



**IMDRF**

International Medical  
Device Regulators Forum

# IMDRF-DITTA Workshop Optimizing Standards for Regulatory Use

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## **Standards Working Group (SWG) Members**

Australia

Brazil

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China

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Japan

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# SWG Goal and Objectives

**Goal:** Enhance the use of standards to harmonize regional and national regulatory approaches

## Objectives

1. Publish recommendations for developing 'regulatory-ready' standards (guidance)
2. Enhance Regulatory Authority (RA) participation in standards development processes
3. Advance IMDRF relationships with ISO and IEC
4. Analyze RAs' approaches to the use of standards in regulatory review
5. Harmonize our approaches to the use of standards



# Current Plan





# Groundwork

- Built
  - Relationships: with each other, standards users and Standards Developing Organizations (SDOs)
- Analyzed
  - How Regulatory Authorities (RAs) participate in standards development
  - Current state of standards for regulatory use
- Published and promoted
  - 2017 Report: *Improving the Quality of International Medical Device Standards for Regulatory Use*
    - Regulatory readiness of standards
    - Participation in Standards Developing Organizations (SDOs)
  - 2018 Guidance: *Optimizing Standards for Regulatory Use*
    - How to improve standards and standards developing processes for use in device review
    - Encourage regulator participation in standards development



# Current Work Item

- Standards Recognition and Use
  - Goal: advance harmonized use of standards
  - Two objectives
    - Compare RAs' recognition and utilization policies (survey)
    - Update list of commonly recognized standards (checklist)
  - Preliminary analysis shows broad commitment to use of standards but differing policies and programs: mostly in how formal RAs' approaches are
  - Proceeding on schedule
    - Tatiana Pika will present preliminary results today
    - Report to MC in September 2019





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## Proposed New Work Item

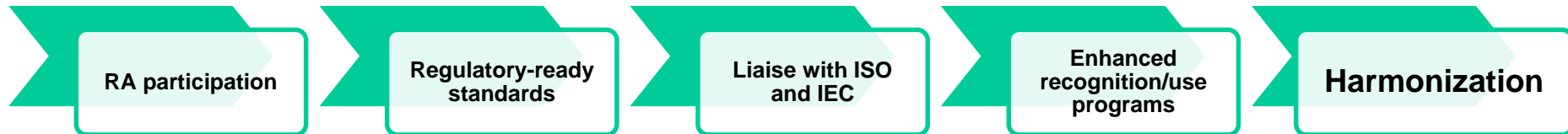
- SDO Liaison Program
  - Establish program parameters for serving as Liaison to IEC and ISO
    - Represent IMDRF effectively in liaised SDO committees and working groups
    - Lead multilateral communications between IMDRF MC, members, liaisons and SDOs
    - Foster and convey consensus among IMDRF members to establish positions of regulatory importance to share with SDOs





## The Future

- NWIP under consideration
  - Guidance: offer best practices and policies for the use and recognition of standards
  - Commitment to real harmonization of practices





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**Thank you**