



**IMDRF**

International Medical  
Device Regulators Forum

# **RPS Strategic Assessment**

## **Panel Discussion**

**Sept, 2015**



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## The Strategic Assessment IS:

- A request for the MC to authorize RPS implementation work for devices
- A request that a transitional non-RPS format also be developed to address industry concerns around RPS cost & complexity
- An overview of stakeholder requirements and views regarding RPS and other potential eSub solutions that can inform and direct implementation efforts

## The Strategic Assessment IS NOT

- The only opportunity industry will have to influence electronic submission format and implementation plans
- A cost – benefit analysis



## Factors Supporting the Recommendation

- Total scores
- Decision from ICH to implement RPS as eCTD v4.0. Alignment with pharmaceutical format may benefit combination products later
- Option 3 viewed as not viable given resources required to develop and govern a custom standard
- The higher scores for Option 2 from the majority of industry resulted in a transitional format being specifically called out in the recommendation



## Recommendation

.... it is recommended that the IMDRF MC endorse RPS as the future electronic information exchange format to be used for medical device submissions; and that the MC charter additional efforts within the RPS WG to develop a harmonized, device specific **implementation** of the RPS standard.....

.... It should be noted that **implementation** of RPS is a long term undertaking, and efforts will most likely take several years.....

.....the RPS WG recommends that gradual steps be taken to **implement** the HL7 RPS Message Standard (e.g. use of a harmonized folder structure as a transition format, etc.).....

.....the full implementation of RPS that will require establishment of an ongoing governance model to maintain harmonization and address proposed changes.....

**As a first step, the RPS WG should develop a public strategy outlining a project plan and key milestones to implement RPS**



## 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



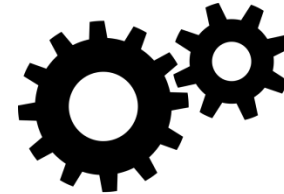
EU IG



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?



# Panel Discussion

