IMDRF International Medical Device Regulators Forum

FINAL DOCUMENT

Title: **IMDRF** Strategic Plan 2020

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I. Introduction

Three years have passed since the launch of IMDRF in 2012. In this early period, IMDRF developed sound foundational procedures and governance arrangements. Also in this period IMDRF has delivered a number of significant work products some of which are a continuation of the Global Harmonization Task Force (GHTF).

IMDRF has now reached a juncture where it should define its strategic direction for the coming years to better coordinate its activities and allocate its limited resources. The IMDRF Strategic Plan 2020 sets out the strategic priorities of the forum from 2016 to 2020.

II. IMDRF Strategic Plan 2020

1. Mission of IMDRF

The IMDRF Strategic Plan 2020 aligns with the following mission defined in IMDRF Terms of Reference (IMDRF/MC/N1FINAL: 2014) (ToR);

"The mission of the IMDRF is to strategically accelerate international medical device regulatory convergence to promote an efficient and effective regulatory model for medical devices that is responsive to emerging challenges in the sector while protecting and maximizing public health and safety."

Under "D. Scope of Activities," the ToR stipulates that "IMDRF will pursue its goals by defining, implementing and evaluating strategic priorities so that objectives are met in an efficient and effective manner." The IMDRF Strategic Plan 2020 is a part of this activity and helps developing prioritized work plans of activities from 2016 to 2020.

2. Strategic Priorities

The IMDRF ToR lists eight objectives to achieve our mission. While all objectives remain important, the Management Committee (MC) intends to put particular focus on the objective, "Support innovation and timely access to safe and effective medical devices" from 2016 to 2020. The focus is in areas where the lack of common regulatory requirements and practice may delay the delivery of medical devices of public health importance already available in one jurisdiction to the patients in other jurisdictions. The IMDRF strategic plan is expected to promote further regulatory convergence among IMDRF members resulting in benefits for patients, healthcare professionals and industry stakeholders. To assure that this objective is met in an efficient and

effective manner, the MC has identified the following strategic priorities for which it will develop New Work Items and work plans:

1) Enhance Post-Market Surveillance; and
2) Improve the Effectiveness and Efficiency of Pre-Market Review.

In pursuing these strategic priorities, IMDRF would seek to assure an appropriate balance between pre-market and post-market requirements as part of a total product lifecycle regulatory approach to medical devices. Striking the right balance between pre-market and post-market requirements, such as pre-market and post-market data collection, can facilitate timely patient access to safe and effective devices by minimizing pre-market requirements to the extent appropriate while assuring that patients receive safe and effective devices. This approach is reflected in IMDRF's work item on Software as a Medical Device for which the framework under development would foster the optimal use of applicable post-market controls to narrowly tailor premarket requirements, as appropriate. IMDRF continues supporting the current work items.

The MC encourages all the stakeholders to recommend NWIs or to submit New Work Item Proposals that are critical for achieving these strategic priorities. IMDRF will undertake NWIs depending on the extent to which the NWI will advance the strategic priority, the feasibility of the NWI, and the availability of adequate resources to develop the proposed outputs. IMDRF will still consider other NWIPs for other topic areas but is not likely to accept those proposals unless there is a sufficiently compelling reason to do so.

Enhance Post-Market Surveillance

Since the inception of IMDRF, the forum has undertaken several work items to enhance post-market surveillance. These work items include:

i) Effective exchange of post-market data by improving the former GHTF NCAR (National Competent Authorities Reports) Exchange Program;
ii) Establishment of common principles on registries;

iii) Harmonization of adverse event terminology to expand the terminology and systems being used to code information relating to medical device adverse events;

iv) Establishment of a Medical Device Single Audit Program; and

v) Development of non-binding rules for creating, using, and maintaining unique device identifiers and related activities.

From 2016 to 2020, the MC intends to build on the work already started or completed as well as consider New Work Items in line with identified objectives.

Improve the Efficiency and Effectiveness of Pre-Market Review

Promoting regulatory convergence of pre-market review while striking the right balance between pre-market and post-market requirements supports innovation by promoting the least burdensome approach to assure devices are safe and effective. Regulatory convergence also supports more timely market entry of safe and effective devices across member jurisdictions by facilitating reliance on data developed for and/or decisions made by one or more jurisdictions to support market approval in other jurisdictions. The MC already has taken an initial step forward to achieve this strategic priority through the early-stage development of Regulatory Product Submissions, including establishment of comprehensive Table of Contents (ToC) for non-IVD market authorization and IVD market authorization. IMDRF will continue this activity. The MC will select further New Work Items (NWIs) to improve the effectiveness and efficiency of pre-market review. These may include assuring the reliability of data submitted to regulatory bodies, improving quantity and quality of clinical data, developing Good Review Practices for pre-market reviews/evaluations which includes competence and training for pre-market reviewers, developing guidance on benefit-risk determinations, and improving the suitability of international standards for regulatory authorities and effective regulatory authority involvement at each stage in standards development.

3. Development and Utilization of IMDRF Outputs

In order to enhance the utilization of IMDRF outputs, MC members will:

a) Share information with stakeholders regarding the implementation of and/or challenges to implementation of IMDRF outputs in their respective jurisdictions; and

b) To the extent feasible and appropriate, support training activities on IMDRF outputs conducted by other organizations.

In addition, in the future when accepting NWIs or New Work Item Extensions, the MC will develop work plans with timetables for completion of deliverables and make them available to the public.

4. Relationships with Stakeholders

IMDRF values transparency and inclusiveness. IMDRF will continue to promote close communication about IMDRF activities and outputs with as well as inclusion of stakeholders, such as medical devices industries, other regulators, international organizations, standards development organizations, patient and professional associations, and academia, in IMDRF working groups, as appropriate.

IMDRF will continue to encourage collaboration and outreach with Affiliate Organizations and other interested regulatory authorities. IMDRF will seek opportunities to develop stronger relationships with organizations that can help advance our mission, such as standards development organizations. In addition, IMDRF will consider new membership requests based on the established IMDRF ToR and Standard Operating Procedures.

5. Review of Progress of IMDRF Strategic Plan 2020

The progress of IMDRF Strategic Plan 2020 will be reviewed in the IMDRF MC and revised as appropriate.