



IMDRF

International Medical
Device Regulators Forum

New Work Item Proposal (NWIP)

“Improving the quality of international medical device standards for regulatory use”

09 March 2016
Brasilia



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BACKGROUND

- IMDRF regions are using standards as a tool for industry to demonstrate compliance with the regulatory requirements.
- IMDRF has already worked on identification/listing of standards which are used within several jurisdictions
- Concerns have been raised by key stakeholders (including regulators and industry) about the need to improve the quality of key standards in the view of their regulatory use
- The IMDRF Strategic Plan 2015-2020 includes among its priorities *"improving the suitability of international standards for regulatory authorities and effective regulatory authority involvement at each stage in standards development"*



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Purpose of the NWIP

To identify and explore possibilities to improve the process of developing international standards used for regulatory purpose in the medical technology domain



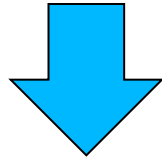
SCOPE

- Mapping of technical issues and concerns, with regard to regulatory aspects of standards developed by some major international standardization committees
- Explore possibilities for improvement & discuss with stakeholders and SDOs
- Describe possible actions to take by IMDRF in order to influence and support the development or amendment of standards for regulatory purposes



ISSUES TO BE ADDRESSED

Shortcomings in the process of standards development that negatively impact suitability of international standards for use in regulatory context



OPPORTUNITY FOR CONVERGENCE

Higher confidence in international standards for regulatory purpose will increase the uptake of international standards at national level, particularly on medical device safety and performance



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TIMING

- End of Mapping phase: September 2016
- Final adoption of a Report + examination/indication of possible actions to take by IMDRF: June 2017 (following a public consultation phase)



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Thank you for your participation!

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