



IMDRF International Medical
Device Regulators Forum



Standards Working Group

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IMDRF

International Medical
Device Regulators Forum

Standards Working Group (SWG) Members

Australia

Brazil

Canada

China

European Union

Japan

Korea

Russia

Singapore

USA

DITTA

GMTA



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 as Category A Liaisons
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
 - Preliminary results shared at Monday's Standards Workshop
 - Report to MC in September 2019



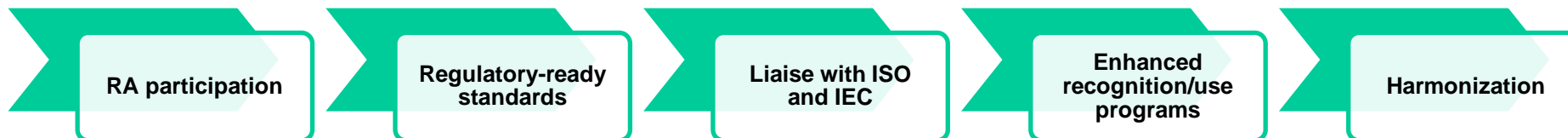
Proposed New Work Item

- 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