CORE-MD

Coordinating Research and Evidence for Medical Devices

Executive Summary

A Roadmap for Education & Training

Perceived training needs of regulators, notified bodies and clinicians for successful implementation of the EU MDR: Survey results and recommendations

Introduction

The combination of new materials (e.g. in tissue engineering), new methods of testing (e.g. computer-aided modelling, simulation), and new technologies (e.g. neuroprosthetics, artificial intelligence) means that regulators, staff in Notified Bodies, and clinical experts such as those acting as advisers to Notified Bodies or as members of Expert Panels, must keep pace with technological developments and continually develop their regulatory capabilities. This increasing complexity of new medical devices fuels discussion about the need for a 'regulatory science' for medical devices to be developed in parallel with the implementation of Regulation (EU) 2017/745 on Medical Devices (MDR).

A recent position paper from the Medical Device Coordination Group (MDCG 2022-14) recognised and emphasised the requirement to build capacity for an effective transition to the MDR and the IVDR [(EU) 2017/746 on In Vitro Diagnostic Medical Devices]. This comprises not only assuring good knowledge of the legislation (MDR, IVDR), regulatory policies, and instruments including MDCG guidance documents – covered under the umbrella term of 'regulatory affairs' – but also enabling more in-depth and specific knowledge of advanced methodologies for the evaluation of medical devices in pre-clinical and clinical investigations and post-market surveillance evaluations. To support this endeavour, it is one intention of CORE-MD to develop recommendations for advanced educational and training courses.

Methods

Aiming at recommendations for the roadmap, a landscape overview of existing training offers and a series of exploratory interviews were conducted, to prepare a survey among regulators, Notified Bodies and clinicians who contribute to the implementation of the medical device regulations. The online survey was launched in summer 2022, and it collected the perceived needs for training in regulatory sciences and in core methodological competencies as well as the views of the respondents on training formats and modalities. The results of the survey were then discussed within the CORE-MD consortium and used to lay the basis for the recommendations.

This task was led by the Austrian Institute of Health Technology Assessment (AIHTA), with contributions from the Biomedical Alliance in Europe, Team-NB and European Society of Cardiology (ESC).

The survey asked respondents to estimate their need for education in core competencies that were structured into six domains (see Table). Three of these (Clinical investigation, Legal/regulatory requirements for market access, and Post-market surveillance) listed detailed skills.

The results of this survey should be interpreted with some caution. It was self-administered and voluntary, so a selection bias might be present, but all major groups of stakeholders were well represented and there was substantial concordance between their replies.

Table: Core competencies for the assessment of high-risk medical devices

Domains	Knowledge and skills (throughout the lifecycle of a medical device)
1. Pre-clinical testing (methodology and evaluation)	Design and development of medical devices
2. Drafting scientific advice to manufacturers	
3. Clinical investigation (methodology and evaluation)	Study designs and their advantages/disadvantages
	Concepts of unmet need in patient populations
	Methods and time points for patient involvement/engagement
	Choice of comparators (standard of care versus sham versus placebo)
	Outcomes' measurements and instruments (standardised and validated instruments)
	Assessment of benefit:risk ratio and thresholds for acceptability
	Use of data from equivalence (especially biocompatibility standard)
	(Functional) safety and performance assessment
	Methods for the evaluation of specific high-risk medical devices (e.g. artificial intelligence, combination devices, devices derived from tissues and cells of human origin)
	Systematic literature review (guidance for method and process)
	Medical statistics (e.g. power calculation of trials, p-values)
	Clinical epidemiology (data and sources for burden of disease, prevalence, incidence)
	Data analysis
	Ethics in clinical trials (e.g. recruitment, patient consent, information on uncertainties)
4. Legal, regulatory for market access	Regulation (EU) 2017/745 on medical devices: requirements, procedures, implementation, update on regulatory developments
	Classification of devices, especially borderline devices
	Quality Management Systems & Good Manufacturing Practices – ISO 13485
	Good Clinical Practice – ISO 14155
	Risk management – ISO 14971
5. Post-market surveillance	Registers and post-launch evidence generation (types of registers, data collections)
	Drafting a post-launch plan
	Collection of vigilance data
	Post-market clinical follow-up plans and evaluation reports
	Types of post-market surveillance data
6. Soft skills	Medical writing, project management

Results – Knowledge

409 experts responded to the survey[1]:

- 68% (278 people) were **clinicians**, of whom 23% (n=64) were already part of an EU Expert Panel.
- 14% identified as **regulators** (n=58)
- 9% were employees of **Notified Bodies** (n=37)
- 9% chose 'other' employment category (n=36)

A majority of the clinicians (65%) and more than half of the regulators (53%) reported that they had never attended educational sessions or training in regulatory science. 68% of the respondents from Notified Bodies had attended such sessions.

The following paragraphs summarise key findings for each group across the first 5 domains.

1. Pre-clinical testing (methodology and evaluation):

- Clinicians: 26% had no knowledge of this topic; 22% considered it not applicable.
- Regulators: 22% reported no knowledge of this domain.
- Notified Bodies: 35% had practical knowledge; a further 24% had advanced knowledge.

2. Drafting scientific advice to manufacturers:

- Clinicians: 34% had no knowledge.
- Regulators: 26% reported no knowledge.
- Notified Bodies: 27% had practical knowledge; a further 8% had advanced knowledge.

3. Clinical investigation (methodology and evaluation):

The majority of all groups had awareness level or practical knowledge. Overall, 35% (n=131) of survey participants for whom this domain was applicable stated that they had no knowledge concerning 'Methods for the evaluation of specific high-risk medical devices'.

- **Clinicians**:

  21–40% indicated that **they had no knowledge of 3 topics**:
  - '(Functional) safety and performance assessment'
  - 'Use of data from equivalence' and
  - 'Methods for the evaluation of specific high-risk medical devices'

- **Regulators**:

  31–41% indicated **6 skills of which they had no knowledge**:
  - 'Concepts of unmet need in patient populations'
  - 'Methods and time points for patient involvement/engagement'
  - 'Choice of comparators'

[1] Only the most important and relevant information from the survey are presented in this summary. For more information and further references see the full report, which is available at the project website www.core-md.eu

- ‘Methods for the evaluation of specific high-risk medical devices’
- ‘Clinical epidemiology’, and
- ‘Data analysis’

And 21–30% indicated **7 different skills for which they were lacking knowledge**:

- ‘Study designs and their advantages/disadvantages’
- ‘Outcomes measurements and instruments’
- ‘Assessment of benefit:risk ratio and thresholds for acceptability’
- ‘Use of data from equivalence’
- ‘Systematic literature review’
- ‘Medical statistics’, and
- ‘Ethics in clinical trials’

- **Notified Bodies:**

  21–30% had **no knowledge in two skills**:
  - ‘Methods and time points for patient involvement/engagement’, and
  - ‘Clinical epidemiology’

4. <u>Legal and regulatory issues for market access</u>:

- **Clinicians**: 30% to >41% **lacked knowledge** of the following topics:
  - ‘Good clinical practice’ for medical devices
  - ‘Regulation (EU) 2017/745 on medical devices’
  - ‘Classification of devices’
  - ‘Good Manufacturing Practice’
  - ‘Risk Management’, and
  - ‘Quality Management System’
- **Regulators**: 21% had no knowledge of ‘Good clinical practice’ for medical devices.

5. <u>Post-market surveillance</u>:

- **Clinicians**: 31–41% had **no knowledge** or lacked knowledge of these topics:
  - ‘Drafting a post-launch plan’
  - ‘Collection of vigilance data’
  - ‘Types of post-market surveillance data’
  - ‘Registers and post-launch evidence generation’, and
  - ‘Post-market clinical follow-up plans and evaluation reports’
- **Regulators**: 34% had practical knowledge; and a further 22% had advanced knowledge.

  21–40% lacked knowledge of the following topics:
  - ‘Drafting a post-launch plan’
  - ‘Collection of vigilance data’
  - ‘Post-market clinical follow-up plans and evaluation reports’, and
  - ‘Types of post-market surveillance data’
- **Notified Bodies**: 43% had practical knowledge; and 38% had advanced knowledge.

Results – Educational preferences

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

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

Survey respondents identified which groups (clinicians, regulators, Notified Bodies) they perceived to **need training in regulatory science**:

- Every group selected their **own group** as having the highest need for training.
- 72% of survey respondents indicated that the highest need for training was for clinicians who contribute to implemention of the MDR, followed by 48% for regulators and 41% for Notified Bodies.
- Only ~1% of all respondents indicated that no training is needed for any of the three groups.

All respondents were asked for their preference regarding the **composition of the training group**:

- Around a third of each group would prefer dedicated educational courses for clinicians, regulators, or Notified Bodies, but a high percentage (including 40% of clinicians) had no preference.
- 15% of all respondents favoured training across the target groups.
- The smallest percentage of every group stated that it depended on the topic/module.

Implications

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:

- For **clinicians** who choose to play an active role contributing to the evaluation of high-risk medical devices or whose daily work is more centered on regulatory affairs, 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.
- For **regulators**, horizon scanning for the advancement of methodologies for clinical investigations of new and emerging and hybrid technologies, may be needed.
- For **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).

Conclusions and recommendations

Concepts of 'regulatory science' have been discussed for at least a decade, and instruments have been developed for improving professional skills and capacity and for advancing methodologies for regulation. Some post-graduate training institutions now offer regulatory science courses for professionals, but mostly in the context of market access for pharmaceutical products. Advanced training for the EU medical device sector is still rare or almost non-existent, despite the large demand for appropriately trained personnel to work in regulatory authorities, in Notified Bodies, and as clinical experts.

Within the CORE-MD project, this survey was complemented by a review of published literature on skills in regulatory science, by an overview of the landscape of existing advanced educational programmes, and by exploratory consultations with stakeholders. Together, these activities provided the basis for proposing a comprehensive list of domains and skills across the lifecycle of a medical device, that might form the starting point for developing specific curricula. In particular, regulators, Notified Bodies and clinicians need training in pre-clinical testing methodologies and evaluation, providing scientific advice to manufacturers, and post-market surveillance, tailored for their specific needs so that they can fulfill their regulatory roles and assignments professionally.

Finally – based on these perceived needs for training and educational courses in regulatory science – the CORE-MD consortium calls for affirmative action, public funding, and new initiatives to build capacity and increase the efficiency of the EU regulatory system to provide safe and effective medical devices.

Recommendation 1: A needs-based (modular) curriculum

A modular curriculum is proposed that can be adapted to the training needs of the three stakeholder groups, encompassing a Core Set of training sessions and activities, complemented by modules for further specialization. The modular composition would offer educational elements tailored for the respective tasks and specific objectives of each group, that can be provided at different stages of a career: at the academic curriculum stage (initial or advanced degree), or during/in parallel to work life (single days, block training modules, webinars, sessions at congresses, practical training on the job, etc.).

Target groups: Regulators, Notified Bodies, Clinicians contributing to regulation

Measures to proceed:

1. Raise awareness by broad dissemination to academic umbrella organisations (e.g. Federation applied universities) and to European medical specialist organisations, ideally in a multidisciplinary context.
2. Interconnect the existing academic programmes for a mutual recognition of modules.

Recommendation 2: Training-on-the job ("job-shadowing")

Hands-on experience, training-on-the-job and re-skilling of professionals often takes place during work life. Possible training opportunities could be the development of an internship scheme, short-term sabbatical attachments with manufacturers, Notified Bodies, competent authorities, similar to activities offered at FDA and TGA. The training-on-the-job needs to ensure that it can be attended next to the main employment (e.g. for clinicians).

Target groups: Regulators, Notified Bodies, Clinicians contributing to regulation

Measures to proceed:

1. Identify and coordinate interested parties to take stewardship to expedite the development of such training-on-the Job programs.
2. Identify EC-grants (e.g. EU4H funds) and submit a proposal for the development of regulatory practice-relevant curricula (see Recomendation 1) and training-on-the Job programs (as in this Recommendation 2).

Recommendation 3: EU Network Training Centres

A Network Training Centre (NTC) at the European Medicines Agency (EMA) supports the educational and training needs of EU pharmaceutical regulators (https://www.hma.eu/about-hma/working-groups/eu-network-training-centre-eu-ntc-former-otsg.html). A new initiative aims to create a similar European-wide network for the national Competent Authorities for medical devices. Its objectives are to improve the quality, consistency and efficiency of the work of the medical device regulatory network; to promote harmonised operation of the regulatory framework and guidelines throughout the European regulatory network; to foster science-based, pragmatic and consistent assessment, and to provide continuous professional development for staff of national regulatory agencies and possibly other stakeholders involved in the development of regulations for medical devices.

Target groups: Regulators, Notified Bodies, clinicians contributing to regulatory processes for medical devices

Measures to proceed:

1. Facilitate exchange among Competent Authorities and national regulators, and with the European Commission, on how to further develop the EU NTCs for medical device training modules.
2. Support the new EU NTC at the EMA, and assist in identifying the most urgent topics for training of Competent Authorities' staff on medical devices.

Recommendation 4: Targeted training for clinicians adjusted to the regulatory science skills they need in their daily jobs

Many clinicians only have a basic understanding of regulatory affairs, the way in which medical devices and medicines that they use are approved, procedures for post-market surveillance, and how clinicians can contribute. They are focused on providing clinical care but they also need a basic knowledge of regulatory affairs, so that for example they can advise policy makers and report potential issues with the health technologies that they use. Because of their heavy workload, flexible approaches are needed.

Target groups: Clinicians not yet contributing to oversight of devices for regulators.

Measures to proceed:

1. Development of sessions on regulatory standards and systems, in curricula in medical schools and professional medical speciality training programmes.
2. Development of informative materials, online training, webinars, sessions in medical congresses, and other CME-related activities for qualified physicians.

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