CORE-MD

Coordinating Research and Evidence for Medical Devices

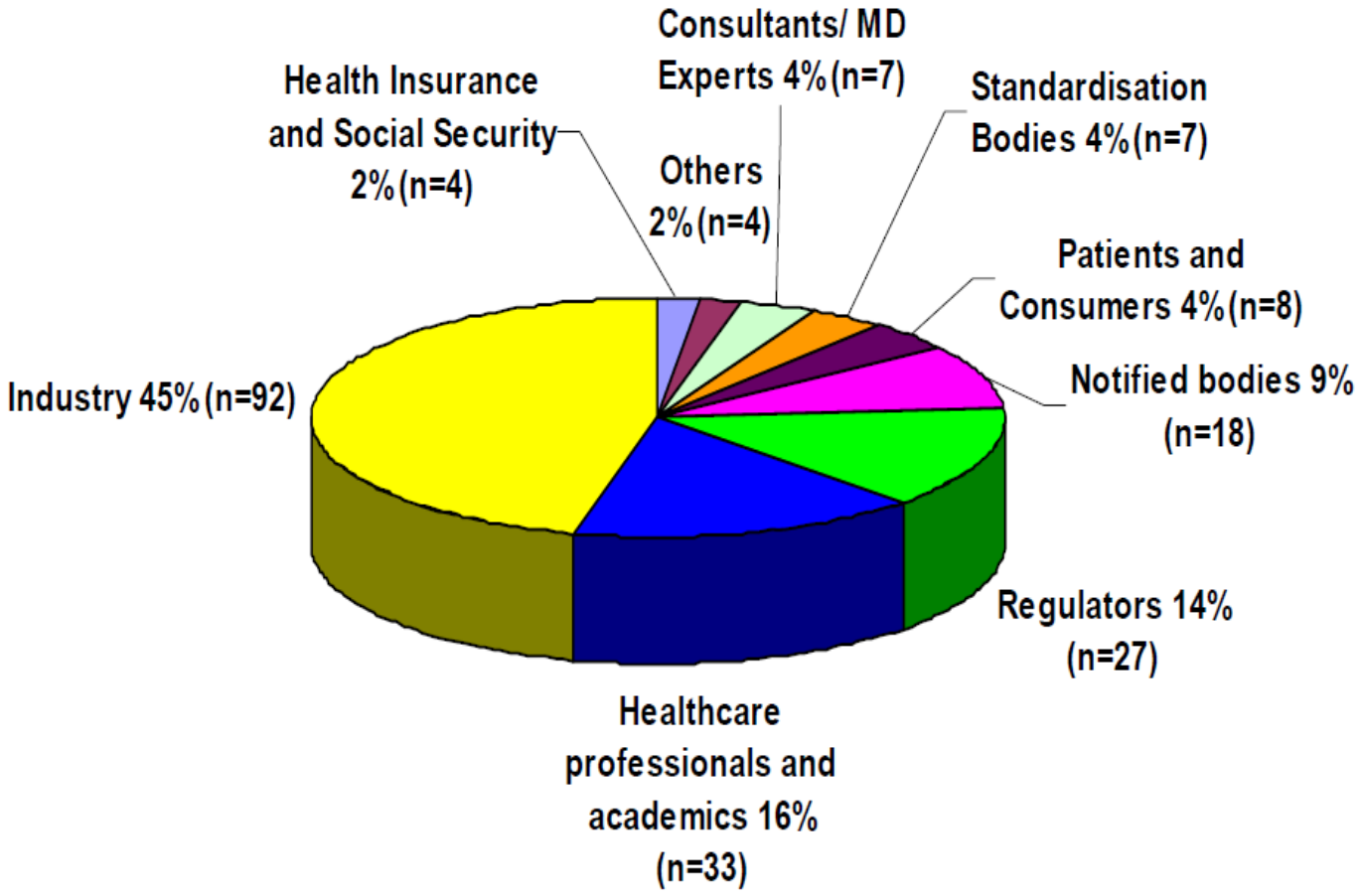
Introduction

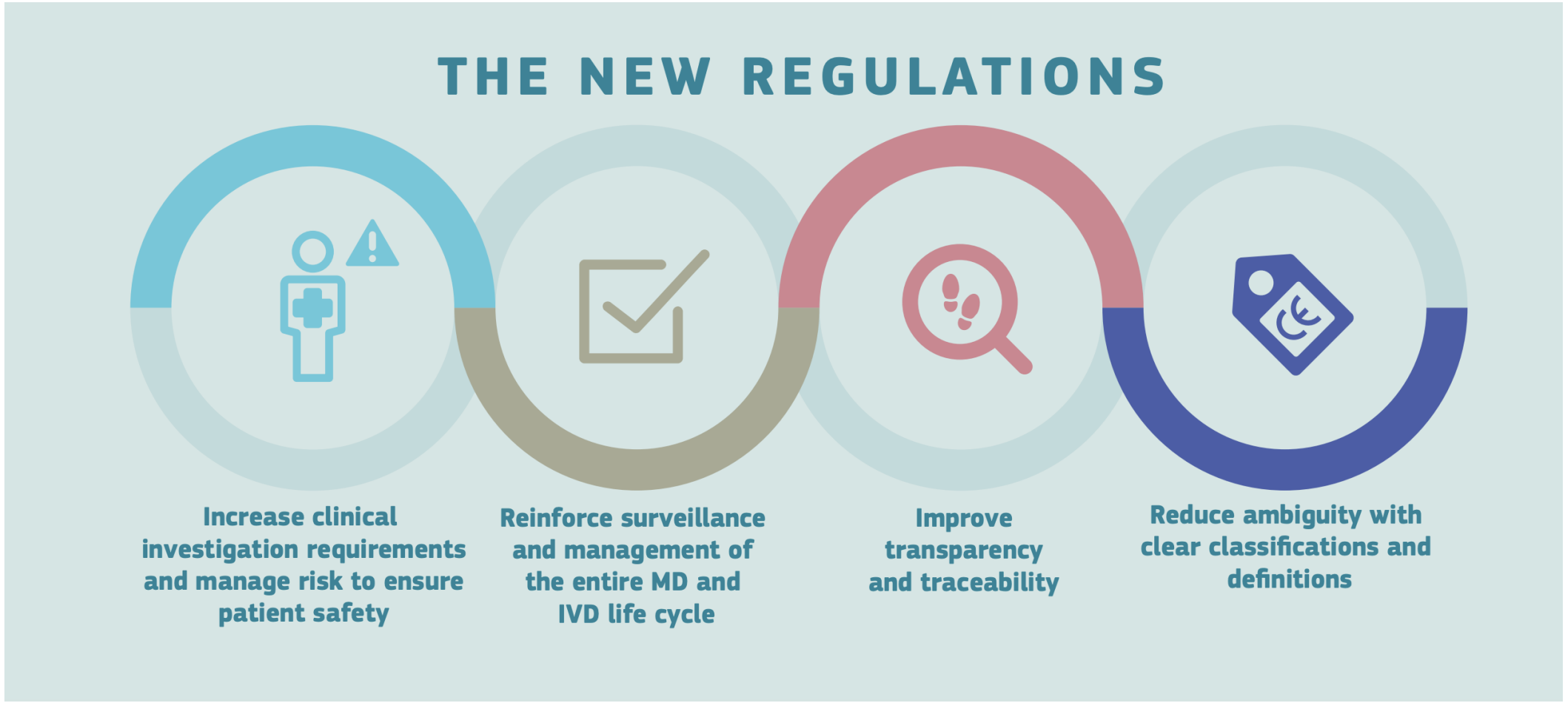
CORE-MD Final Conference
Brussels, 15 March 2024

Alan Fraser

- Public consultation **2008**
- Exploratory process **2009**
- High-level conference
- **Impact assessment**
- Draft text from Commission
- European Parliament
  - Rapporteurs & shadows
  - Committee hearings
  - Political block meetings
- Council of Ministers
- Trialogue / negotiation
- Final version, third reading
- College of Commissioners
- Translation
- Official Journal **2017**

EUROPEAN COMMISSION
SWD(2012) 273




THE NEW REGULATIONS
Increase clinical investigation requirements and manage risk to ensure patient safety
Reinforce surveillance and management of the entire MD and IVD life cycle
Improve transparency and traceability
Reduce ambiguity with clear classifications and definitions

(EU) 2017 / 745

Impact assessment on the revision of the regulatory framework for medical devices

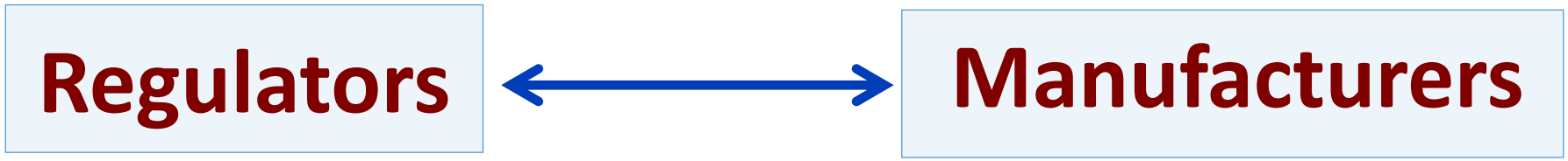
European Commission, Brussels, 26.9.2012

SWD(2012) 273 final

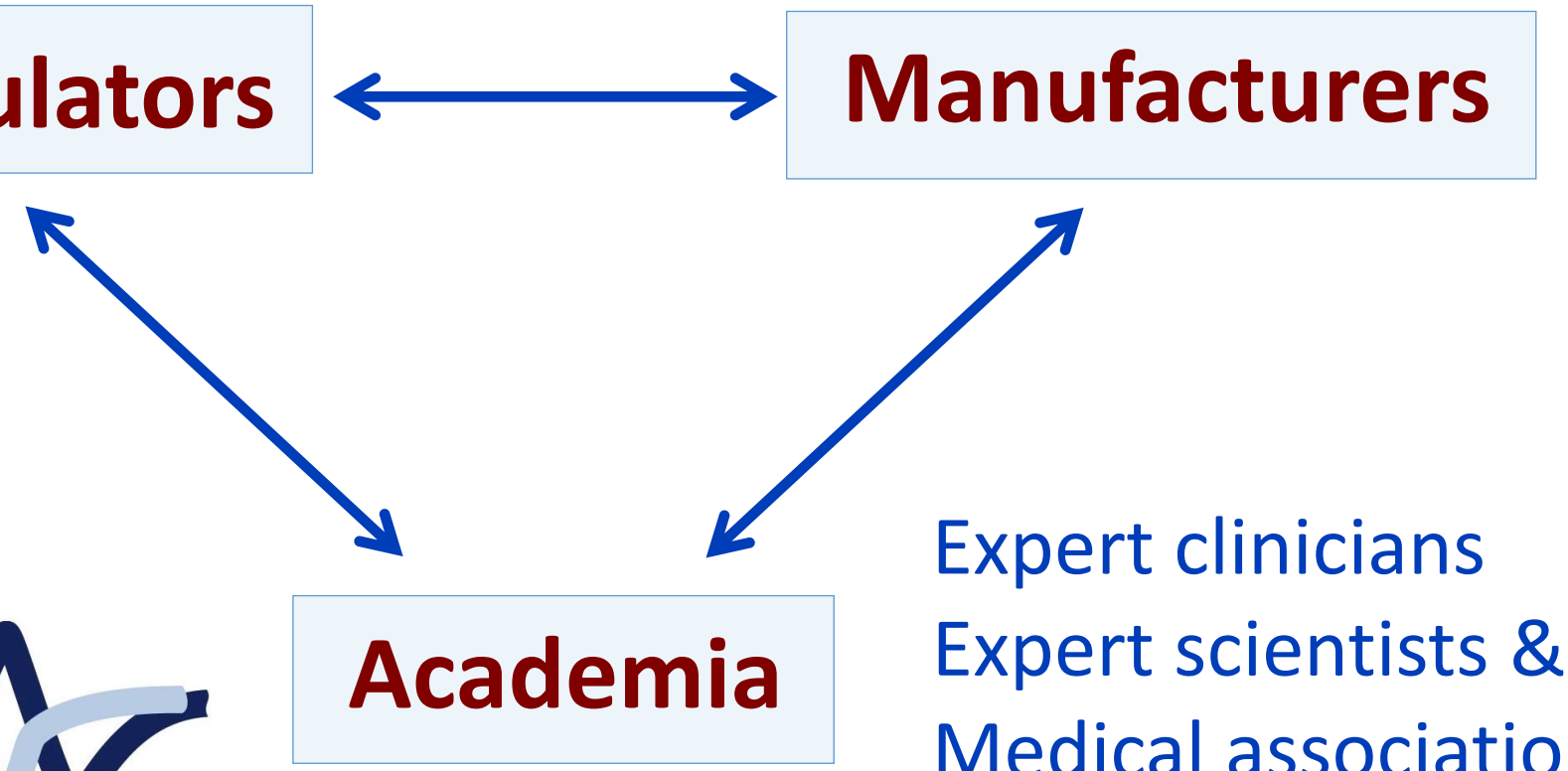
> The major costs for the EU budget generated by the preferred policy options are linked to the effective management of the future regulatory framework, and in particular to human resource requirements (35 to 50 FTE depending on the option eventually chosen), to the development and management of the IT infrastructure (e.g. Eudamed, ca. EUR 2mio/year) and to meetings between national experts (ca. EUR 1.4mio/year).

https://eur-lex.europa.eu/resource.html?uri=cellar:487acc33-213b-4fdf-bdbb-8840209a8807.0001.04/DOC_1&format=PDF

An effective regulatory environment ..?



An *evidence-based* regulatory environment ..



Expert clinicians
Expert scientists & engineers
Medical associations
Patients

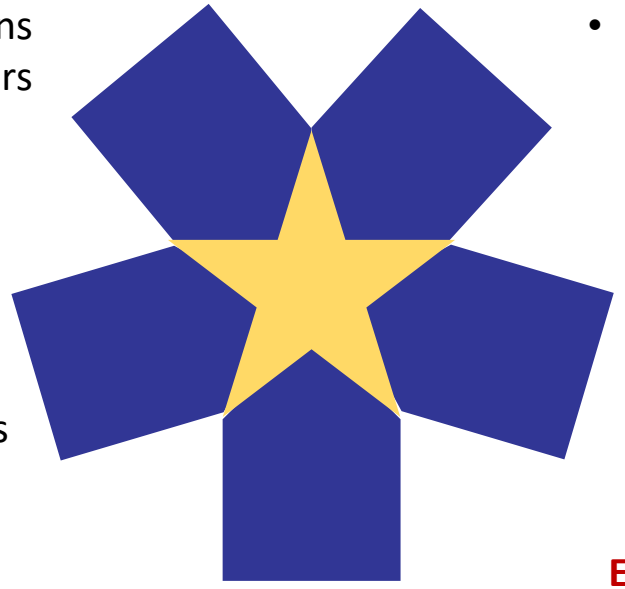
SC1-HCO-18-2020: Developing methodological approaches for improved clinical investigation and evaluation of high-risk medical devices

Physicians and healthcare professionals

- 4 European medical associations
- Biomedical Alliance 36 members
  - 9 academic institutions

European Patients Forum

- 75 patients' organisations



Public health authorities

- 2 National Public Health Institutes
- 2 Health technology assessment bodies

Medical device regulators

- 3 EU National regulatory agencies
- Competent Authorities for Medical Devices

Notified Bodies

- TEAM-NB has 27 members

European Commission DG SANTE

- Unit B6 / D3 – Medical devices, Health Technology Assessment
  - Clinical Investigation and Evaluation Working Group
    - New & Emerging Technologies Working Group

- **Academic collaborators and volunteers**
- **Advisory Board**
- **Industry trade associations**

CORE-MD

Coordinating Research and Evidence for Medical Devices

CORE–MD / Coordination & Support Action / 1.4.21 to 31.3.24

1. To investigate the methodologies of clinical investigations that have been used to evaluate high-risk cardiovascular, orthopaedic, and diabetic medical devices.
2. To review and recommend alternative designs of clinical studies that can provide high-quality clinical evidence for new high-risk medical devices.
3. To review and develop methods for aggregating clinical data from registries and other real-world sources across the life-cycle of high-risk medical devices.
4. To foster exchanges and networking between academic centres and across medical specialties, with notified bodies, regulators, manufacturers, health technology assessment bodies, and patients.

www.core-md.eu

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ESC

EFORT – JOINT EFFORTS

Biomedical Alliance in Europe

EAP European Academy of Paediatrics
Paediatric Section of U.E.M.S

EPF European Patients Forum

LUMC Leiden University Medical Center

UNIVERSITY OF OXFORD

Region Uppsala

RCSI UNIVERSITY OF MEDICINE AND HEALTH SCIENCES

INSELSPITAL
UNIVERSITÄTSSPITAL BERN
HÔPITAL UNIVERSITAIRE DE BERNE

KU LEUVEN

UMIT TIROL
THE TYROLEAN PRIVATE UNIVERSITY

UNIVERSITY OF GOTHENBURG

POLITECNICO MILANO 1863

HPRA
An tÚdarás Rialála Táirgí Sláinte
Health Products Regulatory Authority

LÆGEMIDDELSTYRELSEN
DANISH MEDICINES AGENCY

National Institute for Public Health and the Environment
Ministry of Health, Welfare and Sport

ISTITUTO SUPERIORE DI SANITÀ

aihta
HTA Austria
Austrian Institute for Health Technology Assessment GmbH

AETSA

TEAM NB

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