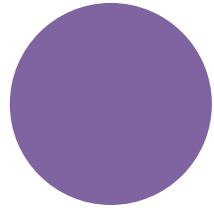
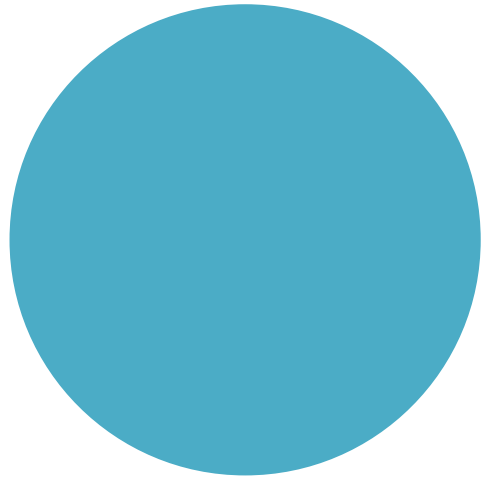


CDRH Communications

Agenda

- Identifying a Communication Need
- CDRH's Communication Team
- Deciding to Communicate
- CDRH's Communication Process
- Communicating Cybersecurity Safety Messages
- Message Dissemination



Identifying a Communication Need

CDRH identifies issues that may need to be communicated through a variety of mechanisms.



CDRH's Communications Team

CDRH's Office of Communication and Education

Team of communication specialists who:

- Collaborate with scientific, medical, legal and regulatory experts within the Center
- Draft messages and communication materials that are scientifically accurate, consistent with the Center's mission and goals, and meaningful (or useful) to target audiences
- Disseminate communication materials to partners inside and outside the FDA to amplify messages
- Evaluate effectiveness of communication vehicles



Deciding to Communicate

- What is the type of issue?
- Who is affected?
- What are the safety issues?
- What are the regulatory issues?
- What is the goal of communicating publicly about this issue?
- What is the value of FDA Communication?

Reasons CDRH May Issue Communication

- Minimize potential risk to device users
- Help prevent potential or additional harm to device users
- Explain and clarify a complex issue for the public
- Expand the reach of a communication issued only by a device manufacturer
- Clarify the FDA's role in an issue
- Help the FDA collect information to better understand the problem
- Notify the clinical community of shortages and potential alternatives
- Increase public trust in the FDA through transparency
- Protect the health of a vulnerable patient population
- Support the FDA's and HHS's communication goals and initiatives

Reasons for NOT Issuing Communication

Communication could lead to:

- Unnecessary or disproportionate concern over health risks
- Individuals stopping beneficial therapy or device use
- Individuals performing unnecessary remediation
- Needless anxiety over an implanted device
- Interference with a regulatory or legal action
- A device shortage

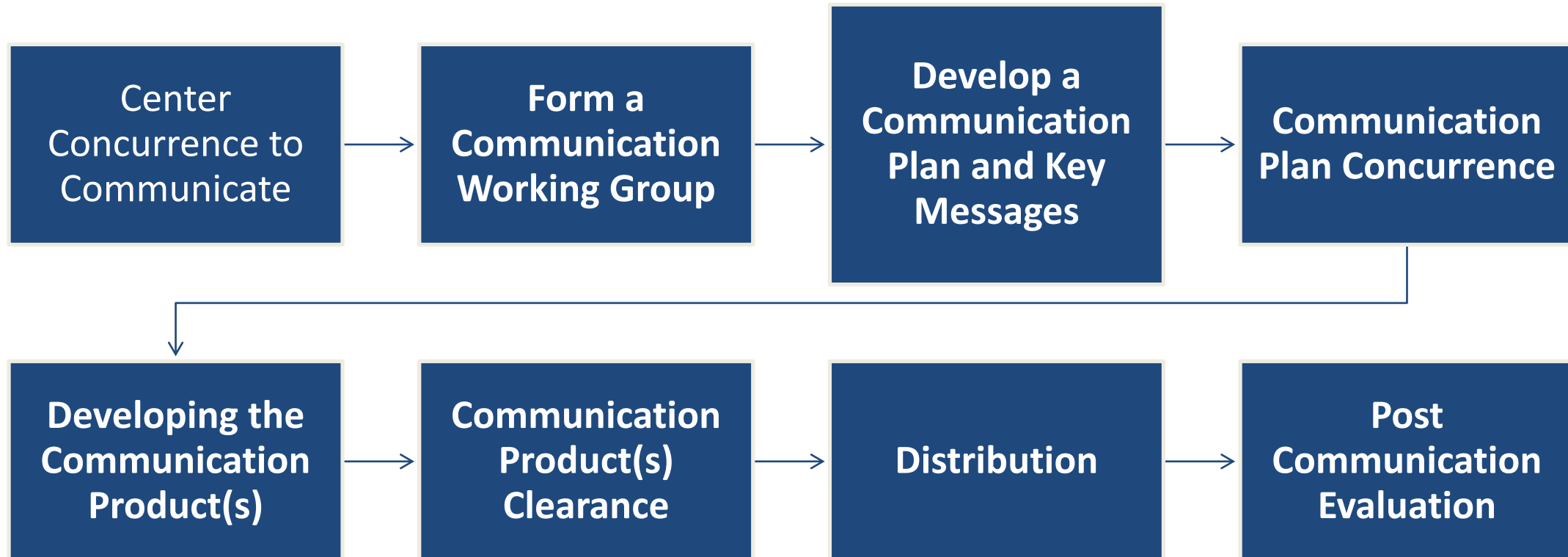
Communication will:

- Not minimize the risk
- Repeat a message that we have already disseminated

Or

- The preliminary recommendations contradict established professional guidelines or standards of care
- The preliminary recommendations deviate from the FDA-approved labeling

CDRH's Communication Process At A Glance





Communicating to the Right Audience

- **Target audiences:** patients, caregivers, health care providers, medical device industry and other external stakeholders.
- *For patients and caregivers:* Medical Device Safety Communication.
- *For health care providers:* Letter to Health Care Providers.

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Challenges with Communicating Safety Concerns

- Audience health literacy
- The effects of stress experienced by target audiences
- Language barriers
- Barriers to Internet access and use

Ensuring Accessibility of Communication

Disabilities

- More than 13 million people in the United States have at least one disability and many use assistive technology like screen readers

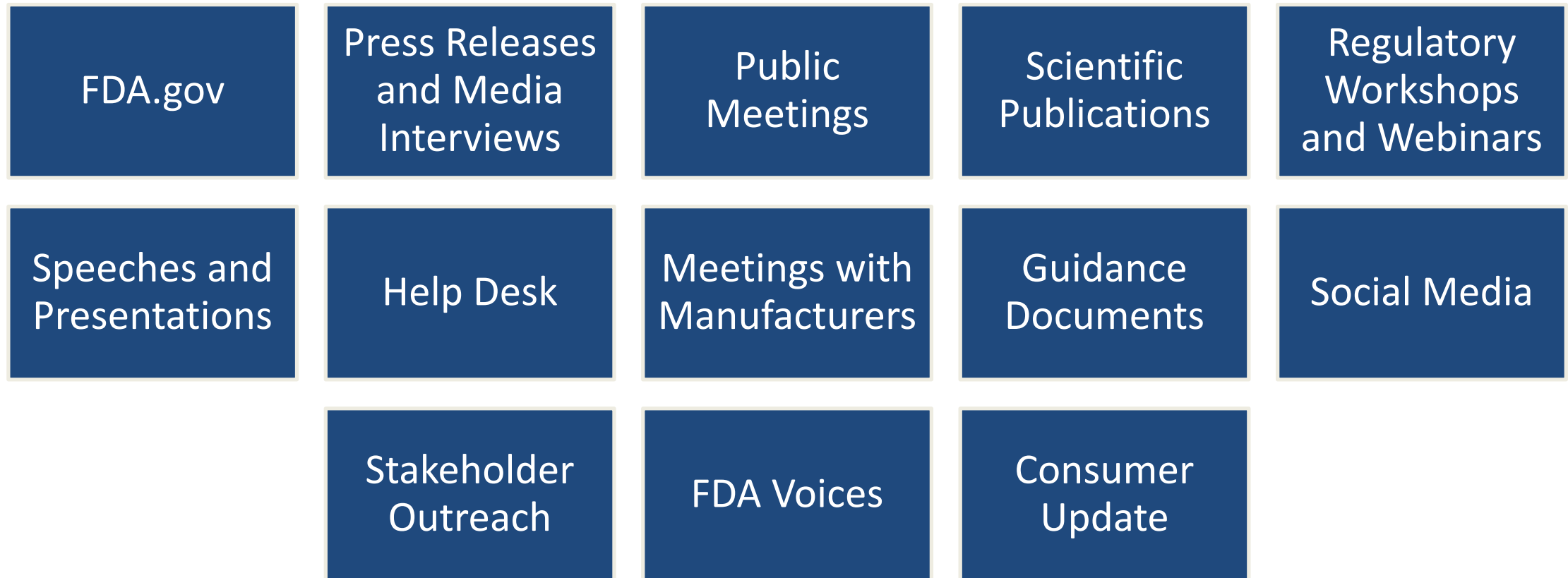
Accessible Content is the Law

- Section 508 of the Rehabilitation Act requires Federal agencies to make all electronic content accessible to people with disabilities

Requirements

- Applies to all internal and external digital content
- Not conforming to Section 508 can create barriers for people with disabilities

Communication Vehicles for Communicating with the Public





Message Dissemination

Multiple vehicles used to reach audiences

- FDA.gov
- Email marketing
- Social media
- Targeted outreach to impacted stakeholders



Communicating About Cybersecurity



Safety Communications on Cybersecurity

The FDA released [Safety Communications](#) on eight unique medical device cybersecurity concerns since June 2013 . Many of these were updated as new information became available.

All of these communication address a cybersecurity issue found in various medical devices, such as implanted cardiac devices and insulin pumps.

Challenges Communicating Cybersecurity

- Communicating about potential cybersecurity risks for which the probability or likelihood of harm is not known.
- Understanding the **motivations** of unidentified, unauthorized persons, **predict** when they may act, **identify** what vulnerabilities would be exploited, **isolate** the action to one type or brand of device, and **capture** the risks associated with that exploitation.
- Lack of cybersecurity risk quantification.

Thank You