MeDevice

Enhancing transparency of medical device communications to improve consumer accessibility

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Presentation Overview

• Background
• Our Solution
• Importance and Impact
• Implementation
• Closing Remarks
Science Priority Areas

Section 8.

Strategic Plan for Regulatory Science
Strengthen Social and Behavioral Science to Help Consumers and Professionals Make Informed Decisions about Regulated Products

Transparency

“We foster public trust and predictability by providing meaningful and timely information about the products we regulate and the decisions we make.”

- Center for Devices and Radiological Health
**Background**

- Pacemaker
- Apple Watch
- Walker
- Bed pan
- Nebulizer
- Catheter
- Breast Implant

**Medical Device**

“An instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article... intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease.”

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**4,000**

Number of devices tracked by the FDA

**42.6%**

The U.S. is the largest region in the global medical devices market

**$88,980,000,000**

Amount spent in the U.S. by 2018
Problem

The FDA website has several tools to access information on Medical Devices, ranging from recalls to premarket approvals to registering a device.

There is no user-friendly tool that synthesizes all of the information regarding medical devices.

Current Apps for Medical Devices:

- SoftwareCPR
- Atlas of Medical Devices on Chest Radiography
- Endovascular Today Device Guide App

Our Solution:
MeDevice

A mobile app that holds all information about your medical device
App Icon & Splash Screen

Profile
Search

Favorites
Medical Device Profile

Impact and Importance

- Enhancing and promoting understanding of medical device use
- Fostering patient awareness and safety through an all-inclusive tool
- Impacting patients on a macro-level with ease of use, accessibility, and streamlined features
MDIC and NESTcc

MDIC
The Medical Device Innovation Consortium
Current FDA partner that aims to advance regulatory science in the medical device industry

NESTcc
The National Evaluation System for health Technology Coordinating Center
MDIC initiative that aims to ensure the safety of medical devices through generating real-world evidence and innovative research

Implementation

- All necessary medical device information currently exists in various FDA databases

- Investment: MDIC, Manufacturers and Healthcare Institutions
  - Promotes post-market surveillance
  - Ease device use
 Closing Remarks

MEETING

Public Meeting - Food and Drug Administration's Communications About the Safety of Medical Devices

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THANKS!
ANY QUESTIONS?

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