IMDRF ToC Pilot

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March 9, 2016
Pilot Plan

• Pilot intended to evaluate RPS Table of Contents structure with real, live, regulatory submissions sent to multiple regions

• Previous evaluations used historical submissions, which had limitations
  – Limited samples involving more than one region
  – No specific guidelines for building submission pre-RPS
Pilot Plan

• Each region has a classification matrix that sets out specific folder structure

• Manufacturer populates the structure with the relevant information
Pilot Objectives

• Develop and validate documentation supporting the use of the ToC using industry feedback
• Identify potential challenges for industry and develop proposals to address them moving forward
• Provide industry and regulators with experience using ToC in a controlled setting
Pilot Objectives

- Evaluate the proper usage of ToC headings and placement of documents within headings
- Identify additional ToC harmonization opportunities
- Establish and ensure ToC pilot technical guidelines are fit for purpose and harmonized amongst regions to the extent possible
Participants

• Australia, Brazil, Canada, China, Europe, 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
• Expected to run for 1 year or until all objectives are met
• 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
Industry Feedback

• Early feedback focused on technical limitations of ToC
  – Character limit
  – Length of folder names
  – Requiring numerous sub-headers instead of amalgamating under one
Pilot Status

• Pilot and regional information for potential participants now posted on IMDRF website

• Certain regions discussing if scope should be expanded to encourage more submissions
Pilot Status

- Application breakdown by region:
  - Australia: 1
  - Brazil: 10
  - Canada: 4
  - China: 4
  - EU: 3
  - USA: 5
Next Steps

• Increase industry awareness of ToC Pilot and encourage more submissions

• Share pilot application experiences and discuss industry feedback amongst participating regions through regular meetings
Questions?