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

Medical Device Registries
IMDRF/Registry WG/N33
- DEVICE
- QUALITY IMPROVEMENT SYSTEM
- BENEFICIAL CHANGE
- EFFICIENCY
- ACTIONABLE DATA
- TRANSPARENCY
- LINKABILITY
- TPLC

Assessment Tool

Methodological Principles
IMDRF/Registry WG/N42
- Clinical Evaluation of Performance/Effectiveness and Safety (using International Registry Data)
- Signal Detection
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
<table>
<thead>
<tr>
<th>ELEMENTS</th>
<th>REGULATORY USE</th>
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<tbody>
<tr>
<td></td>
<td>Primary Approval</td>
</tr>
<tr>
<td>Device Identification</td>
<td></td>
</tr>
<tr>
<td>Unambiguous Device Identification (preferably internationally recognized UDI system)</td>
<td>needed</td>
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<tr>
<td>Patient Identification</td>
<td></td>
</tr>
<tr>
<td>Patient Identification</td>
<td>unique</td>
</tr>
<tr>
<td>Linkability (Registry with other data source)</td>
<td></td>
</tr>
<tr>
<td>Deterministic</td>
<td>XX</td>
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<tr>
<td>Probabilistic (not recommended)</td>
<td>XX</td>
</tr>
<tr>
<td>Transparency and Governance</td>
<td></td>
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<tr>
<td>Governance structure and processes</td>
<td>XX</td>
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<tr>
<td>Legal requirements for data collection/handling</td>
<td>XX</td>
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<tr>
<td>Policy on COI</td>
<td>XX</td>
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<tr>
<td>Policy on access to data</td>
<td>XX</td>
</tr>
<tr>
<td>Report; Key elements and frequency of reports</td>
<td>X</td>
</tr>
<tr>
<td>Website and web-reporting</td>
<td>X</td>
</tr>
<tr>
<td>Essential information available for verification by relevant authority (e.g. competent authority, notified body)</td>
<td>XX</td>
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<tr>
<td>-----------------------------------------------------------------------------------------------------------------</td>
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<tr>
<td>Information on Patient Data Protection (e.g. if Exempt from consent, Opt-out, Opt-in)</td>
<td>XX</td>
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<tr>
<td>Quality and Methodology Processes Leading to Actionable Data</td>
<td></td>
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<tr>
<td>List of Relevant Variables and Use of Controlled Vocabularies</td>
<td>XX</td>
</tr>
<tr>
<td>Use of nationally/internationally harmonized minimum data model</td>
<td>X</td>
</tr>
<tr>
<td>Registry Management processes (e.g. coverage, completeness, data quality control and assurance, etc.)</td>
<td>XX</td>
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<tr>
<td>Conduct of analyses across different types of analysis frameworks</td>
<td>NA</td>
</tr>
</tbody>
</table>

**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!