ESIG MEDICAL DEVICES

EFSPI 2026

Omnipresent but exotic?

Statistical concepts for medical device trials

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Why this ESIG?

Medical device evidence is shaped by

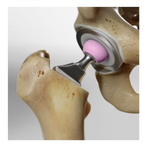
- device mechanisms,
- procedural context,
- user interaction, and
- region-specific regulation.

Our ESIG creates a forum to translate this diversity into practical statistical guidance.

Cardiovascular
– Pacemakers
– Synthetic valves
– Coronary stents

Neurology & pain
– Deep brain stimulators
– Spinal cord stimulators
– Vagus nerve stimulators

Orthopedics
– Total hip replacements
– Total knee replacements
– Spinal fusion implants



Ophthalmology
– Intraocular lenses
– Glaucoma drainage
– Retinal implants

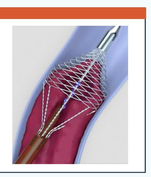
Respiratory
– Mechanical ventilators
– CPAP / BiPAP devices
– Endobronchial valves

Endocrine & metabolic
– Insulin pumps
– Glucose monitors
– Artificial pancreas

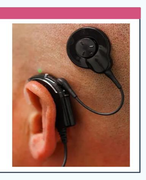
Gastrointestinal
– Capsule endoscopes
– Gastric bands
– Enteral feeding pumps

Renal & urology
– Hemodialysis machines
– Urinary stents
– Bladder stimulators

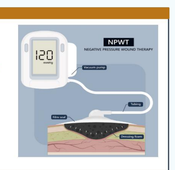
Vascular
– Peripheral vascular stents
– Vascular grafts
– Thrombectomy devices



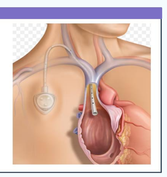
ENT & hearing
– Cochlear implants
– Hearing aids
– Bone hearing devices



Wound care
– Negative pressure therapy
– Bioelectric dressings
– Dermal substitutes



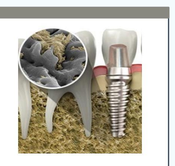
Oncology
– Brachytherapy seeds
– Infusion ports
– Tumor treating fields



Women's health
– Intrauterine devices (IUDs)
– Contraceptive implants
– Fetal heart rate monitors

Diagnostics & monitoring
– Cardiac monitors
– Wearable biosensors
– Hemodynamic monitors

Dental & maxillofacial
– Osseointegrated implants
– Orthodontic aligners
– Jaw reconstruction plates



Dermatology
– Phototherapy (UV)
– Fractional laser devices
– Cryotherapy probes

Scientific heterogeneity
Model the device, not only the patient

- Mechanical or electronic endpoints
- Endpoint distributions and causal roles
- Hybrid or combination devices
- Diagnostic / AI performance

Explore

Clinical challenges
Make treatment effects interpretable

- Estimands adapted to medical devices
- Interactions between investigational device and procedure, additional devices, and user (patient/clinician)
- Challenging comparators and large number of intercurrent events
- Usability, learning, and experience

Design

Regulatory complexity
Turn rules into study design choices

- Device classes and development stage
- EU MDR / Notified Body context
- FDA pathways: 510(k), de novo, PMA
- ISO 14155
- Regional evidence expectations

Consolidate

From diversity to shared statistical questions

1 Device mechanism
What generates the endpoint?

2 Use context
Who uses it, how, and where?

3 Evidence decision
What will regulators, payers, clinicians, and patients need?

4 Statistical method
Design, estimand, Bayesian model, and report with clarity

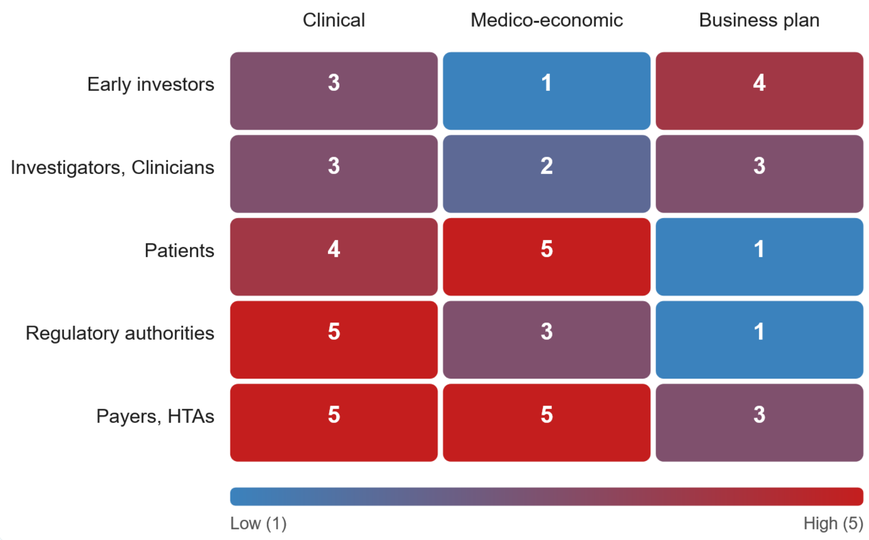
Three take-home messages

1 Devices are not "small pharma"
Mechanical, electronic, software, procedural, behavioral, and social mechanisms matter.

2 Statistical questions repeat across diversity
Endpoints, causal roles, estimands, comparators, and evidence thresholds can be framed consistently.

3 The SIG turns complexity into usable guidance
A cross-industry forum to align terminology, examples, and practical methods.

Evidence needs vary by stakeholder



We are looking for contributors on

Endpoint modelling · **Estimands** · **Intercurrent events**
Comparators · **AI & diagnostic devices** · **Bayesian methods**
Regional regulations · **RWD/RWE**

Our work

- Raise awareness
- Forum for statisticians
- Development of specialized algorithms
- Publish guidance, case studies, and conference sessions

Contact Workshop Participants:
Emilie Gérard • Rada Dakovic • Michael Mader (SIG chair)
PSI / EFSPI SIG Medical Devices

Selected sources

MDCG guidance on software qualification/classification; MDCG medical device classification guidance; Bakker et al. 2025 V3+ framework; EU AI Act; EMA reflection paper on patient experience data.

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contributors' employers enabled participation in this cross-industry working group.

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