IMDRF International Medical Device Regulators Forum

Integrating Device Registries, UDI and Innovative Tools for Medical Device Evaluation

An Update to the IMDRF Management Committee
February 2015

Scope

- Evaluate, compare & contrast current approaches to international data models in different device areas:
  - ICOR (orthopedics)
  - TVT (cardiovascular)
- Generate essential principles document(s) for international collaboration & data sharing related to:
  - Data access, security, governance, informatics and related issues
  - Analytic methodologies for safety signal detection, device effectiveness & reliability
- Complete proposal in two stages:
  - Essential principles of data linkage for regulatory convergence (Stage 1)
  - Essential principles of analytic methodologies for device evaluation (Stage 2)

Update

- IMDRF Registry Working Group (Main Group)
  - Regulators
  - Industry
  - Academia
  - Professional Associations
  - Registries
- MDEpiNet Mirror Working Group
  - Broad representation from international multi-stakeholders

Subgroup 1

- Vision/context
  - Scientific (methodology, infrastructure)
  - Levels (active surveillance, evidence synthesis, regulatory research)
  - Policy (decision making)
  - Catalogue of the efforts have been successful/assessment
    - Cardiovascular
    - Orthopedics
  - Best practices
- Gaps (assessment/prioritization

Subgroup 2

- Data access
- Data security
- Data quality
- Informatics formats

Subgroup 3

- Linkage of electronic patient, device and outcome data sources
- Confidentiality
- Transparency
- Governance
- Other aspects

MDEpiNet Mirror Group

- Support the Main Group
- Ensure broad stakeholder input
- Address specific questions
- Provide the review and comments

Other updates

- Updated Working Group directory
- Created Collaborative Share point space maintained by the MDEpiNet Coordinating Center
- Created an outline of the report
- Planning face to face mtg in Tokyo
  - April 20-23