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Patient Perspectives on Home Uses Device by the Rare Disease Community

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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.

Patients Input Impacts Medical Device Development and Evaluation

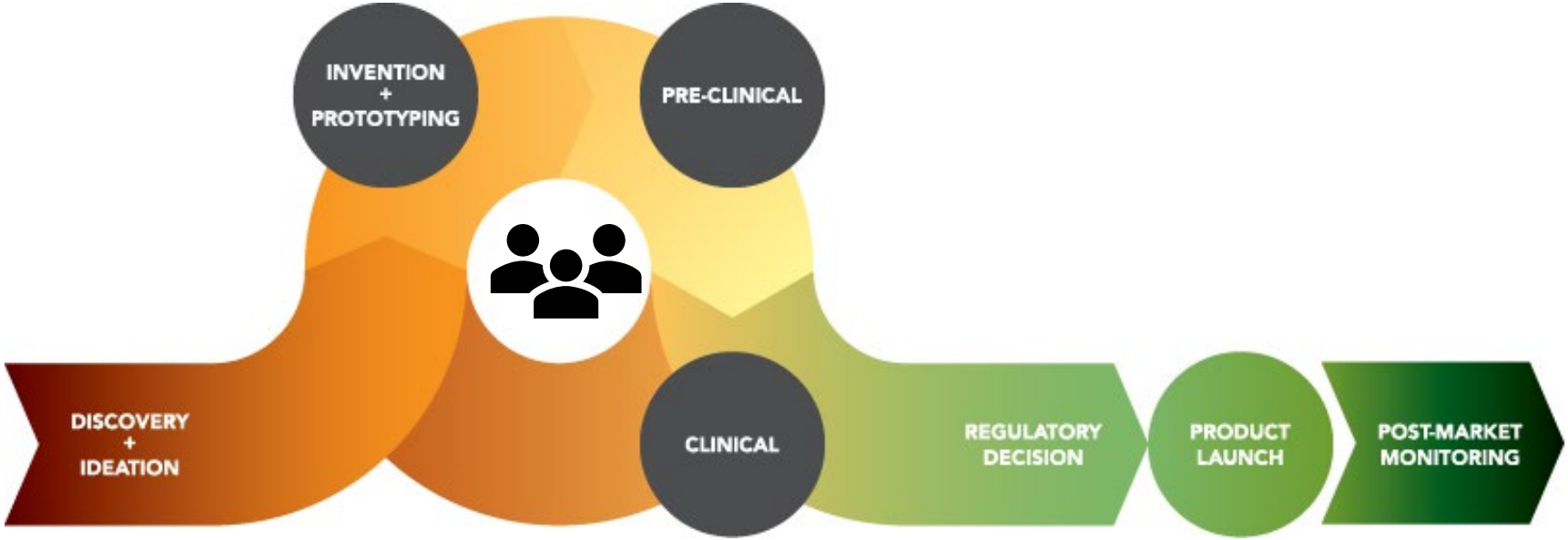
Patient Engagement

Patient-Reported Outcomes

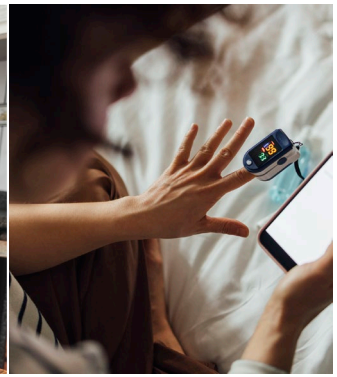
Patient Preference Information

Patient-Generated Health Data

Patient Input Benefits All Phases of the Total Product Lifecycle (TPLC)



CDRH PATIENT AND CARE GIVER CONNECTION PARTNER ORGANIZATIONS



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CDRH Patient Engagement Town Hall

PERSPECTIVES ON HOME USE DEVICES BY THE NATIONAL ORGANIZATION OF RARE DISEASE (NORD) COMMUNITY

Wednesday, September 13, 2023

HOME USE MEDICAL DEVICES USED BY PANELISTS

Respiratory Devices	*Neurological and Mobility Devices*	*Gastro devices*	*Diagnostic devices*	*Other*
•*Home ventilator* •*Continuous positive airway pressure* •*At home pulse-oximeter Holter monitor machine*	•*Spinal cord stimulator* •*Feeding Pump* •*Vagus Nerve Stimulator (VNS)* • *Cane, knee-ankle-foot-orthotic (KAFO)*	• *Feeding tubes (gastronomy tube, nasogastric (NG) feeding -g tube)* •*Total parenteral nutrition (TPN) infusion* •*Ventriculoperitoneal shunts* •*Insulin pump used to deliver cortisol-* •*Ostomies (ileostomy, jejunostomy)*	•*COVID-19 at home testing*	• *Wound vac for fistulas*

PATIENT PANEL KEY FINDINGS

- Facilitate Better Quality Of Life
- Flexibility Enabling Participation in Activities
- Concerns About Transitioning From Traditional Healthcare Setting
- Information For Off-label Use
- Alignment of Device Function With Lifestyle
- Updated Information as Condition Progresses
- Devices that Meet Health Equity Needs

PATIENT FEEDBACK ON FDA INFUSION PUMP COMMUNICATIONS

Survey Objective

- To better understand rare disease patient and caregiver experiences with infusion pumps
- Improve communications about these devices

Impact

- Clear patient-friendly information to support safe and effective use of infusion pumps

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Total Product Life Cycle Advisory Program (TAP) Overview

Goal of TAP Pilot: Show that the process improvements to FDA's early interactions with device companies and others who support the vision for TAP can be done and have benefit

Vision: The long-term vision for TAP is to help spur more rapid development and more rapid and widespread patient access to safe, effective, high-quality medical devices of public health importance. A mature TAP will also help ensure the sustained success of the Breakthrough devices program.

EDUCATION FOR PATIENTS

Goal

To facilitate industry efforts to collaborate with patients in key areas by generating patient-friendly educational modules on device trials, real-world data, device development tools, and regulatory frameworks. FDA will also make these educational modules publicly available, as appropriate

Objective

To increase the number of publicly available trainings for patients to facilitate preparing them for effective interactions with medical device sponsors and other members of the healthcare ecosystem


WHAT ROLE CAN PATIENTS PLAY IN ONGOING DEVICE REGULATORY EFFORTS?

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

- For Patient-Reported Outcome Questions:
  CDRH-PRO@fda.hhs.gov
- For Patient Preference Information Questions:
  CDRH-PPI@fda.hhs.gov
- For Patient Engagement Questions:
  CDRH_PatientEngagement@fda.hhs.gov

Questions


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