IMDRF International Medical Device Regulators Forum

IMDRF Registry Working Group

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Update

- Face to Face mtg in Tokyo – Dec 4-8, 2017
- Addressed comments and finalized the Tool for Assessing the Usability of Registries for Regulatory Decision Making
- Developed New Work Item focusing on RWE data sources beyond registries

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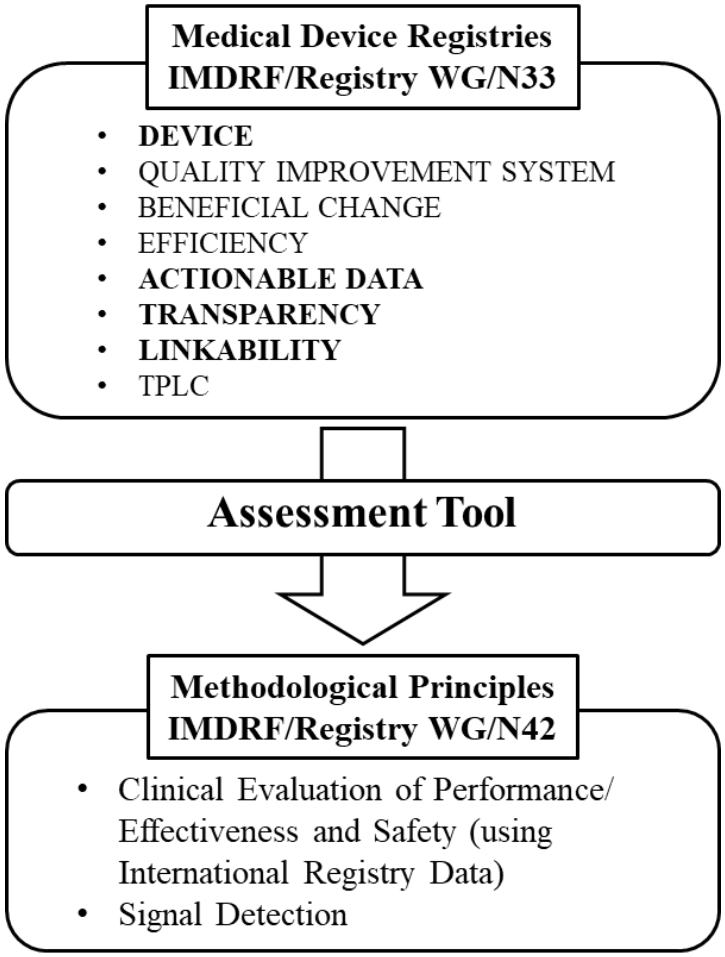
Tools for Assessing the Usability of Registries in Support of Regulatory Decision-Making

Relationship of IMDRF Registry Documents



Methods/Process

- Weekly conference calls
- Face to face meetings
  - Rome – Held in June, 2017 in conjunction with HTAi annual meeting
  - Tokyo - 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

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
  - Field safety corrective actions

ELEMENTS	REGULATORY CATEGORIES						
	Initial Approval*	Broadening Indication**	Post market study	Postmarket Surveillance	Development of OPC/PG	Device Tracking	Field Safety Corrective Actions
Governance							
Governance structure and process	XX	XX	XX	X	XX	X	X
Quality Management System							
Legal requirements for data collection/handling	XX	XX	XX	X	XX	X	X
Information on Patient Data Protection (e.g. if Exempt from consent, Opt-out, Opt-in)	XX	XX	XX	X	XX	X	X
Policy on access to data	XX	XX	XX	XX	XX	X	X
Essential information available for verification by relevant authority (e.g. competent authority, notified body)	XX	XX	XX	XX	XX	XX	XX
Data Gathering							
Relevant Variables	XX	XX	XX	XX	X	X	X
Unambiguous Device Identification (preferably internationally recognized UDI system)	XX	XX	XX	X	X	X	X
Linkability (Registry with other data source):							
Deterministic	XX	X	X	X	X	X	X

Probabilistic	NR	X	X	X	X	X	X
Use of Controlled Vocabularies	XX	XX	XX	X	X	X	X
Use of nationally/internationally harmonized minimum data model	X	X	X	X	X	X	X
Data Storage							
Security Protection against hacking, altering, deleting or stealing data	XX	XX	XX	XX	XX	XX	XX
Methodologies Leading to Actionable Data							
Conduct of analyses across different types of analysis frameworks	XX	XX	XX	XX	XX	X	X
Data Interpretation	XX	XX	XX	XX	XX	X	X
Transparency/ Display/ Distribution							
Report; Key elements and frequency of reports	X	X	X	X	X		
Website and web-reporting	X	X	X	X	X	X	

Legend

XX - Highly Recommended
X - Recommended
☐ - *Optional*
NR- Not Recommended

*Situations where registry data are used for purposes of initial approval are likely to be narrow at present, and include use as a concurrent control group for a clinical trial or for an orphan disease or device.
**While the clinical data collected in registries can involve unapproved uses of marketed devices ("off-label use"), this document does not explicitly encourage such off-label use beyond that which would occur as part of standard clinical practice. Systematic collection of clinical data involving off-label use should comply with any relevant regulations in a given jurisdiction.