DITTA GLOBAL DIAGNOSTIC IMAGING, HEALTHCARE IT & RADIATION THERAPY TRADE ASSOCIATION

IMDRF International Medical Device Regulators Forum

DITTA Report

IMDRF Open Stakeholder Forum

Wednesday 23 September 2020

Nicole Denjoy, DITTA Chair

Secretary General, COCIR

Including brief results of the IMDRF-DITTA virtual workshop on cybersecurity of 21 Sept. 2020

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DITTA GLOBAL PRESENCE

2018: DITTA as a recognized non state actor in official relations with WHO
2016: DITTA MoU with the World Bank
2015: DITTA was granted a NGO status with WHO
2014: DITTA has official liaison with AHWP

DITTA: 10 WORKING GROUPS

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1. Regulated Product Submission (RPS) Working Group
2. Medical Device Single Audit Program (MDSAP) Working Group
3. Unique Device Identification (UDI) Working Group
4. Standardisation (STA) Working Group
5. Clinical Evaluation (CE) Working Group
6. Global Health (GH) Working Group
7. Environmental Policy (ENVI) Working Group
8. Good Refurbishment Practice (GRP) Working Group
9. Cybersecurity Working Group
10. Medical Software & AI (MSW & AI) Working Group

NEW!

IMDRF

IEC ISO

AHWP

IAEA International Atomic Energy Agency

World Health Organization

WORLD BANK GROUP

BASEL CONVENTION

UNEP

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1. Key point on IMDRF work items

2. Other Topics

- IMDRF Guidance Implementation
- Medical Device Single Audit Program (MDSAP)
- IMDRF / DITTA Virtual Workshop on Cybersecurity

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1. DITTA FEEDBACK ON IMDRF WORK ITEMS

1. Cybersecurity
2. Clinical Evaluation
3. Artificial Intelligence
4. Standards
5. Regulated Product Submission (RPS)
6. Good Regulatory Review Practice (GRRP)

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KEY POINTS (1 OF 2)

1. Cybersecurity

DITTA welcomes publication of final guidance (March 2020) and supports work item extension to operationalise

2. Clinical Evaluation

DITTA supports releasing the draft guidance document on Post-Market Clinical Follow-up (PMCF) for public consultation

3. Artificial Intelligence

DITTA welcomes creation of New Work Item and is actively involved

KEY POINTS (2 OF 2)

4. Standards

1. DITTA emphasizes that international standards are vital for global convergence

2. DITTA urges IMDRF to operationalize the liaisons to ISO and IEC to ensure regulators directly contribute into development of standards for regulatory use

5. Regulated Product Submission (RPS)

DITTA supports further work on Table of Contents as essential building block towards Single Review Program

6. Good Regulatory Review Practice (GRRP)

DITTA supports to expand the current work of the WI on GRRP and moving towards a single regulatory premarket review process to satisfy in whole or in part the needs of multiple regulatory jurisdictions for selected medical devices

Note: Scope/Goal of GRRP was defined that *"The goal is to promote global harmonization in the premarket review processes."*

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IMPLEMENTATION

- Development of IMDRF outputs is very successful and resulted in high-quality guidance for regulators and manufacturers
- Examples (like Unique Device Identification) of differing implementation exist and are causing problems for manufacturers
- Need for analysis of IMDRF guidance implementation in various jurisdictions
- Continuing pre-and post-market convergence and adoption in various jurisdictions on completed work items and assess possible gaps

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MEDICAL DEVICE SINGLE AUDIT PROGRAM (MDSAP)

- DITTA continues to support the MDSAP programme
- DITTA recommends that additional jurisdictions accept MDSAP reports in place of their need for audits

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IMDRF / DITTA VIRTUAL WORKSHOP ON CYBERSECURITY – 21 SEPT. 2020

Goals:

- Discuss the implementation of the IMDRF cybersecurity guidance in different jurisdictions
- Learn from healthcare providers on steps towards ensuring their facility is secure
- Learn what the medical device industry is doing to make devices more secure and prevent cyber attacks

Attendance: 500 registered participants - 322 attendees (regulators, auditing organisations, healthcare providers, scientific societies and industries)

Speakers: 18 from 6 jurisdictions (Singapore, USA, Canada, EU/Germany/Belgium, Japan, South Korea)

Key Take-Aways:

- All actors (regulators, healthcare providers, HCPs, industry) in the medical device regulatory system consider cybersecurity a priority and take active steps to ensure safety and security of devices
- Published IMDRF cybersecurity guidance is an excellent first step towards global convergence
- Further work is necessary on, for example, the practical implementation of security for legacy/transitional devices and shared responsibility at international level
- Cybersecurity is a shared responsibility across healthcare stakeholders

Link: https://www.globalditta.org/media-centre/events/article/imdrf-ditta-joint-virtual-workshop-cybersecurity-where-are-we-today.html

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CONCLUSIONS BY IMDRF CYBERSECURITY WG CHAIRS

"The IMDRF-DITTA Cybersecurity Virtual Workshop on September 21, 2020 hosted a wide variety of stakeholders and allowed various perspectives to be shared from regulators, healthcare providers, standards experts, and industry on medical device cybersecurity.

The workshop also allowed for the presentation of an overview of the IMDRF Guidance document entitled, Principles and Practices for Medical Device Cybersecurity. The discussions were informative and allowed various stakeholder groups to gain insights on some of the strengths and challenges presented by each stakeholder group.

For example, regulators were very much aligned in the need for global harmonization; healthcare providers described some of the challenges in asset management; exciting standards work is being pursued in relation to security requirements; industry is pursuing useful developments in the adoption of MDS2 and continues to have challenges in legacy devices.

The virtual workshop was an excellent platform to understand the current state of medical device cybersecurity and to inform future work of the IMDRF Cybersecurity working group in operationalizing the legacy device conceptual framework and further developing the idea of transparency of software components, including the implementation of a software bill of materials (SBOM)."

Marc Lamoureux, M.Sc.
Health Canada | Santé Canada

Suzanne B. Schwartz, MD,MBA
US Food & Drug Administration

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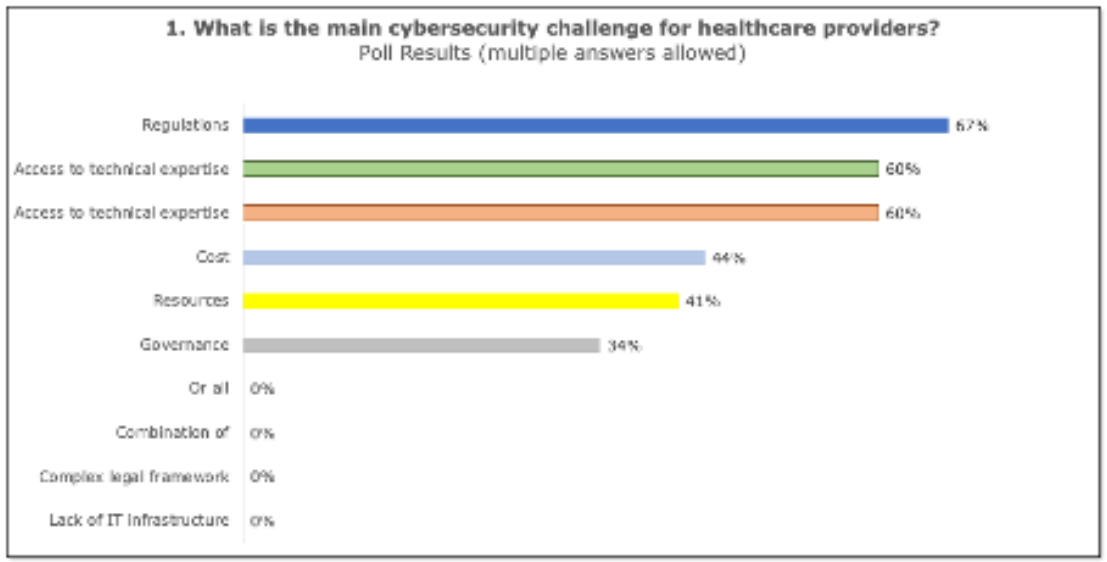
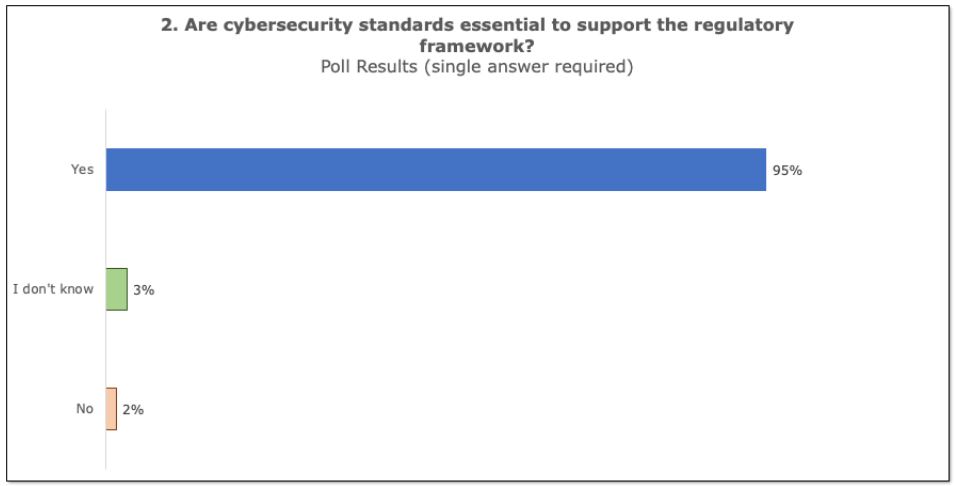
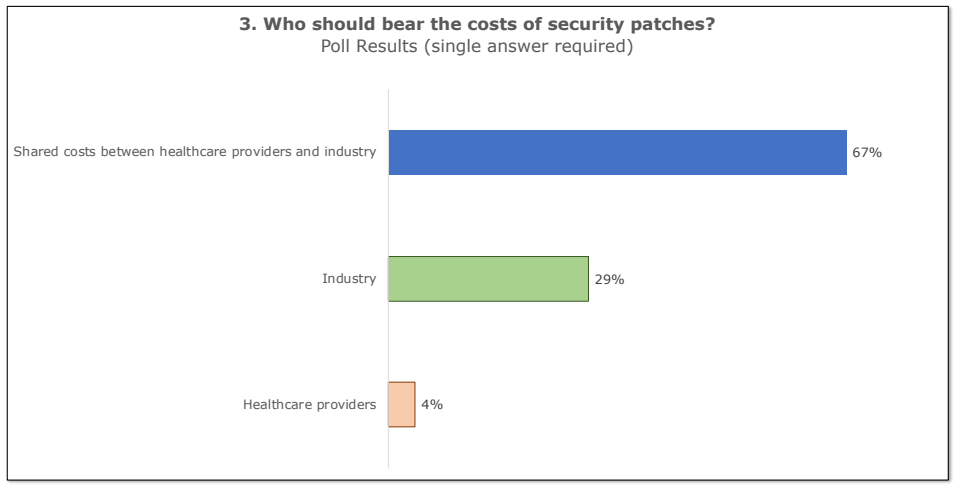
POLLING RESULTS







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THANK YOU!

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