Medical Device Security: The Next Frontier

Denise Anderson

President

National Health Information Sharing & Analysis Center (NH-ISAC)

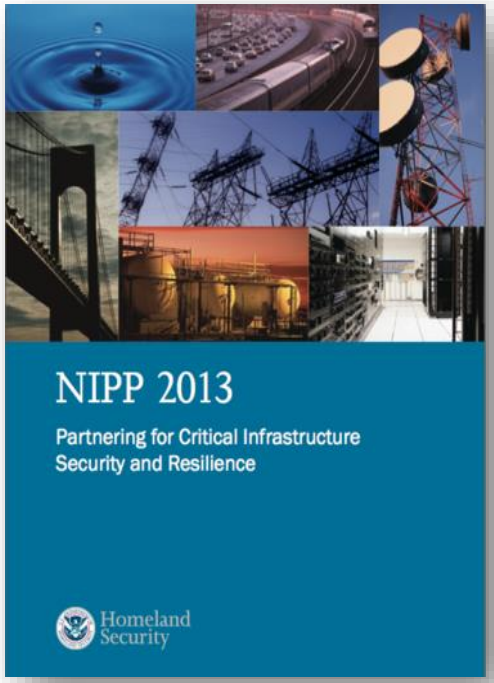
Chair, National Council of ISACs

NationalCouncilofISACs

What is an ISAC?

Why ISACs?

Evolution



PDD 63
1998

HSPD-7
2003

PPD 21
2013

NIPP 2013

CISA
2015

Why ISACs?

- Trusted entities established by CI/KR owners and operators.
- Comprehensive sector analysis aggregation /anonymization
- Reach-within their sectors, with other sectors, and with government to share critical information.
- All-hazards approach
- Threat level determination for sector
- Operational-timely accurate actionable

ISACs

- Auto ISAC
- Aviation ISAC
- Communications ISAC
- Defense Industrial Base ISAC
- Downstream Natural Gas ISAC
- Electricity ISAC
- Emergency Management & Response ISAC
- Financial Services ISAC
- Information Technology ISAC
- Maritime ISAC
- Multi-State ISAC

ISACs

- National Health ISAC
- Oil and Natural Gas ISAC (ONG)
- Over the Road & Motor Coach ISAC
- Public Transit ISAC
- Real Estate ISAC
- Research and Education ISAC
- Retail ISAC
- Supply Chain ISAC
- Surface Transportation ISAC
- Water ISAC

NH-ISAC

DARE TO SHARE

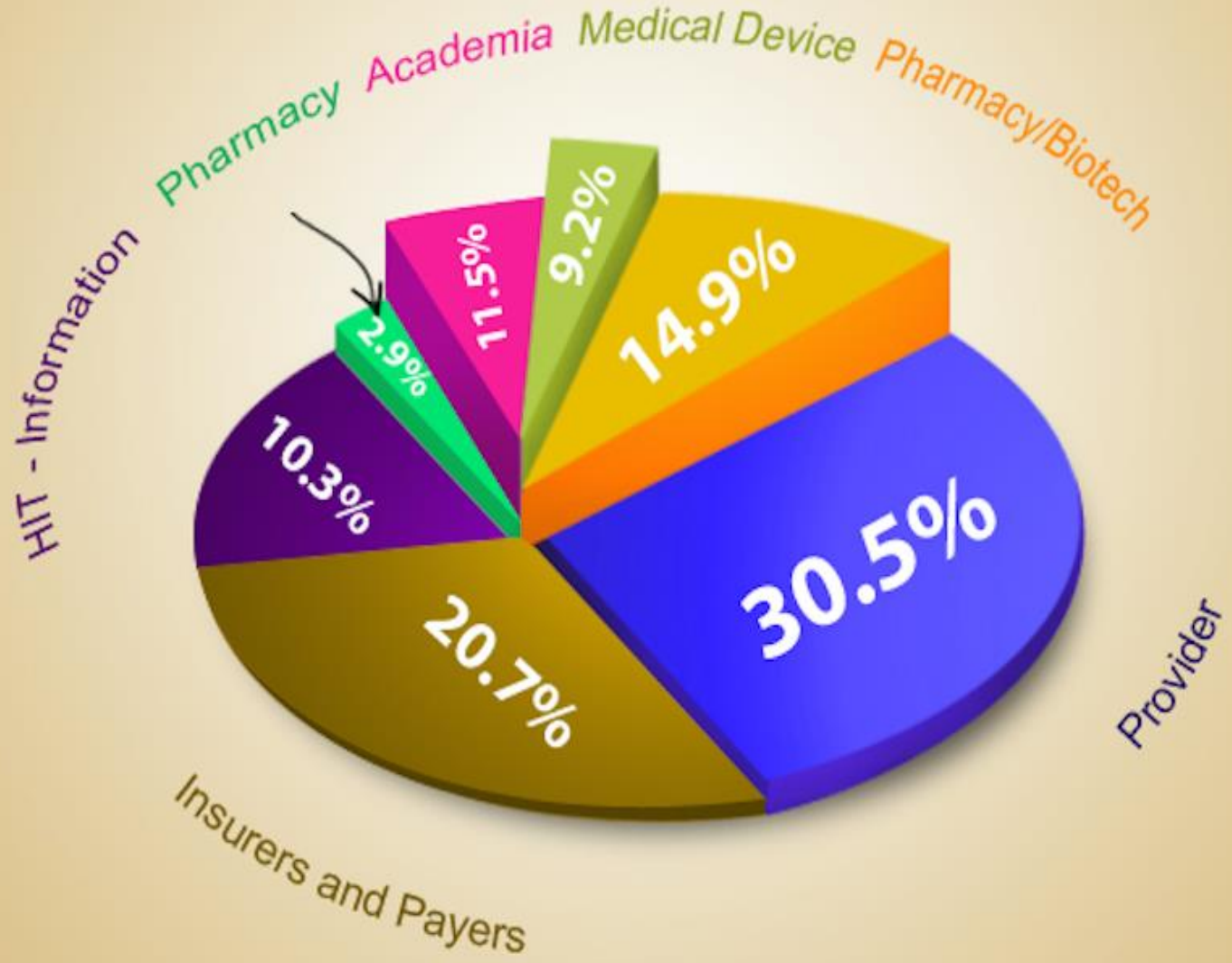
Overview of NH-ISAC

NH-ISAC

Founded in 2010

Sharing Community
Intelligence and Alerts
Newsletter
Exercises
Webinars/Threat Calls
Conferences & Workshops
White Papers
Working Groups/Committees
Tools – Symphony, Soltra, Brightpoint
Playbook & Threat Level
CyberFit
Special Interest Groups

NH-ISAC - 2017 Membership Mix



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Information Sharing

Value

Trust

Structure

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Information Sharing: Traffic Light Protocol

- Restricted to a defined group (e.g., only those present in a meeting.) Information labeled RED should not be shared with anyone outside of the group
- This information may be shared with ISAC members.
- Information may be shared with ISAC members and partners (e.g., vendors, MSSPs, customers). Information in this category is not to be shared in public forums
- This information may be shared freely and is subject to standard copyright rules

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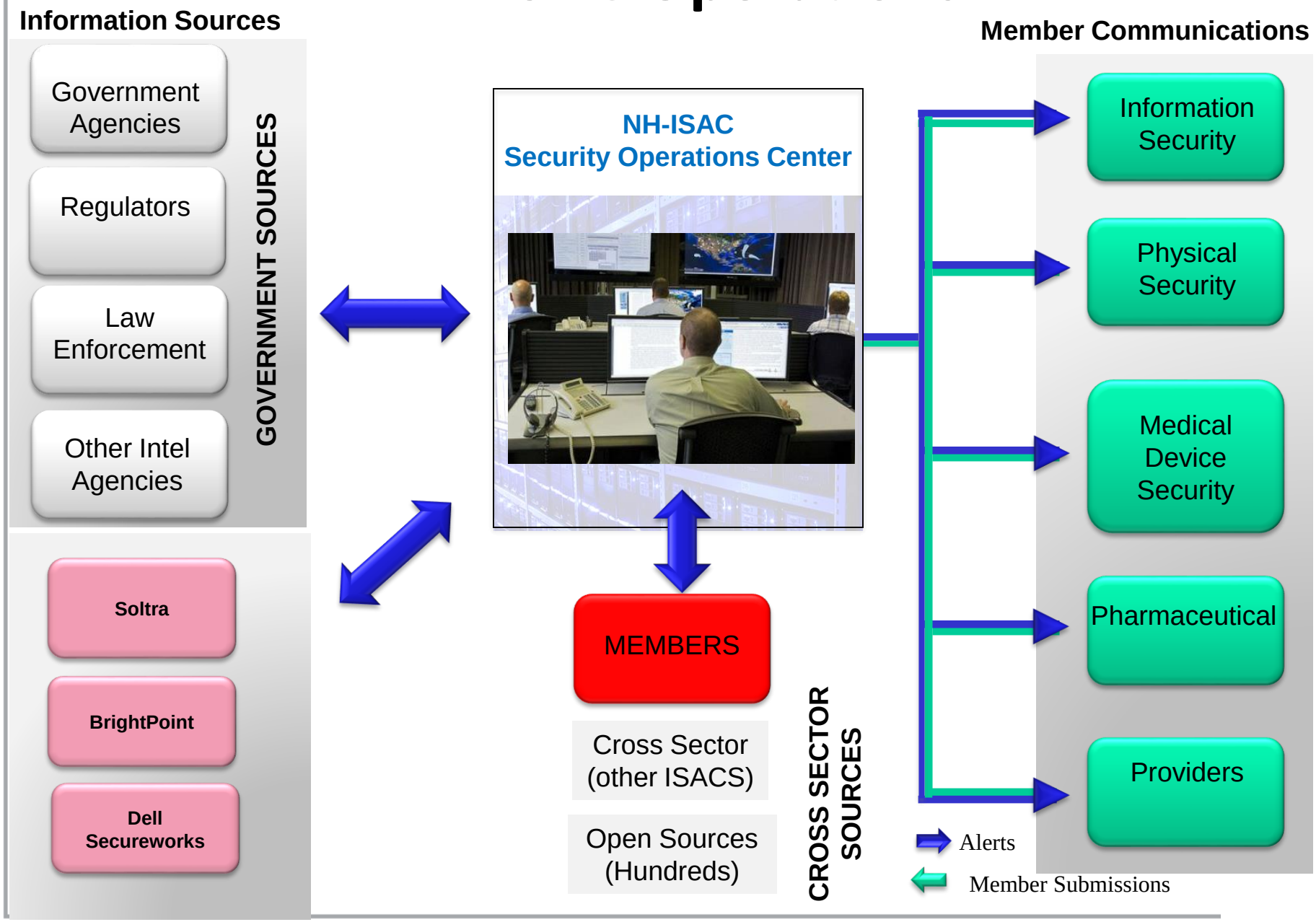
NH-ISAC Operations



Types Of Information Is Shared

- Cyber Threats, Vulnerabilities, Incidents

✓ Malicious Sites
✓ Threat Actors, Objectives
✓ Threat Indicators
✓ TTPs, Observables
✓ Courses of Action
✓ Exploit Targets
✓ Denial of Service Attacks
✓ Malicious Emails: Phishing/ Spearphishing
✓ Software Vulnerabilities
✓ Malicious Software
✓ Analysis and risk mitigation
✓ Incident response

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Sample of ISAC Sharing

Indicators of Compromise

IP Address, Subject Line, MD5, TTP, Malware

Ask a question

Anyone else seeing?...

What do you do in this situation?....

How do you handle?……*mobile device management*

Share a Best Practice

Here's how we……

Share a Mitigation Strategy

Here's a script you can use……*MIFR*

We did this……

TLP AMBER

PROPRIETARY INFORMATION

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Primary Ways Information Is Shared

- ✓ Portal/Alerts
- ✓ Listservers
- ✓ Automation

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Alert

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NATIONAL HEALTH - ISAC

Neutrino Exploit Kit Distributes DMA Locker Ransomware

*This information is marked TLP **AMBER**: Recipients may only share TLP: AMBER information with members of their own organization who need to know, and only as widely as necessary to act on that information.*

In early January 2016, researchers observed a resurgence in Neutrino exploit activity…....

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Sample of Sharing Thread

•The Threat actors compromised several domain admin accounts. ……

•Samples of hostnames are:

•· you can't catch me

•· hello I'm malware

•Source IP addresses found so far:

•· 123.456.789

• 198.233.456

• 456.789.234

•· **A couple of files most likely associated**

•· Imbad.zip

•· clickonme.zip

•· score.zip

0 hits last 7 days

•Can I get hashes?

•Two of these are reported on known bad lists

•One might be false positive

•We've seen traffic from 123.456.789 and 198.233.456

•Traffic from 198.199.206.2 contained "important file" headers.

Security Automation

STIX™

TAXII™

Trusted Automated eXchange of Indicator Information

Over 155 Organizations with over 700 users

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What is Cyber Threat Intelligence?
8 Constructs of STIX

Atomic

What threat activity are we seeing?

Tactical

What threats should I look for on my networks and systems and why?

Operational

Where has this threat been seen?

What can I do about it?

What weaknesses does it exploit?

Strategic

Who is responsible for this threat?

Why do they do this?

What do they do?

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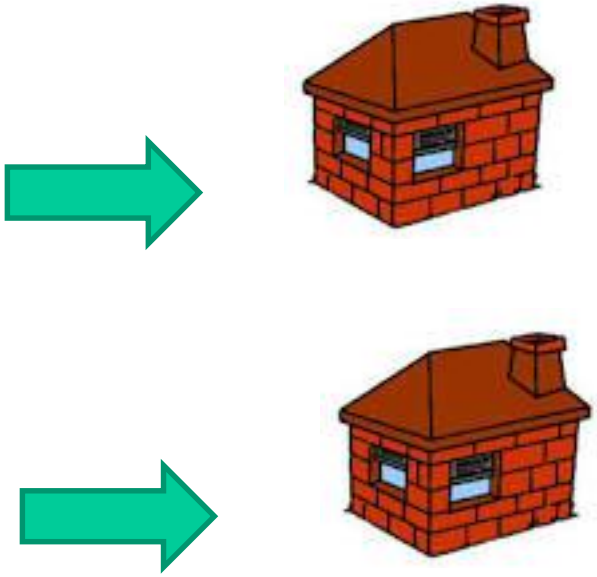
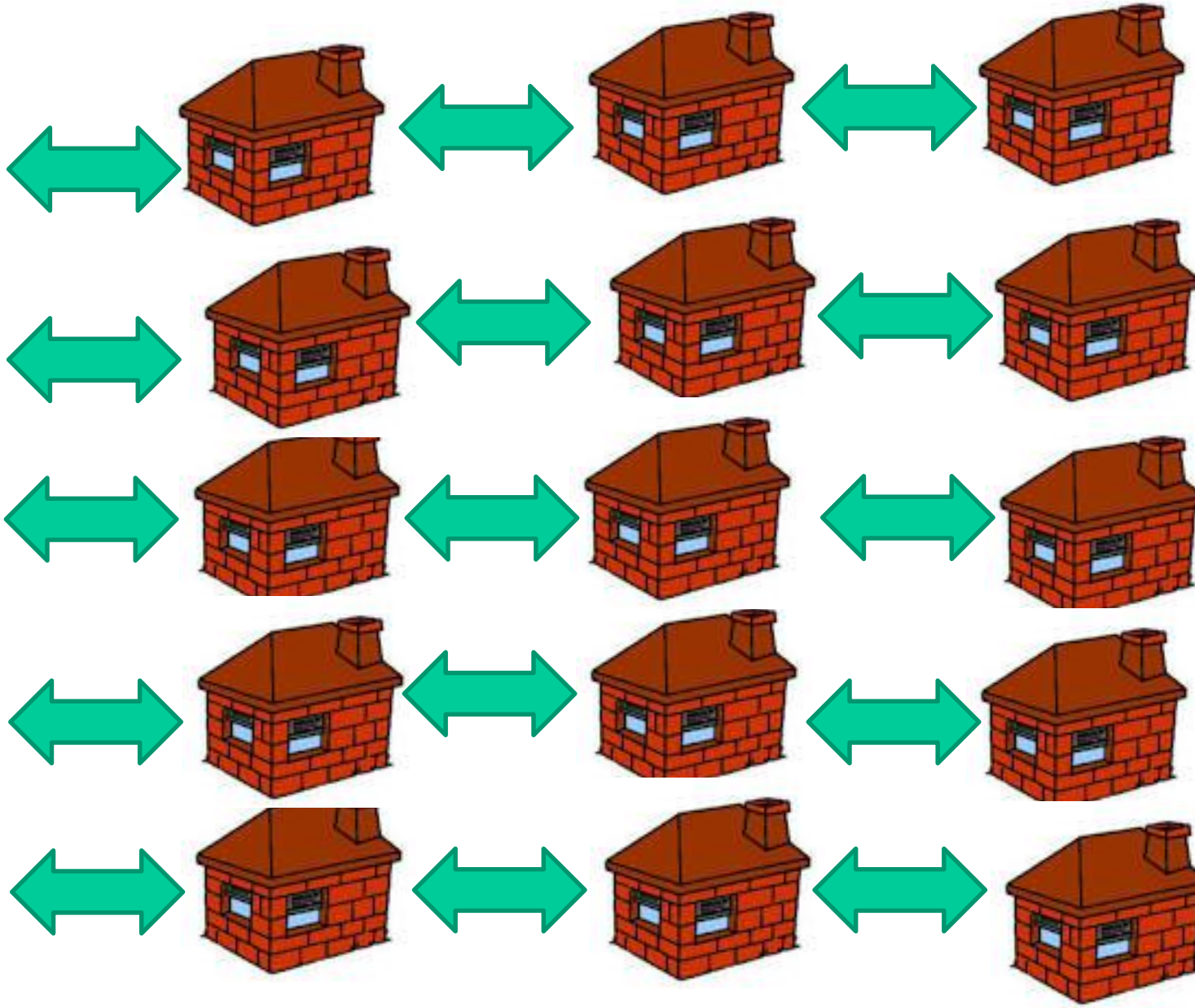
A Force Multiplier





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The Situation

Remember This?

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It’s Now This…

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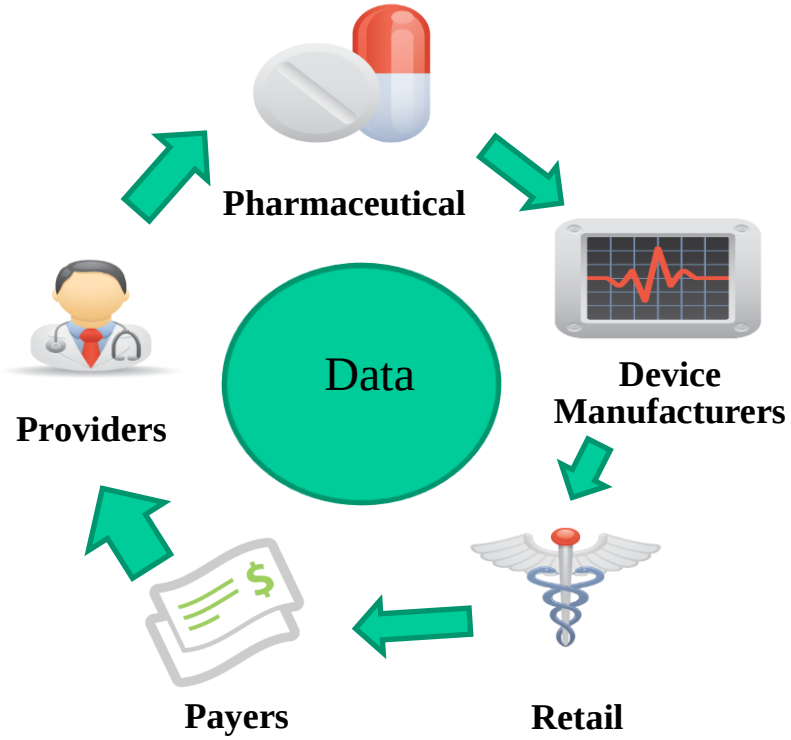
The Ecosystem – Portability



It's Not About the Ones & Zeroes

-Financial
-Reputation

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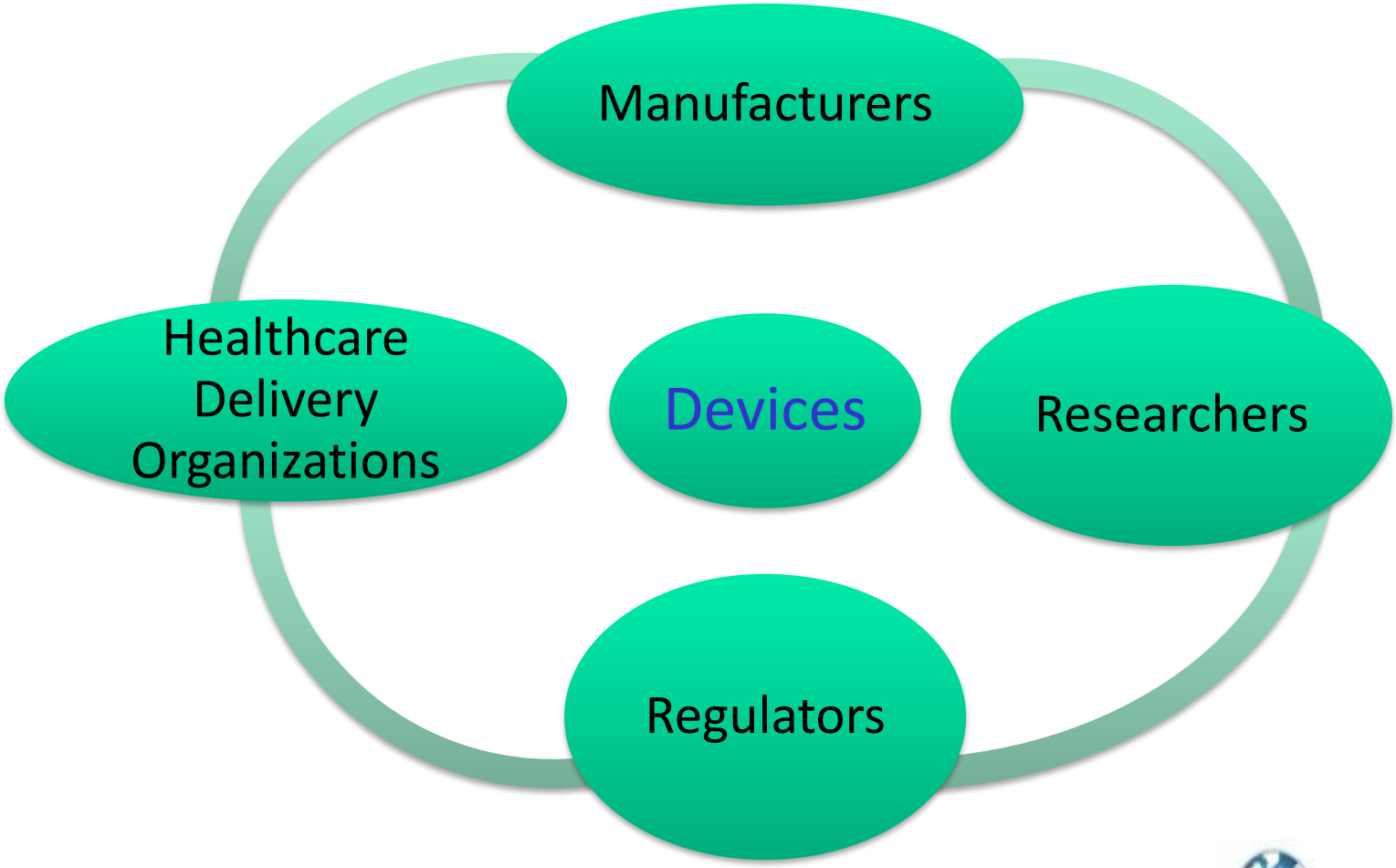
Chasms and Challenges



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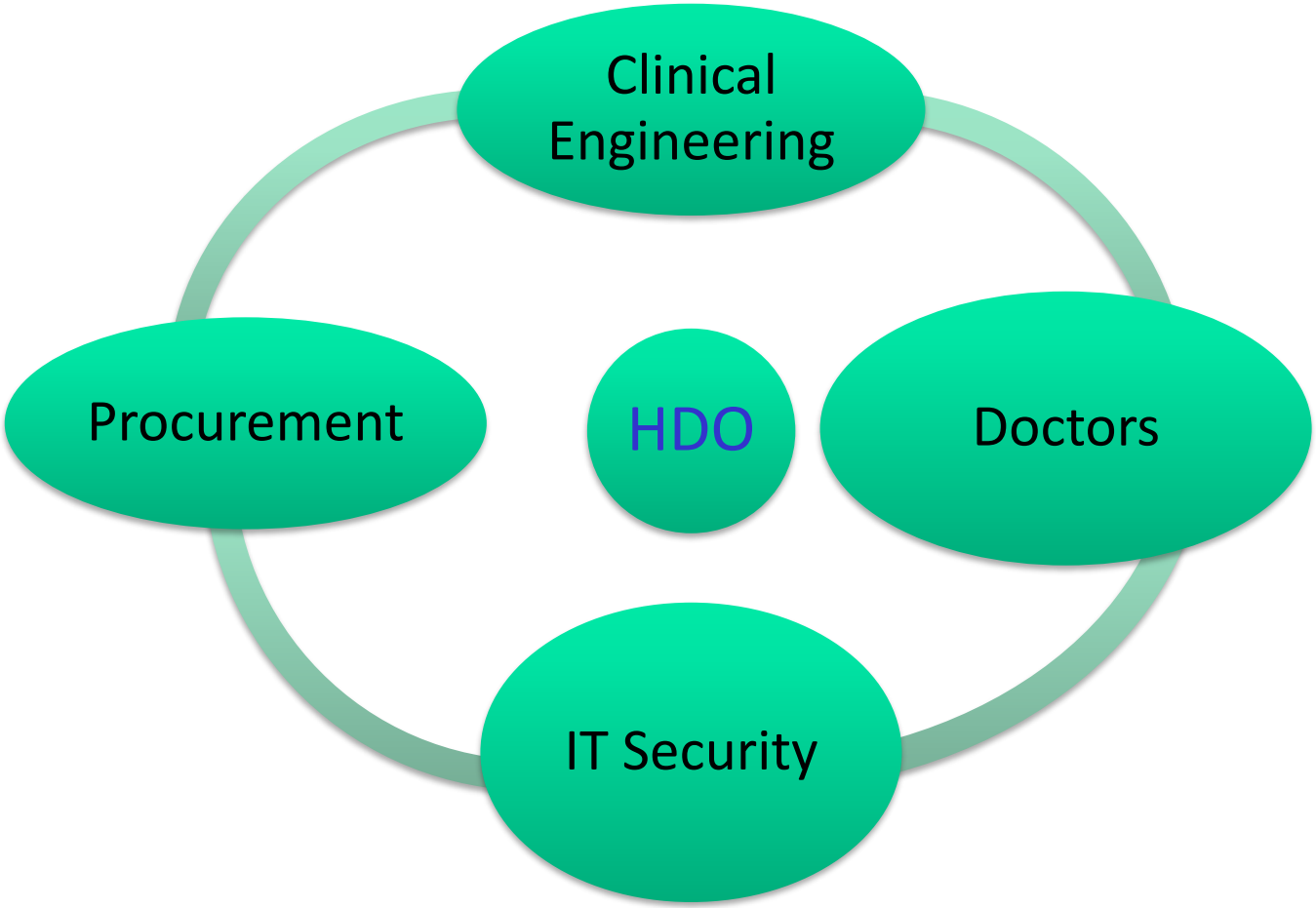
Chasms and Challenges



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A Public Health Problem

Challenge – Tens of Thousands of Devices

- Little or no security built in
- Legacy platforms
- Patching
- Mobility
- Communication and oversight gaps
- Physical teams v. IT security
- Connected to networks
- Vetting of devices

The Challenge

Over next 10 years

100 Billion Exposures

Between patients and connected medical devices

People

- 1 billion healthcare visits
- 1.5 M nursing home residents

Places

- 6,000 hospitals
- 17,000 nursing homes

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Estimating patient exposures to digitally enabled and networked medical devices

1. **One billion patient** encounters per year
2. Estimate each encounter, on average, has **10 exposures** to a medical device
3. Assume 10 years of legacy risk as the national healthcare landscape will continue to have inadequately secured devices
4. Over ten years, 100 billion patient exposures with medical devices

Exploring Probability of Adverse Events

1% (.01)	10,000,000
0.10% (.001)	1,000,000
0.01% (.0001)	100,000
0.001% (.00001)	10,000
0.0001% (.000001)	1,000

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What is Needed

Three parameters define the importance of a public health problem

- Breadth of exposure, e.g. incidence/prevalence
- Depth of impact, e.g. morbidity and mortality
- Preventability

Clear definitions for security risks and medical device associated adverse events

Develop methods to **establish valid estimates for the prevalence and incidence** of malware and other security breaches in medical devices and associated impact on patient outcomes

Identify, track, and trend security incidents based on a model that protects the interests of patients, providers, manufacturers and regulators

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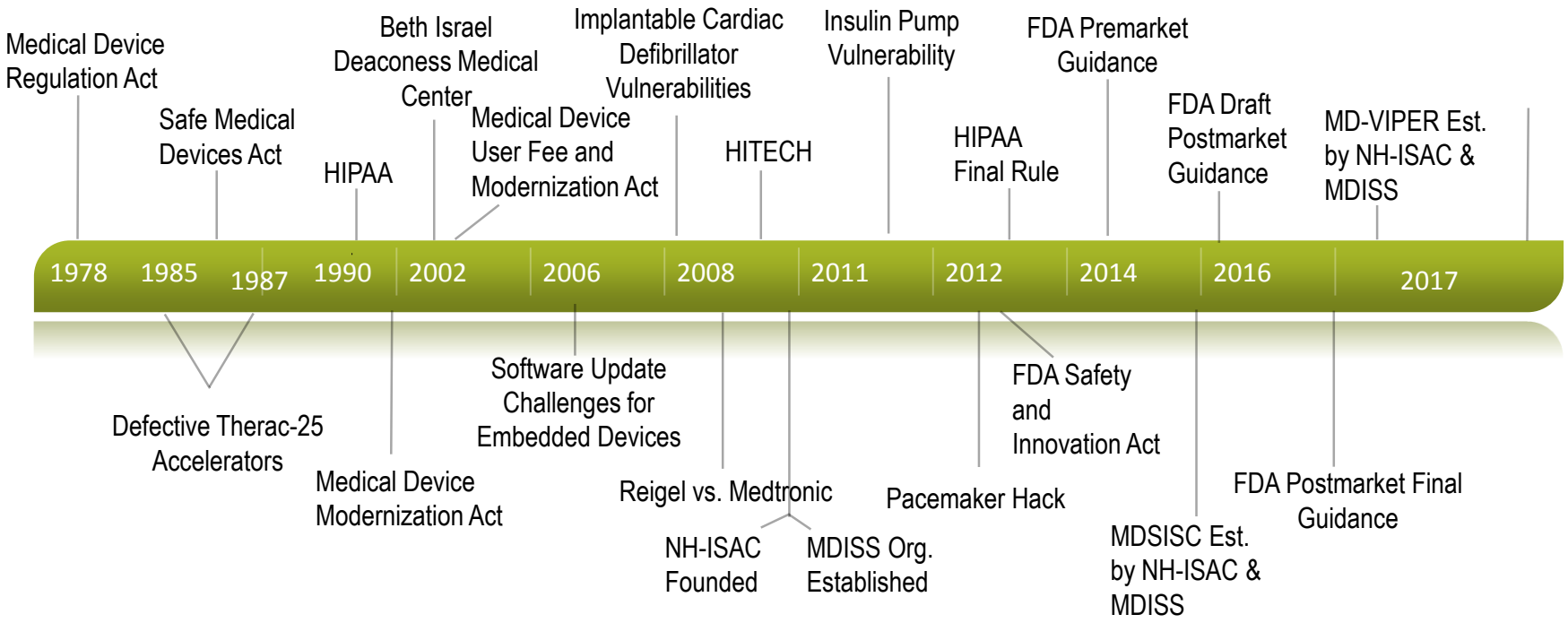
A Brief History

Evolution of Medical Device Security



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Meeting the Challenge

MDISS

MDISS: Medical Device Innovation, Safety and Security Consortium

MDISS
MEDICAL DEVICE INNOVATION, SAFETY & SECURITY CONSORTIUM

- Non-profit public health initiative and patient safety organization founded in 2011.
- Focused on medical device cybersecurity
- First organization dedicated to these important medical device cyber health challenges

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Medical Device Security Information Sharing Council (MDSISC)

- Co-Chaired by NH-ISAC & MDISS
- Mission:
  - Engage stakeholders
  - Execute best practices for secure information sharing
  - Exchange information to promote efficient, secure and safe use of medical devices and associated networks

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NATIONAL HEALTH - ISAC

MDISS
MEDICAL DEVICE INNOVATION, SAFETY & SECURITY CONSORTIUM

Current membership:
118 individuals
56 organizations

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MDSISC Current Activities

- Medical Device Security Information Sharing Initiative
- Listserv to share and exchange information
- Monthly meetings
- Threat briefings
- White papers on threats and best practices
- Medical device track at NH-ISAC summits
- Medical device security workshops
- Sub-groups focused on specific topics

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MDSISC Workshops

Completed 2017

- January 2017 Eskanazi Health - IN
- March 2017 Intermountain - UT

Coming Up 2017

- June 2017 Smiths Medical - MN
- June 2017 University of Vermont - VT
- July 2017 UC San Diego – CA
- September 2017 Medtronic - MN

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NH-ISAC and MDISS Memorandum of Understanding With FDA

- Press release October 2016
- Addresses shared interest and collaboration around medical device cybersecurity

NH-ISAC and MDISS Sign Memorandum of Understanding (MOU) with FDA Around Collaboration of Medical Device Cybersecurity

A shared interest and collaboration in encouraging the identification, mitigation, and prevention of cybersecurity threats to medical devices fosters a MOU between NH-ISAC, MDISS and FDA

Kennedy Space Center, FL, October 18, 2016 – The National Health Information Sharing and Analysis Center, (NH-ISAC), the Medical Device Innovation, Safety and Security Consortium (MDISS), and the U.S. Food and Drug Administration (FDA) Center for Devices and Radiological Health (CDRH) recently signed a MOU to collaborate in areas of mutual interest.

The goals of collaboration include the following:

Create an environment that fosters stakeholder collaboration and communication, and encourages the sharing of information about cybersecurity vulnerabilities that may affect the safety, effectiveness and security of the medical devices, and/or the integrity and security of the surrounding healthcare IT infrastructure;

Develop awareness of the Framework for Improving Critical Infrastructure Cybersecurity and enable HPH sector stakeholders to successfully adapt and operationalize the framework for their organizations and products;

Encourage stakeholders within the HPH Sector, to develop innovative strategies to assess and mitigate cybersecurity vulnerabilities that affect their products; and

Build a foundation of trust within the HPH community so that all healthcare technology and medical device stakeholders can directly benefit from the sharing of cybersecurity vulnerability- and/or threat information identified within the HPH Sector, as well as intelligence feeds from other Critical Infrastructure Sectors that may secondarily affect healthcare and the public health.

NH-ISAC & MDISS MOU with FDA

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Building A Foundation

Call to Action

Memorandum of Understanding **(MOU)**
October 2016
FDA & NH-ISAC & MDISS

- Create an environment that fosters **stakeholder collaboration and communication**
- Develop timely awareness of the Framework for Improving Critical Infrastructure Cybersecurity **(NIST CSF)**
- Develop innovative strategies to **assess and mitigate** cybersecurity vulnerabilities before hazard
- Build a **foundation of trust** within the HPH community

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Initiatives

Promote device security, patient safety and critical infrastructure protection

- Medical Device Risk Assessment Platform (MDRAP)
- Medical Device Surveillance and Threat Intelligence (MDSATI)
- Medical Device Vulnerability Information Sharing (MD-VIPER)

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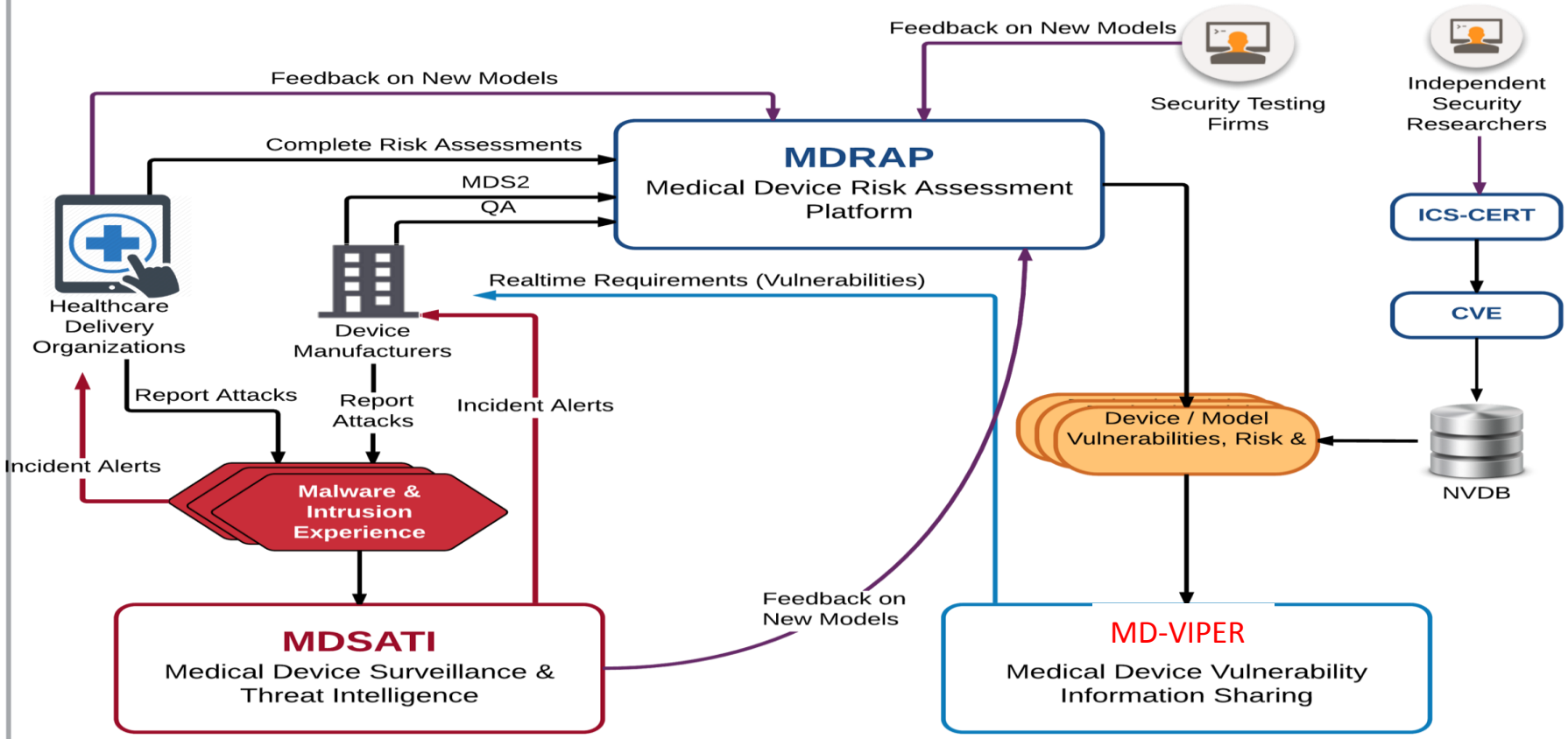
Initiatives



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How It Fits

http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ UCM482022.pdf

Contains Nonbinding Recommendations

Postmarket Management of Cybersecurity in Medical Devices

Guidance for Industry and Food and Drug Administration Staff

Document issued on December 28, 2016.

The draft of this document was issued on January 22, 2016.

For questions regarding this document, contact Suzanne Schwartz, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, rm. 5434, Silver Spring, MD 20993-0002, 301-796-6937. For questions regarding this document as applied to devices regulated by CBER, contact the Office of Communication, Outreach and Development in CBER at 1-800-835-4709 or 240-402-8010 or ocod@fda.hhs.gov.

FDA U.S. FOOD & DRUG ADMINISTRATION CENTER FOR DEVICES & RADIOLOGICAL HEALTH

U.S. Department of Health and Human Services
Food and Drug Administration
Center for Devices and Radiological Health
Office of the Center Director
Center for Biologics Evaluation and Research

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MD-VIPER

The *MD-VIPER Vulnerability Report* is designed to serve as an alternate reporting process to FDA's requirements for *21 CFR Part 806* reporting if cybersecurity vulnerabilities are involved.

Manufacturers are not held to *21 CFR Part 806* reporting requirements if:

- ❑ the manufacturer is a active participant in an ISAO (NH-ISAC)
- ❑ the manufacturer is conducting a correction/removal to address a cybersecurity vulnerability
- ❑ the cybersecurity vulnerability in question has not led to any known serious injuries or deaths
- ❑ the manufacturer will meet the timeline criteria for communicating to its customers and then validating and distributing the deployable fix such that the residual risk is brought to an acceptable level

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Participation in MD-VIPER

- Open to all medical device security stakeholders
- Free and voluntary*
- Tracking each event (submissions, data sharing event, communication event, etc.)
- Each event is triggered by the manufacturer
- Collaboration with manufacturer
- Responsible sharing of information regarding vulnerabilities and threats in light of specified vulnerabilities for stakeholder awareness

**Need to register and sign NDA*

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MD-VIPER Reporting Process

- Vulnerability reporter contacts MD-VIPER
- Conversation between reporter and MD-VIPER
- Reporter proceeds with sharing of vulnerability
- Once reported, all data is stationary until a data owner, manufacturer, advises in writing to share the data
- If a third party shares the data, they should be able to advise us, in writing, to share the data

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MD-VIPER Site Information

https://mdviper.org/

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MD-VIPER Submission Process

SUBMISSION PROCESS

Where to Report

Vulnerability Reports should be made by using the MD-VIPER Vulnerability Reporting Form on this website.

Confirmation of Submission

All reports submitted will receive confirmation of receipt of the report at the email address provided by the manufacturer in the completed report.

Submitting Updates to a previously submitted Report

Updates to previously submitted reports (including updated remediation plans, communication plans, and timelines) may be filed in accordance with the instructions provided in the confirmation email.

Questions

Direct all questions/inquiries about MD-VIPER Vulnerability Reporting to:

- Telephone: (405) 45VIPER or (405) 458-4737
- Email: mdviper@nhisac.org or mdviper@mdiss.org

Site Search

Search ...

MD-VIPER

- Home
- About Us
- MD-VIPER Vulnerability Reporting
  - FDA Postmarket Management of Cybersecurity in Medical Devices – Final Guidance and Key Concepts
  - Vulnerability Reporting to MD-VIPER
  - MD-VIPER Vulnerability Reporting Form
  - Question Inventory and Source for Vulnerability Report Form
  - Submission Process

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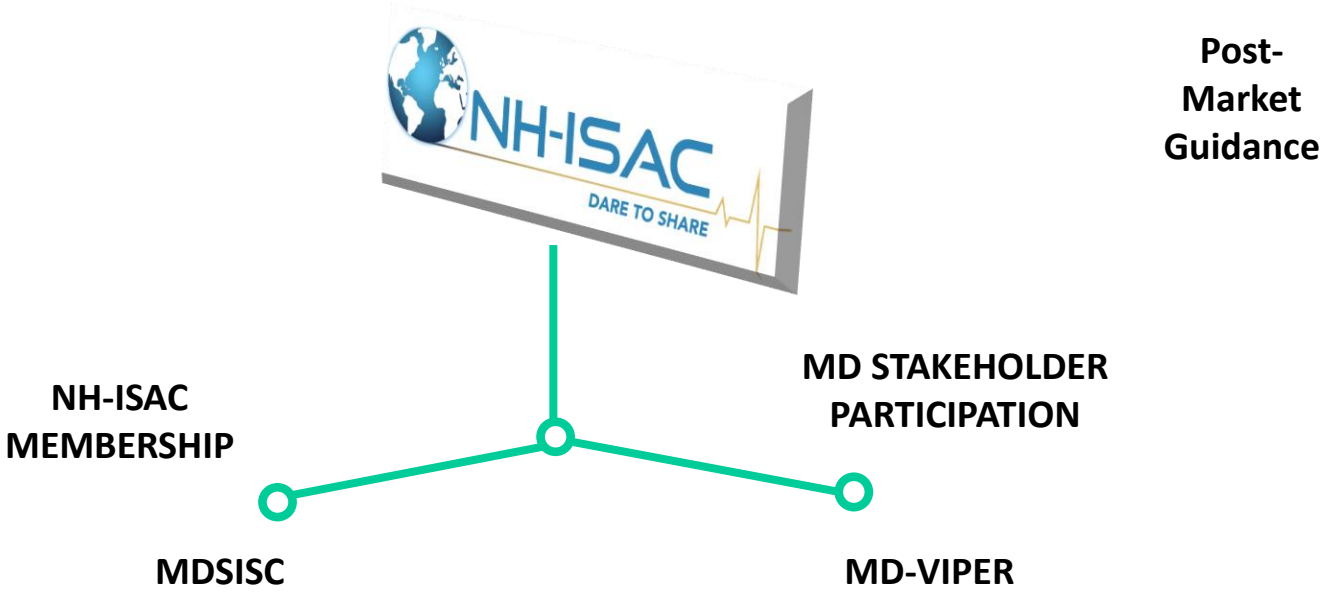
How It All Fits



- NH-ISAC Membership is dues based and open to organizations that meet membership criteria.
- MDSISC is a special interest Council under the NH-ISAC co-led by MDISS. Open to NH-ISAC & MDISS members.
- MD-VIPER is a NH-ISAC /MDISS initiative open to medical device security stakeholders.

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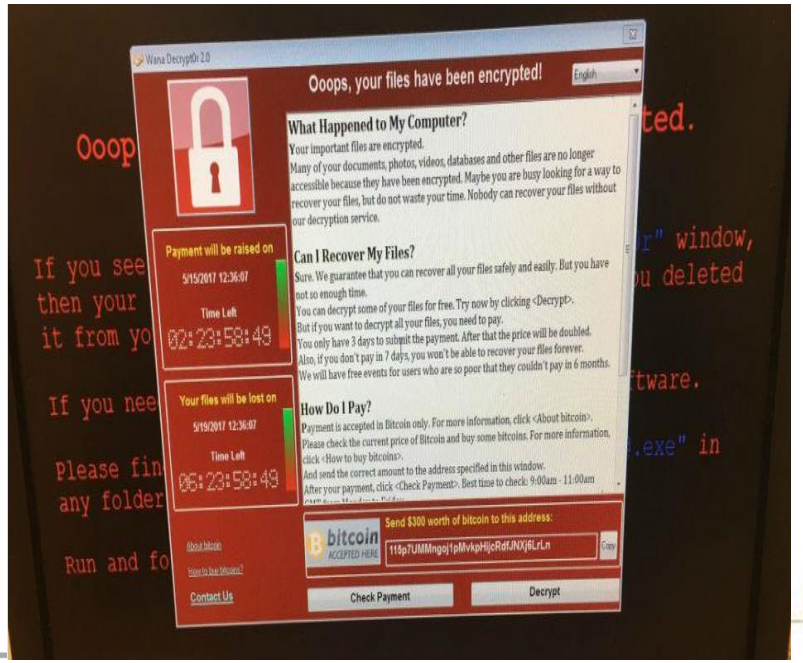
Case Study

WannaCry

WannaCry

- On May 12, 2017, 4:00am ET multiple companies in Europe started reporting massive ransomware infections several hospitals within the National Health System Trust (NHS) in the UK have their phones systems disabled, turn away patients and cancel surgeries.

- This new ransomware variant is called “WannaCry / WCry / WanaCrypt0r”.



The Facts

- As of 5/22/17 the ransom campaign stands at approximately 296 payments across 3 bitcoin wallets totaling 49 BTC or $104k.
- Ransomware spread using an SMB vulnerability that was patched by Microsoft in March 2017. Microsoft took the extraordinary step to send out a patch to Windows XP, Windows 8, and Windows Server 2003 versions of software.
- Ransomware sought vulnerable machines over port TCP 445. No infections were seen coming from email or phishing or Remote Desktop Protocol (RDP).

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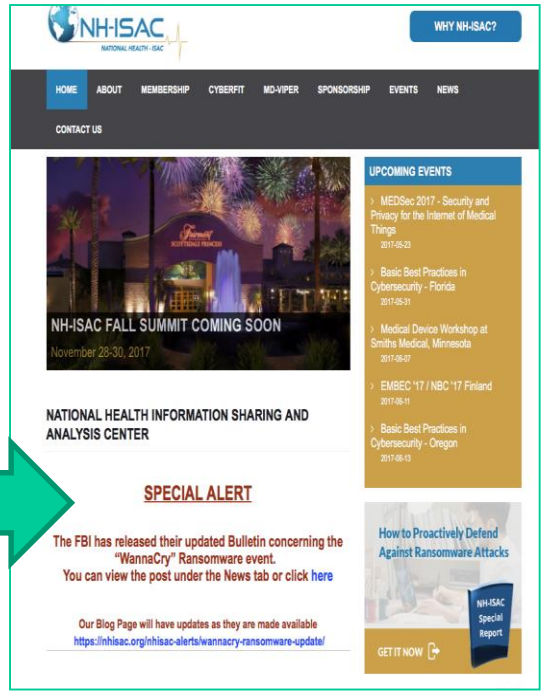
Community In Action

- Sector calls
- Cross-sector calls and collaboration
- NH-ISAC member sharing
- Sharing on NH-ISAC website
  - IOCs
  - Best Practices
  - Threat Intelligence
- Sharing with partners



www.nhisac.org

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Community In Action

.wnry, .wcry, .wncry, and .wncryt

GOOD ANALYSIS WEBSITES

– www.endgame.com/blog/wcrywanacry-ransomware-technical-analysis
– blog.malwarebytes.com/threat-analysis/2017/05/the-worm-that-spreads-wanacrypt0r/
– intel.malwaretech.com/botnet/wcrypt/?t=24h&bid=all

MICROSOFT Guidance

https://blogs.technet.microsoft.com/msrc/2017/05/12/customer-guidance-for-wannacrypt-attacks/
https://technet.microsoft.com/en-us/library/security/ms17-010.aspx
http://www.catalog.update.microsoft.com/Search.aspx?q=KB4012598

SAMPLES TESTING RESULTS

– Attempts to infect a XP Pro SP2/SP3 device via SMB were unsuccessful. All attempts resulted in a BSOD on the target and auto reboot. Infection executed locally is successful
– Confirmed that disabling SMBv1 on Win7 Pro SP1 protects it from infection via SMB.
– Attempts to locally infect the same Win7 lab device were unsuccessful. DNS query for kill-switch domain was observed after execution (NXDOMAIN response was forged) but ransomware nor worm components executed.

MITIGATION STEPS

– Install MS17-010 patch (http://www.catalog.update.microsoft.com/Search.aspx?q=KB4012598)
– PowerShell cmdlet used to disable SMBv1: Set-ItemProperty -Path "HKLM:\SYSTEM\CurrentControlSet\Services\LanmanServer\Parameters" SMB1 -Type DWORD -Value 0 -Force
– Confirmed that disabling SMBv1 via PowerShell does not require a reboot
– Switch ACL to turn off SMB services

SNORT SIGS (http://docs.emergingthreats.net/bin/view/Main/2024218)

```
alert smb $HOME_NET any -> any any (msg:"ET EXPLOIT Possible ETERNALBLUE MS17-010 Echo Response"; flow:from_server,established;
content:"|00 00 00 31 ff|SMB|2b 00 00 00 00 98 07 c0|"; depth:16; fast_pattern; content:"|4a 6c 4a 6d 49 68 43 6c 42 73 72 00|"; distance:0;
flowbits:isset,ETPRO.ETERNALBLUE; classtype:trojan-activity; sid:2024218; rev:1;)

alert smb $HOME_NET any -> any any (msg:"ET EXPLOIT Possible ETERNALBLUE MS17-010 Echo Response"; flow:from_server,established;
content:"|00 00 00 31 ff|SMB|2b 00 00 00 00 98 07 c0|"; depth:16; fast_pattern; content:"|4a 6c 4a 6d 49 68 43 6c 42 73 72 00|"; distance:0;
flowbits:isset,ETPRO.ETERNALBLUE; metadata: former_category EXPLOIT; classtype:trojan-activity; sid:2024218; rev:1;)

alert smb $HOME_NET any -> any any (msg:"ET EXPLOIT Possible ETERNALBLUE MS17-010 Echo Response"; flow:from_server,established;
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flowbits:isset,ETPRO.ETERNALBLUE; classtype:trojan-activity; sid:2024218; rev:1;)
```

Community In Action
Go to NH-ISAC .org
For WannaCry
Mitigation Strategies

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Mitigation Strategies

- **Ensure all patches are up to date**. Microsoft has patches available for all software versions Microsoft XP and higher.
- Issue a companywide communications putting all staff on high alert.
- Prevent delivery and download of .exe attachments both direct and contained inside zip files.
- Ensure SMB (**disable ports 139** and **especially 445**) is not permitted into your environment from external sources. Note especially 3rd party VPN connections.

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Mitigation Strategies

- Apply anti-virus patches, many new updates provided since May 12th.
- Block attempts to communicate to unauthorized and new domains.
- Detect/block known hashes. There are multiple lists, including those shared with NH-ISAC membership.
- Review the list of IP hits against the sinkholed domain keeping in mind some positive hits might be from your own security team.
- Continue to share and participate on NH-ISAC forums.

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Medical Device Community

https://mdviper.org/

- The Press
- The Community
- MDSISC
  - Manufacturer Statements
  - Best Practices
  - Events
  - Facts/Definitions

- United We Stand Divided We Fall

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Case Study #2 Responsible Disclosure

Disclosure

- St. Jude Medical disclosed by Muddy Waters Hedge Fund; no coordination with manufacturer

ST. JUDE MEDICAL

St. Jude Medical, Inc.
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sjm.com

News Release

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csflippin@sjm.com

St. Jude Medical Announces Cybersecurity Updates

Company continues to lead the way in advancing cyber security protections in partnership with FDA and ICS-CERT

ST. PAUL, Minn. Jan. 9, 2017 – As part of its commitment to continuous improvement and the security of its electronic devices, today St. Jude Medical, Inc. announced that it will immediately deploy the latest release of cyber security updates for its Merlin™ remote monitoring system that is used with implantable pacemakers and defibrillator devices. The improvements include security updates that complement the company's existing measures and further reduce the extremely low cyber security risks.

All medical devices using remote monitoring are exposed to the risk of a potential cyber security attack. St. Jude Medical is not aware of any cyber security incidents related to a St. Jude Medical device, nor is it aware that any specific St. Jude Medical device or system in clinical use has been purposely targeted. In recognition of the changing cyber security landscape and the increased public attention on highly unlikely medical device cyber risks, we are informing the public about these ongoing actions so that patients can continue to be confident about the benefits of remote monitoring.

"There has been a great deal of attention on medical device security and it's critical that the entire industry continually enhances and improves security while bringing advanced care to patients," said cyber security expert Ann Barron DiCamillo, former director of U.S. CERT and advisor to St. Jude Medical's Cyber Security Medical Advisory Board. "Today's announcement is another demonstration that St. Jude Medical takes cyber security seriously and is continuously reassessing and updating its devices and systems, as appropriate."

"We've partnered with agencies such as the U.S. Food and Drug Administration (FDA) and the U.S. Department of Homeland Security Industrial Control Systems Cyber Emergency Response Team (ICS-CERT) unit and are continuously reassessing and updating our devices and systems, as appropriate," said Phil Ebeling, vice president and chief technology officer at St. Jude Medical.

As technology evolves, St. Jude Medical made seven software updates in three years to the Merlin@home™ transmitter alone, and it will immediately release its latest software update to Merlin@home™, which will begin to be implemented today. The update includes additional validation and verification between the Merlin@home™ device and Merlin.net. St. Jude Medical has collaborated with the FDA, DHS ICS-CERT and other regulators in implementing this update. The company also plans to implement additional updates in 2017.

As is always recommended, patients should make sure that their Merlin@home™ unit is plugged in and connected via landline or cellular adapter so they can receive these and any future automatic security

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Case Study #2 Responsible Disclosure

Impact of Disclosure Process

- St. Jude Medical and Researcher have not met
- Exact research methods, vague and don't support an efficient process by manufacturer to assess the issues and to develop compensation controls
- Resulted in inefficient assessment process and did not support the manufacturer's ability to clearly assess the assertions
- Less than optimal for the manufacturer and the patient

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Case Study #2 Responsible Disclosure

- Johnson & Johnson was disclosed in coordinated manner, per best practices by manufacturer, researcher and ICS-CERT
- Collaborated on a review along with ICS-CERT and FDA
- Led to efficient understanding and development of compensating controls
- Final release coordinated and contained the vulnerabilities, compensating controls and residual risk
- Enabled all parties to make informed clinical decisions

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Questions?

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