CORE-MD

Coordinating Research and Evidence for Medical Devices

MDCG CIE Working Group

and its role in the European medical device regulatory system

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CORE-MD Webinar #7 - Guidance in Pivotal Clinical Investigations

Agenda

MDCG CIE Working group

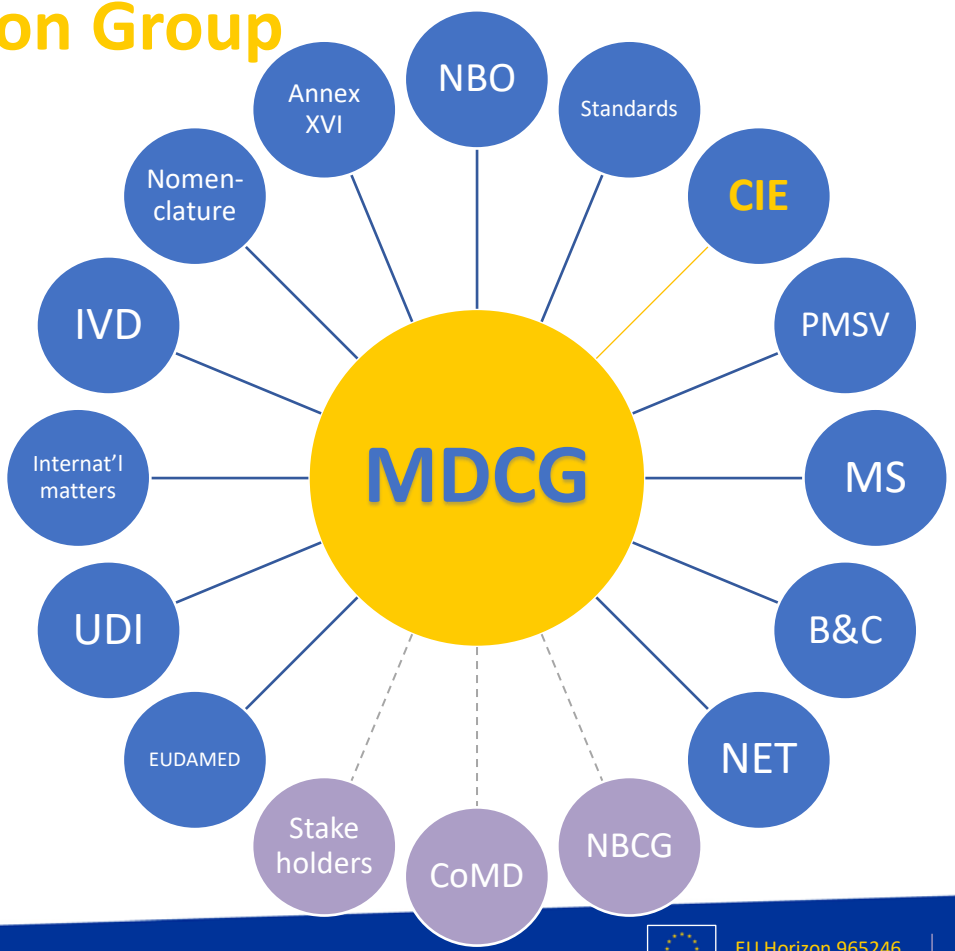
The role of competent authorities

Challenges

Future guidance

Medical Device Coordination Group

- Expert committee
- CA / national representatives
- Chaired by EU Commission
- Harmonised implementation of MDR and IVDR
- 13 subgroups
- WG 3: Clinical investigation and Evaluation (CIE)
  - Assist MDCG
  - Draft guidance
  - Proposals for clinical CS
  - Stakeholder engagement



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Role of the Competent Authority in CI regulation

Prior to submission

- Guidance
- Pre-submission meetings

Pre-market

(non-CE marked devices)

- Authorisation of CI applications
- Includes pilot and pivotal CIs

Post-market

(CE-marked devices)

- Notified of certain PMCF investigations
- Authorisation if outside intended purpose

Ongoing CI's

- Safety reporting
- Site inspections
- Substantial modifications
- CI reports

Focus of Review by Regulator

Are the study risks justified when weighed against the expected clinical benefits?

- Device design and manufacture
- Risk management
- Pre-clinical testing
- Clinical data
- GSPRs
- Study design
- Documentation
- MDR Annex XV

Regulatory challenges

- How to create and sustain a medical device environment that is
  - Safe,
  - Predictable,
  - Transparent,
  - Innovative,
  - Scientifically founded,
  - Fair and proportionate for all devices,
  - Consistent and harmonised across the EU

Regulatory challenges - CIE

Scientific guidance	Diversity of devices	Harmonisation
• Science vs procedure • Clinical investigations • Clinical evaluation • Sufficient clinical data • Expert panel advice	• Special cases • Device-specific guidance • Common specifications • State of the art	• De-centralised • National considerations • Combined studies • Global • ISO standards

Predictability

Future guidance

Clinical Investigation

- MDCG 2021-6 rev 1 Q+A on CI's
- Guidance on CIP & IB
- CI Summary report
- Mandatory CI's
- Pilot vs Pivotal CI

Clinical evaluation

- MEDDEV 2.7/1 update
- Scientific validity
- Methodology
- Lifecycle evaluation

Device specific

- Orphan devices
- CORE-MD outputs
- Expert panel advice
- EU HORIZON

Harmonisation

- CI coordinated assessment procedure
- COMBINE Project
- EN ISO Harmonisation

CORE-MD, Coordinating Research and Evidence for Medical Devices, aims to translate expert scientific and clinical evidence on study designs for evaluating high-risk medical devices into advice for EU regulators.

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For more information, visit: www.core-md.eu

ESC
EFORT
Biomedical Alliance in Europe
European Academy of Paediatrics
EPF European Patients Forum
Leiden University Medical Center
University of Oxford
Region Uppsala
RCSI University of Medicine and Health Sciences
INSELSPITAL Universitätsspital Bern Hôpital universitaire de Berne
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