HOW DOES FDA INCLUDE PATIENTS IN MEDICAL DEVICE REGULATORY EFFORTS ?

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HERE'S WHAT WE WANT YOU TO LEARN TODAY

1. WHAT IS THE U.S. FOOD AND DRUG ADMINISTRATION?
2. WHAT DO WE DO?
3. WHY ARE PATIENTS IMPORTANT TO FDA AND HOW DO WE ENGAGE THEM IN OUR WORK?
4. HOW ARE STAKEHOLDERS BECOMING MORE PATIENT FOCUSED AND WHAT ARE SOME TOOLS THAT MAY HELP?
5. WHAT ARE SOME BENEFITS OF INCLUDING PATIENTS AS ADVISORS IN THE DESIGN AND CONDUCT OF MEDICAL DEVICE CLINICAL STUDIES?

WHAT DOES FDA DO?

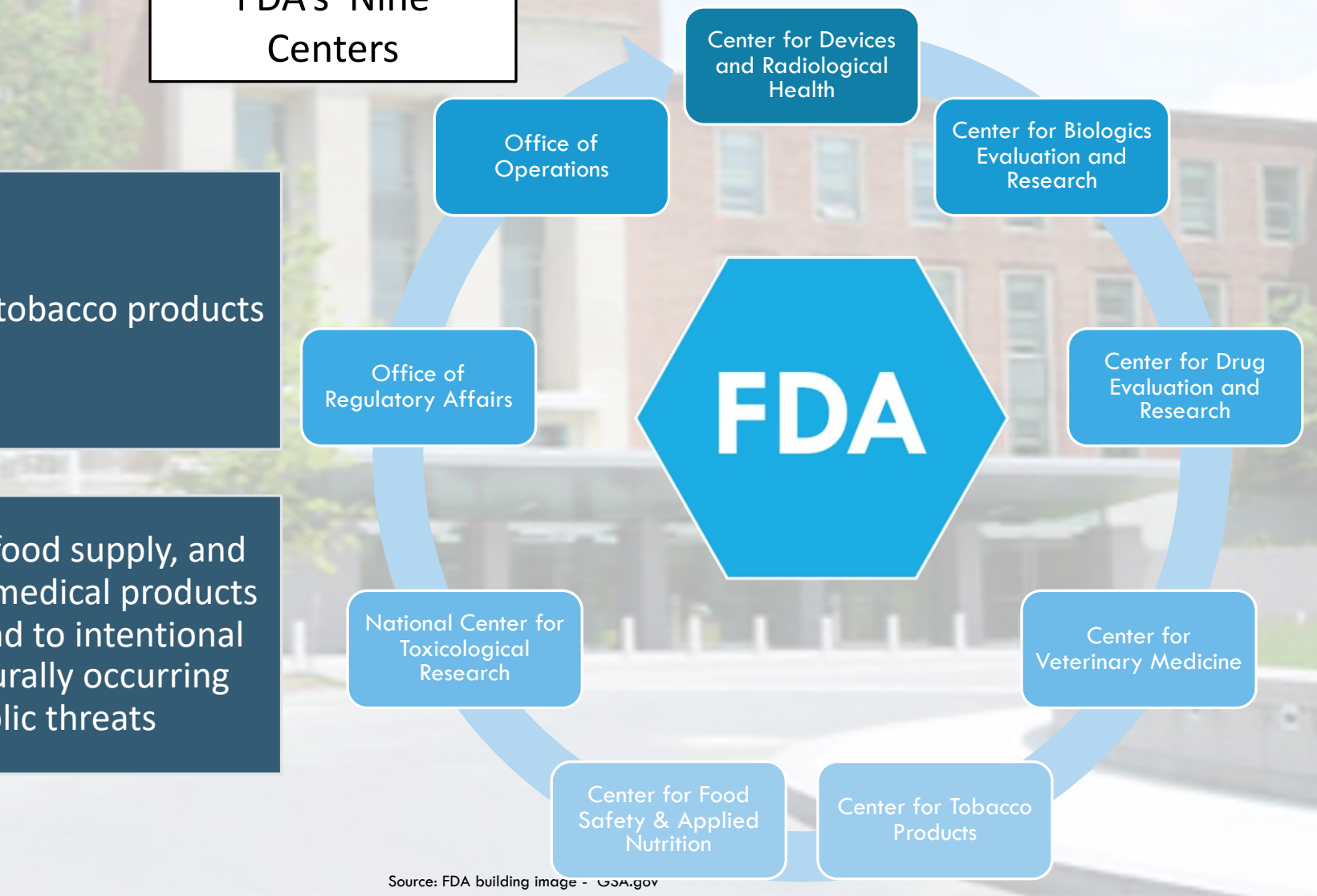
Protects the public health

Regulates tobacco products

Advances public health through medical product innovation

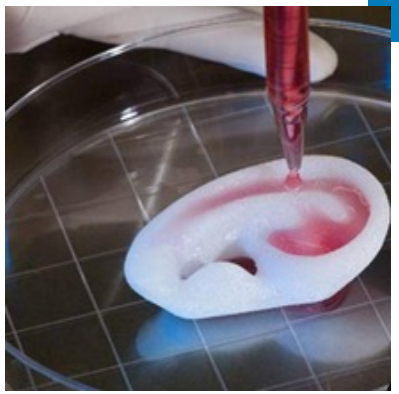
Protects food supply, and develops medical products to respond to intentional and naturally occurring public threats

FDA's Nine Centers

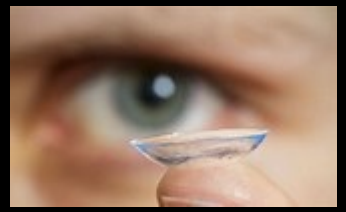


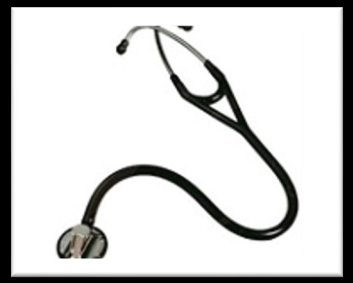
Source: FDA building image - GSA.gov

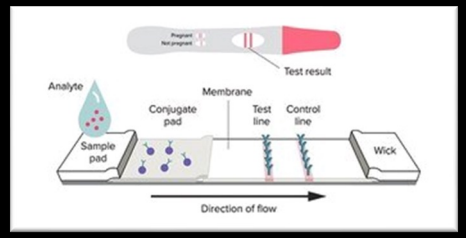
WHAT DOES CDRH DO?

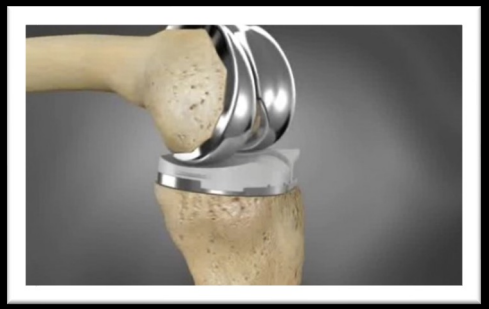


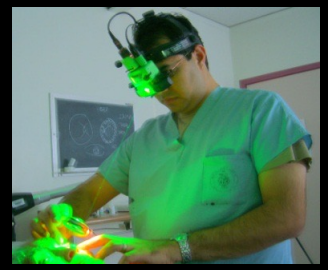
THE DIVERSITY OF MEDICAL DEVICES

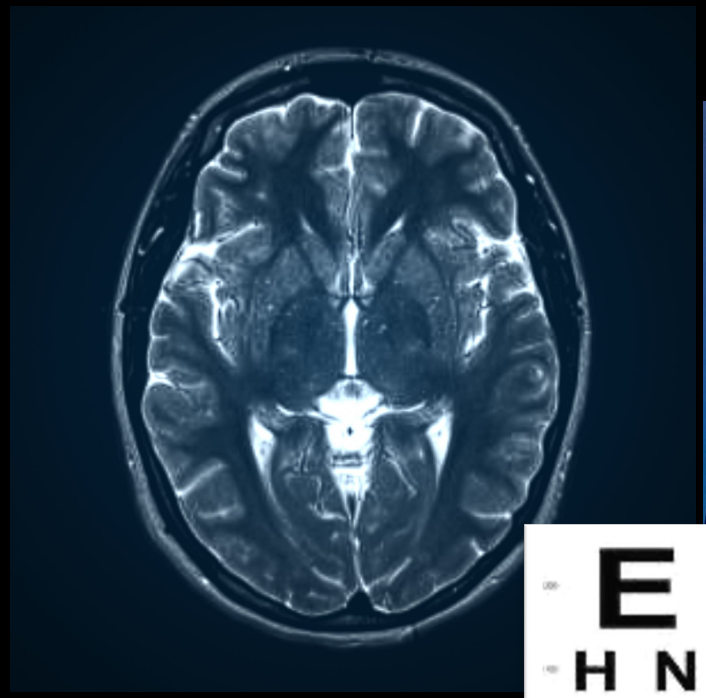


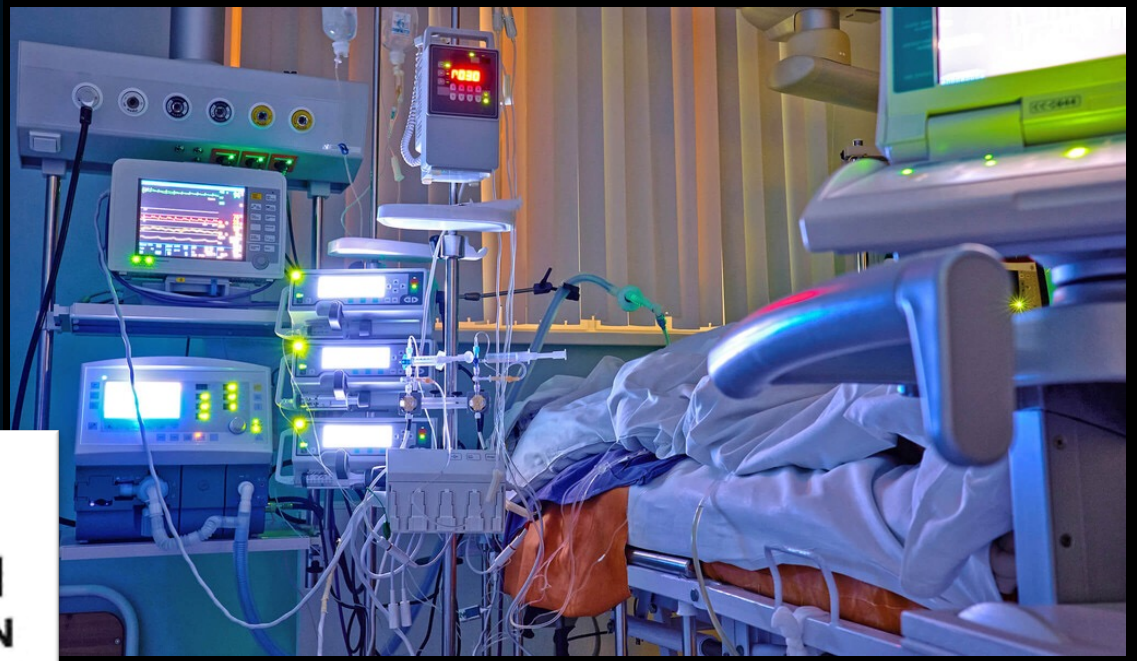


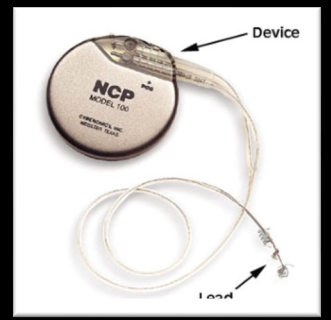






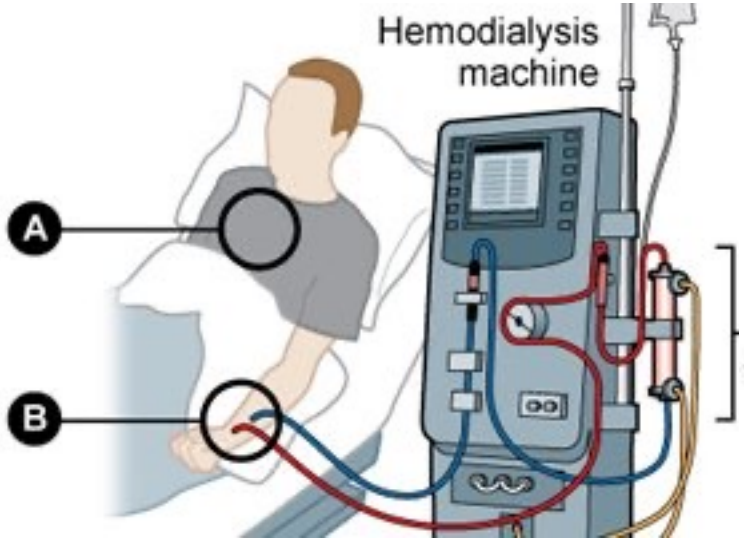






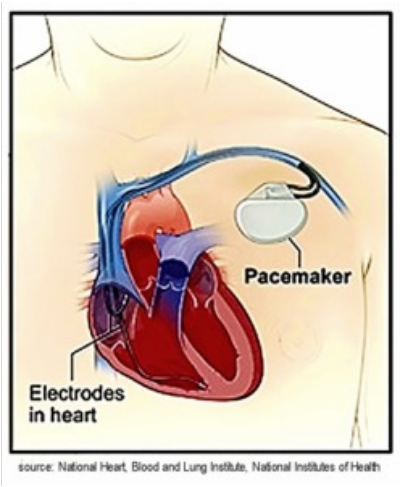
RISK-BASED PARADIGM FOR DEVICE REGULATION

The law gives us the flexibility to calibrate our regulatory approach to the level of potential risk posed by new products

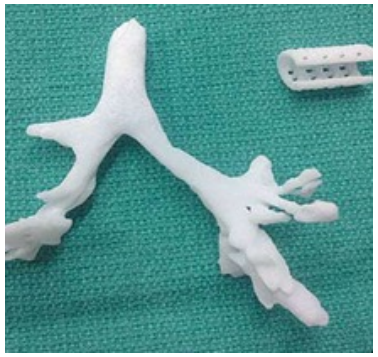


Hemodialysis Machine
510(k)

Retinal Implants
HDE



Pacemaker
PMA



Patients are at the Heart of All We Do

CDRH Vision:

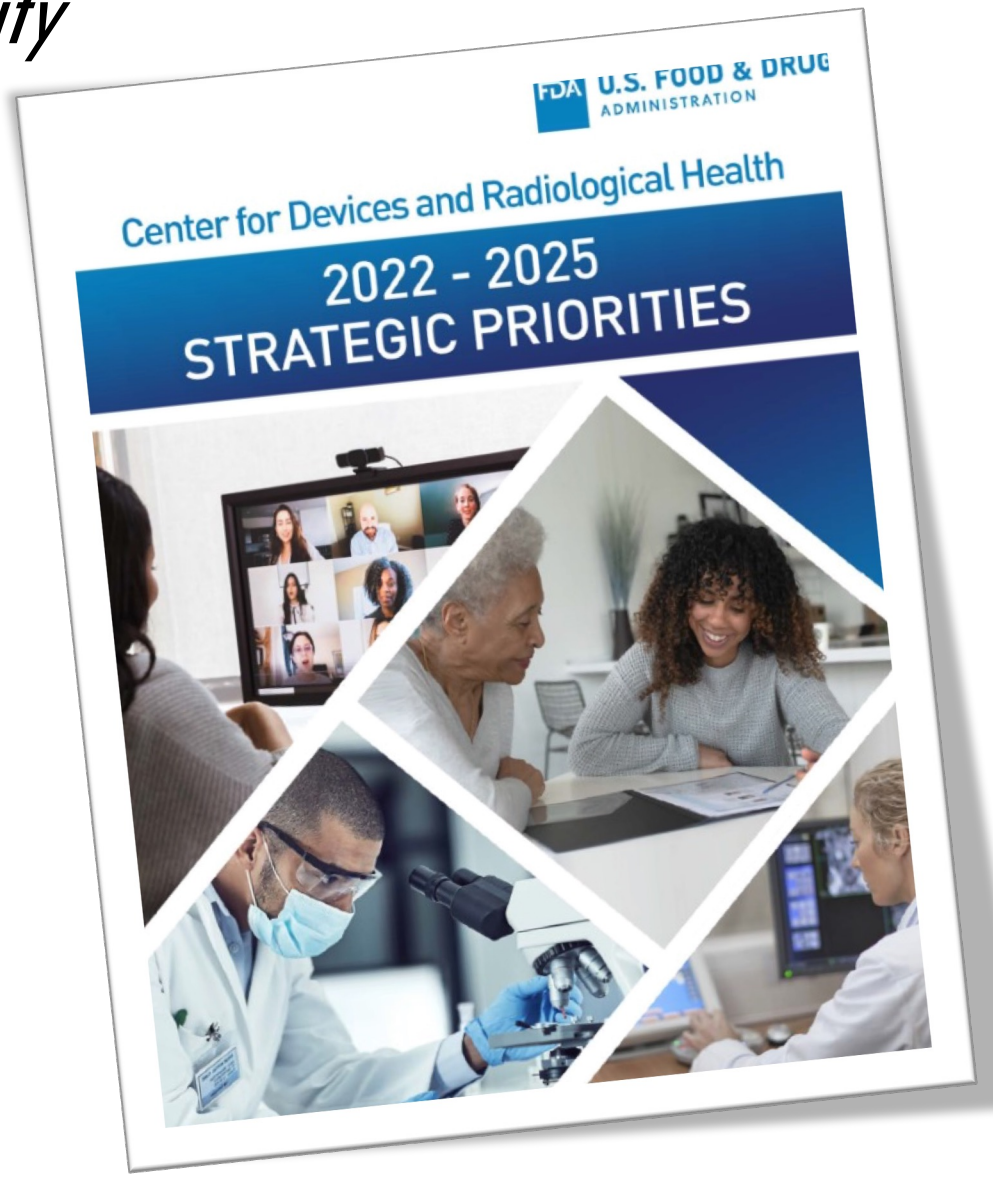
- Patients in the U.S. have access to high-quality, safe, and effective medical devices of public health importance, first in the world.

WHY ARE PATIENTS IMPORTANT?

CDRH STRATEGIC PRIORITY:

Advancing Health Equity

- CDRH helps advance the development of knowledge for safe and effective technologies to meet the needs of all patients and consumers
- Technology can help bridge the divide while advancing better healthcare, quality of life, and wellness for all
- No person should be left behind in health care

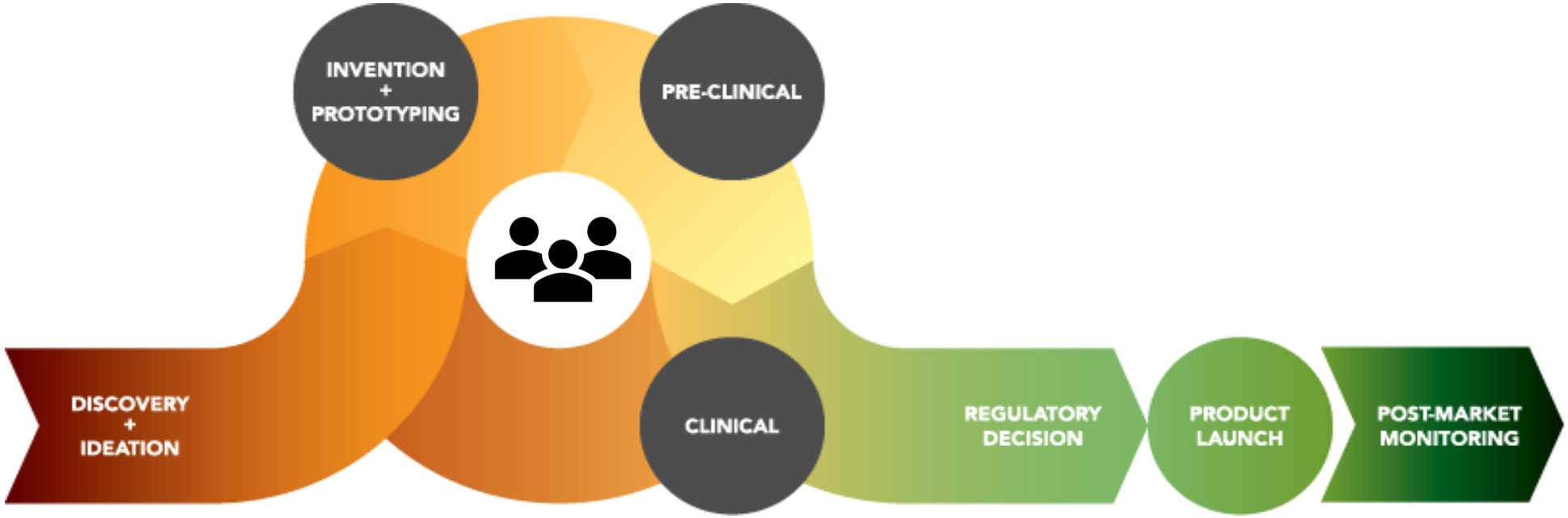


DEFINING PATIENT ENGAGEMENT

Patient engagement is defined as intentional, meaningful interactions with patients that provide opportunities for mutual learning and effective collaborations

Source: https://www.fda.gov/about-fda/center-devices-and-radiological-health/cdrh-patient-engagement

PATIENT INPUT BENEFITS ALL PHASES OF THE TOTAL PRODUCT LIFECYCLE (TPLC)



Inform device or clinical study design	Bring to light new considerations to inform thinking on current issues	Raise or confirm problems that may exist with specific devices	Communicate benefits and risks of medical devices	Identify specific population's views on benefit-risk for a given treatment

HOW DOES FDA ENGAGE PATIENTS?

Patient Listening Sessions

Patient Engagement Advisory Committee (PEAC)

Patient & Caregiver Connection (PCC)

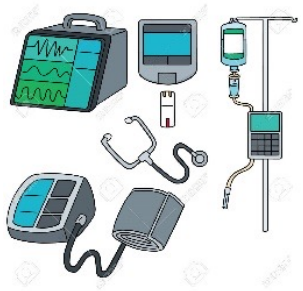
Patient Engagement Collaborative (PEC)

Patient-Focused Medical Product Development (PFDD) Meetings

FDA Patient Representative Program

PATIENT & CAREGIVER CONNECTION*: GOALS

To provide CDRH staff with access to **patients** & **caregivers** who are willing to share their individual experiences regarding:



Medical devices used for diagnosis, treatment, or management of their disease

Living with their specific disease

Current issues or trends related to medical devices

Provides FDA **timely** access to **aggregate patients' voices**

*FDA is not seeking, nor will patients or caregivers formally or informally provide, group opinions, advice, or recommendations to CDRH.

PATIENT & CAREGIVER CONNECTION PARTNERS

HOW DOES CDRH ENGAGE PATIENTS?

PCC SURVEYS

PATIENT GROUP CONVERSATIONS

CDRH TOWNHALLS

PUBLIC HEALTH SYMPOSIUMS

AD HOC (e.g.) POST- MARKET SAFETY SIGNALS

PEAC

CDRH PATIENT ENGAGEMENT ADVISORY COMMITTEE (PEAC)

PEAC role: To help ensure patients' needs and experiences are considered in FDA's work on medical devices

PEAC members are diverse patients, caregivers, and patient advocates who

- Share perspectives and expertise on various issues
- Advise and provide formal recommendations to FDA
- Serve as a resource to CDRH as a body of experts in patient experience, needs, and the activities of the patient community

Patient-focused and relevant recommendations

1-2 Homework assignments per year

1-2 PEAC Meetings per year

TOPICS OF PEAC MEETINGS

1. Patient Engagement in Clinical Trials

2. Patient-Generated Health Data & Medical Device Safety

3. Communicating Cybersecurity Vulnerabilities

4. Artificial Intelligence & Machine Learning

5. Medical Device Recalls

6. July 12 - 13, 2022
Augmented Reality (AR) & Virtual Reality (VR) Medical Devices

PATIENT SCIENCE AND ENGAGEMENT NEWSLETTERS

FDA U.S. FOOD & DRUG ADMINISTRATION

Patient Science and Engagement Updates from CDRH

U.S. Food and Drug Administration sent this bulletin at 04/27/2021 12:06 PM EDT

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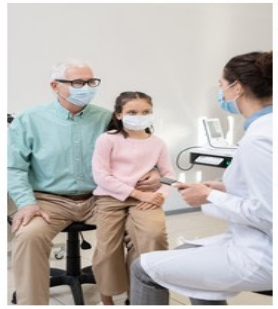
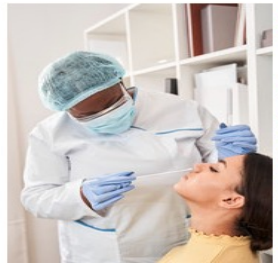


Patients are experts in their conditions and offer valuable information to the U.S. Food and Drug Administration (FDA) about living with the condition and its treatments. Patient input can significantly impact the development, evaluation, and monitoring of medical devices.

Discover how the FDA's Center for Devices and Radiological Health (CDRH) **puts patients first** with its Patient Science and Engagement Program.

Patient Engagement and Research



Communicating About COVID-19 Testing to Underrepresented Populations

CDRH and the PATIENTS Program at the University of Maryland Center of Excellence in Regulatory Science (CERSI) are conducting a qualitative study to better understand underrepresented populations' attitudes towards COVID-19 testing and their willingness to share these data in national information banks.

Underrepresented populations in the study include African Americans, individuals whose primary language is Spanish,

FDA U.S. FOOD & DRUG ADMINISTRATION

Patient Science and Engagement Updates from CDRH

U.S. Food and Drug Administration sent this bulletin at 01/26/2021 12:17 PM EST

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Patient Engagement and Digital Health

Artificial Intelligence and Imaging

Patients shared their perspectives on this emerging technology during a February 2020 workshop on the **Evolving Role of Artificial Intelligence in Radiological Imaging**. Device developers at the meeting commented on how helpful the patients' insights were to their product development considerations. Read more

Digital Health Center of Excellence

CDRH ENCOURAGES PATIENT ENGAGEMENT THROUGH GUIDANCE

Contains Nonbinding Recommendations

Patient Engagement in the Design and Conduct of Medical Device Clinical Studies

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Guidance for Industry, Food and Drug Administration Staff, and Other Stakeholders

Document issued on January 26, 2022.

The draft of this document was issued on September 24, 2019.

For questions about this document regarding CDRH-regulated devices, contact Michelle Tarver in the Office of Strategic Partnerships and Technology Innovation (OST) at (301) 796-6884 or by email CDRH_PatientEngagement@fda.hhs.gov. For questions about this document regarding CBER-regulated devices, contact the Office of Communication, Outreach, and Development (OCOD) at 1-800-835-4709 or 240-402-8010, or by email at ocod@fda.hhs.gov.

U.S. FOOD & DRUG ADMINISTRATION

U.S. Department of Health and Human Services
Food and Drug Administration
Center for Devices and Radiological Health
Center for Biologics Evaluation and Research

https://www.fda.gov/regulatory-information/search-fda-guidance-documents/patient-engagement-design-and-conduct-medical-device-clinical-investigations

POTENTIAL BENEFITS OF DIVERSE PATIENT ADVISOR INPUT IN CLINICAL STUDIES

- Faster study/research participant recruitment, enrollment, and study completion
- Greater study/research participant commitment and retention, resulting in less missing data and decreased loss to follow-up
- Greater study/research participant adherence resulting in fewer protocol deviations and violations
- Greater study/research participation by diverse populations
- Fewer protocol revisions
- Streamlined data collection resulting in better quality data
- More relevant data on outcomes that matter to patients

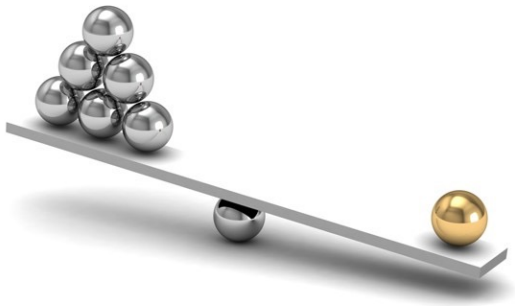
EXAMPLES OF PATIENT ENGAGEMENT ACTIVITIES IN THE DESIGN AND CONDUCT OF CLINICAL STUDIES

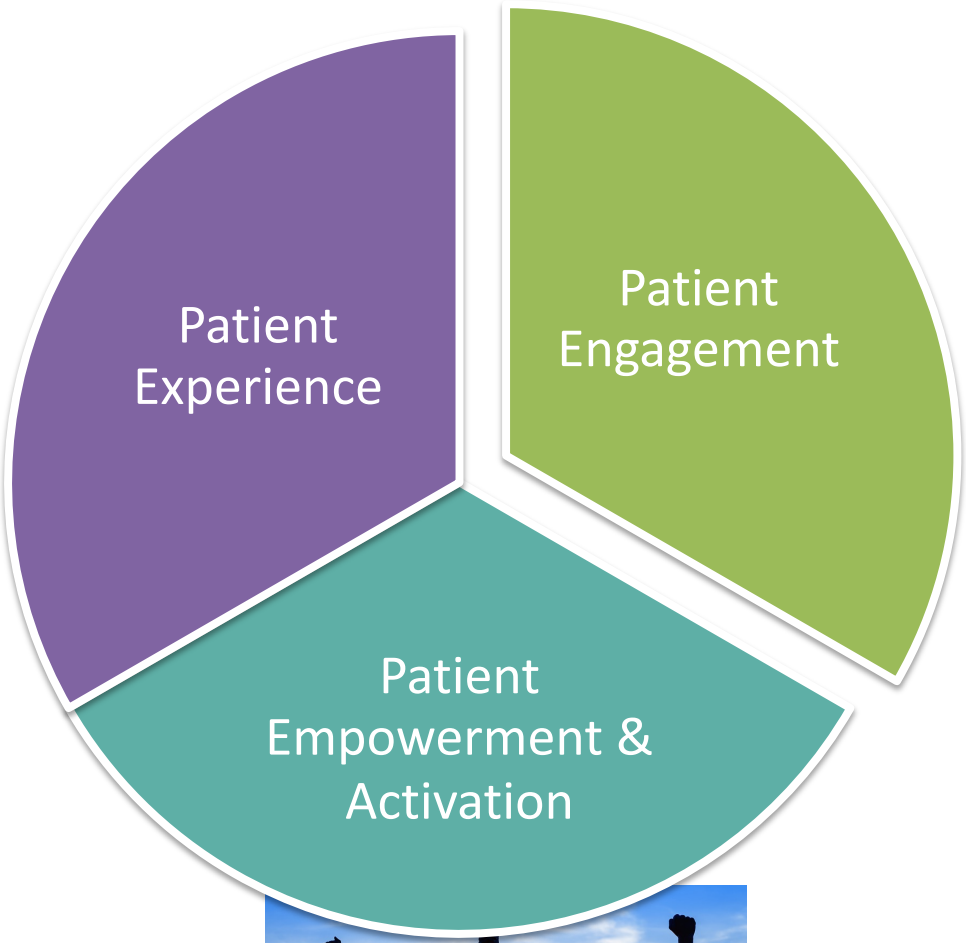
- Informed consent clarity
- Flexible options for data collection and follow up visits
- Recruitment barriers and study delays
- Potential endpoints
- Patient-Reported Outcomes (PRO) concepts
  - "A measurement based on a report that comes directly from the patient (i.e., study subject) about the status of a patient's health condition without amendment or interpretation of the patient's response by a clinician or anyone else." [1]
- Patient Preference Information (PPI) study design
  - "PPI is a type of patient experience data that incorporates the patient perspective in CDRH's regulatory decision-making."[2]

1 As defined in the BEST (Biomarkers, Endpoints, and other Tools) Resource Glossary, developed by FDA-NIH Biomarker Working Group. Available at: https://www.ncbi.nlm.nih.gov/books/NBK326791/

2 https://www.fda.gov/about-fda/cdrh-patient-science-and-engagement-program/patient-preference-information-ppi-medical-device-decision-making

ENGAGEMENT FOSTERS EMPOWERMENT





HOW CAN I GET INVOLVED?

- Sign up for FDA email notifications
  - https://public.govdelivery.com/accounts/USFDA/subscriber/new
  - https://www.fda.gov/about-fda/center-devices-and-radiological-health/subscribe-cdrh-email-lists
- Report poor outcomes with medical devices
  - MedWatch: The FDA Safety Information and Adverse Event Reporting Program | FDA
- Consider participating in medical device clinical trials
  - Clinical trials.gov and search for your medical condition, recruiting studies
- Contact our mailbox
  - CDRH_PatientEngagement@fda.hhs.gov
- Attend our workshops, especially the PEAC
  - CDRH Patient Engagement Advisory Committee | FDA

Patient Engagement Resources

How Can I Learn About CDRH Patient Engagement?

- *Patient Engagement*: https://www.fda.gov/about-fda/center-devices-and-radiological-health/cdrh-patient-engagement

How Do I Report Adverse Events To FDA Or Receive Safety Alerts For FDA-regulated Products?

- *Report medical product safety concerns to MedWatch:* https://www.fda.gov/safety/medwatch-fda-safety-information-and-adverse-event-reporting-program
- *Report Medical Device Problems:* https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems

Who Can I Ask Questions About A Medical Device Topic?

- *Ask Medical Device Questions to the Division of Industry and Consumer Education (DICE):* https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice

Contacts for Medical Devices

FDA

PEAC: https://www.fda.gov/about-fda/cdrh-patient-engagement/cdrh-patient-engagement-advisory-committee

Patient & Caregiver Connection: https://www.fda.gov/about-fda/cdrh-patient-engagement/cdrh-patient-and-caregiver-connection

For Patient Engagement Questions:

CDRH_PatientEngagement@fda.hhs.gov

FDA U.S. FOOD & DRUG ADMINISTRATION

& Devices

QUESTIONS AND ANSWERS