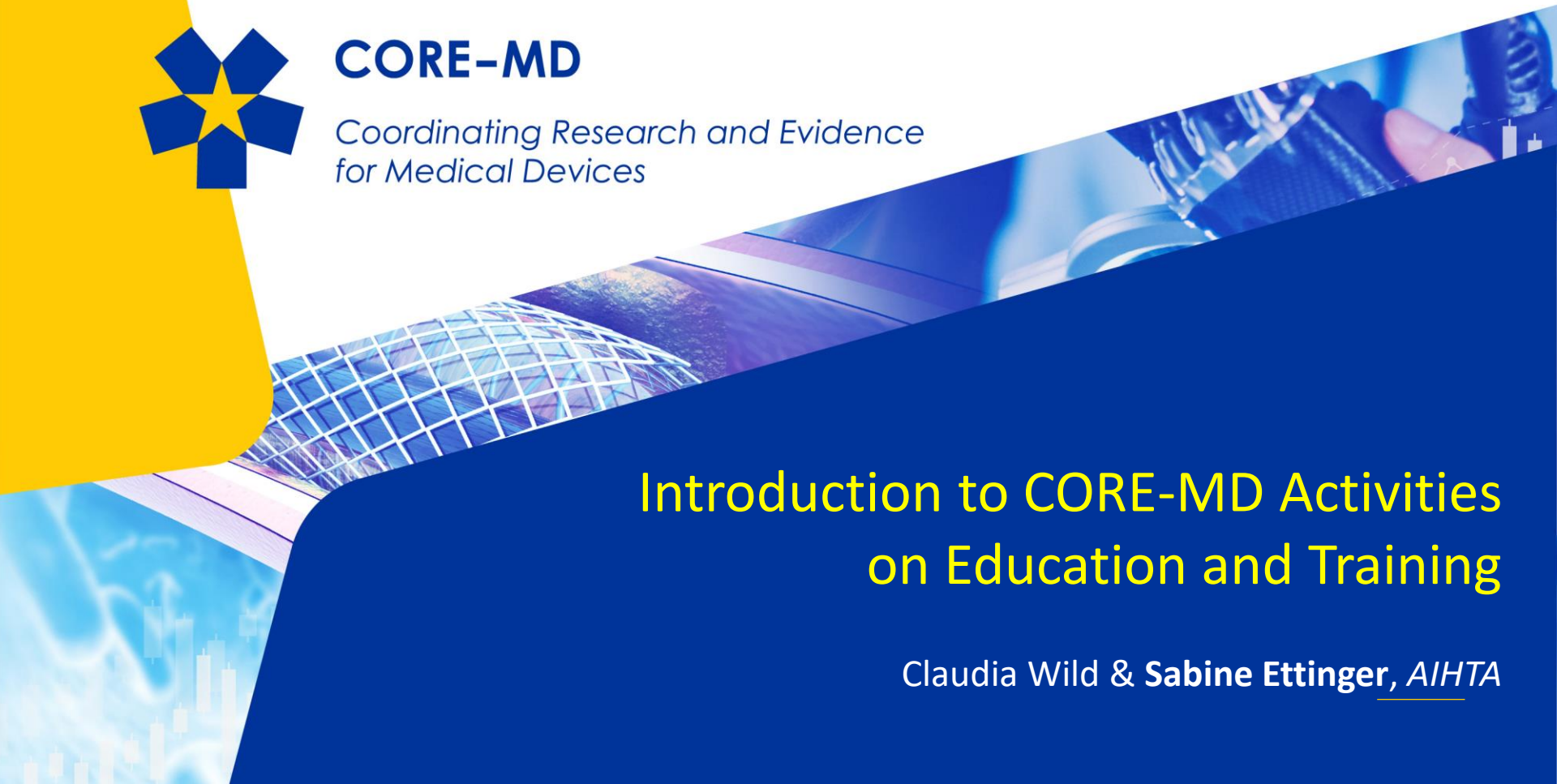
CORE-MD

Coordinating Research and Evidence for Medical Devices



Introduction to CORE-MD Activities on Education and Training

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Content

- Activities and Results
- Recommendations

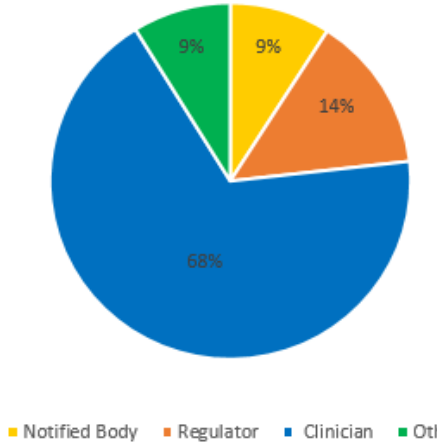
CORE-MD Activities

Aim To identify the needs for advanced training for the assessment of high-risk medical devices, in the context of the EU Medical Device Regulation (MDR).

Outcome Roadmap (separate executive summary) for education & training - Notified Bodies, Regulators, Clinicians, which includes:

- **Overview** of literature regarding “regulatory science and regulatory affairs”
- **Landscape** of available advanced trainings, qualifications related to MDR
- **Exploratory interviews with stakeholders** (notified bodies, clinicians, regulators)
- **Online survey** to stakeholders. Content: 25 questions, ~ 15 min, perceived needs for training in regulatory affairs, core methodological competencies as well as view on training formats and modalities.

Survey results: main employment survey respondents



In total 409 responses

- Clinicians (68%, 278 persons)
- Regulators (14%, 58 persons)
- Notified bodies (9%, 37 persons)
- Other employment category (9%, 36 persons)

Core competencies

Pre-clinical testing (methodology and evaluation)

Drafting a Scientific Advice to Manufacturers

Clinical investigation (methodology and evaluation)

- 14 sub-skills

Legal, regulatory for market access

- 6 sub-skills

Post-market surveillance

- 5 sub-skills

Soft skills (e.g. medical writing, project management)

1) 'Does not apply (not relevant for my job)'
2) 'I have no knowledge of this domain'
3) 'I have awareness level knowledge/skills'
4) 'I have practical knowledge/skills'
5) 'I have advanced knowledge/skills'

Survey results: real gaps

This survey identified both real gaps (defined by critical skills needed by a stakeholder to do their job correctly), and 'ideal' needs (defined by additional nice-to-have skills). The real gaps identified for each stakeholder group are as follows:

Clinicians (with an active role)	• Educational resources are needed concerning methodologies for clinical trials and post-market surveillance – so that they are better qualified to participate in clinical investigations (as clinical trialists) and in conformity assessments (as medical experts). Internships with Notified Bodies and Regulatory Agencies (Competent Authorities) could complement 'on the job' training for this group of clinicians.
Regulators	• Horizon scanning for the advancement of methodologies for clinical investigations of new and emerging and hybrid technologies, may be needed.
Notified Bodies	• Regular training courses are needed on new MDCG guidance documents and on advanced methodologies to assess clinical data, especially in highly specific medical areas (e.g. artificial intelligence, robotics).

Survey results: top 3 skills

Respondents selected in particular the **top 3 skills** in which they would like to have **training over the next 3 to 5 years**.

- **'Assessment of benefit:risk ratio and thresholds for acceptability'** was mentioned among among their first, second and/or third choice for training opportunities, by *all stakeholder groups.*
- '**Pre-clinical testing** (methodology and evaluation): Design and development of medical devices' was also frequently stated as a first choice by *Notified Bodies and regulators.*
- **'Study designs and their advantages/disadvantages'** was the skill that was mentioned most frequently as a first choice by *clinicians*.

Recommendations

- Needs-based (modular) Curriculum
- Training-on-the Job: Internship Program for Clinical Reviewers
- EU Network Training Centers for Capacity Building and Harmonization of Curricula
- Targeted training for clinicians adjusted to the regulatory affairs skills they need in their daily job

Thank you!

Publication available: https://www.core-md.eu/wp-content/uploads/2023/06/JMDRMay2023-Training.pdf

Roadmap (full technical report) and executive summary soon to be found on the CORE-MD website: https://www.core-md.eu/

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