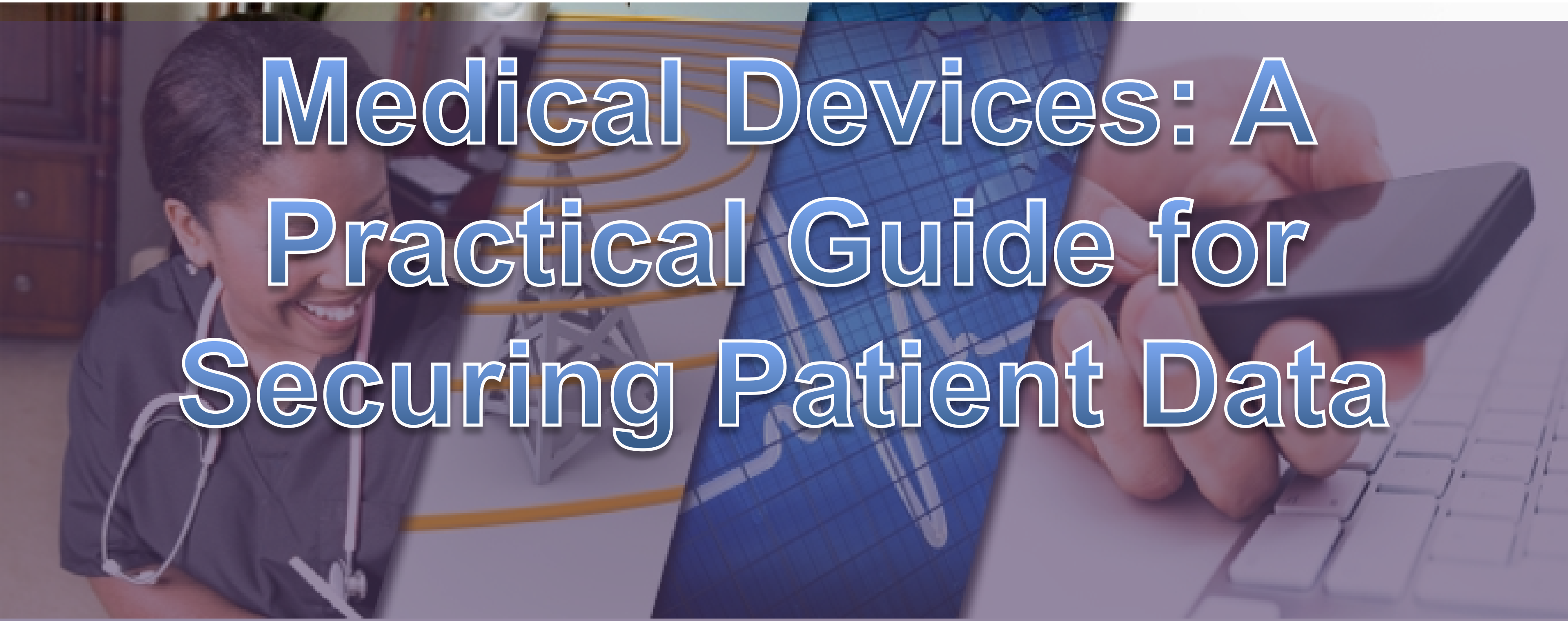

Medical Devices: A Practical Guide for Securing Patient Data

Safeguarding Health Information:
Building Assurance through HIPAA Security
HHS Office of Civil Rights and
National Institute of Standards & Technology
Tuesday September 23, 2014

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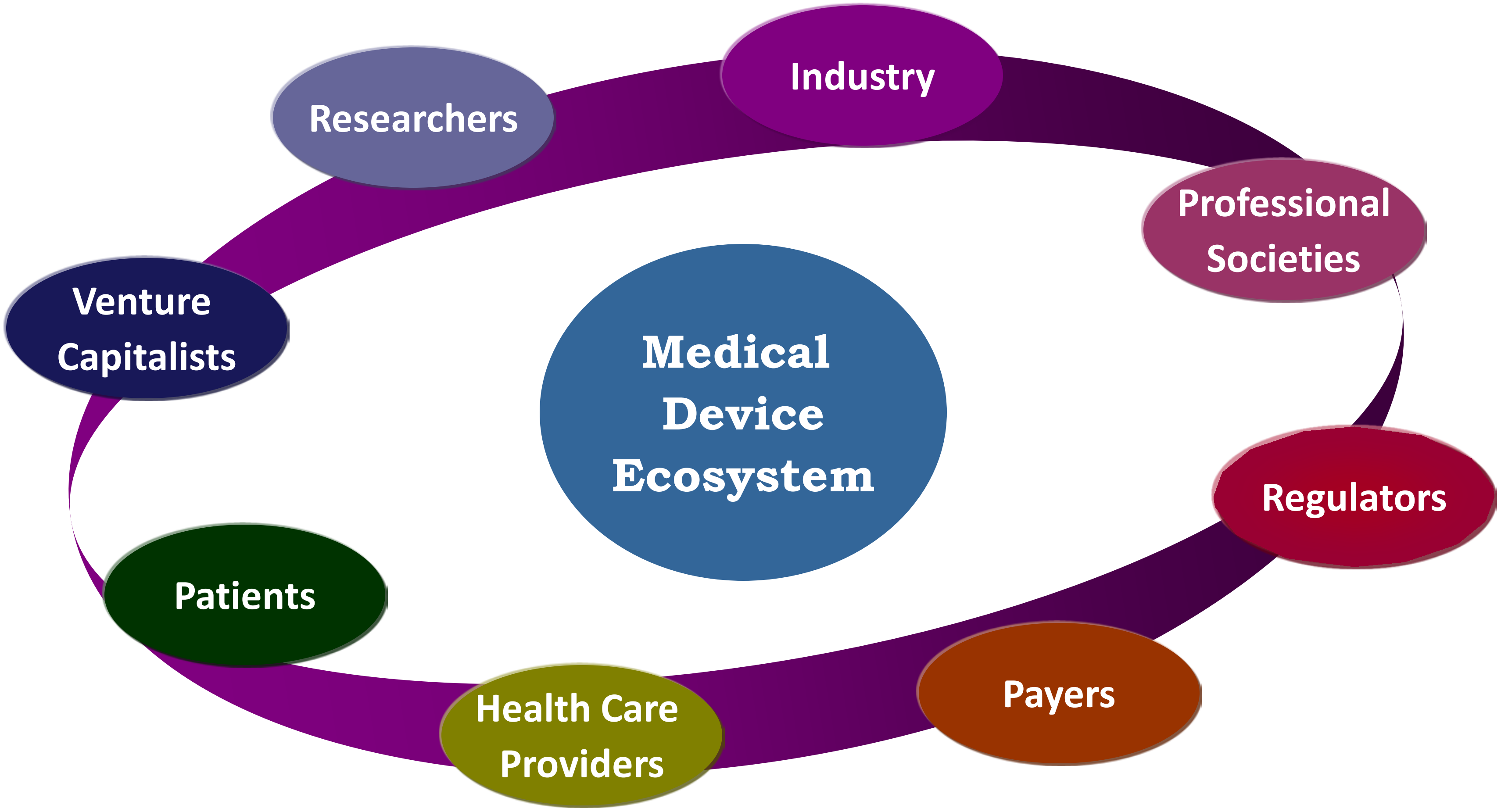
Director Emergency Preparedness/Operations & Medical Countermeasures (EMCM Program)
CDRH/FDA

September is National Preparedness Month

"Failing to prepare means preparing to fail"

Whole of Community Approach



Three Core Concepts

- Awareness

- Preparedness

- Collaboration

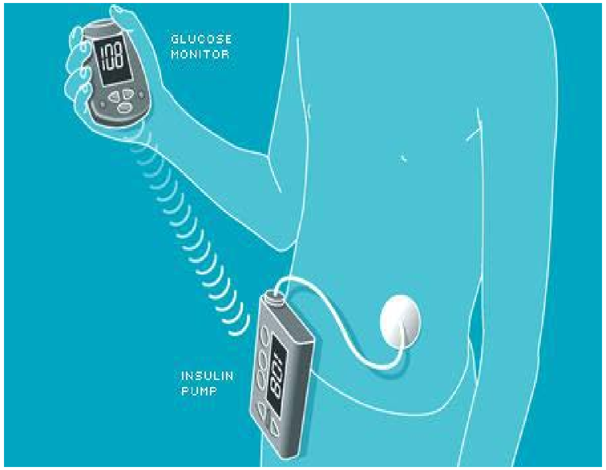
Roadmap for Today's Discussion

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

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



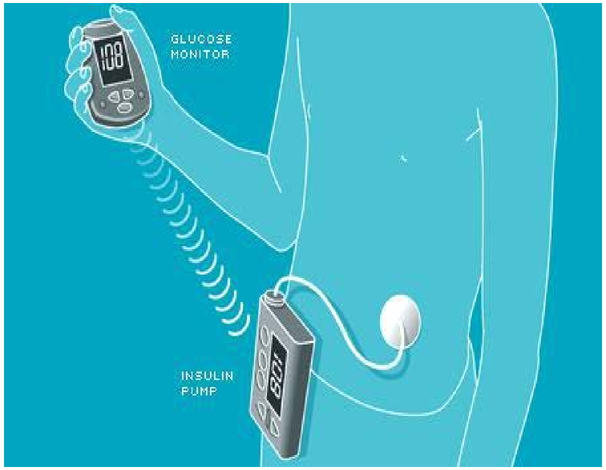
MEDICAL DEVICES

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

USE ENVIRONMENT

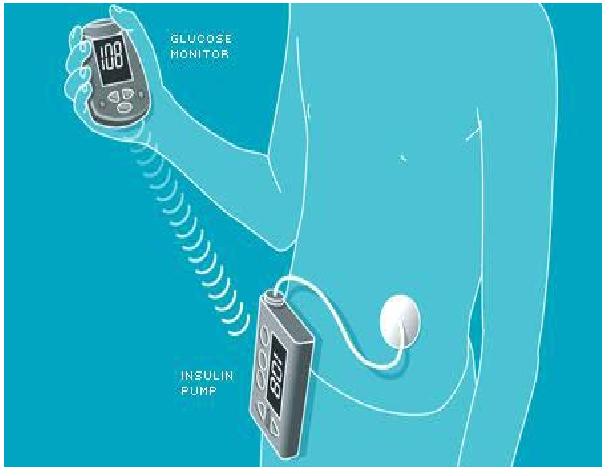
- Varied responsibilities for purchase, installation and maintenance of medical devices, often silo-ed
- Variable control over what is placed on the network
- Inconsistent training and education on security risks

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)

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

Collaboration with Federal Partners

Premarket CS Expectations

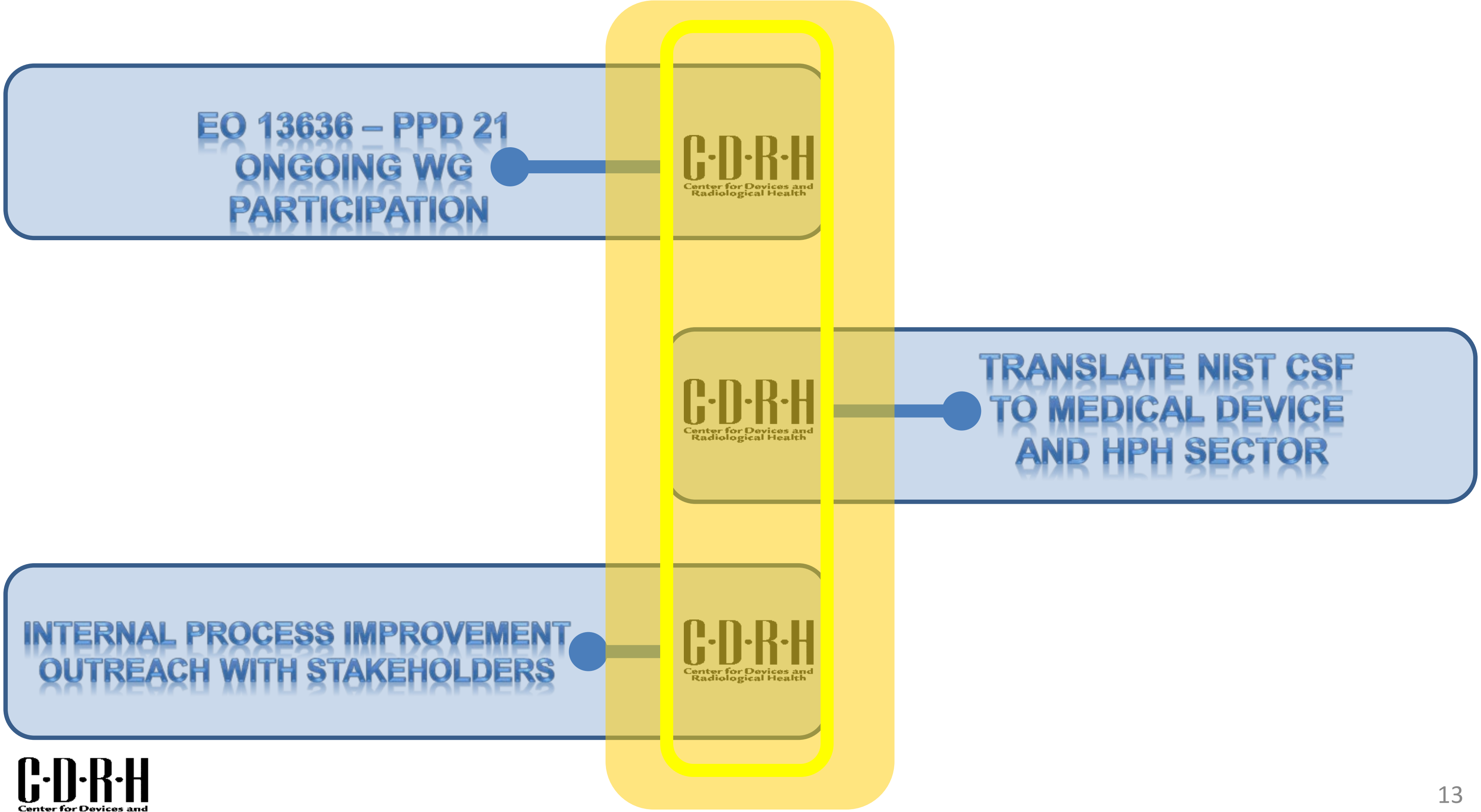
Maintaining Awareness Unintentional / Intentional Threats

Postmarket Surveillance

Stakeholder Engagement

C·D·R·H Center for Devices and Radiological Health

Aligning with EO13636 & the Cybersecurity Framework for the HPH Sector



EO 13636 – PPD 21 ONGOING WG PARTICIPATION

TRANSLATE NIST CSF TO MEDICAL DEVICE AND HPH SECTOR

INTERNAL PROCESS IMPROVEMENT OUTREACH WITH STAKEHOLDERS

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Save The Date!!

Public Workshop:

'Collaborative Approaches for Medical Device and Healthcare Cybersecurity'

October 21st-22nd 2014

National Intellectual Property Rights Coordination Center, Arlington, Va

More info: Suzanne.Schwartz@fda.hhs.gov