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

IMDRF International Medical Device Regulators Forum

DITTA Report

IMDRF Open Stakeholder Forum

Wednesday 23 March 2021

Masaaki Ohtsuka, DITTA Chair

Secretary General, JIRA

COCIR Advancing Healthcare · JIRA · Medtech Canada · MITA Medical Imaging & Technology Alliance · THAIMED · IMEDA · 中国医疗器械行业协会 China Association for Medical Devices Industry · ABiMED · Kmdica Korea Medical Devices Industrial Coop. Association · KMDIA Korea Medical Devices Industry Association · ITAC Information Technology Association of Canada

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DITTA GLOBAL PRESENCE

NEW!

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

IMDRF
IEC ISO
AHWP
GHWP
IAEA International Atomic Energy Agency
World Health Organization
WORLD BANK GROUP
BASEL CONVENTION
UNEP

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1. DITTA FEEDBACK ON IMDRF WORK ITEMS

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

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KEY POINTS

1. Clinical Evaluation

- DITTA welcomes publication of the guidance document on Post-Market Clinical Follow-up (PMCF)

2. Artificial Intelligence

- DITTA supports draft guidance on terminology & definition for Machine Learning as first step, with further work necessary to achieve global convergence

3. Standards

- DITTA emphasizes that international standards are vital for global convergence
- DITTA urges IMDRF to operationalize its liaisons to ISO and IEC to ensure regulators' input into development of standards for regulatory use

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KEY POINTS

4. Cybersecurity

- DITTA welcomes the approval of the New Work Item Extension Proposal in September 2020
- This will bring a useful aid to implement IMDRF/Cyber WG/N60 in the IMDRF jurisdictions

5. RPS

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

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KEY POINTS

6. MDSAP

- DITTA continues to support the MDSAP program and encourages continuous improvement of the program based on experience and input from manufacturers, AOs, and regulators
- DITTA recommends that additional jurisdictions accept MDSAP reports in place of their need for audits

7. Good Regulatory Review Practice (GRRP)

- DITTA supports to expand the current work of the work item 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: Goal of GRRP: *"The goal is to promote global harmonization in the premarket review processes."*

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KEY POINTS

8. UDI

- Support global harmonization of UDI requirements
- DITTA published a whitepaper on UDI, outlining needs for harmonization and providing solutions
- DITTA strongly recommends that document IMDRF/UDI WG/N53 FINAL:2019 "Use of UDI Data Elements across different IMDRF Jurisdictions" need to be updated

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IMDRF / DITTA VIRTUAL WORKSHOP ON COVID-19 16 MAR. 2021

WHAT TO LEARN FROM COVID-19?

Workshop Objectives:

- Learn how regulators have responded to the challenges posed by COVID-19, including the use of emergency authorizations or other measures
- Better understand how the medical device industry has contributed to the fight against COVID-19
- Learn how COVID-19 has impacted the supply of medical devices at global level & the difficulties industry faced
- Exchange views on the lessons learned from COVID-19 to improve regulatory frameworks for medical devices and make them resilient for future crises

Attendance: 480 registered participants
(regulators, auditing organisations, healthcare providers, scientific societies and industries)

Keynote Speakers: South Korea MFDS, WHO

Speakers:

- IMDRF Jurisdictions: South Korea MFDS, US FDA, European Commission, Australia TGA, Japan MHLW
- Healthcare Providers: Severance Hospital of Yonsei University, Mayo Clinic
- Industries: DITTA, GMTA, KMDIA

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Conclusion:

We have learned from this pandemic,

1. Medical devices have been a critically important tool in the fight to diagnose and treat COVID-19
2. Regulators have been partners with industry to ensure medical devices are accessible and available to all parts of the world

Our hope is that in this moment of international collaboration and cooperation, that we keep the momentum going so we can be prepared for the next pandemic, and not repeat the same mistakes, but build on what worked and make those improvements more permanent.

Programme,
https://www.globalditta.org/fileadmin/Media_Centre/Media_Centre_2021/IMDRF_-_DITTA_Joint_Virtual_Workshop_What_to_learn_from_COVID-19_-_Program.pdf

Presentations,
https://www.globalditta.org/media-centre/events/article/imdrf-ditta-joint-virtual-workshop-what-to-learn-from-covid-19.html

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THANK YOU!

www.globalditta.org

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