IMDRF International Medical Device Regulators Forum

IMDRF Registry Working Group Update

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Highlights

- Face to face meeting was held in Moscow, Russia, December 2016
- *IMDRF/Registry WG/N42: Essential Methodological Principles in the Use of International Medical Device Registry Data* document was finalized and submitted to IMDRF management committee for consideration
- Registry pilot projects concepts have been further developed and refined
- Real World Evidence used as context for registry
- New Work Item Proposal (NWIP) submitted to IMDRF management committee

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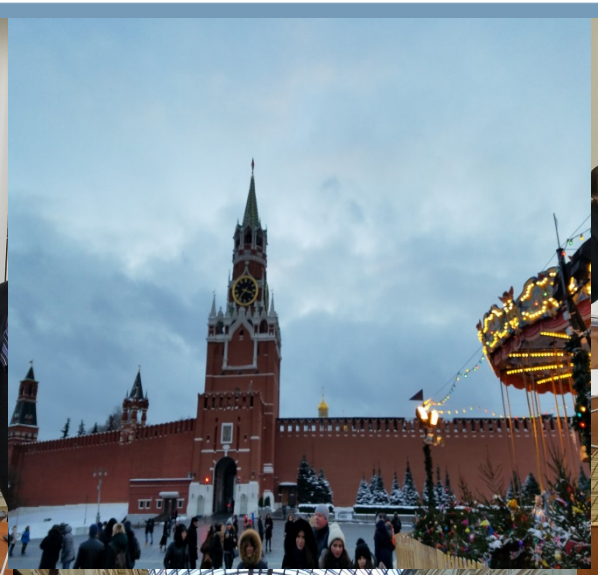

Face to Face Meeting

- Objectives:
  - Address any comments received during the public consultation process on the methodology document and finalize the document
  - Discuss potential pilot projects
  - Discuss the use of Real World Evidence (RWE) - extension of the registries essential principles to evaluate other data sources
  - Discuss and develop a NWIP

Pilot Projects

- Example of candidate projects presented and discussed with potential sponsors
  - Vascular, TAVR/SAVR, scoliosis treatments , flexible knee
- Discussed industry interest
- Pilots should proceed independently from IMDRF Registry WG - but the WG members will serve as regulatory champions on each pilot project
- Registry WG will develop metrics to assess impact of the essential principles document on efficiencies conducting each pilot

NWIP – Purpose

- To develop an:
  - IMDRF Registry Qualification Tool
  - IMDRF Real-World Evidence essential principles document and a catalogue of existing RWE efforts

NWIP – Rationale

- Opportunity to converge regulatory use of RWD/RWE efforts in a broader context (registries, EHR, claims, etc.)
  - Developing IMDRF qualifying tool for registries and other RWD sources for regulatory decision making will facilitate the convergence
  - Creating a catalogue of existing international RWE efforts and principles documents for use of other data sources beyond registries will fill an important gap

Phased Approach

- **Phase 1**
  - Create a qualification tool for international registries taking into consideration a variety of regulatory decisions (e.g. clearance/approval, label extension, signal detection).
  - The qualification tool will incorporate recommendations from the IMDRF registry principles documents to produce a practical qualification tool.
- **Phase 2**
  - Develop principles for evaluation of the real world data sources beyond registries.
  - This work is critical for regulatory convergence in evidence generation and appraisal for those clinical areas where no registry/consortia or coordinated registry networks exist.

Phase 1:
Registry Qualification Tool Timeline

Draft principles document:	Spring 2017
Face-to-face meeting:	June 2017
Proposed draft:	July 2017
Management Council document review:	September 2017
Comment period:	October/November 2017
Face-to-face meeting, review & resolve comments:	January 2017
Proposed final document submitted:	February 2018

Phase 2: RWE Essential Principles and Catalogue of RWE Efforts Timeline

Draft principles document:	Spring 2018
Face-to-face meeting:	June 2018
Proposed draft:	July 2018
Management Council document review:	September 2018
Comment period:	October/November 2018
Face-to-face meeting, review & resolve comments:	January 2019
Proposed final document submitted:	February 2019

Thank You