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Agenda of the novel Special Interest Group for Medical Devices: Finding Similarity within Diversity

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SIG Medical Devices

Introduction

There are **fundamental differences** in the scientific, clinical, and regulatory aspects of the development of **medical devices relative to drugs and biologics**.

The **Special Interest Group for Medical Devices (SIG MedDev)** was formed as part of the PSI and EFSPI organizations in **December 2025** to study the implications of these differences for the **application of statistical methods**. The working group comprises **12 members from 12 organizations** representing (small & large) medical device manufacturers, contract research organizations, notified bodies, and regulators, at present.

So far, the group has identified the following high-impact **topics of interest** with special relevance for medical devices.

Motivation

SCIENTIFIC PERSPECTIVE

- **Comprehensive health model of patient:** anatomical, physiological, biochemical, psychological, social, functional
- **Broad range of mechanisms of action (Figure 1)**
  - Primary: mechanical and electronic
  - Secondary: chemical, biological, psychosocial, functional
- **Difference to Drugs & Biologics:** mechanical and electronic aspects, eg (long-term) permanence and performance
- **Challenges:**
  - Understanding of domain-specific mechanisms of action
  - Application of domain-specific endpoints

CLINICAL PERSPECTIVE

- **Intended Use & Context of Use is essential (Figure 2)**
- **Performance of a medical device as combined effect** of device, procedure, user (eg patient or clinician) (**Figure 2**)
- **Difference to Drugs & Biologics:** Effects of clinician/procedure (eg learning) and patient/application (eg usability)
- **Challenges:**
  - Selection of context of use and intended use
  - Definition of estimands (cf, difficulty of blinding!)
  - Separation of the contribution of components (eg, effects of medical device, clinician/procedure, and patient/application).

STATISTICAL PERSPECTIVE

- **Same basic principles and methods**
- **Difference to Drugs & Biologics:**
  - Different objectives and applicable standards for required evidence, ie for study design and statistical analysis
  - Challenges in controlling or modelling effects of medical device (version), clinician/procedure (eg learning, expectation), patient/application (eg cognitive skills, expectation) in small sample sizes
- **Challenges:**
  - Meet expectations by various Notified Bodies & regulators within constraints by sponsors while using optimal statistical methods
  - Blinding of patients, operator and assessor

REGULATORY PERSPECTIVE

- **Interpretation of (inter)national regulations and standards**
- **Difference to Drugs & Biologics:**
  - Regulatory framework (eg ISO standards, MDR regulation)
  - Notified Bodies
  - Role of device class, development stage, & target audience
  - Pathways to market access & reimbursement
- **Challenges:**
  - Application of a consistent, pragmatic regulatory strategy to all aspects of a clinical trial following (inter)national regulations
  - Application of (inter)national regulations for specific technologies, eg Bayesian Statistics, Machine Learning, Artificial Intelligence

Topics of Interest

SCIENTIFIC TOPICS

- Selection of **domain-specific primary endpoints** for technical performance, clinical effectiveness, and clinical safety
- Selection of methods to study **hybrid treatments** combining medical devices with drugs or biologics, eg drug-device combination (DDC) products

CLINICAL TOPICS

- **Estimand Framework** (ICH E9 R1, 2020)
  - Major impact on the development of drugs and biologics
  - Adoption and adaptation of the estimand framework for medical devices in ISO14155 (March 2026) are expected to provide similar benefits in terms of clarity, consistency, and quality, eg:
    - Selection of comparators for medical devices
    - Definition of device-specific intercurrent events & strategies

Figure 1: Overview of Medical Device Categories

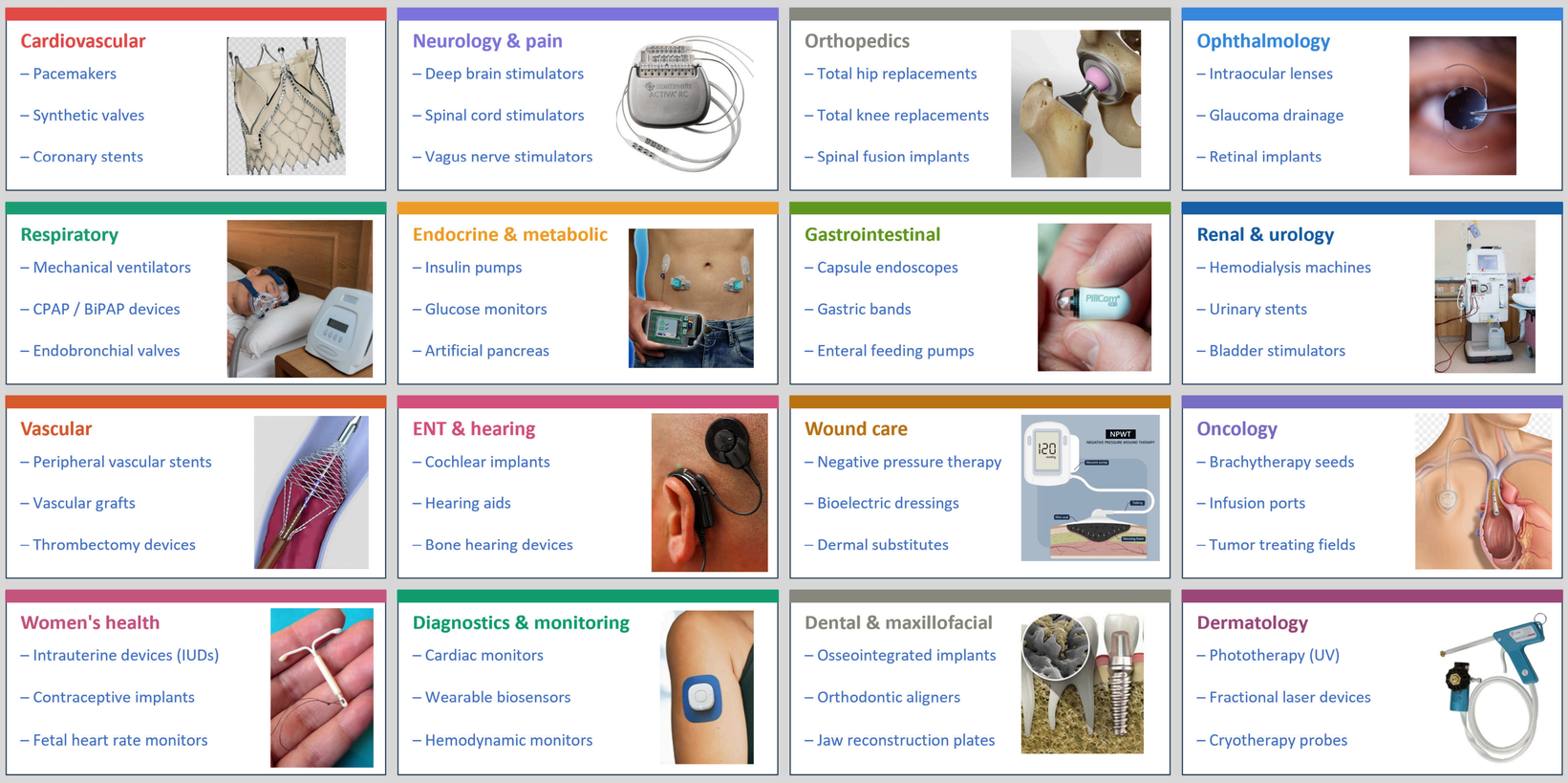
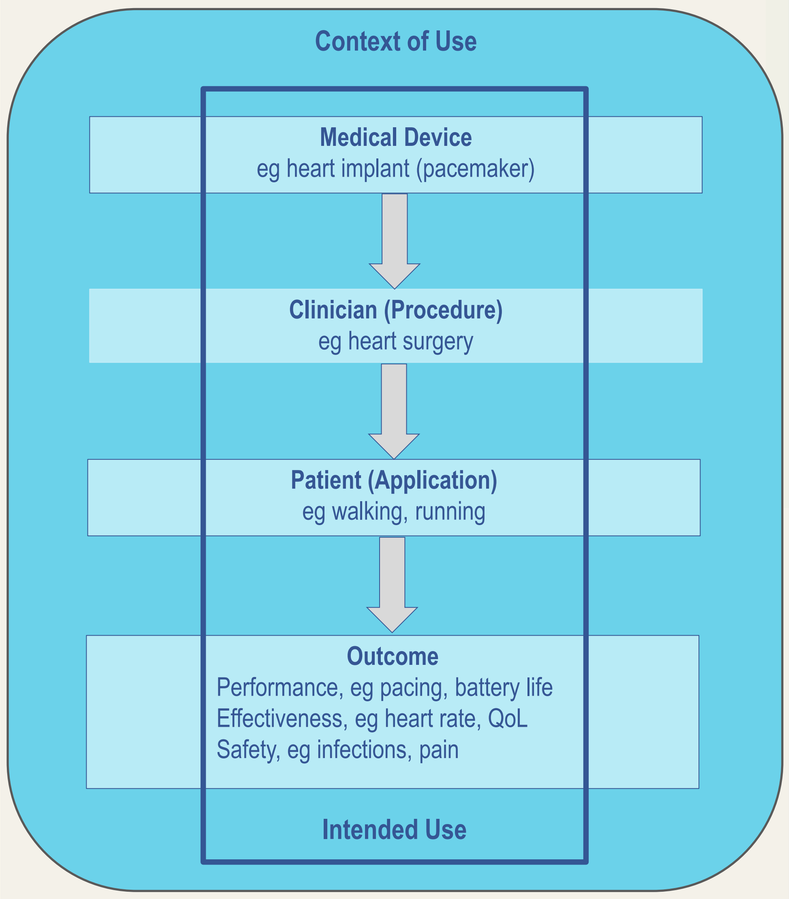


Figure 2: Conceptual Model for Medical Devices



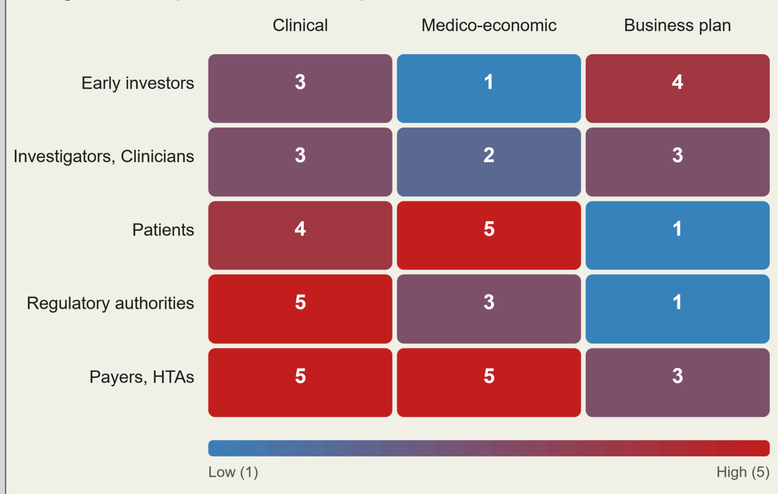
STATISTICAL TOPICS

- **Selection of study design and analysis to meet specific evidence requirements** by various decision makers, eg for patients, sample size, operating characteristics (**Figure 3**)
- **Modelling of domain-specific variables** regarding their specific statistical properties, eg distribution, relationship, or causal role
- **Separation of contribution of components** (incl. interactions)
- **Integration of prior knowledge**, esp. from previous device versions (eg modelling real-world data or historical studies using Bayesian analysis)
- **Integration of advanced statistical and data science methods** (eg Bayesian Statistics, Machine Learning, Artificial Intelligence)
- **Clinical Outcome Assessments** (incl. patient-reported outcomes & experiences, clinician-reported outcomes), eg on learning & usability

REGULATORY TOPICS

- Identification of **common & specific requirements** depending on:
  - Development stage (pilot, pivotal)
  - Device class (I, II, III)
- **Regional legislations and institutions**, eg:
  - CE marking under MDR (EU) 2017/745 by Notified Bodies in the EU, eg clinical evaluation and post-market clinical follow-up plan
  - 510(k) clearance, De Novo grant, or PMA approval by the FDA in the USA, ie evidence expectations depend on whether a predicate device exists
  - Asian region, eg population representativity in clinical trials
- **Evidence requirements for specific target audiences**, eg: regulators, payers, investors, prescribers, patients

Figure 3: Map of Evidence Requirements



Conclusion

- SIG Medical Devices (PSI/EFSPI) started in December 2025
- Forum for interested members of the (statistical) community
- High-impact topics with special relevance for medical devices covering scientific, clinical, statistical and regulatory aspects

JOIN US! :-)

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