IMDRF International Medical Device Regulators Forum

International Medical Device Regulators Forum updates

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The International Medical Device Regulators Forum (IMDRF) was conceived in February 2011 as a forum to discuss future directions in medical device regulatory harmonization.

The current members are: Australia, Brazil, Canada, China, Europe, Japan, Russian Federation, Singapore, South Korea, and the United States of America.

The World Health Organization (WHO) is an Official Observer. The Asian Harmonization Working Party (AHWP), Pan American Health Organization (PAHO) and APEC LSIF Regulatory Harmonization Steering Committee are IMDRF Regional Harmonization Initiatives.

Documents and procedures

IMDRF/MC/N2FINAL:2019 (Edition5): “IMDRF Standard Operating Procedures”

Last update 21/03/2019

IMDRF technical documents

IMDRF procedural documents

IMDRF information documents

IMDRF outcome statements

GHTF final documents

Current working groups

Work item	Working Group Membership	Coordinator
Principles of In Vitro Diagnostic (IVD) Medical Devices Classification	Regulator and Regional Initiatives membership	Tatyana Buryakina, Roszdravnadzor, Russia
Medical Device Cybersecurity Guide	Regulator and stakeholder membership (membership to be advised)	Suzanne Schwartz, US FDA Marc Lamoureux, Health Canada
Medical Device Clinical Evaluation	Regulatory and stakeholder membership	Dr Yinghui Liu, China
Personalized Medical Devices	Regulator membership	Dr Elizabeth McGrath, Australia
Standards - Improving the quality of international medical device standards for regulatory use	Regulatory and stakeholder membership	Scott A Colburn, USA
Adverse Event Terminology	Regulator membership	Hiroshi Ishikawa, Japan
Good Regulatory Review Practices	Regulator membership	Melissa Torres, USA
Regulated Product Submission	Regulator only and regulator and stakeholder membership	Nancy Shadeed, Canada

Chairmanship of Russian Federation in 2019
hosted by the Federal Service for Surveillance in Healthcare (Roszdravnadzor)

24 January, 2019 Management Committee Teleconference

March 18 – 21, 2019
The XV meeting in Moscow, Russia

27 June, 2019 Management Committee Teleconference

September 16–19, 2019
The XVI meeting in Yekaterinburg, Russia

Workshop "Optimizing Standards for regulatory use"

18 March, 2019, Moscow

- The goal of IMDRF/DITTA joint workshop was to communicate and promote the concepts and provisions of the IMDRF Standard guidance document (IMDRF/Standards WG/N51 FINAL:2018)
- role of standards for regulatory purposes,
- expected improvements by IMDRF Standard guidance document,
- current state and future for several core standards.

Workshop "Artificial Intelligence in Healthcare"

16 September, 2019, Yekaterinburg

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

March 18 – 21, 2019
The XV meeting in Moscow, Russia

19 March 2019– Open Stakeholders Forum Day
20 March 2019 – Open and closed sessions of IMDRF MC
21 March closed session of IMDRF MC

September 16–19, 2019
The XVI meeting in Yekaterinburg, Russia

17 September 2019– Open Stakeholders Forum Day
18 September 2019 – Open and closed sessions of IMDRF MC
19 September 2019 closed session of IMDRF MC

More than 300 participants from 28 different countries

Final Documents of The XV and XVI IMDRF MC meeting

- Final N9 document, "Non-In Vitro Diagnostic Medical Device Market Authorization Table of Contents (nIVD MA ToC)"
- Final N13 document, "In Vitro Diagnostic Medical Device Market Authorization Table of Contents (IVD MA ToC)"

Final N43 document "Terminologies for Categorized Adverse Event Reporting (AER): terms, terminology structure and codes (Annex E-F)"

Final N52 document "Principles of Labeling for Medical Devices and IVD Medical Devices"

- Final N48 document "Unique Device Identification System (UDI system) Application Guide",
- Final N53 document "Use of UDI Data Elements Across IMDRF Jurisdictions"
- Final N54 document "System Requirements related to the use of UDI in healthcare including selected use cases"

Final N55 document "Clinical Evidence – Key Definition and Concepts"
Final N56 document "Clinical Evaluation"
Final N57 document "Clinical Investigation".

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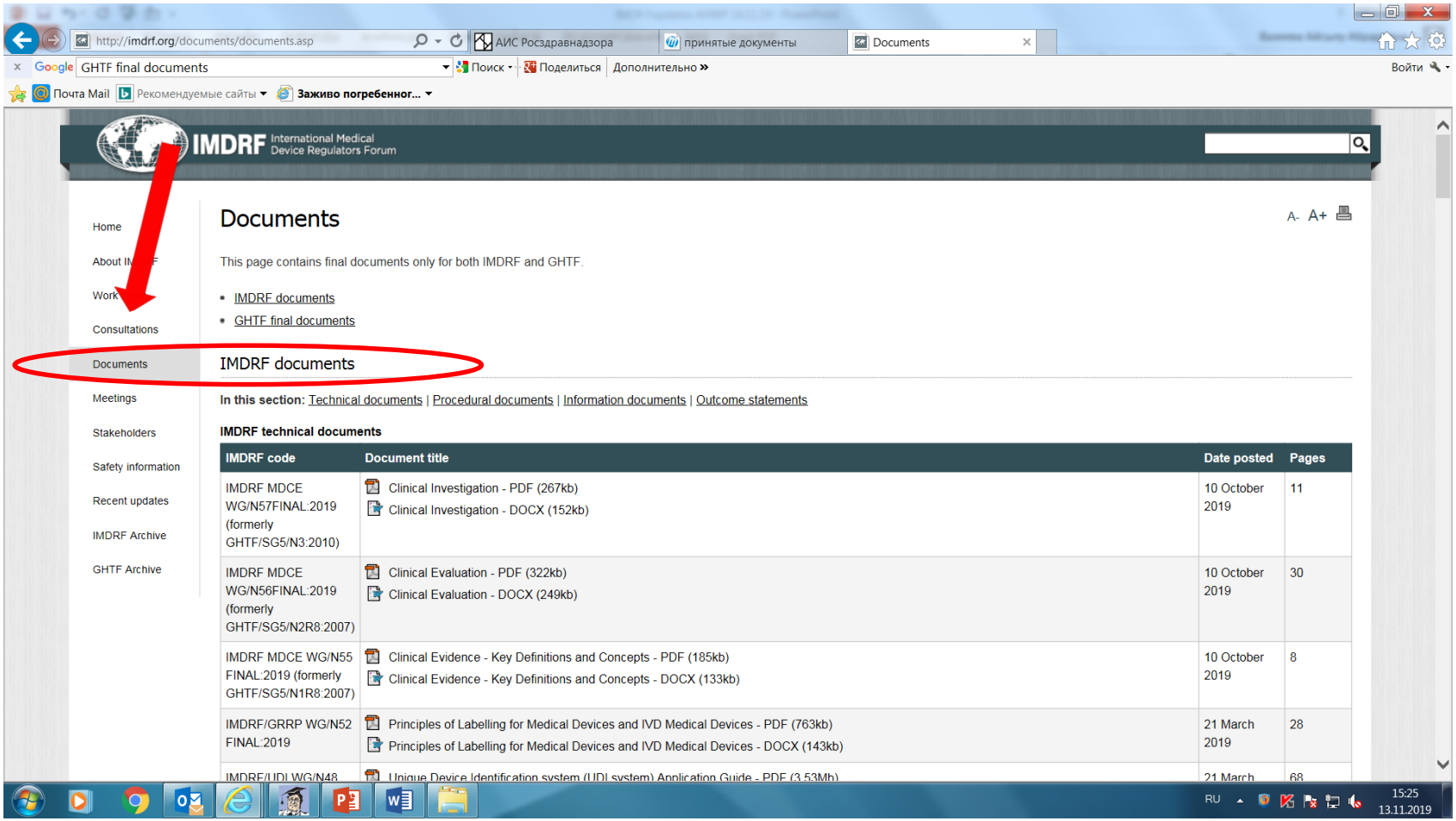

Current consultations

Consultation item	Working Group	Coordinator	Closing date
IMDRF Principles and Practices for Medical Device Cybersecurity	Medical Device Cybersecurity Working Group	Suzanne Schwartz and Marc Lamoureux	2 December 2019
Requirements for Regulatory Authority Recognition of Conformity Assessment Bodies Conducting Medical Device Regulatory Reviews	Good Regulatory Review Practices	Melissa Torres	3 October 2019

Important decisions of The XV and XVI IMDRF MC meeting

- **NWIP: Review and Update of the GHTF Principles of In-Vitro Diagnostic (IVD) Medical Devices Classification (GHTF/SG1/N45:2008) was approved. New WG was established chaired by the Russian Federation.**
- **NWIP: IMDRF Standard Developing Organizations (SDO) Liaison Program was approved under Standards Working Group.**
- **NWIE: Post-Market Clinical follow up studies (update of GHTF/SG5/N4) was approved under MDCE Working Group.**
- **China announced their intention to join the NCAR program.**
- **The MC continued their discussions on the preparation of a document outlining the implementation status of IMDRF documents by member jurisdiction**

Chairmanship in 2020 and 2021

Singapore will be IMDRF-2020 Chair

South Korea will be IMDRF-2021 Chair

Thank you for your attention!

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