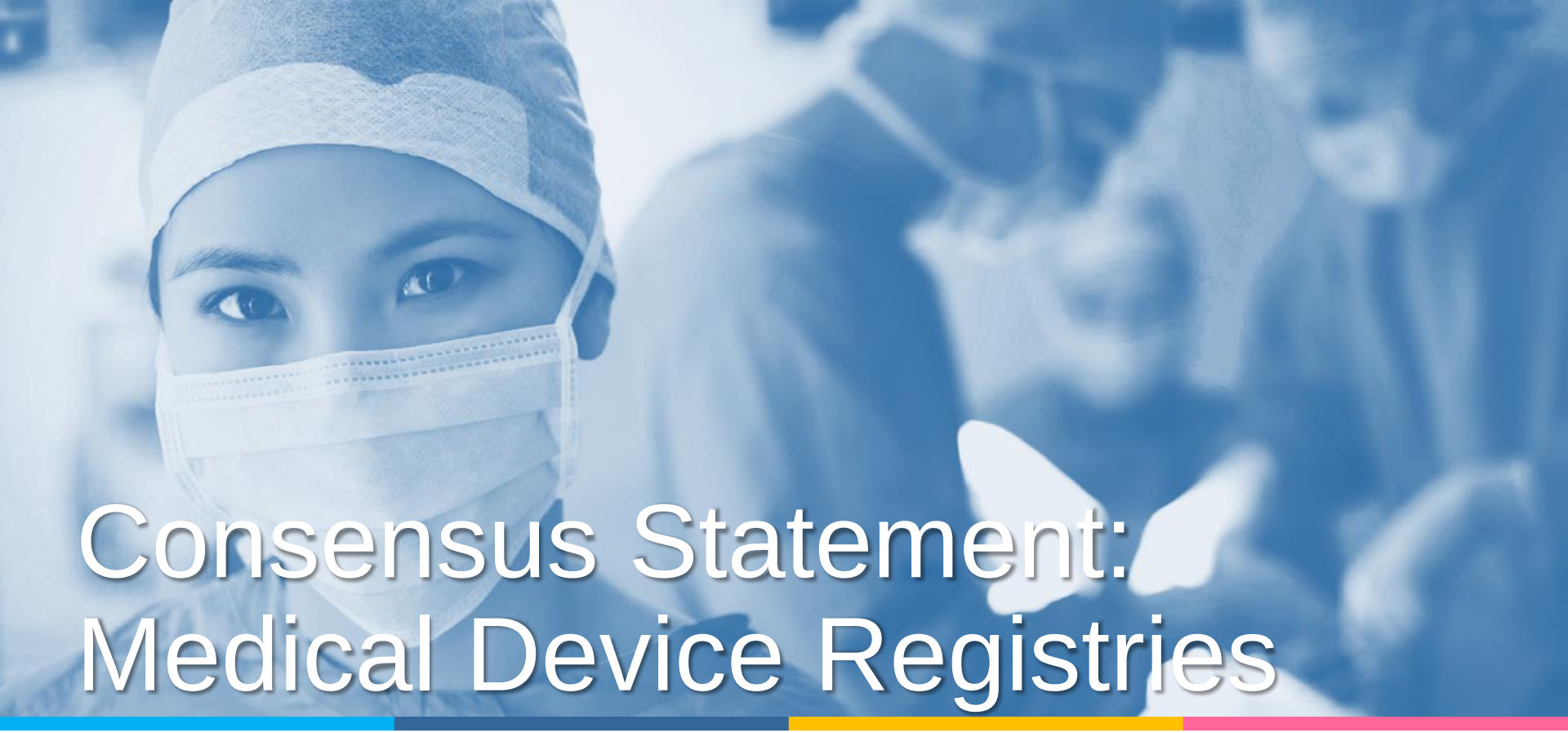

Consensus Statement: Medical Device Registries

Members-Only Webinar

Wednesday 1st March 2017

APACMed ASIA PACIFIC MEDICAL TECHNOLOGY ASSOCIATION

亚太医疗技术协会

APACMed Medical Device Registry Webinar Series: Introduction

- First in a series of three webinars on this topic
  - WEBINAR One: *Introduction and Overview*
  - WEBINAR Two [6th April]: *Medical Device Registry Guiding Principles*
  - WEBINAR Three [7th June]: *Future of Medical Device Registries*

- Webinar hosted by APACMed Medical/Clinical Affairs Committee

- **Amit J. Shanker, MD, FACC, FHRS**
  Chair, APACMed Medical Affairs Committee
  Chief Medical Officer, Boston Scientific
  Asia, Australia, Middle East and Africa
- **Laurent Metz, MD, MBA**
  Vice-Chair, APACMed Medical Affairs Committee
  HEMA CoE Lead, Medical Devices Asia Pacific, Johnson & Johnson Medical Asia Pacific

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Today's Agenda

- ***Introduction***
  - What is a Medical Device Registry?
  - Overview of Medical Device Registries across the world
  - Why will Medical Device Registries become more important in our region?
- ***Value of the Consensus Statement***
  - Why do we need a Consensus Statement?
  - Region-specific considerations mandating the need for a Consensus Statement
- ***Implementation***
  - How can our members use this Consensus Statement?
  - Next steps
- ***Audience Participation:*** Question & Answer

Medical Device Registries

- Official definition from world health agencies
- How do registries differ from a defined clinical study?

	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.

Clinical Registries

A Clinical Registry is an organized system for the collection, storage, retrieval, analysis, and dissemination of information on individual persons*

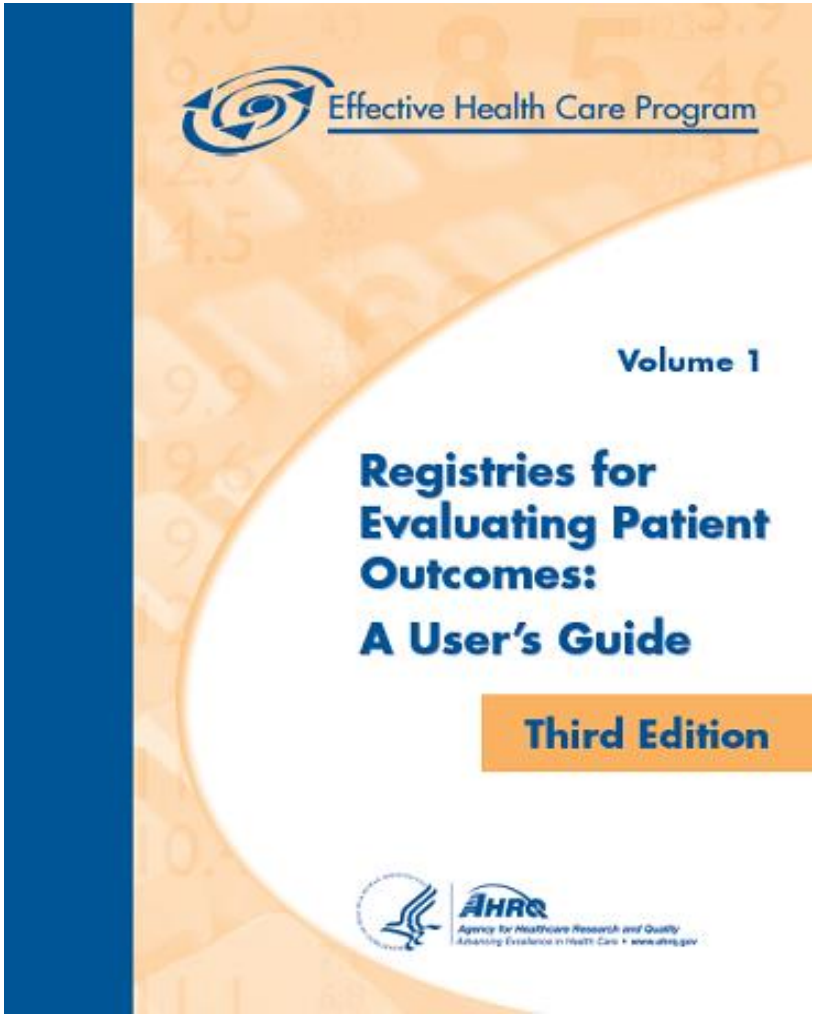
Well-designed and well-executed clinical registries provide insights into safety, clinical outcomes, comparative effectiveness, and cost effectiveness.

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*



Source: http://effectivehealthcare.ahrq.gov
Definition: The US National Committee on Vital and Health Statistics

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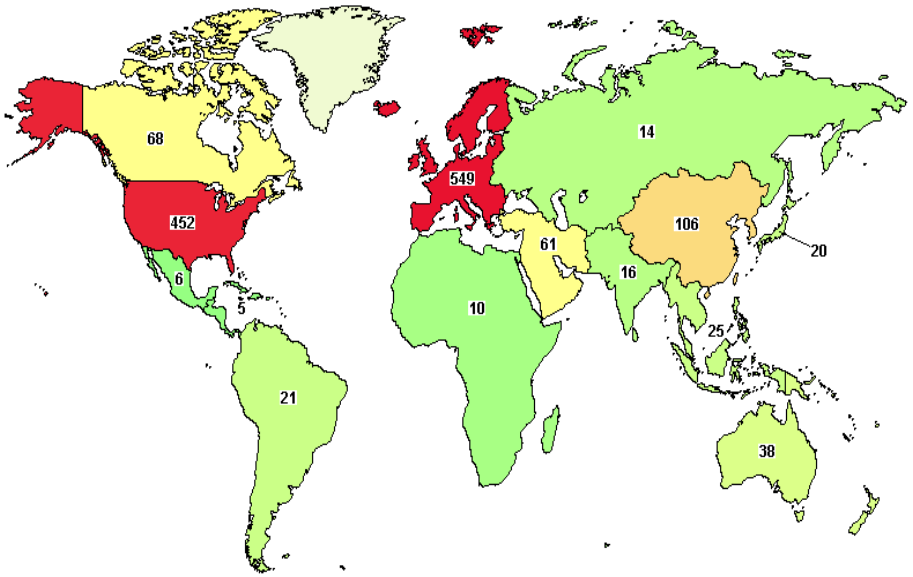
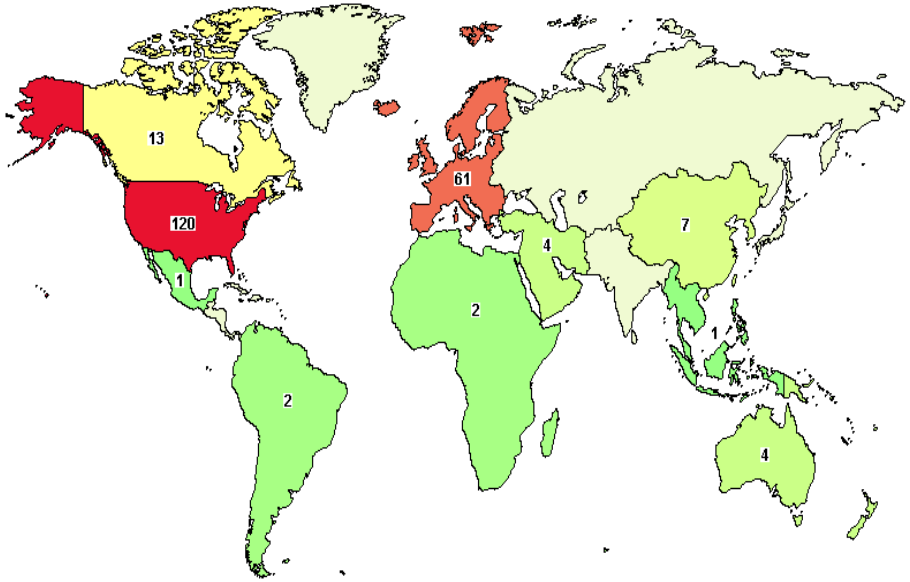
Medical Device Registries: A Growing Footprint Across Asia-Pacific and MENA

- Current Worldwide Prevalence: Increasing evidence barriers in emerging markets will require local, real-world evidence focused on cost-effectiveness.
- Emerging Markets: Balance between budget neutrality and expanding patient access to therapies.

CARDIOVASCULAR REGISTRIES: 1301



ORTHOPEDIC REGISTRIES: 204



Clinical Registries: Key Objectives

- Improve patient care by providing granularity in the outcomes of medical device technologies: Impact on best practices with health care professionals, and on facility care pathways.

- Facilitate patient access to technology/therapy adoption: Regulatory, reimbursement dossiers and buttress informed coverage decisions.

- Evaluate the "real world" safety and/or effectiveness of medical technologies beyond randomized controlled clinical trials or other clinical study paradigms.

- Meet regulatory requirements for post-market data surveillance as a quality gate as regards patient safety.

Medical Device Registries: Objectives

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 (level of evidence procedural indications or appropriate use criteria) that characterize best clinical practices for specific disease states.

***Source*: http://effectivehealthcare.ahrq.gov**

Asia-Pacific/MENA-Specific Considerations Mandating Need for a Device Registry Consensus Document

- Increasing ***local*** evidence thresholds to inform regulatory and/or reimbursement decisions by governments.
- Recognition by authorities for need to capture local data that accurately reflects region/country-specific disease prevalence, and anatomic/physiologic population-specific variation.
- Address region-specific capability gaps in medical device registry development, implementation, and maintenance.
- Advocate for and implement a consistent standard in medical device registry governance and acquisition of quality of data.

Addressing the Region-Specific Paradigm Shift in Local Evidence Thresholds

- APACMed/MTAA/Mecomed support principles of evidence-based medicine that support medical technology access to patients.
- Provide a perspective on evolving region-specific geopolitical trends in healthcare utilization that support a growing paramount role for Medical Devices Registries in our region.
- To characterize elements critical to the development, implementation, and maintenance of medical device registries (concordant with ISO-14155 GCP): Ensure appropriate adjudication of quality data by providers, payers, patients, policymakers and other interested stakeholders.
- Serve as a regional reference standard for all stakeholders to ensure uniformity and agreement with best practices.

*How to Leverage this Consensus Statement with **Internal** Stakeholders*

- Increase Awareness in your Firm of Registries as being an evolving critical component to "Market Access" Strategy in our Region

  Broad Audience: RA, MA, Clinical, HE&R, Senior Leadership Team

- Position the Consensus Statement as a Reference Guide to appropriate internal stakeholders involved in Clinical Strategy

- Educate Appropriate Internal Functions with this Webinar Conference Series

*How to Leverage this Consensus Statement with **External** Stakeholders*

- **<u>Facilitate the development of evidence to support our technologies</u>**
  - Registries data will facilitate patient's access to new technologies
- **<u>Engage with Policy Makers</u>**
  - Position the Consensus Statement as a Reference Guide to Policy Makers to shape a more equitable and standardized environment for Medical Device Registry.
  - Educate Appropriate Policy Makers who have limited experience with Medical Device and Diagnostics with this Webinar Conference Series.
- **<u>Educate Clinical Stakeholders</u>**
  - Medical Professional Societies and/or Health Care Professionals who have Limited Experience in Registry Development, Implementation, and Maintenance.

QUESTIONS & ANSWERS

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APACMed Medical Device Registry Webinar Series: Next Steps

WEBINAR Two [6th April, 2017]

Medical Device Registry Guiding Principles

WEBINAR Three [7th June, 2017]

Future of Medical Device Registries

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