IMDRF International Medical Device Regulators Forum

# IMDRF Registry Working Group Update

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

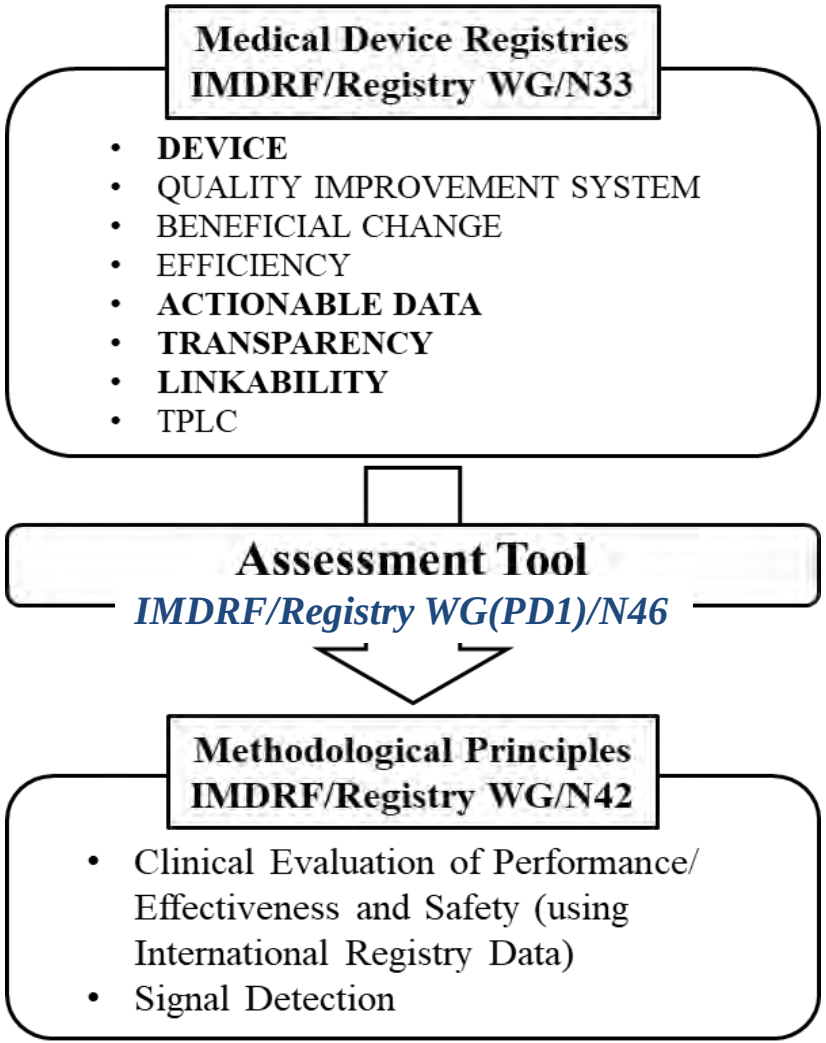
- Goals:
  - Create a qualification tool for international registries taking into consideration a variety of regulatory decisions (e.g. clearance/approval, label extension, signal detection).
  - Incorporate recommendations from the IMDRF registry principles documents to produce a practical qualification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

# Rationale

- There is an opportunity to converge regulatory use of registry-derived data to support various regulatory decisions.
  - Development of 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:
  - Initial 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 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.

# Methods/Process

- Comments (pre-consultation)
  - Total of 147 comments received and addressed
    - Via internal regulatory agencies review
    - Via MDEpiNet Mirror Group review ( 78 multi-stakeholder international group)
- Comments received during consultation period
  - Total of 5 comments received and addressed
- Additional review and comments during face-to-face meeting in Tokyo - December 2017
  - Re-grouping the essential elements of the document and updating the checklist with more granular information

# Current Status

- Final draft of IMDRF/Registry WG(PD1)/N46 sent to MC for consideration as final document
- Recommendation to close Registry WG at this time to provide opportunity for jurisdictions to implement already completed documents
- Potentially pursue pilot projects outside of IMDRF in coordination with other regulatory authorities, manufacturers, consortia, etc. which would apply the essential principles from the IMDRF registry documents

# THANK YOU!