Medical Device Registries: Guiding Principles and Future Directions

Members-Only Webinar

Thursday 6th April 2017

APACMed ASIA PACIFIC MEDICAL TECHNOLOGY ASSOCIATION

亚太医疗技术协会

APACMed Medical Device Registry Webinar Series: Introduction

- Second in a series of three webinars on this topic
  - WEBINAR One [1st March]: : *Introduction and Overview*
  - WEBINAR Two [***TODAY***]: *Medical Device Registry Guiding Principles*
  - WEBINAR Three [7th June]: *Future of Medical Device Registries*

- Webinar hosted by APACMed Medical/Clinical Affairs Committee

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Today's Agenda

- *Introduction*
- *Objectives of a Medical Device Registry*
- *Key Elements in the Development, Implementation and Maintenance of a Medical Device Registry*
  1. Scope and Objectives
  2. Governance
  3. Funding Mechanisms
  4. Data Quality and Protection
  5. Access and Transparency
  6. Infrastructure and Capabilities
  7. Jurisprudence and Regulatory Considerations
- *Audience Participation:* Question & Answer

Objectives of a Medical Device Registry

1. Improve patient care
2. Facilitate patient access to required diagnostics and therapies
3. Obtain local, credible and readily verifiable data
4. Evaluate the “real world” safety and/or effectiveness
5. Meet regulatory requirements
6. Reduce pre-and post-market requirements for data collection
7. Provide an accurate assessment in the comparative effectiveness of technologies
8. Develop additional hypotheses for future evaluation
9. Provide background relevant data
10. Accelerate reimbursement process for new technologies or procedures

Key Elements in the Development, Implementation and Maintenance of a Medical Device Registry

- Scope and Objectives
- Governance
- Funding Mechanisms
- Data Quality and Protection
- Access and Transparency
- Infrastructure and Capabilities
- Jurisprudence and Regulatory Considerations

Key Elements of a Medical Device Registry: Scope and Objectives

- What is within and what is beyond the scope of the proposed registry?
- Has a comprehensive evidence assessment been performed? Are there other ongoing investigational activities?
- Are there better alternatives?
- Will the data collected adequately answer the proposed research question?
- Will answering this question have a significant impact on health care delivery?
- Have data elements been incorporated that will allow for comparison across geographies?
- How could establishment of this registry affect new and/or innovative medical device therapy access for patients?

Key Elements of a Medical Device Registry: Governance

- A data governance committee should be established before registry initiation
- Appropriate quality assurance mechanisms should be mandated
- Develop a process for adverse event adjudication with pre-specified individuals who own the process
- Encourage participation from different relevant stakeholders
- Facilitate communication and collaboration with other national or international registries
- Leverage and welcome past/current registry experience from members
- Encourage inclusion of data elements that will allow comparison across geographies

Key Elements of a Medical Device Registry: Funding

- A sustainable long-term funding model is vital
- Funding should be shared across stakeholder groups whenever possible
- Responsibility for registry funding should not rest solely with one stakeholder group
- A funding model where a levy is paid by manufacturers for device registry participation will be difficult to implement across the wider Asia-Pacific and Middle East region

Key Elements of a Medical Device Registry: Facilitate Collection of Quality Data Metrics with Data Protection

- Collection of readily verifiable, reproducible data is vital in drawing accurate conclusions in any registry
- Data Quality metrics include : accuracy, completeness, relevance, reliability and consistency
- Use of universally validated scales and instruments are strongly recommended (SF36)
- Other factors to consider to achieve optimal quality data : Appropriate duration of follow-up, well-defined end-points, and strong methodology addressing potential biases/absent data

Collaborative stakeholder engagement will facilitate the robustness in data quality and the value of the registry

Key Elements of a Medical Device Registry: Guarantee Data Access, Data Sharing, and Transparent Reporting

- All stakeholders involved registry development, funding, and implementation should have access to : Published peer-reviewed registry data, key findings and annual registry reports.

- Key registry findings should be communicated in a timely manner to relevant stakeholders

Key Elements of a Medical Device Registry: Ensure Adequate Institutional Infrastructure and Capabilities

- There is an increased interest by multiple stakeholders to implement registries across Asia-Pacific and MENA
- At the same time there are significant gaps across the region in knowledge, resources, and institutional infrastructures to ensure adherence to ICH-GCP and ISO 14155 principles for medical device clinical activity
- For this reason APACMED support the development of self-sustaining, institutional capabilities via standardized educational certification programs covering the following aspects :
  - Evidence generation, data interpretation, and utilization
  - Medical device registry development, governance, implementation, and maintenance
  - Training on ICH-GCP/ISO 14155 practices to all interested participants
  - Addressing scope (limitations and benefits) of observational registry data
  - Developing mechanisms that closely monitor and minimize information bias and loss of enrolled subjects in registries

Key Elements of a Medical Device Registry: Jurisprudence and Regulatory Considerations

- APACMed/MTAA/Mecomed support the universally accepted legal and regulatory statutes with medical device registry implementation and maintenance that have been characterized by ICH-GCP/ISO 14155 and the Declaration of Helsinki.
- APACMed/MTAA/Mecomed consider that the following element may require additional focus in Asia Pacific :
  - Impact of the legal and privacy conditions when re-using previously collected data.
  - Assurance in protection of patient privacy.
  - Identification and embargo of confidential manufacturer, physician, and hospital data.
  - Reporting of adverse events. Registry inclusion does not nullify mandatory facility, physician or manufacturer reporting obligations as required under applicable laws or regulations.
  - Reporting of non-discoverable data (unpublished registry data) should not be used in legal proceedings.
  - Use of legally marketed medical devices for off-label indications.

QUESTIONS & ANSWERS

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APACMed Medical Device Registry Webinar Series: Next Steps

WEBINAR Three [7th June, 2017]

Future of Medical Device Registries

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