IMDRF International Medical Device Regulators Forum

IMDRF Registry Working Group Update

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NWIP

Tools for Assessing the Usability of Registries in Support of Regulatory Decision-Making

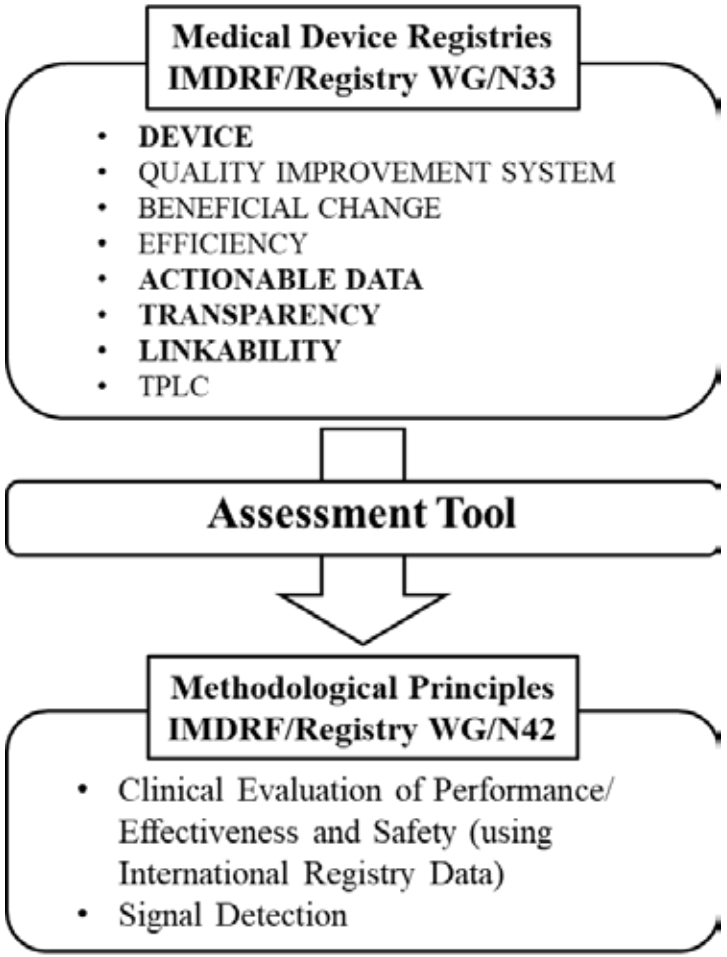
- Create a qualification tool for international registries taking into consideration a variety of regulatory decisions (e.g. clearance/approval, label extension, signal detection).
- The qualification tool will incorporate recommendations from the IMDRF registry principles documents to produce a practical qualification tool.

Rationale

- There is an opportunity to converge regulatory use of registry-derived data
- Developing IMDRF tools for assessing usability could facilitate the convergence

Background:

Relationship of IMDRF Registry Documents



Scope

Identify key processes and features to be considered in assessing the usability of registry data for regulatory purposes

Variety of Regulatory Uses

- The registry assessment tool makes recommendations with regard to the six regulatory uses as follows:
  - Primary approval
  - Expanded/Broadened indication
  - Post-market study
  - Post-market surveillance
  - Objective Performance Criteria/ Performance Goals - OPCs/PGs
  - Device tracking and field safety corrective actions

ELEMENTS	REGULATORY USE					
	Primary Approval	Broadening Indication	Post Market Study	Postmarket Surveillance	Development of OPC/PG	Device Tracking and Field Safety Corrective Actions
Device Identification						
Unambiguous Device Identification (preferably internationally recognized UDI system)	needed	needed	needed	needed		needed
Patient Identification						
Patient Identification	unique needed	limited acceptable	limited acceptable			unique needed
Linkability (Registry with other data source)						
Deterministic	XX	X	X			
Probabilistic	(not recommended)	XX	XX	XX		
Transparency and Governance						
Governance structure and processes	XX	XX	XX	X	XX	X
Legal requirements for data collection/handling	XX	XX	XX	X	XX	X
Policy on COI	XX	XX	XX	XX	XX	XX
Policy on access to data	XX	XX	XX	XX	XX	XX
Report; Key elements and frequency of reports	X	X	X	X	X	
Website and web-reporting	X	X	X	X	X	X

Essential information available for verification by relevant authority (e.g. competent authority, notified body)	XX	XX	XX	XX		
Information on Patient Data Protection (e.g. if Exempt from consent, Opt-out, Opt-in)	XX	XX	XX		XX	XX
Quality and Methodology Processes Leading to Actionable Data						
List of Relevant Variables and Use of Controlled Vocabularies	XX	XX	XX	XX	X	X
Use of nationally/internationally harmonized minimum data model	X	X	X	X	X	
Registry Management processes (e.g. coverage, completeness, data quality control and assurance, etc.)	XX	XX	XX	XX	XX	
Conduct of analyses across different types of analysis frameworks	NA	NA	NA	XX	XX	

Legend

XX - Highly Recommended
X - Desirable
☐ - Optional
NA - Not Applicable

Methods/Process

- Weekly conference calls
- Face to face meetings
  - Rome – Held in June 2017 in conjunction with HTAi annual meeting
  - Tokyo – planned for first week of December 2017 in conjunction with HBD meeting
- Initial comments
  - Via internal review
  - Via MDEpiNet international Mirror Group
  - 147 comments received/incorporated/addressed

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: December 2017
- Proposed final document submitted: February 2018

Additional Registry WG Efforts

- Several registries, consortia and manufacturers approached the WG with potential studies that would apply the essential principles from the first two IMDRF registry documents
- Working with stakeholders to develop the protocol for expanding the indications for vascular devices for rAAA study via study nested in International Consortium of Vascular Registries (ICVR)

THANK YOU!