



# DITTA Report IMDRF Open Stakeholder Forum

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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





















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

## DITTA: 9 WORKING GROUPS



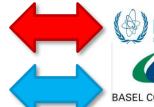






















MITA

MEDICAL IMAGING



























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## 1. DITTA FEEDBACK ON ON-GOING IMDRF WORK ITEMS

- 1. Cybersecurity
- 2. Clinical Evaluation
- 3. Standards
- 4. Regulated Product Submission (RPS)























# 1.1. KEY POINTS (1)

### 1. Cybersecurity

- 1. Support endorsement of cybersecurity guidance for public consultation looking forward to further refinement
- 2. Suggest discussion on feasibility and implementation of the document in each jurisdiction

### 2. Clinical Evaluation

- 1. Support endorsing the draft guidance documents for publication
- 2. Support adoption of New Work Item on Post-Market Clinical Follow-Up























# 1.2. KEY POINTS (2)

#### 3. Standards

- 1. Ensure the implementation of the guidance on optimizing standards for regulatory use
- 2. Support operationalisation of IMDRF liaison to ISO and IEC
- 3. Align mechanisms for recognition of standards across jurisdictions

### 4. Regulated Product Submission (RPS)

- 1. Recognize the value of a globally harmonized ToC as a foundation to support a future global single submission format
- 2. Support focus on ToC stabilization and implementation

### 5. Good Regulatory Review Practice (GRRP)

- 1. Recognize the value of work in GRRP WG
- 2. Plan to submit feedback on consultation document on recognition of CABs























## 1.3. CONCLUSIONS

- 1. Cybersecurity Support endorsement of cybersecurity guidance for public consultation looking forward to further refinement
- 2. Clinical Evaluation Support endorsing the draft guidance documents for publication & adoption of NWIP on PMCF
- 3. Standards Support operationalization of IMDRF liaison to ISO and IEC
- 4.RPS Support focus on ToC stabilization and implementation
- 5.GRRP Support on-going work & plan to submit feedback























# 2.1. UNIQUE DEVICE IDENTIFICATION (UDI)

- Commend IMDRF for work completed with the UDI Working Group
  - Application guide
  - Use of Data Elements
- Support consistent implementation globally, including nomenclature
- Principles: flexibility, availability of guidance and mapping documents
- Encourage adoption and use of IMDRF guidance and tools by IMDRF member countries
- Emphasize commonality for key aspects of a UDI system























# 2.2. MEDICAL DEVICE SINGLE AUDIT PROGRAM (MDSAP)

Continuing strong industry support for MDSAP programme

 Desire to have additional jurisdictions accept MDSAP Reports in place of their need for audits























# 2.3. OUTCOMES OF IMDRF / DITTA WORKSHOP ON AI

Goal: discussion on the opportunities and challenges of Artificial Intelligence in healthcare

Attendance: over 100 participants

Speakers: regulators, healthcare professionals & industry from 7 jurisdictions Key Take-Aways:

- High level of interest and engagement from all stakeholders
- Necessity for harmonised healthcare-specific AI terminology
- Consider enriching existing IMDRF guidance to foster more convergence
- Issue of access to high-quality data























# THANK YOU! Спасибо!

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