DITTA Report
IMDRF Open Stakeholder Forum

Wednesday 23 March 2021

Masaaki Ohtsuka, DITTA Chair
Secretary General, JIRA
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
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<th>Working Group</th>
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<td>Regulated Product Submission (RPS) Working Group</td>
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<td>Medical Device Single Audit Program (MDSAP) Working Group</td>
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<td>Unique Device Identification (UDI) Working Group</td>
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<td>10.</td>
<td>Medical Software &amp; AI (MSW &amp; AI) Working Group</td>
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1. DITTA Feedback on IMDRF work items

2. Outcome of IMDRF/DITTA Virtual Workshop on COVID-19
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
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• DITTA supports draft guidance on terminology & definition for Machine Learning as first step, with further work necessary to achieve global convergence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
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
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."
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
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
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,

Presentations,
THANK YOU!

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