IMDRF International Medical Device Regulators Forum

# Regulated Products Working Group Open Stakeholder Meeting March 2016

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# RPS Implementation Plan

| | 2015 | 2016 | | | | 2017 | | | | 2018 |
|---|---|---|---|---|---|---|---|---|---|---|
| | Q4 | Q1 | Q2 | Q3 | Q4 | Q1 | Q2 | Q3 | Q4 | Q1 |
| Scope & Process Definition | | | | | | | | | | |
| Draft Implementation Guide Preparation | | | | | | | | | | |
| Testing | | | | | | | | | | |
| Implementation Approach & Governance | | | | | | | | | | |

# What is “Implementation”?

**STANDARD**
Defines all possible data and relationships

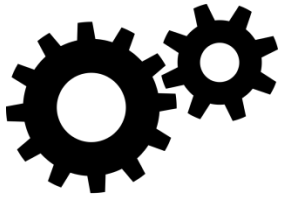
**Implementation Guide**
Specifies which parts of the standard will be used and how.

**Software tools**
Built based on the implementation guide. Presents a customized user view to the submission information

IMDRF Harmonized IG

The harmonized IG is the basis for the regional IGs.

US IG  EU IG  Canada IG  Brazil IG



Submissions (i.e. Shonin, Class III Application, or PMA)

How should we use the RPS standard to enable the business process?

Harmonized or regional approach?

# Scope & Process Definition

Oct 2015 → April 2016

**Objectives**

- RPS Work Plan
- Define the submission types and regulatory processes for each region that will be in scope for initial RPS work
- Document detailed requirements for each in scope regulatory process

**Opportunities for Stakeholder Engagement**

- March 2015 MC overview of work plan
- Communication of scope after the March meeting through industry associations

# Draft IG Preparation

April 2016 → Nov. 2016

**Objectives**

- Define how each documented regulatory process should be supported by the RPS standard
- Develop draft controlled vocabulary to be used for RPS
- Draft RPS Implementation Guide to be used for testing

**Opportunities for Stakeholder Engagement**

- Implementation Guide overview at MC Open Stakeholder meeting in Sept. 2016
- Public Consultation on draft implementation guide and controlled vocabulary

# Testing

Oct. 2016 → Sept. 2017

**Objectives**

- Final Harmonized Implementation Guide and vocabulary for testing
- Regional IG and Vocabulary to support testing
- Engagement with vendors
- Test plan, scripts and results

**Opportunities for Stakeholder Engagement**

- Review of test results with industry

# Implementation Approach & Governance

Jan. 2017 → Mar. 2018

**Objectives**

- RPS Implementation strategy for each region
- Draft governance process to maintain RPS as a harmonized submission format
- Final harmonized and regional implementation guides
- Final harmonized and regional vocabulary

**Opportunities for Stakeholder Engagement**

- Public Consultation on implementation strategies, governance process, implementation guides and vocabulary

# Table of Contents WG Update Pilot Plan

- Australia, Brazil, Canada, China, EU and the United States are participating regions

- Regional pilots are also currently being undertaken by some IMDRF members

# Pilot Status

- Pilot initiated October 1, 2015
- 22 requests received, 11 accepted
  - 10 nIVD, 1 IVD
- Teleconference convened early February to discuss first impressions
  - Only a few applications received to date
  - Still too early to draw any conclusions
- Pilot and regional information for potential participants now posted on IMDRF website

# Common Data Elements WG - Update

- The final document does not provide the detailed specifications for the data use requirements for each regulatory authority.
- It is recommended that the WG further specifies the characteristics of the existing common data elements to see if these requirements could be leveraged to provide more consistent device identification in electronic data submissions across regions.

# Common Data Elements WG - Update

- WG  is seeking review and approval of final draft document IMDRF RPS N19 “Common Data Elements for Medical Device Identification”
- Document outlines common data elements for medical device identification that may be used through regulatory activities or processes
- Covers the harmonization of terms and their definition.

# Phase 2 Workplan

1. Analysis and documentation by each regulatory region of existing regulatory usage and allowable values of each common data element.
2. Compilation of regulatory region data element specifications and mapping to data types and controlled vocabularies.
3. Documentation of existing exchange messages that are available for regulatory reporting.
4. Mapping of common data elements to existing exchange messages.
5. Recommendations for data exchange guidelines of common data elements.

# Phase 2 Workplan - Timelines

- Phase 2 activities completed over 18 months (February 2016 - September 2017)
- Initial Teleconferences will focus on tasks 1-4 including a review and further refinement of materials developed during Phase 1.
- Face-to-Face meeting in May 2016 (Ottawa) to draft data exchange guidelines
- Submit Proposed Draft Data exchange guidelines to September 2016 MC

# Questions & Discussion