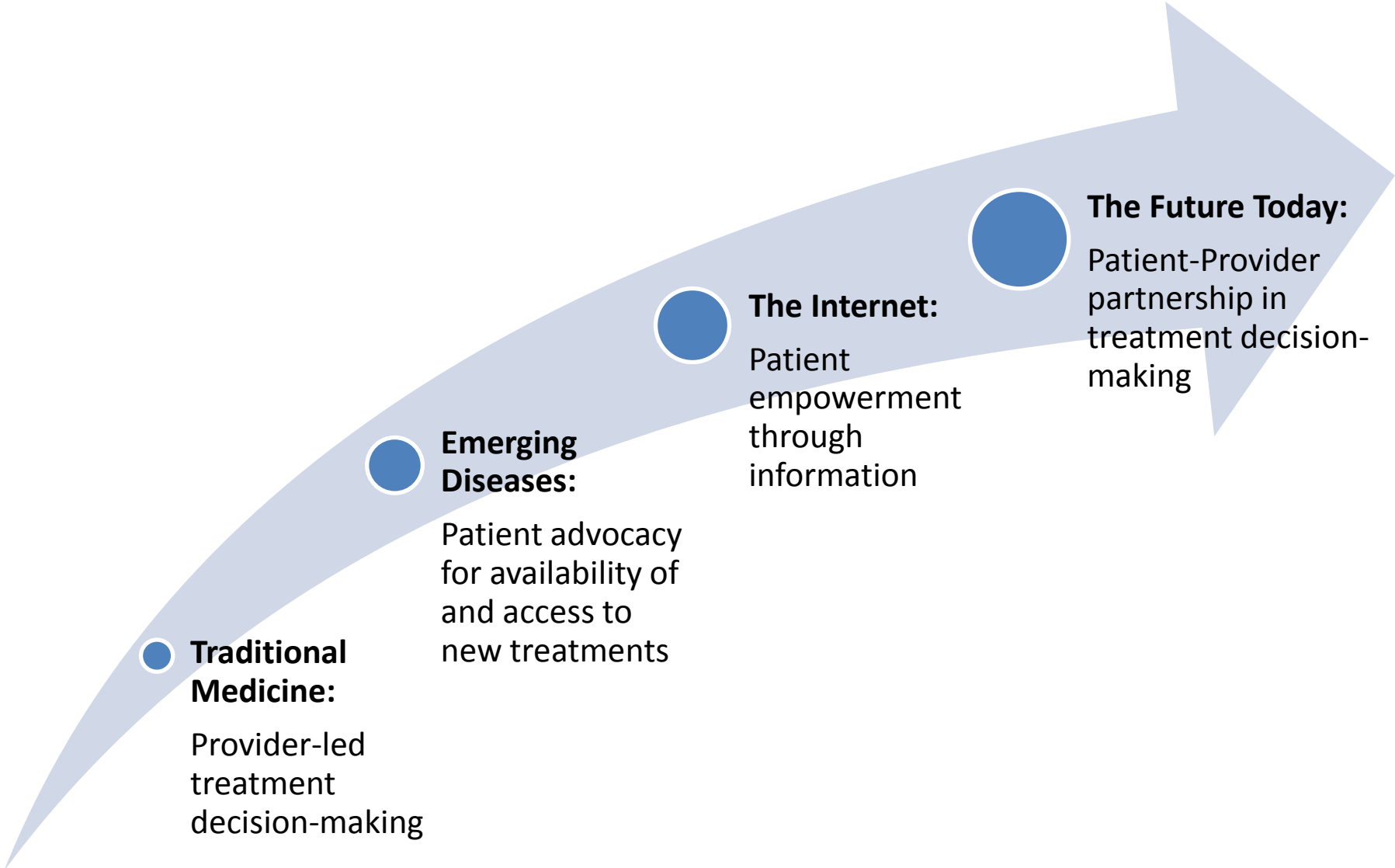
Patients are at the Heart of All We Do



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.

Evolution of the Patient's Role



**Traditional
Medicine:**
Provider-led
treatment
decision-making

**Emerging
Diseases:**
Patient advocacy
for availability of
and access to
new treatments

The Internet:
Patient
empowerment
through
information

The Future Today:
Patient-Provider
partnership in
treatment decision-
making

Investing in Culture

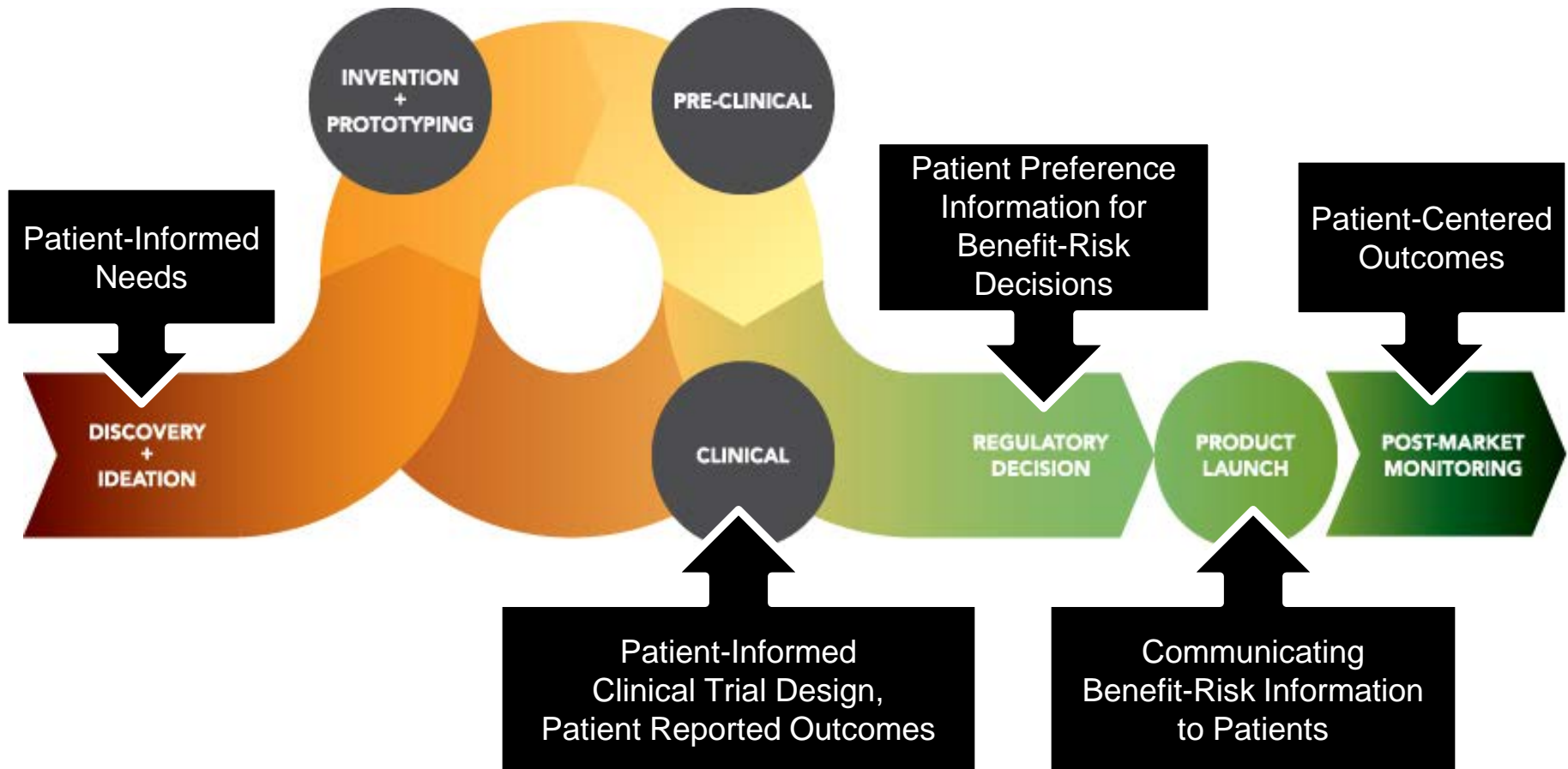


Partner with Patients

We interact with patients as partners and work together to advance the development and evaluation of innovative devices, and monitor the performance of marketed devices.

1. Promote a culture of meaningful patient engagement by facilitating CDRH interaction with patients.
2. Increase use and transparency of patient input as evidence in our decision-making.

Where is Patient Input Useful?





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

PATIENT ENGAGEMENT

Model for Culture Change

**PROMOTE A CULTURE OF MEANINGFUL PATIENT ENGAGEMENT
BY FACILITATING CDRH INTERACTION WITH PATIENTS**



Interaction

Meaningful
engagement

Partnership

Strengthening a Culture of Patient Engagement



- Patient Engagement Advisory Committee
- PITCH & PROPEL Staff Competitions
- Town Hall Meetings
- Patient & CarePartner Connection
- Patient Organization Awareness Day

Patient Science and Engagement Competitions

Purpose: *To facilitate CDRH staff engagement and capacity building*

PITCH Patient Engagement Competition

- Funding for staff to hold meaningful patient engagement activities
- Staff determined and pitched what they considered meaningful engagement



Propel Patient Science Competition

- Funding for staff research to advance the science of patient input
- Staff determined areas where PROs and PPI would be of most benefit in their work



Over **75** staff from across the Center competed, and hundreds participated, in inaugural contests held in early 2016.

Investing in Culture: Patient Focused



MDUFA IV Agreement in Principle

Patient input in clinical trials

Patient preference information (PPI)

Patient reported outcomes (PRO)

Patient Engagement: Employee Comments

“Hearing patient experiences and suggestions is extremely valuable to our mission.”

“ Puts a needed human face to our actions. ”

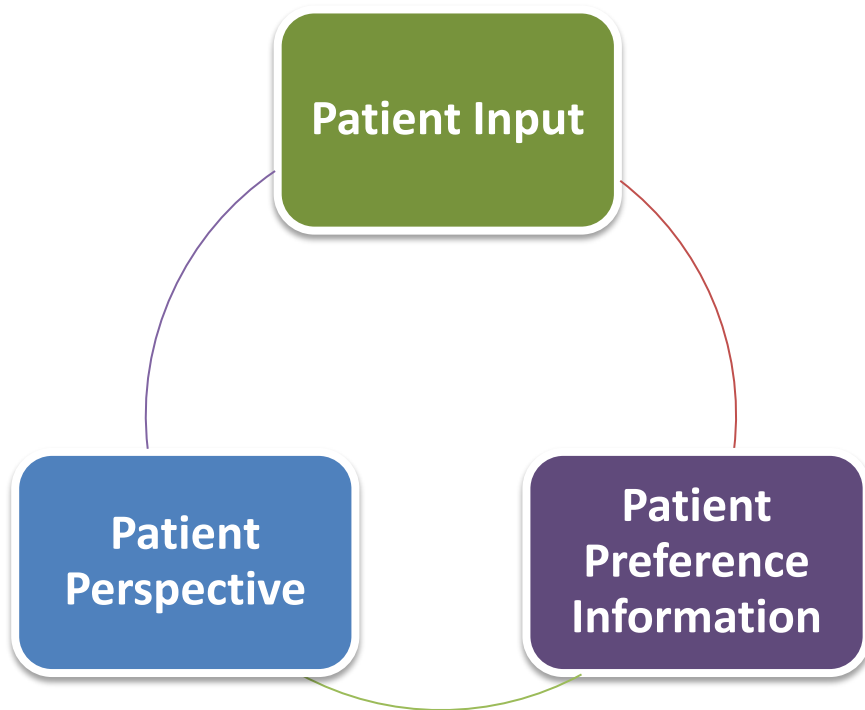
“Hearing patients’ personal experience was extremely powerful and moving.”

*Increase use and transparency of patient input as evidence
in CDRH decision-making*

SCIENCE OF PATIENT INPUT

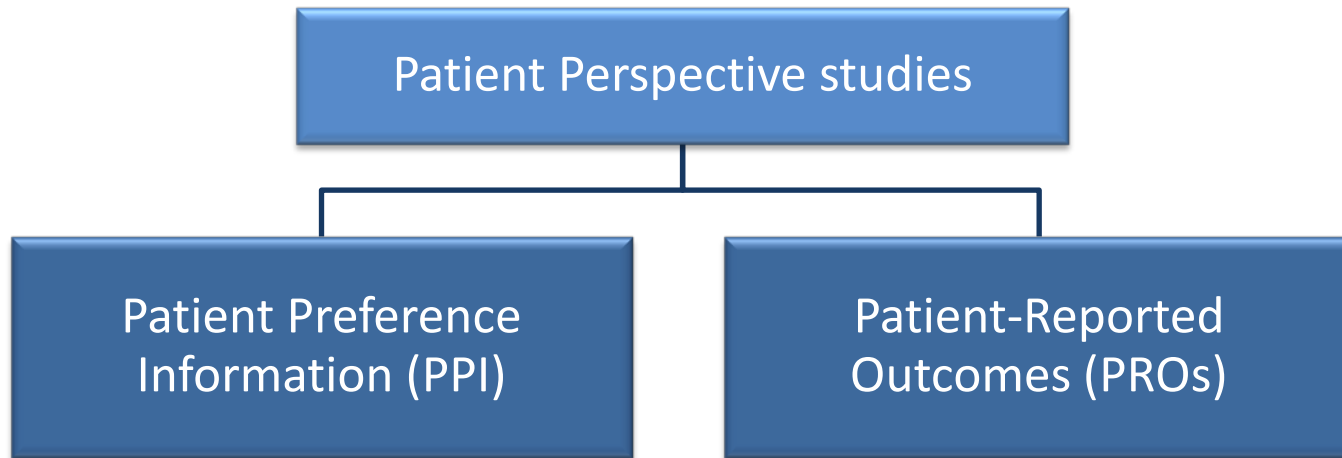
Patient Input

Patient input includes a range of different types of information:



- Anecdotal comments in correspondence to the FDA
- Testimony at Advisory Committee meetings
- Patient opinions expressed publicly including through social media
- Patient responses to qualitative *ad hoc* surveys
- Quantitative measurements of patient-reported outcomes

Patient Perspective Studies



Patient perspective on trade-offs of benefits and risks

Health status reported from patient without involvement of physician

What can PROs and PPI tell us?

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

Thank You



