Int'l Medical Device Regulators Forum

- Established Oct 2011, building on work of Global Harmonization Task Force on Medical Devices (GHTF)
- Representation: Australia, Brazil, Canada, China, EU, Japan, Russia, United States; also WHO, other affiliates
- Work item examples (www.imdrf.org)
  - Roadmap for Implementation of UDI System (25 Sept 2012)
  - Registry Workgroup (current) – principles related to linkage of patient, device and outcomes registries for medical device evaluation

IMDRF Registry Workgroup - Chapters

4. Vision for international system of registries linked to other data sources and tools
5. What can we learn from the existing efforts in orthopedic, vascular and cardiac fields?
   - Current major international collaborations (ICOR, ICTVR, ICVR)
6. Quality and robustness of registry data needed for regulatory decision making
7. Assuring analysis validity when linking data sources

IMDRF Registry Workgroup Report

Key Registry Desiderata

- Use of controlled vocabularies (standardized data dictionaries)
- Use of a common data model (e.g. OMOP)
- Inclusion of device identifier, performance and outcomes information
- Implementation of a data quality plan
- Governance that anticipates the conduct of analyses across different types of analysis frameworks