



Asia-Pacific Medical
Technology Association
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Consensus Statement on the Future of Medical Device Registries Across Asia-Pacific & Middle East-North Africa

A Report of the APACMed Medical and Clinical Affairs Committee

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We would like to thank AdvaMed and MedTech Europe for their excellent work on medical device registries, which served as a framework for our own, region specific paper.

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Preamble: Global Trends and the Potential Impact on the Asia-Pacific and Middle East-North Africa Medical Device Registry Landscape

Current global trends suggest that outcomes data from medical device registries will be increasingly scrutinized by governments as they endeavor to seek equipoise between expanding patient access to quality health care and maintaining federal budget neutrality. In Asia-Pacific, the growth of Health Technology Assessments (HTA) and requirements from regulatory authorities will progressively mandate local market-specific clinical data in informing regulatory approval, reimbursement, and coverage decisions. This has been identified as a clear and present trend by both the Regulatory Affairs Professionals Society (RAPS) and the International Society for Pharmacoeconomics and Outcomes Research (ISPOR). As is being observed in the United States with the recent passage of the Medicare Access and CHIP Reauthorization Act of 2015 (MACRA), public and governmental agencies in select markets across Asia-Pacific and Middle East could increasingly request that performance measures focus more on patient clinical outcomes, patient-reported symptoms, physical function, and quality of life.^{1,2} These patient centered outcomes research (PCOR) metrics could profoundly influence patient care paradigms in rapid fashion with real-time reporting (particularly with web-based registries) of actionable outcomes data metrics to clinicians, individual sites, and healthcare networks.³

The new standard from the Clinical Data Interchange Standards Consortium (CDISC) released in 2016 will help industry generate submissions for multiple, global clinical trial registries adjudicated by the World Health Organization (WHO), European Medicines Association (EMA) EudraCT Registry and United States ClinicalTrials.gov from a single file application.⁴ This call for standardization largely reflects the increased prevalence of transparent data sharing amongst multiple stakeholders across the globe. This has included recent efforts in the United States to enforce data sharing provisions recommended by the International Committee of Medical Journal Editors (ICMJE) which according to some legislators “has incredible potential to strengthen academic research, the practice of medicine, and the integrity of the clinical trial system”.⁵ As governments in Asia-Pacific/Middle East increase their own calls for mandated registries, it is highly plausible that risk-adjusted outcomes registry data and data from these other sources could provide a posteriori justification to realign payment incentives and reimbursement for medical device and diagnostic therapies.

This document was commissioned to provide a region-specific perspective on medical device registries from medical equipment, devices and in vitro diagnostics trade associations across Asia-Pacific and Middle East-North Africa (MENA). Due to region-specific considerations and capability gaps, it is our surmise that more support from commercial stakeholders might be required than has been traditionally observed in other regions of the world. The contents included herein characterize our perspective on the role of commercial stakeholders in supporting medical registry development, implementation and maintenance that espouses :

- 1) Appropriate governance
- 2) Acquisition of appropriate qualitative/quantitative outcomes data metrics and performance measures
- 3) Processes that focus on data quality
- 4) Implementation of quality gates for data entry and registry execution/maintenance
- 5) Appropriate data interpretation with adjudication by multiple stakeholders

The writing committee anticipates that this statement will prove valuable to providers, payers, patients, policy makers, and other interested stakeholders.

The Current State of Medical Device Registries in Asia-Pacific and MENA: An Evolving, Heterogeneous Landscape

APACMed/MTAA/Mecommed support principles of evidence-based healthcare that promotes health wellness. The wellness of populations across Asia-Pacific and the MENA depends on the adoption of effective decision-making paradigms that facilitate responsible therapy access in a timely manner. To that end, registries can serve as a compelling foundational tool in developing evidence-based paradigms for best medical practices, provide real-time actionable feedback to stakeholders (industry, hospitals, health care providers), and improve quality of care and outcomes.⁶

The US National Committee on Vital and Health Statistics defines a registry as “an organized system for the collection, storage, retrieval, analysis, and dissemination of information on individual persons who have either a particular disease, a condition (eg, a risk factor) that predisposes [them] to the occurrence of a health-related event, or prior exposure to substances (or circumstances) known or suspected to cause adverse health effects.”⁷ Well-designed and well-executed clinical registries provide insights into safety, clinical outcomes, comparative effectiveness, and cost effectiveness.⁸⁻¹⁰ The observational design of registries provides: a) Standardized information about a group of patients who share a condition or experience, b) Insights in the results of a therapy in real-world practice, and c) More representative quality-of-life information. It is for these reasons that clinical registries will play a paramount role in monitoring appropriate healthcare delivery across markets in Asia-Pacific, MENA, and worldwide.⁸⁻¹³

Non-clinical stakeholders/payers/insurers across Asia-Pacific are increasing evidence thresholds by ramping up requirements to generate real-world evidence, local clinical evidence, health economics and outcomes data to support claims and medical technology utilization. Local registries will provide this important information for patient decision making, possibly facilitating more effective payment and incentive strategies. As registries are generally observational rather than investigational (*vis-à-vis* randomized controlled trials), the focus of registries is on capturing data that reflect “real-world” clinical practice (following the standard of care) in local representative patient populations. Regulatory bodies across Asia-Pacific (i.e. People’s Republic of China) are increasingly mandating the need for local clinical data as a primary criterion for technology registration. Not surprisingly, reimbursement authorities are also increasingly mandating the need for local cost-effectiveness data in informing reimbursement and coverage decisions.

Globally, there is an increasing emphasis on measuring and improving the quality and efficiency of medical care. This has promulgated the proliferation of clinical registries designed to understand care and outcomes in “real-world” medical settings. In the United States, the Centers for Medicare and Medicaid Services introduced the concept of qualified clinical data registries into the Physician Quality Reporting System (PQRS) program.¹⁴ The PQRS program established stringent requirements for registry designation but also made it possible for qualified registries to develop their own performance metrics on the basis of clinically enriched data. These requirements and level of standardization are largely terra incognita across Asia-Pacific/Middle East, with significant complexity and market-specific variability. Moreover in contrast to what is observed in the United States and Europe, local medical professional societies in this region lack the necessary infrastructure and expertise to provide meaningful guidance and unbiased adjudication. Local registry implementation is further obfuscated with the increasing prevalence of web-based registries requiring additional specialized skillsets. Market-specific support from industry to help address these gaps might be necessary to facilitate standardization of processes that support acquisition and responsible interpretation of appropriate data metrics. Assistance in the development of these processes would ensure transparency and effect appropriate action when necessary.

Across Asia-Pacific and MENA, there are significant barriers to initiate a new registry. These include the need for dedicated (and experienced) full-time staff, software vendors, data warehouses, and analytical centers. In addition, registries must generally rely on significant support and involvement from medical professional societies and their physician leaders who help develop and periodically revise data elements and oversee registry operations. This required level of commitment from local professional societies is absent largely due to significant capability gaps. While local hospitals and governments may be willing to invest in medical device registries, significant deficits have been observed in the knowledge required to develop, implement, and maintain registry operations. Initial (and perhaps sustained) commercial support might be necessary to help collaboratively build these required capabilities.

Cost also remains a consequential barrier to the development and implementation of medical device registries in these markets. Although there is an initial upfront cost, efficiently executed clinical registries can become self-sustaining over time. Submitting data to registries is in itself associated with a real cost to medical centers and practices, requiring physician leaders to advocate for additional funding to support registry efforts. In this context, financial support required for registry development and ongoing operation is a significant consideration across Asia-Pacific, Middle East, and Africa. This will increasingly necessitate consideration of alternative funding mechanisms that hitherto may not have been considered viable options. Additional government or commercial support for both nascent and established medical device registries would be invaluable. This market-specific injection of capital could expedite participation eventually culminating in a self-sustaining registry.

Guiding Principles and Future Directions in the Development, Implementation, and Maintenance of a Medical Device Registry in Asia-Pacific and MENA

APACMed/MTAA/Mecommed believe that these region-specific gaps in registry development and implementation may represent opportunities to strengthen public-private collaborative partnerships. The hope of these collaborative partnerships would be to :

- 1) Provide adjunctive support and guidance with registry governance, 2) Facilitate government body ownership and adjudication, 3) Provide a framework that ensures standardized collection and responsible interpretation of appropriate data elements, 4) Provide educational support to clinical and non-clinical stakeholders in evidence generation and registry management that is congruent with good clinical practice (ICH-GCP/ISO 14155) standards and the Declaration of Helsinki.¹⁵⁻¹⁷ The contents included below are in acquiescence and provide guidance with universally accepted principles in medical device registry development and implementation.

A) Objectives of Medical Device Registries:

1. Improve patient care by providing granularity in the outcomes of medical device technologies, health care professionals, facilities, and care pathways.
2. Facilitate patient access to required diagnostics and therapies by collecting actionable data elements to support regulatory and reimbursement dossiers.
3. Obtain local, credible and readily verifiable data to support coverage decisions and the development of value messaging tools.
4. Evaluate the “real world” safety and/or effectiveness of medical technologies beyond investigational, randomized controlled clinical trials or other clinical study paradigms.
5. Meet regulatory requirements for post-market data surveillance.
6. Reduce pre-and post-market requirements for data collection by providing regulators with an alternative method for medical device performance surveillance.
7. Provide an accurate assessment in the comparative effectiveness of different medical technologies for a given disease state.
8. Develop additional hypotheses for future evaluation in investigational, controlled medical device trials.
9. Provide background relevant data in the development or assessment of patient care guidelines that characterize best clinical practices for specific disease states.
10. Accelerate reimbursement process to new technologies or procedures by addressing specific questions that remain unanswered by existing evidence during a comprehensive health technology assessment.

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

The following seven key elements should be considered in medical device registry development, implementation, and maintenance:

1. SCOPE AND OBJECTIVES: Clarify scope and clearly define objectives
2. GOVERNANCE: Establish appropriate governance
3. FUNDING MECHANISMS: Ensure fair and transparent funding amongst all stakeholders

4. **QUALITY AND PROTECTION:** Facilitate collection of quality data metrics with data protection and embrace novel, standardized collection platforms intended for harmonization
5. **ACCESS AND TRANSPARENCY:** Guarantee data access, data sharing, and transparent reporting
6. **INFRASTRUCTURE AND CAPABILITIES:** Ensure adequate institutional infrastructure and capabilities
7. **JURISPRUDENCE AND REGULATORY CONSIDERATIONS**

1. Clarify scope and clearly define objectives

As there are some inherent limitations in interpretation of registry data, a well-defined scope is of paramount importance in registry development. A scope too broad might not sufficiently address current evidence gaps. A scope too narrow might preclude ongoing, future investigative endeavor of newly observed, evolving evidence gaps. The high level of required investment (in terms of funding, time, and resources) to establish and operate a registry necessitates clearly defined objectives designed to sufficiently address the observed gap(s) in evidence.

As acquisition of quality data metrics can be costly and time-consuming for healthcare professionals, registries should only be established when the public health value and benefit of the data can be unequivocally demonstrated. If adequate information related to the question is available from other sources or if there is no clear and specific research question, establishing a registry should be questioned.

CONSIDERATIONS:

We would encourage stakeholders to consider the following with registry development:¹⁸

- What is within and what is beyond the scope of the proposed registry?
- Has a comprehensive evidence assessment been performed from other external sources to ensure that the collected registry data is clinically relevant and meaningful? Are there other ongoing investigational activities with a similar defined scope?
- Are there better alternatives to go about the proposed investigation?
- Will the data collected adequately answer the proposed research question?
- Will answering this question have a significant impact on health care delivery (or therapy access) to justify the required investment in the registry?
- Have data elements been incorporated that will allow for comparison across geographies with other existing clinical research data?
- How could establishment of this registry affect new and/or innovative medical device therapy access for patients and overall utilization in other disease states?

2. Establish appropriate governance

Establishing appropriate governance processes is absolutely essential in the development and responsible implementation of medical device registries. An experienced and qualified coordinator or steering committee should be appointed/established that acquiesce to universally accepted GCP principles and behaviors. Stakeholders involved in registry governance should follow transparent procedures and embrace constructive, respectful dialogue to facilitate collaboration. To that end, special provisions should be well characterized on how and who can change the data generated to preclude unauthorized data manipulation. These provisions should be strictly adhered to and advocated by the governing body. Involvement of multiple parties (including public entities) in the governance body with implementation of robust processes will buttress strong governance and contribute to the quality and objectivity of the registry.

CONSIDERATIONS:

When establishing a governance body for medical device registries, we would encourage relevant stakeholders to implement the following considerations:

- Before initiation of the registry and patient enrollment, a data governance committee should be established. This committee should be tasked with developing written procedures for ownership, access, analysis and interpretation of data.
- Appropriate quality assurance mechanisms (including periodic auditing) should be mandated.
- Develop a process for adverse event adjudication, with pre-specified individuals who own the process. Implementation of diligence mechanisms must be a top priority.
- Encourage participation from different relevant stakeholders .
- Facilitate communication and collaboration with other national or international registries with a similar, defined scope and research question.
- Leverage and welcome past/current registry experience from members of the governing body.
- Encourage inclusion of data elements that will allow for comparison across geographies with other existing clinical research data.

3. Ensure fair and transparent funding amongst all the stakeholders

Funding and in-kind support is a fundamental issue that should be managed and agreed upon early in the registry development process. All potential future sponsors should be included early in the process to define all the relevant parameters. Registries funded by a single stakeholder tend to be considered as having inherent bias by public and other non-industry stakeholders. Multiple stakeholders will typically have an interest in the creation of registries that engender actionable data metrics. Funding or contribution to the registry may be a pre-requisite for access to predefined data sets. Funding allocation should ideally be proportionate to the research question and value received from the registry for each stakeholder.

Assurances should be in place requiring sustainable funding through the duration of the proposed registry: From development and implementation to maintenance of the registry. Importantly, a registry should be periodically re-evaluated to ensure that its original intended scope is being adequately addressed.

CONSIDERATIONS:

When ensuring sustainability and transparency of funding mechanisms through the course of a proposed medical device registry, we would encourage relevant stakeholders to consider the following:

- A sustainable long-term funding model is vital to the success of any registry. Whenever possible, funding should be shared across those stakeholder groups that realize cost and/or quality benefits related to the work of a registry.
- Responsibility for registry funding should not rest solely with one stakeholder group, rather the model utilized should provide for multiple funding sources including (but not limited to) governments agencies, private health insurers, professional groups, manufacturers, and other invested parties.
- A funding model that has been employed in developed, reimbursed markets where a levy is paid by manufacturers for device registry participation (i.e. Australia) will be difficult to implement across the wider Asia-Pacific and Middle East region as many of these other markets are unreimbursed, price-sensitive, 'patient pay' markets.

4. Facilitate collection of quality data metrics with data protection and embrace potential novel, standardized collection platforms intended for harmonization

Clarifying the scope and clearly defining the objectives of a registry provide the critical framework necessary to determine relevant, market-appropriate quantitative and qualitative outcomes data metrics that are in acquiescence with market-specific requirements. The degree of granularity desired will depend on the objectives that are to be addressed. Collection of readily verifiable, reproducible data (quality data metrics) is vital in drawing accurate conclusions in any registry. Aspects of data quality metrics include accuracy, completeness, relevance, reliability and consistency. Use of universally validated scales and instruments (i.e. quality of life questionnaires such as SF-36, socioeconomic assessments, etc.) should be encouraged to permit relative comparisons across markets.¹⁹ Collaborative stakeholder engagement and use of validated instruments will facilitate the robustness in data quality and the value of the registry to the global evidence base for that specific disease state.

Other factors to consider to achieve an optimal quality data set include (but is not limited to): Appropriate duration of follow-up, well-defined end-points, and strong methodology addressing potential biases/absent data. Collaborative stakeholder engagement is vital in this process. For instance, in medical device registries, the data obtained characterizing implant outcomes should include procedural technique, operator and hospital/site outcomes. This level of granularity would allow individual stakeholders to interpret relevant data and make accurate surveillance assessments of a vendor-specific device, overall therapy, or procedural implant technique for a given disease state.

The registry should implement robust quality gates with a pre-defined data management plan that expedites real-time monitoring of data quality for the duration of the registry. This consideration is particularly cogent with the emergence of web-based registries. While we support the use of contemporary information technology platforms (recognizing the gained efficiencies), mechanisms must be in place that ensure data protection and patient confidentiality.

A new standard known as the Clinical Trial Registry (CTR- XML) from the Clinical Data Interchange Standards Consortium (CDISC) released in 2016 will help commercial entities generate submissions for multiple, global clinical trial registries adjudicated by the World Health Organization (WHO), European Medicines Association (EMA) EudraCT Registry and United States ClinicalTrials.gov from a single file application.⁴ This call for standardization largely reflects the increased prevalence of transparent data sharing amongst multiple stakeholders across the globe. CTR-XML will help firms harmonize messages to international registries. Technology vendors will be able to support a "write once, use many times" tool based on a single XML file. The standard is based upon the common elements mapped between the registries, which are based upon the 20-item WHO Trial Registration Data Set.²⁰

At the time of this publication, CDISC is planning for CTR2 which will include: Registration & Results, Protocol and IDMP compliance components. The focus of CTR2 will shift to fully structured protocol and results summary elements requiring the development of an updated protocol standard

To ensure global regulatory compliance, CTR2 will also map to the ISO IDMP Standards (Identification of Medicinal Products) introducing a greater level granularity with specific medical technologies to facilitate the traceability of registry information.⁴

CONSIDERATIONS:

- Use appropriate statistical techniques to mitigate confounding.
- Ensure standardized mechanisms are in place that enroll and follow patients systematically.
- Implement zero-tolerance processes that ensure patient confidentiality.
- Develop methodological guidance to facilitate the collection of reproducibly verifiable high quality outcomes data metrics (with the appropriate level of granularity) that contribute to the global evidence base.
- Conduct in-depth agile, real-time risk analysis strategies that assess the registry's ability to obtain required quality data metrics. This is particularly important with web-based registries.
- Leverage past and current experience/expertise from multiple stakeholders when determining appropriate quality data metrics.
- Develop an automated data quality assurance system to verify adherence to accepted, best practices.

5. Guarantee data access, data sharing, and transparent reporting

Published peer-reviewed registry data, key findings and annual registry reports should be readily accessible to stakeholders intimately involved with registry development, funding, and implementation. Recent efforts by the International Committee of Medical Journal Editors (ICMJE) have supported data sharing. Many politicians, including U.S. Senator Elizabeth Warren, have extolled the virtues of these new requirements stating, "Compliance with the more rigorous ICMJE requirements, though it will not automatically harmonize existing regulations, could nonetheless create a baseline expectation that data will be shared and prepare researchers to comply with other mandates."⁵

To that end, we strongly support data sharing with open and transparent access to registry data for all stakeholders in the Asia-Pacific and MENA region. In the spirit of transparent reporting, key registry findings should be communicated in a timely manner to relevant stakeholders. Communication of these findings at scientific congresses provides relevant feedback to the medical community and supports the importance and relevance of the specific registry: Facilitating acceptance and participation.

CONSIDERATIONS:

- Assess and comprehensively report the extent of missing data.
- Use sensitivity analyses to determine the impact of major decision/key assumptions on the research assumptions.
- To ensure transparency and due diligence, policies should be implemented that support the use and publication of registry data by multiple stakeholders and "outside registry" data users. These policies should ensure appropriate transparency.
- All stakeholders intimately involved with either registry development, funding or implementation should have complete, open registry data access.
- Develop processes that reflect best practices by providing clear definitions, transparent explanations and methodologies with data collection.
- Establish clear roles regarding access to data for different users (primary users, secondary users).
- Develop a stakeholder-specific publication strategy that addresses relevant registry objectives.
- Endeavor to publish an online annual report, preferably including a patient-specific summary.
- Government agencies should seek counsel from and share relevant information with specific stakeholders prior to taking any action based upon any available registry data.²¹
- Establish a process for data requests.

6. Ensure adequate institutional infrastructure and capabilities

There is an increased interest by multiple stakeholders to implement registries across Asia-Pacific and MENA. While we fully support this activity, 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. As such we fully support the development of self-sustaining, institutional capabilities via standardized educational certification programs. These educational programs should address the following observed region-specific technical gaps: 1) Study Design and Protocol Development, 2) Data Management, 3) Statistical Analysis, 4) Records Retention and Periodic Reporting Requirements, 5) Audit/Inspection Readiness.

We recommend the following aspects be considered for educational programs that develop self-sustaining capabilities AND institutional memories to all relevant stakeholders:

- 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

7. Jurisprudence and Regulatory considerations

There are 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.¹⁵ APACMed/MTAA/Mecommed fully support these articles and feel specific aspects in Asia-Pacific and MENA might require additional focus. This includes (but is not limited to):

- 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. In unique circumstances, health care professionals may exercise their medical judgment and use legally marketed medical technologies for off-label indications. The collection of off-label use data does not represent off-label promotion by the medical technology manufacturer and might more accurately reflect “real world” evidence.²¹

C) Future Directions of Medical Device Registries in Asia-Pacific and MENA

1. Unique Device Identifiers

In 2015, the United States Food and Drug Agency issued draft guidance requiring medical device manufacturers to establish unique device identifiers (UDIs) for their technologies.²² While a similar request has not been mandated by many regulatory agencies in markets across Asia-Pacific and Middle East, APACMed/MTAA/Mecommed are aligned with the notion that UDIs would provide the granularity necessary to definitively assess device performance.

As this is not currently mandated in this region, we feel that incorporation of specific data elements (knowledge of the specific device model and serial number, the manufacturing site, the lot, operator/surgeon, site/hospital) in a registry would provide greater transparency in real-time surveillance of device, operator, and site performance. At present, we strongly advocate incorporation of these data elements in all medical device registries when possible.

2. The Emergence of Web-Based Registries

Online registry platforms allow for the collection of large pools of data across vast geographies. The traditional advantage of this platform was monitoring low prevalence disease states. However, these platforms are increasingly being utilized for other applications as they allow for rapid analysis of large pools of data while effectively monitoring trends permitting constant vigilance. A key point of consideration is ensuring that the software used is compliant with adequate patient privacy and data security mechanisms in place. Publication cadence from web-based disease-state registries in Asia-Pacific and Middle East has started increasing over the past few years. In fact, Asia-Pacific and MENA combined have produced more web-based publications than the United States.

3. Traditional registries versus web-based registries

Advantages of a web-based registry compared with a traditional registry (document-based):

- Provides better quality real world clinical evidence (compared with a claims database) at a lower cost (compared with investigative clinical research)

- Provides an early warning system in real-time for outcome trending analysis (versus waiting for presentation or publication of data) allowing for constant vigilance and surveillance
- An online platform has the ability to capture a sufficiently large patient population and large data pool of rare disease states over large geographies
- More quickly create actionable information

4. Web-based registry publications across the globe

A. Publication of web-based registry studies by country

Web-based registry publications predominantly originate from the United States (7). However, both Asia-Pacific and Middle East come in tied for a close second (each with 5 total web-based registries).

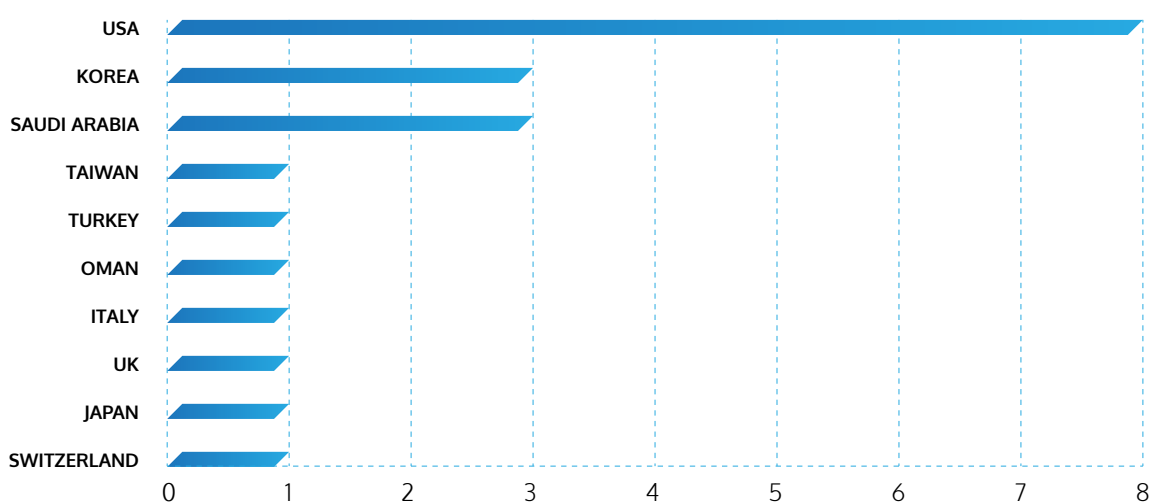


Figure 1 Number of publications of web-based registries by country

B. Publication of web-based registry studies by year

Since 2002, web-based registry publications have been on the rise.

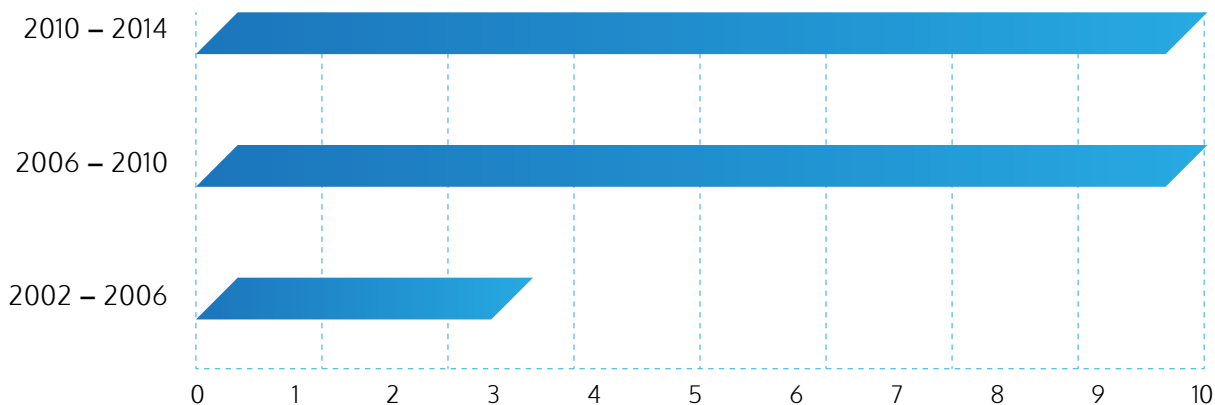


Figure 2 Number of publications of web-based registry by year

C. Publication distribution between disease registry and device registry

Disease (not Device) web-based registry publications comprise the majority of publications (96%).

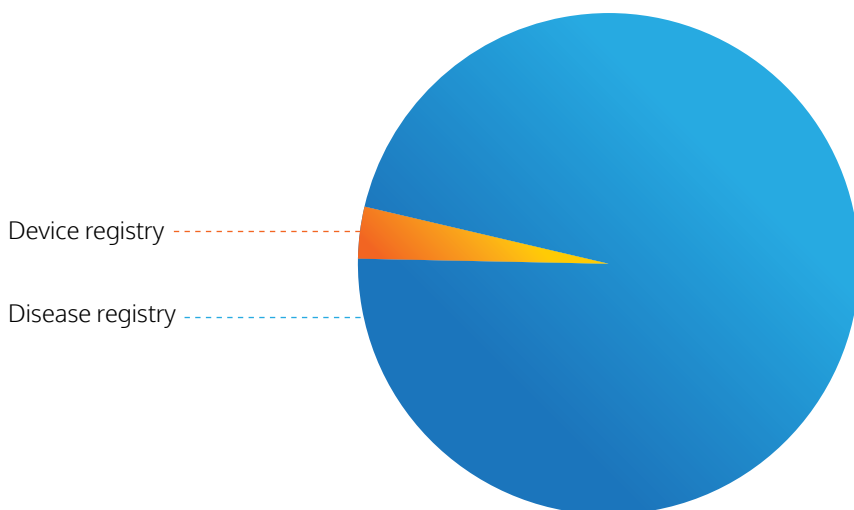


Figure 3
Distribution of disease registry vs. device registry

Summary

APACMed/MTAA/Mecommed support principles of evidence-based healthcare. Market-specific, readily verifiable, credible data elements acquired from medical device registries will be increasingly scrutinized and utilized by governments across Asia-Pacific and MENA in informing regulatory approval, reimbursement, and coverage decisions. With the increased prevalence of transparent data sharing amongst multiple stakeholders across the globe, it is highly plausible that risk-adjusted outcomes registry data and data from other sources could realign payment incentives and reimbursement for medical device and diagnostic therapies. Due to region-specific considerations and capability gaps, more support from commercial stakeholders might be required than has been traditionally observed in other regions of the world. APACMed/MTAA/Mecommed will continue to work with all relevant stakeholders to support the development, implementation, and maintenance of medical device registries critical to determining therapy access for patients.

Appendix

1. Definitions of Registries

AHRQ

Registries for Evaluating Patient Outcomes: A User's Guide [Internet]. 3rd edition. Gliklich RE, Dreyer NA, Leavy MB, editors. Rockville (MD): Agency for Healthcare Research and Quality (US); 2014 Apr.

A patient registry is an organized system that uses observational study methods to collect uniform data (clinical and other) to evaluate specified outcomes for a population defined by a particular disease, condition, or exposure, and that serves one or more predetermined scientific, clinical, or policy purposes.

A registry database is a file (or files) derived from the registry. Registries are classified according to how their populations are defined. For example, product registries include patients who have been exposed to biopharmaceutical products or medical devices. Health services registries consist of patients who have had a common procedure, clinical encounter, or hospitalization. Disease or condition registries are defined by patients having the same diagnosis, such as cystic fibrosis or heart failure.

International Medical Device Regulators Forum

“An organized system with a primary aim to improve the quality of care that uses observational study methods to collect relevant data and evaluate outcomes relevant to patients, and, comprehensively covers the population defined by exposure to particular device(s) at a reasonable generalizable scale (national, regional or health system)”.

European Medicines Agency

Patient registries are organized systems that use observational methods to collect uniform data on a population defined by a particular disease, condition, or exposure, and that is followed over time.


http://www.ema.europa.eu/ema/index.jsp?curl=pages/regulation/general/general_content_000658.jsp&mid=WC0b01ac0580961211

2. Registries and Post-Market Studies: Similarities and Differences

Registry	Post-market study
1 An organized system to collect uniform data (clinical and other).	An organized project / plan to collect uniform data (clinical and other).
2 Include everyone (where possible) having the defined disease, condition, or exposure where there is very few (if any) selection criteria); criteria are set at the study level.	Include participants that satisfied a more narrow set of eligibility criteria.
3 Several independent studies may be planned or organized around the dataset available.	Single study with limited scope to expand beyond the study itself.
4 Focus is on the patients and usually non-product specific.	Focus is usually on specific products or a much more narrow target scope.
5 Large dataset (sample size) collected over a long period of time and may not have an end date.	Smaller dataset with defined end date.
6 Typically funded by non-commercial entities.	Funded by both commercial and non-commercial entities.
7 Always an observational study design.	Use observational or interventional study design. Not all observational studies are registry studies.
8 Registry study can be considered a post-market study.	Post-market study includes but not limited to registry study.

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