# Assessing Security for FDA Approval:

***Panel I - Infrastructure Challenges for the Medical Device Industry***
***Innovation Policy Forum***
***Medical Devices Innovation: Opportunities, Threats and Challenges***

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# *September is National Preparedness Month*

***"Failing to prepare***

***means preparing to fail"***

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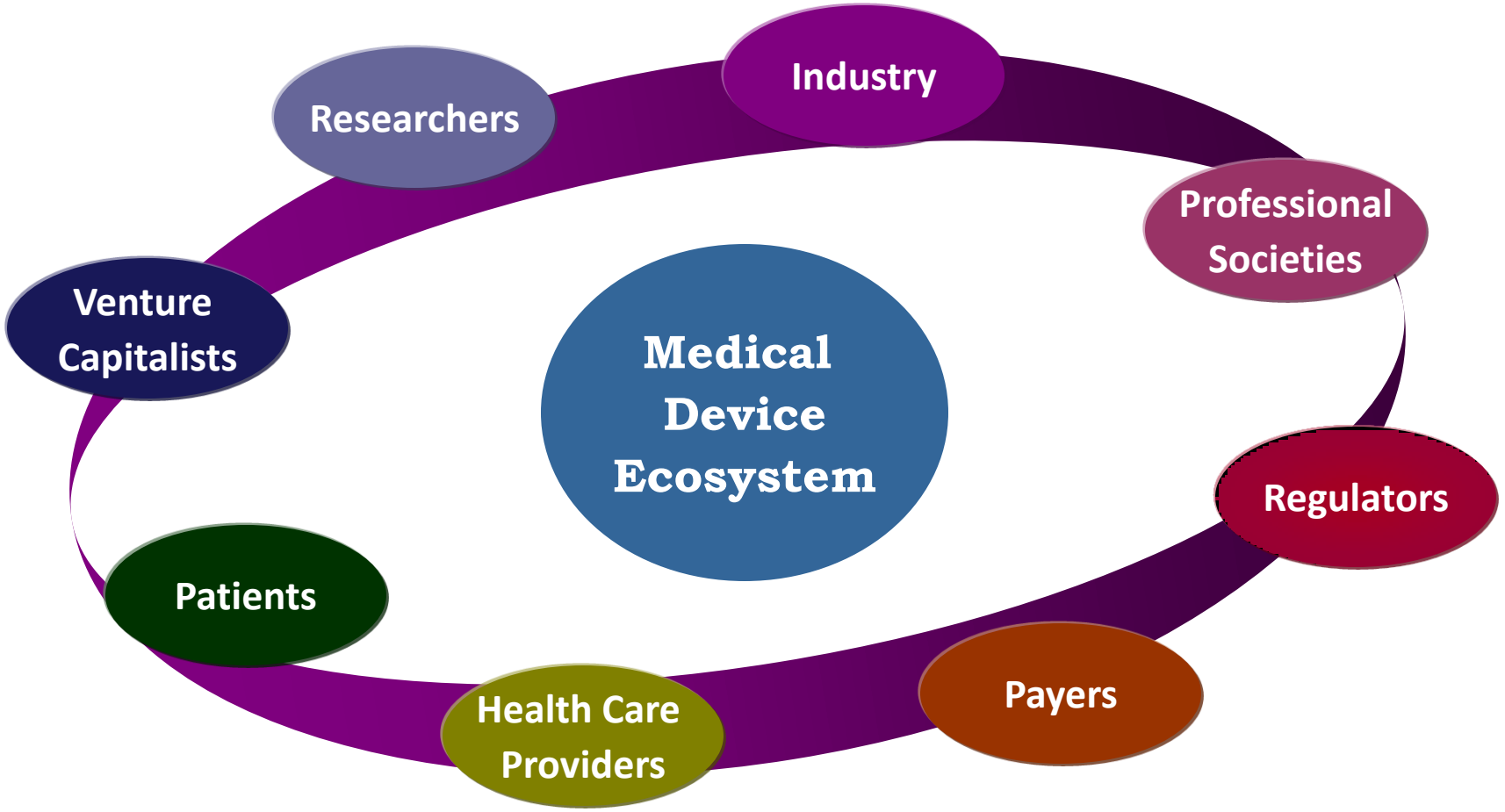
# *Whole of Community Approach*

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# *Three Core Concepts*

- Awareness
- Preparedness
- Collaboration

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# *Roadmap for Today's Discussion*

- Understanding the Current Landscape
- Our CDRH/FDA Medical Device Cybersecurity Program
- Our Vision Ahead

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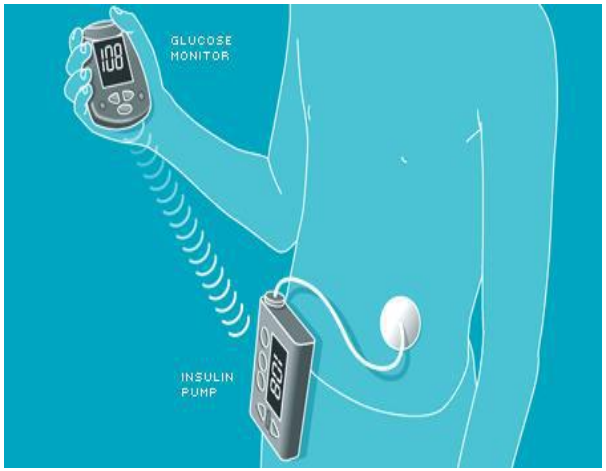
# *Scope of Public Health Impact*

- Centers for Disease Control and Prevention (CDC) estimates of annual patient encounters
  - 35 million hospital discharges
  - 100 million hospital outpatient visits
  - 900 million physician office visits
  - Billions of prescriptions
- Most of these encounters likely include a networked medical device

# *Medical Device Cybersecurity Background*




## MEDICAL DEVICES

- Contain configurable embedded computer systems
- Increasingly interconnected
- Wirelessly connected
- Legacy devices

## USE ENVIRONMENT

- Varied responsibilities for purchase, installation and maintenance of medical devices, often silo-ed
- Variable control over what is placed on the network
- Inconsistent training and education on security risks

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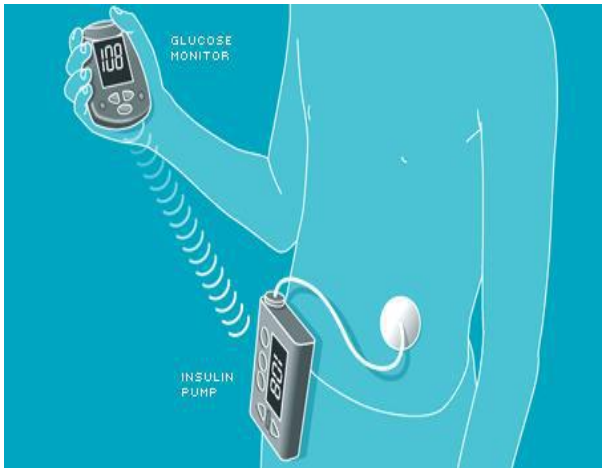
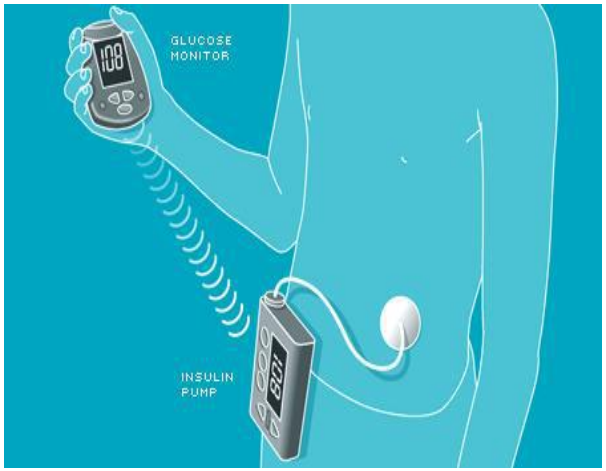
# *Medical Device Vulnerabilities*




- Network-connected medical devices infected or disabled by malware
- Malware on hospital computers, smartphones/tablets, and other wireless mobile devices used to access patient data, monitoring systems, and implanted patient devices
- Uncontrolled distribution of passwords
- Failure to provide timely security software updates and patches
- Security vulnerabilities in off-the-shelf software designed to prevent unauthorized device or network access

# *Incidents & Researcher-Demonstrated Exploits*




- VA Cath Lab temporary closure (1/10) due to malware infecting computers used during interventional cardiac procedures
- “Hacking” of implantable insulin pump (Radcliffe, 8/11)
- Security researchers present CDRH with cyber vulnerabilities of medical devices (Rios & McCorkle, 4/13)

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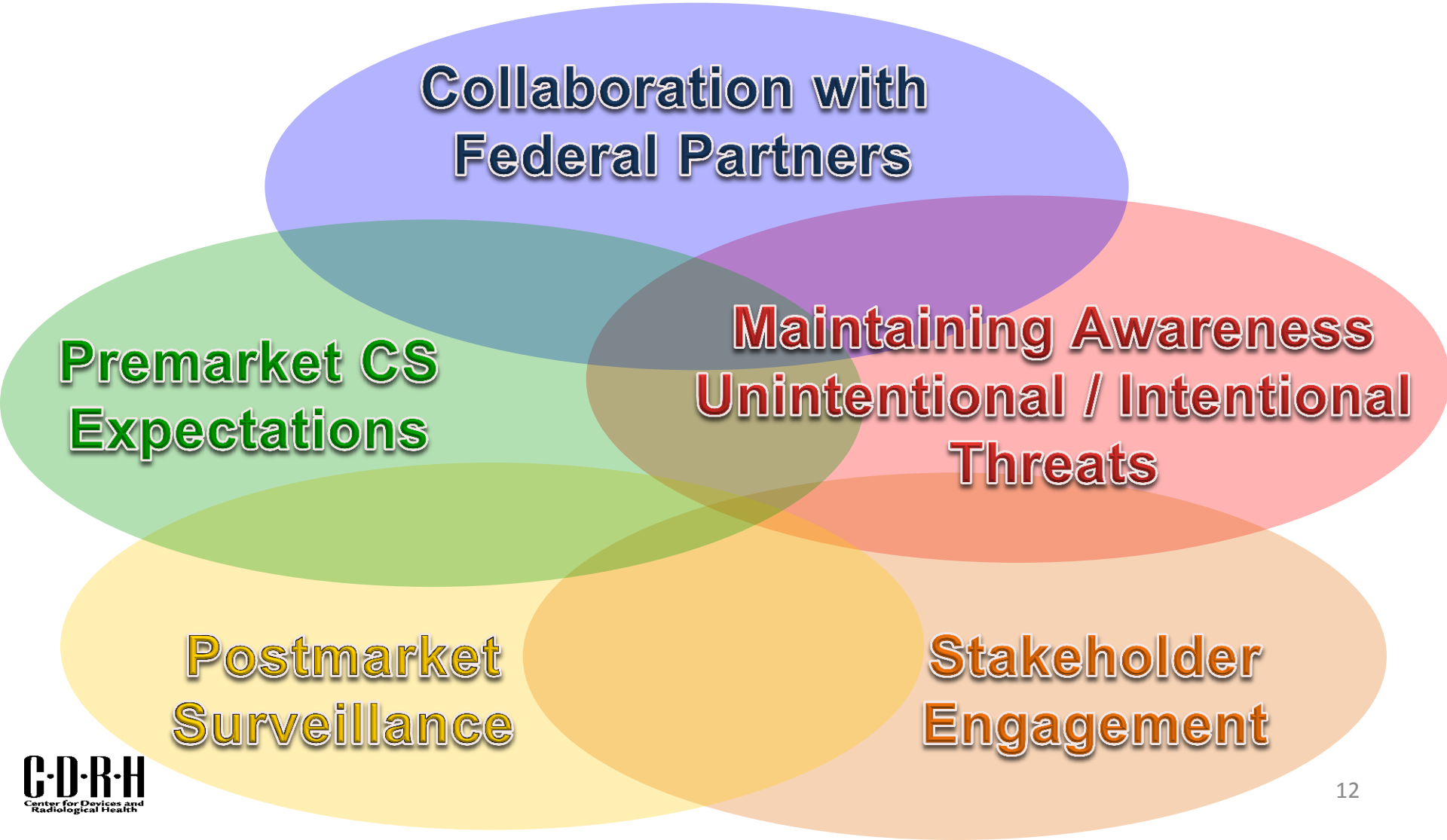
# *CDRH/FDA Activities*

- **Guidance**
  - Premarket (Draft, 2013)
  - Wireless Technology (2013)
  - CS for Networked Devices with OTS Software (2005)
- **Standards**
  - Cybersecurity (2013)
  - Interoperability (2013)
- **Public Communication**
  - Safety Communication to Stakeholders (2013)
  - CS for networked medical devices shared responsibility (2009)
- **Organization**
  - Established CSWG of Subject Matter Experts (2013)
  - Stood up Cyber Incident Response Team under EMCM (2013)

# *CDRH/FDA Collaborations*

- New partnership with **Department of Homeland Security**
  - Coordinating incident response with ICS-CERT
  - Participating in EO13636-PPD21 Integrated Task Force WGs
  - DHS-led Cyber-Physical Functional Exercise (Cracked Domain) planners and players
- Enhanced communication & partnering with **HHS**
  - HHS/Critical Infrastructure Protection
  - Cyber Threat Analysis Center (CTAC)
- Strengthen collaboration with **NIST** through standards and CSF Working Group
- Engaging proactively with diverse stakeholders
  - Outreach/education of hospital, healthcare & medical device community
- New collaboration with **NH-ISAC**

# CDRH/FDA Ongoing Activities

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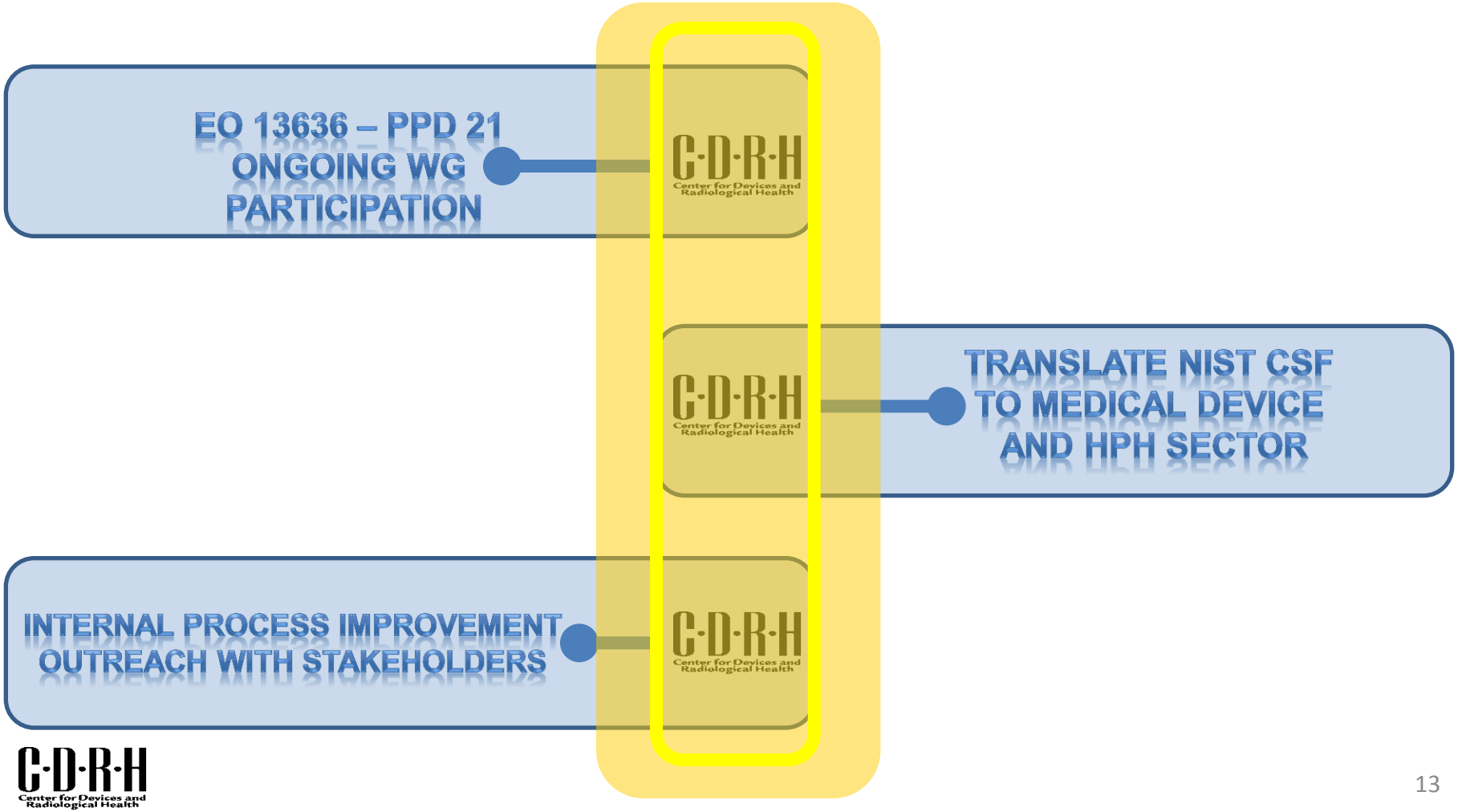
# *Aligning with EO13636 & the Cybersecurity Framework for the HPH Sector*

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