CORE-MD

Coordinating Research and Evidence for Medical Devices

Roadmap for education & training:

Notified Bodies, Regulators, Clinicians

Technical-Scientific Report

Executive Summary

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02/06/2023	1.0		Final version

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Acronyms

AFMPS	Agence Fédérale des Médicaments et des Produits de Santé/ Federal Agency for Medicines and Health Products (BE)
AIHTA	Austrian Institute for Health Technology Assessment
ATMP(s)	Advanced Therapy Medicinal Products
BioMed Alliance	Biomedical Alliance in Europe
CAMD	Competent Authorities for Medical Devices
CE	Conformité Européenne
CIE	Clinical Investigation and Evaluation
CORE-MD	Coordinating research and evidence for medical devices
CPD	Continued professional development
CRSI	Centre for Regulatory Science and Innovation (UK)
DIA	Drug Information Association
EC	European Commission
EEA	European Economic Area
EMA	European Medicines Agency
ESC	European Society of Cardiology
EU	European Union
FDA	Food and Drug Administration (USA)
GCP	Good Clinical Practice
GMP	Good Manufacturing Practice
HPRA	Health Products Regulatory Authority
HTA	Health Technology Assessment
IOM	Institute of Medicine
ISO	International Organization for Standardization
IT	Information Technology
IVD	In-vitro Diagnostic

IVDR	In-vitro Diagnostic Regulation (Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 on in vitro diagnostic medical devices and repealing Directive 98/79/EC and Commission Decision 2010/227/EU)
MBA	Master of Business Administration
MD	Medical Device
M.D.	Medical Doctor – professional qualification for the profession of physician in all specialties
MDR	Medical device regulation (Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC)
MSc	Master of Science
NANDO	New Approach Notified and Designated Organisations
NB	Notified Body
NBCG-Med	Notified Body Coordination Group for Medical Devices
NPO	Non-Profit-Organisation
PhD	Doctor of Philosophy (research degree at the highest academic level, for programs across academic fields)
PICO	Population, Intervention, Comparator, Outcome
PMCF	Post-market clinical follow-up
PMDA	Pharmaceuticals and Medical Devices Agency (Japan)
PMS	Post-market surveillance
QMS	Quality Management System
RAPS	Regulatory Affairs Professionals Society
RIVM	Rijksinstituut voor Volksgezondheid en Milieu (National Institute for Public Health and the Environment) (NL)
RA	Regulatory Affairs
RS	Regulatory Science
RWE	Real-World-Evidence
STARS	Strengthening Training of Academia in Regulatory Science
Team-NB	The European Association for Medical Devices of Notified Bodies
TGA	Therapeutic Goods Administration (TGA) (Australia)
TOPRA	Organisation for Professionals in Regulatory Affairs
TÜV	Technischer Überwachungsverein/Technical Inspection Association
UDI	Unique Device Identification
UK	United Kingdom
USA	United States of America
WP	Work Package

1. Introduction

1.1 CORE-MD

The coordinating research and evidence for medical devices (CORE-MD) project is a European Union (EU) Horizon 2020 project running from April 2021 until March 2024. It reviews methodologies for the clinical evaluation of high-risk medical devices, in order to translate expert evidence into advice for EU regulators and to recommend an appropriate balance between innovation, safety, and clinical effectiveness. Furthermore, it provides recommendations for how new trial designs can contribute, offers advice on methods for aggregating real-world data from medical device registries and experience from clinical practice. The CORE–MD consortium involves medical associations, EU regulators, national public health institutes, notified bodies, academic institutions, patients' groups, and health technology assessment (HTA) agencies, with participation of manufacturers' trade associations. The CORE–MD consortium is led by the European Society of Cardiology (ESC) and the European Federation of National Associations of Orthopaedics and Traumatology (EFORT). Further information about the CORE-MD project can be found on the website: https://www.core-md.eu/

See Figure 1 for an overview of the different work packages (WP) in CORE-MD. WP4 is responsible for networking and community building and is the main driver of creating the current roadmap for education and training of notified bodies, regulators and clinicians.

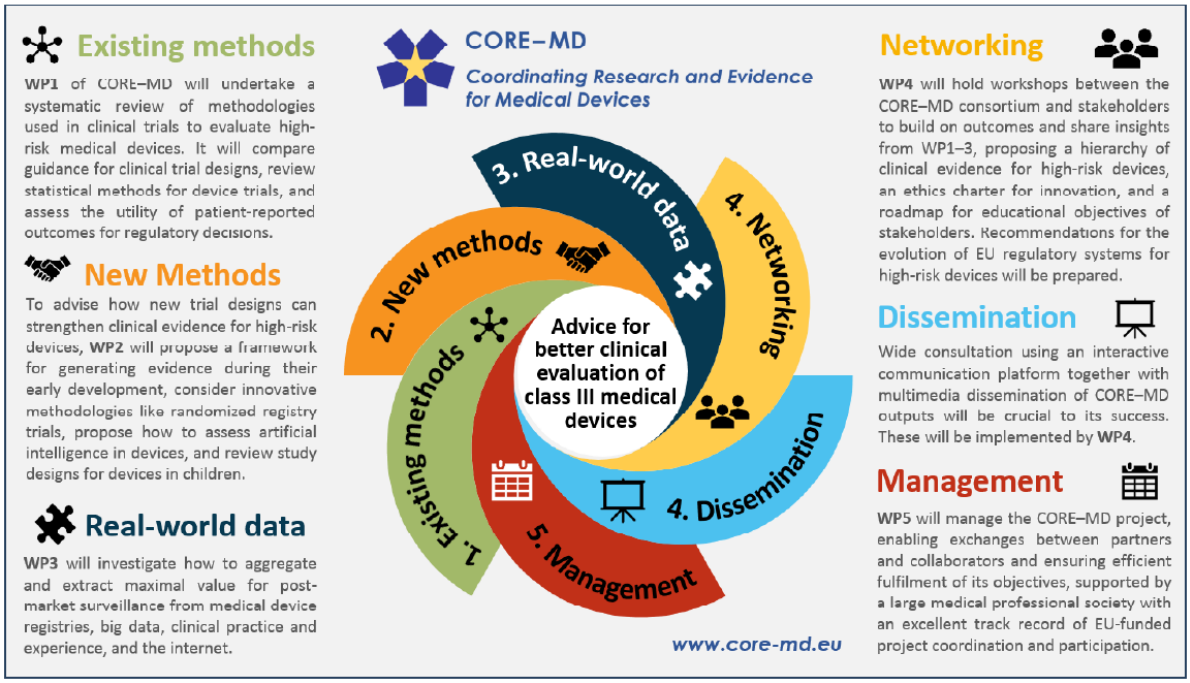


Figure 1: Summary of CORE–MD Work Packages (source: CORE-MD proposal)

1.2 Aim and development of the roadmap

The aim of the roadmap is to present the training needs of stakeholders namely notified bodies, regulators and clinicians, to develop appropriate educational objectives, and to provide respective recommendations. One major part of the roadmap is based on the results of this CORE-MD survey, which aimed at identifying the needs for methodological expertise and educational requirements for the assessment of high-risk medical devices, specifically in the context of the EU Medical Devices Regulation (MDR). This CORE-MD survey also helped to assess the current status of knowledge of respondents with regard to regulatory sciences (specifically in the field of medical devices), what training they participated in and what gaps in the knowledge exist. In the future there might be funding from the European Commission (EC) for training and therefore an overview of the existing needs and recommendations is essential.

The CORE-MD T4.3. Task Members (AIHTA, Biomed Alliance, ESC, Team-NB) conducted regular e-meetings to discuss the progress of the current roadmap. After an internal review round of the draft roadmap, the recommendations were presented to the whole CORE-MD Consortium during the meeting in April 2023 and their input was implemented.

1.3 Target audience of the roadmap

The target audiences of the roadmap are the EC, the three stakeholder groups (notified bodies, regulators, clinicians) as well as education and training providers including universities. Also individuals and institutions responsible for the implementation of the recommendations of the roadmap are aimed to be addressed.

1.4 Regulatory science (RS) and RS in medical devices (MD): definitions, concepts

1.4.1 Rationale and definitions

Citizens, patients and clinicians expect regulators to provide an unbiased, rigorous and technically sound assessment of investigational therapies in a transparent manner: regulatory assessments that inform these stakeholders, but also HTA agencies supporting payers to make decisions on health care resources. In recent years, especially medical device regulators were scrutinized for their lack of transparency on data and materials used for their decisions and on deficiencies in methodologies applied [1-3]. The publication of the "Implant Files" investigations in 2018 (https://www.icij.org/investigations/implant-files/) disclosed many faulty medical devices, and revealed this information to the public. Not only the criticism on faulty medical devices and the lack of transparency in methods and processes motivated the implementation of the MDR in the EU, but also the increasing complexity of new devices feeds the discussion on the need for a Regulatory Science for Medical Devices to evolve in tandem with the MDR [4]. The combination of materials and techniques combine knowledge from different medical and technical disciplines. Examples are the

combination of neuroscience, biomedical engineering and robotics for neural prosthetics (also neuroprosthetics) or computer-based modelling, simulation and artificial intelligence for diagnostic tests and digital therapeutics or scaffolds, cells and biologically active molecules for tissues-engineering and functional tissues [5, 6]. It is all too obvious that regulators are in need to keep track of the technologically development and to advance the regulatory skills.

For at least a decade "Regulatory Science" has been discussed and concepts developed – though primarily in the context of pharmaceuticals - as instrument for improving professional skills and capacity of regulators and for advancing methodologies for regulation. In 2011 the US Food and Drug Administration (FDA) has published its first "Strategic Plan for Regulatory Science" followed by a detailed report on "Advancing Regulatory Science at FDA – Focus Areas of Regulatory Science (FARS)" in 2021 [7], several years later in 2018 the European Medicines Agency (EMA) [8] has launched its strategy for "Regulatory Science to 2025", followed by a detailed list of "Regulatory Science – Research Needs" in 2021 [9]. All documents encompass the intentions of these plans and strategies [10] such as by

(1) enforcing regulators keeping up with the most recent science in order to enable high-quality and critical evaluations of the benefit-risk,
(2) advancing innovation in methods and standards for the evaluation of quality, safety, and efficacy of medicinal products throughout their product life cycle, and
(3) enabling innovation by a broad arrange of activities related to reaching out to stakeholders (ie, patients and health care professionals), for ensuring patient safety, safeguarding public health, and innovation.

While the intentions are clear, the spectrum of ideas how to achieve these goals are manifold as are the definitions used. Over time, the definitions developed from covering the core activities of regulators (FDA) towards more concrete areas such as methodological tools and guidelines for the data production and assessment (PMDA, EMA) along the whole life-cycle (EMA) of medical products – see Table 1. In summary, the succus of all definitions is to base regulatory decisions on the best scientific knowledge available [11].

Table 1: *Definitions of Regulatory Science by National Regulators (USA, Japan, EU)*

Originator	Definitions of Regulatory Science (RS)
FDA (USA) 2010 [12-14]	The science of developing new tools, standards, and approaches to assess the safety, efficacy, quality, and performance of FDA-regulated products.
FDA (USA) 2014 [15]	RS is an interdisciplinary and multidisciplinary branch of science constituting the scientific foundation and tools of policy decisions including legislative, judicial, and particularly regulatory decisions.
PMDA (Japan) 2011 [16]	RS as providing a scientific basis for introducing new therapeutic agents or devices into society for the benefit of patients and consisting of three functions: new tools for data production, data assessment, and balancing various factors.
EMA (EU) 2016 [17]	RS as comprising basic and applied research that enables co-evolution of science, legislation, guidelines, and policies for benefit/risk assessment in medical product-regulatory decision-making throughout the development and life-cycle management of medical products.

CRSI (UK) 2022 [18]	RS achieves this by bringing together multiple disciplines with one focus – ensuring the quality, safety and efficacy of new medicinal products throughout their lifetime: from drug discovery and clinical trials, to introduction and adoption in clinic.

CRSI: Centre for Regulatory Science and Innovation; EMA: European Medicines Agency; FDA: Food and Drug Administration; PMDA: Pharmaceutical and Medical Device Agency

However, most often the term is used in the context of medicines and ideas for regulatory science for medical devices is still in its infancy, at least in the EU. In the USA the FDA has started to develop concepts already in 2010, while the uptake of reflections on regulatory science started nearly a decade later in the EU. Nevertheless, the concepts taken to establish regulatory science for medicines can serve as a role model for equal activities for medical devices. The scientific methods and disciplines used in the regulatory processes (as well as by other actors in the ecosystem of evidence generation and use [19] – independent of medical products – cover a broad range of methodological knowledge (from study designs for safety and efficacy assessment, quality and performance assessment in the post-marketing phase) and of scientific disciplines (from biomedical engineering, material science, toxicology, epidemiology, IT and health data science, artificial intelligence, etc. [6].

Last, but not least Regulatory Science (RS) has to be distinguished from Regulatory Affairs (RA). RA encompasses the knowledge on the regulation and laws to ensure the compliance, while Regulatory Science as defined by FDA [12-14] implies the development of new tools, standards and approaches for regulatory decisions. Although there is some overlap between the concepts, RA and RS serve different purposes. In the context of this report on training RA is taught to comply with the regulation while RS is taught to advance and reflect regulatory approaches. There is a need for many more people to be trained in RA than RS. Ideally those trained in RS would first be trained or have experience in RA.

1.4.2 Concepts and perceived needs (areas of interest)

Several initiatives have set the scene to develop and advance regulatory science and workforce training programs in recent years. FDA has first launched a Strategic Plan for Regulatory Science in 2010 and 2011 [12, 20] (see Box 1), followed by a detailed report on Workforce Development in 2012 [21] and an Implementation Plan in 2013 [22]. Since then, the FDA cooperates with four Centers of Excellence in Regulatory Science and Innovation (CERSIs: University of Maryland; UCSF-Stanford; Johns Hopkins University, and Yale-Mayo Clinic) to advance regulatory science through innovative research, training, and scientific exchanges to foster a robust, collaborative, regulatory science culture to address the scientific challenges in the development of medical products (see also section on Regulatory competencies in Regulatory Science mentioned in publications).

Box 1: FDA Strategic Plan for Regulatory Science for medical products in humans [12]

Modernize toxicology to enhance product safety. FDA plans to develop better models of human adverse response, identify and evaluate biomarkers and end points that can be used in nonclinical and clinical evaluations, and use and develop computational methods and in silico modelling.

Stimulate innovation in clinical evaluation and personalized medicine. FDA seeks to develop and refine clinical trial designs, end points, and analysis methods; leverage existing and future clinical trial data; identify and qualify biomarkers and study

end points; increase the accuracy and consistency, and reduce interplatform variability, of analytical methods to measure biomarkers; and develop a "virtual physiologic patient."

Support new approaches to improve product manufacturing and quality. FDA plans to enable development and evaluation of novel and improved manufacturing methods, develop new analytical methods, and reduce the risk of microbial contamination of products.

Ensure FDA readiness to evaluate emerging technologies. FDA will stimulate development of innovative medical products while concurrently developing novel assessment tools and methodologies, develop assessment tools for novel therapies, assure safe and effective medical innovation, and coordinate regulatory science for emerging technology product areas.

Harness diverse data through information sciences to improve health outcomes. FDA plans to enhance information technology infrastructure development and data mining; develop and apply simulation models for product life cycles, risk assessment, and other regulatory science uses; analyse large-scale clinical and preclinical data sets; incorporate knowledge from FDA regulatory files into a database integrating a broad array of data types; and develop new data sources and innovative analytical methods and approaches.

Strengthen social and behavioural science to help consumers and professionals make informed decisions. FDA seeks to know its audience, reach that audience, ensure audience understanding, and evaluate the effectiveness of communication about regulated products.

In 2018, EMA launched its Strategic Reflection on "Regulatory Science to 2025" [8] (see Box 2) and followed the FDA's example to first reflect on the challenges of regulation and then to define areas of needs for advanced knowledge (developed in regulatory science). EMA [8] identified five areas for the science-based advancement of regulation. Network-led partnerships with academic/research centres to undertake research in strategic areas of regulatory science are recommended for leveraging collaborations between academia and network scientists to address rapidly emerging regulatory science research questions, to identify and enable access to the best expertise across Europe and internationally and to disseminate and exchange knowledge, expertise and innovation across the network and to its stakeholders.

Box 2: EMA Strategic Reflection on "Regulatory Science to 2025" for human medicines [8]

Catalysing the integration of science and technology in medicines' development

- Support developments in precision medicine, biomarkers and 'omics
- Support translation of advanced therapy medicinal products (ATMPs) into patient treatments
- Promote and invest in the PRIME scheme
- Facilitate the implementation of novel manufacturing technologies
- Create an integrated evaluation pathway for the assessment of medical devices, in vitro diagnostics and borderline products
- Develop understanding of, and regulatory response to, nanotechnology and new materials in pharmaceuticals
- Diversify and integrate the provision of regulatory advice along the development continuum

Driving collaborative evidence generation – improving the scientific quality of evaluations

- Leverage non-clinical models and 3Rs principles
- Foster innovation in clinical trials
- Develop the regulatory framework for emerging clinical data generation
- Expand benefit-risk assessment and communication
- Invest in special populations initiatives
- Optimise capabilities in modelling, simulation and extrapolation
- Exploit digital technology and artificial intelligence in decision making

Advancing patient-centred access to medicines in partnership with healthcare systems

- Contribute to HTA's preparedness and downstream decision making for innovative medicines
- Bridge from evaluation to access through collaboration with payers
- Reinforce patient relevance in evidence generation
- Promote use of high-quality real-world data (RWD) in decision-making
- Develop network competence and specialist collaborations to engage with big data
- Deliver improved product information in electronic format (ePI)
- Promote the availability and support uptake of biosimilars in healthcare systems
- Further develop external engagement and communications to promote trust and confidence in the EU regulatory system

Addressing emerging health threats and availability/ therapeutic challenges

- Implement EMA's health threats plan, ring-fence resources and refine preparedness approaches
- Continue to support development of new antibacterial agents and their alternatives
- Promote global cooperation to anticipate and address supply problems
- Support innovative approaches to the development, approval and post-authorisation monitoring of vaccines
- Support the development and implementation of a repurposing framework

Enabling and leveraging research and innovation in regulatory science

- Develop network-led partnerships with academic/research centres to undertake research in strategic areas of regulatory science
- Leverage collaborations between academia and network scientists to address rapidly emerging regulatory science research questions
- Identify and enable access to the best expertise across Europe and internationally
- Disseminate and exchange knowledge, expertise and innovation across the network and to its stakeholders

2. Methods

2.1 Published literature

A hand-search was conducted for publications on “regulatory science and regulatory affairs” in Medline and in Google Scholar in June 2022. Since it was not intended to conduct a comprehensive systematic review only official publications (by regulators) and citations on regulatory science for medical devices were selected.

2.2 Landscape

The initial step was to get an overview of advanced training courses and qualifications related to medical devices and the MDR that are currently available. To this end, an initial hand search on the internet was performed from July until September 2021.

The information collected was initially presented in a Microsoft Excel document and the overview was structured according to the types of institutions that offered different kinds of advanced training: notified bodies, regulators, medical device industry, medical societies, private companies (e.g. consultancies), other organisations (e.g. standardisation bodies) and universities. The Notified Bodies mentioned in the overview were cross-checked with the database of notified bodies (NANDO - New Approach Notified and Designated Organisations) and the European Association for Medical Devices of Notified Bodies (Team-NB) website in order to ensure that the list is correct and complete. Further details recorded were website link, link to course program, topics offered, type of training (procedural, clinical, methodological), language of training and other information such as duration of the course.

The overview was sent to the CORE-MD T4.3. Task members for their check and input. Thereafter, their feedback was implemented and an additional search on the internet was performed, where required. Also, after the exploratory consultations with key stakeholders (see section “exploratory consultations with stakeholders” below) were finished, the further mentioned information was added.

The overview of advanced training courses and qualifications related to medical devices and the MDR was neither intended to be complete nor exhaustive. The aim was to show what kind of advanced training is already available, what the modules/areas are, and if there are any fields where no or limited training is provided. The purpose of the analysis was not to list individual courses, but rather to provide a summarized overview of modules and topic areas that could be used for further evaluation and presentation in the roadmap.

In the current roadmap, the name of the institutions, country and website link were presented in separate tables for notified bodies (Europe) – see Table 4, medical device industry and consultancies – see Table 5, clinical (learned) societies and regulatory affairs societies – see Table 6 as well as

academic institutions and universities (Europe) – see Table 7. Table 8 summarizes the content and mode of advanced training courses and qualifications.

2.3 Exploratory consultations with stakeholders

Before setting up this CORE-MD survey, it was agreed among CORE-MD T4.3. Task members to perform exploratory consultations with key stakeholders in order to collect some background information to help clarifying the questions for the survey. The exploratory consultations also aimed at evaluating specific training needs of these stakeholders.

Exploratory consultations were performed by Team-NB with two representatives: one from a Competent Authority AFMPS (Agence Fédérale des Médicaments et des Produits de Santé / Federal Agency for Medicines and Health Products) and one from a notified body TÜV SÜD (Technischer Überwachungsverein/Technical Inspection Association). The Austrian Institute for Health Technology Assessment (AIHTA) held consultations with three representatives from regulators: one former Clinical Investigation and Evaluation (CIE) chair/member; one Clinical Manager, Medical Devices from HPRA (Health Products Regulatory Authority); one representative from the joint assessment process of notified bodies (medical devices) at the European Commission.

The consultations took place from September 2021 until January 2022 and were recorded for internal purposes. Summaries of the consultations were created so that relevant information could be extracted. Main issues identified from the exploratory consultations with notified bodies and regulators can be found in Table 9.

The **broad questions for the notified bodies and regulators** were:

1. Where do you and your colleagues get the training from?
2. Which major training needs do you perceive as necessary (for your target group) to support/facilitate the successful implementation of MDR?
3. For whom – in other target groups – do you perceive training needs: in which areas?
4. How could this training best be organized (private, academic, ..)?

For the **stakeholder group of clinicians** a short exploratory survey was sent out by BioMed Alliance because it was deemed a more suitable format for this specific target group to get a balanced response from a broad variety of medical fields. The questions posed can be found in the Appendix 1. Relevant answers were summarized in section “Exploratory survey by BioMed Alliance”.

Within the context of this report on training in regulatory science the stakeholder group of clinicians is defined by their respective context-specific (different) roles in contributing to regulation

- Clinicians contribute to the safety of devices.
- Clinicians work clinical trialist.
- Clinicians contribute to regulatory work as members of expert panels.
- Clinicians working in clinical care.

2.4 CORE-MD Survey

The aim of this CORE-MD survey was to ask about perceived needs for training in regulatory sciences, core methodological competencies as well as the view on training formats and modalities. Therefore, the survey was structured into different chapters such as demographics, occupation and education, training, core competencies and training needs, training formats and modalities, and additional comments / follow up / results. For clinicians additional questions were added about "knowledge on regulatory affairs/sciences", which only showed up if the category "clinician" was selected as "main employment". Also other questions had different follow-up questions depending on the answer(s) given beforehand. Information regarding data protection was indicated at the beginning of the survey. The respective text was checked by RIVM (National Institute for Public Health and the Environment, CORE-MD Data Protection Manager). In total, the survey included around 25 questions, which took approximately 15 minutes to complete. The survey could be completed anonymously.

The results from the landscape overview, the exploratory consultations and the exploratory survey, were considered when drafting the survey. Especially the landscape overview and the results from the exploratory consultations were helpful for coming up with the list of core competencies for the assessment of high-risk MDs.

Furthermore, an online participation at the WorkInHealth Foundation Launch Event, organised by the European Institute of Innovation and Technology (EIT) on Nov 23, 2021, enabled the identification of interesting aspects mentioned during the dedicated sessions on high value care – closing the training gap in healthcare professionals and regulatory skills gap. These were also incorporated in the list of core competencies, where applicable. For example, it highlighted the need for patient centred care and patients should be involved throughout the innovation cycle, which was covered in the skills ("concepts of unmet need in patient populations" and "methods and time-points for patient involvement/engagement).

A table with public health competencies was used as an example for this list [23] and was adapted to the needs of the present evaluation. The core competencies were structured according to development cycle of medical devices – see Figure 2 [24]: preclinical testing, clinical investigations, conformity assessment and post-market surveillance and the respective reporting and documenting requirements in a Clinical Evaluation Assessment Report (CEAR), a Clinical Evaluation Report (CER), a post-market clinical follow-up (PMCF) Plan, and a Summary of Safety and Clinical Performance (SSCP).

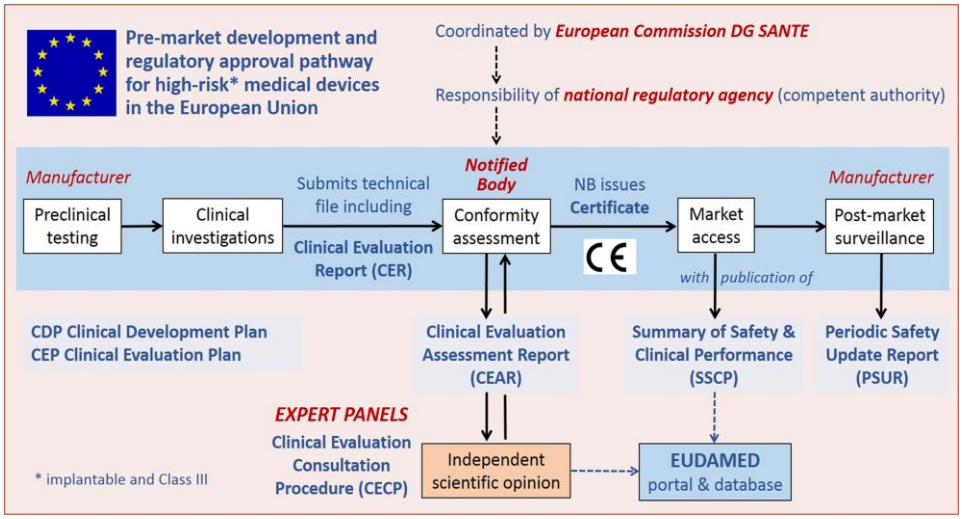


Figure 2: Development cycle of medical devices [24]
* To notice that the figure is only related to the Technical File (does not include the quality management system)

A first version of the survey was created by AIHTA, discussed among the CORE-MD T4.3. Task members and adapted based on the feedback received. Then, it was set up on the EU-survey tool with the following link: https://ec.europa.eu/eusurvey/runner/CORE-MD-WP4-Survey-2022. The survey was accessible to everyone who had access to the link, no password was needed. In the end, the persons who completed the survey could download their own results in a PDF document.

The online survey was piloted by six CORE-MD Consortium members (two regulators, two clinicians, one notified body, one researcher) and some minor modifications were implemented before the final version went public on April 20, 2022. Reminders were sent and the deadline for completion of the survey was extended twice (initial deadline was May 20, 2022; deadline extension to June 10, 2022; and final extension to June 30, 2022) and it finally closed on July 7, 2022. The survey can be found in Appendix 2.

In order to enhance participation in the survey, some dissemination activities were performed and the survey link was sent directly to the applicable groups (see Table 2).

***Table 2:** Distribution of the survey link*

Category	Recipients
Notified Bodies	• Survey link sent to 30 notified body organisations (minimum of two persons per notified body, sometimes six or seven per notified body) • Encouraged to forward link to their colleagues • Survey was presented at Notified Body Coordination Group for Medical Devices (NBCG-Med) meeting on April 5-7, 2022
Regulators	• Survey link sent to members of the Clinical Investigation and Evaluation (CIE) working group (around 40 persons) • Survey link sent to wider HPRA medical devices department (around 40 persons)
Clinicians	• Survey link sent by EMA to members of the medical device expert panels (around 150 persons). An email template was created that was sent out by EMA representatives.

	In the email we indicated that the medical devices expert panel members should select "clinicians" as their main employment. • BioMed Alliance sent survey link to its 348 contacts, posted the link on their website, twitter and LinkedIn and included it in their newsletter. Targeted emails were sent to 20 societies. • ESC made an email campaign to the European Heart Rhythm Association (EHRA), European association of Percutaneous Cardiovascular Interventions (EAPCI) and the Heart Failure Association (HFA). The total number of recipients was: 13.446.
Mixed	• CORE-MD: an article on the CORE-MD website, newsletter and social media (twitter), email to CORE-MD consortium members. • Individual CORE-MD consortium members might have distributed survey through their own channels.

Furthermore, the T4.3. CORE-MD survey was announced during two meetings:

- The Core-MD project (including survey) was presented at the NBCG-Med plenary meeting on October 5, 2021
- The Core-MD project (including survey) was explained at the BioMed Alliance General Assembly Meeting on 29-30 November, 2021

Since the exact number of recipients is not known, no response rate for the survey could be determined.

The analysis of the survey was performed in Microsoft Excel including all survey results except the pilot surveys. The answers from the respondents from all countries were included. The rationale was to get an overall picture of professionals working in the field of regulatory sciences, considering that professionals could change jobs and countries (especially clinicians, who represent majority of survey respondents). In addition, the survey did not inquire about home country or place of education, it was specifically asking about the country of current main employment. However, a sensitivity analysis was done by leaving out the non-EU/EEA countries, but by including United Kingdom (UK) whose legislation is still based on the EU Medical Device Directive (EU MDD) and Turkey who transposed the MDR into their national legislation. Furthermore, all persons that were part of an EU expert panel for the evaluation of medical devices or in-vitro diagnostics, were included see section "Results of sensitivity analysis".

The figures from the results section (and the appendices) were created in Microsoft Excel.

3. Results / Key findings

3.1 Competencies in Regulatory Science mentioned in publications

As described in the introduction, core competencies were identified by FDA and EMA as part of the multidisciplinary pursuit of regulatory science. Key areas of competencies and needs for a regulatory science training program include the understanding of research and scientific methodology, and the science that underpins the regulatory process. See Table 3 for competency areas identified.

Table 3: *Competency areas (from pharma) that also apply to medical devices*

Competency areas	In-/directly addressed by
Product safety: • models of human adverse response, • identify and evaluate biomarkers and end points that can be used in nonclinical and clinical evaluations, and • use and develop computational methods and in silico modelling, • Multiple-devices full life-cycle failure-cause analysis [6]	FDA
Innovation in clinical evaluation along the life-cycle: • refine clinical trial designs (e.g. (registry-nested trials [6]), • end points (patient relevance in evidence generation), and analysis methods, • leverage existing and future clinical trial data, • identify and qualify biomarkers and study end points, • increase the accuracy and consistency, and reduce inter-platform variability of analytical methods to measure biomarkers, and • develop a "virtual physiologic patient", investing in special populations initiatives.	FDA EMA Lübbeke 2021
Novel manufacturing technologies: • development and evaluation of novel/improved manufacturing methods, • develop new analytical methods, and • reduce the risk of microbial contamination of products.	FDA EMA
Evaluation of emerging technologies: • developing novel assessment tools and methodologies for novel therapies, and • coordinate regulatory science for integrated evaluation pathway for the assessment of medical devices, in vitro diagnostics and borderline products, new materials, nanotechnology.	FDA EMA
Data generation through information sciences: • improve health outcomes by enhancing information technology infrastructure, data mining, • develop and apply simulation models for product life cycles, risk assessment, and other regulatory science uses, • analyse large-scale clinical and preclinical data sets, • incorporate knowledge from regulatory files into a database integrating a broad array of data types (e.g. Multiple-devices full life-cycle failure-cause analysis [6], • develop new data sources („Big Data") and innovative analytical methods and approaches (Post-marketing surveillance: (Multi-) Registry-studies, the use of real-world-evidence (RWE) [25], • leverage non-clinical models and 3Rs principles, optimise capabilities in modelling, simulation and extrapolation.	FDA EMA
New regulatory instruments: • for emerging clinical data generation and to enable promising innovation, to provide accelerated access [5] such as Certificates under Conditions, risk-sharing tools, • exploit digital technology, artificial intelligence and the use of RWD in decision making, • deliver improved product information in electronic format (ePI).	EMA, Calvert 2021
Resources Management: • guidances and tools facilitating the consistency of regulatory implementation [5].	Calvert 2021
Ethics: • responsible innovation: in pre-clinical as well as in the clinical phase, • scientific integrity [26], • transparency on conflicts of interest [1].	Wallach 2018 Demasi 2022
Collaborations and synergies in the ecosystem: • Scientific Advice on study designs and outcomes (incl. patient-reported outcomes), • data generation [19] and data harmonization along the development continuum, • strategic oversight with horizon scanning [5],	EMA Schünemann 2022 Calvert 2021

• contribute to HTA´s and payers´ assessments, • global cooperation to anticipate and address supply problems.	
Communication: • on benefit-risk assessment, • engagement and communications to promote trust and confidence in the EU regulatory system.	EMA

Most recently (2019-2022, https://www.csa-stars.eu/), an EU-funded Coordination and Support Action (CSA) project entitled "Strengthening Training of Academia in Regulatory Science (STARS)", developed a core curriculum and specifies aspects of regulatory knowledge that are considered as essential by the STARS consortium and relevant stakeholders [27].

The STARS core curriculum is mainly targeted at graduate students (bachelor and master's degree) interested in regulatory science and in gaining basic regulatory knowledge / training of European regulations on medicinal products and borderline between medicines and medical devices. The project was a collaboration between 18 European National Competent Authorities (NCAs/EU IN members), four associate countries and EMA. The Core Curriculum covers the basic knowledge in regulatory science of pharma products illustrating the different levels of regulatory requirements applying at different stages during product development. See Figure 3 [28].

Figure 3: *STARS Core Curriculum*

The Comprehensive Curriculum is designed for an advanced training level to acquire more in-depth knowledge in regulatory science and to gain more information on different and especially innovative regulatory areas with the overarching goal to successfully develop novel medicinal products and technologies for patients. Target audience is researchers and healthcare professionals involved in medicinal development. The advanced training is divided into five different modules. See Figure 4 [29].

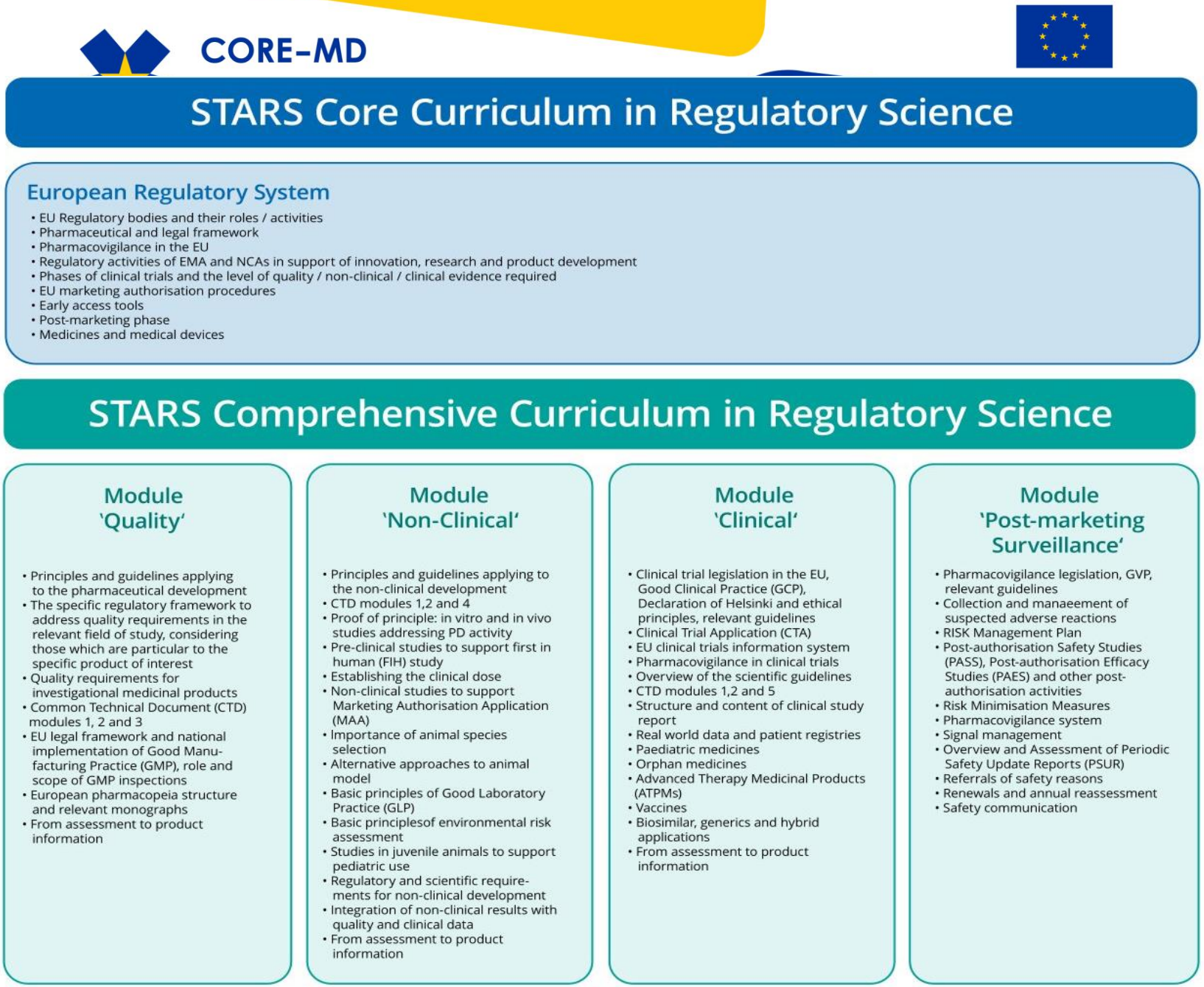


***Figure 4**: STARS Advanced Training Curriculum [29]*

Other sources reflecting competencies for regulatory science identified the following areas:

- New regulatory instruments to enable promising innovation, to provide accelerated access [5] such as Certificates under Conditions, risk-sharing tools
- Resources: guidances and tools facilitating the consistency of regulatory implementation [5]
- Responsible innovation: in pre-clinical as well as in the clinical phase,
- Scientific integrity [26], transparency on conflicts of interest [1], research ethics [30]
- Collaborations and synergies in the ecosytem: Scientific Advice on study designs and outcomes (incl. patient-reported outcomes), data harmonization, generation, etc. [19], strategic oversight with horizon scanning [5]
- Post-marketing surveillance: (Multi-) Registry-studies, the use of real-world-evidence (RWE), e.g. for [25]
- Multiple-devices full life-cycle failure-cause analysis [6]
- Advanced clinical research study designs (registry-nested trials) [6]
- Communication: risk-communication, evidence communication [30]

3.1.1 Modes and Models of Education and Training on Regulatory Science

The following elements have been recognized by the Institute of Medicine (IOM) in their report on "Strengthening a Workforce for Innovative Regulatory Science" to start to develop and advance regulatory science [21]:

- Recognize regulatory science as a discipline
- Define the discipline
- Define the qualifications
- Define educational needs
- Create academic homes and promotion/tenure tracks

For fostering of the regulatory science it is recommended to recognize role models within the academic institution and start developing [21] and implementing [7] tailored programs for specific stakeholder groups and their respective tasks with basic courses and extension in-depth module advancing from knowledge to expertise [31].

- Education and training programs: academic master´s programs, advanced post-graduate training, professional certificate programs for continued professional development (CPD)
- Appropriate tenure tracks
- Training opportunities within and outside of regulatory agencies with exchanges in form of internships and fellowships to create an ecosystem
- Collaborations with research communities and infrastructure
- Government funding

3.2 Landscape of available (advanced) training, qualifications on MD-regulation (MDR)

As initial step a mapping of advanced training courses and qualifications related to medical devices and the MDR was conducted and information was collected on providers, on content of the advanced training courses and on modes and models of the educational courses. As Europe is diverse the overview of the advanced training courses and qualifications related to medical devices and the MDR is neither intended to be complete nor exhaustive and – since the needs for advanced training are perceived by all actors – new programs evolve constantly.

3.2.1 Provider of advanced training courses and qualifications and addressees

Providers of qualifications on regulatory science or advanced training can be broadly assigned into five categories:

1. **Notified Bodies:** The notified bodies and their associated Academies are offering more focused courses and training (Continuing Education) for their staff members.
2. **Medical Device industry** an **commercial businesses (consultancies):** Among medical device industry representatives, often the National Trade Associations are offering focused courses and training, next to private (commercial) institutions specialised in training of professionals.
3. **Medical (Learned) Societies** offer Continuing Medical Education and Training for healthcare professionals and researchers in a wide range of areas including on the conduct of clinical trials and the engagement in regulatory affairs.
4. **Societies for Regulators and Regulatory Affairs** offering postgraduate qualifications and advanced training as professional development.
5. **Academic institutions** are offering Master-Programs (MSc.) often in connection a development program for regulators, for notified bodies or for experts in market access in industry.

Examples for the four categories of providers are presented in table 4 to 7.

Other educational providers including Clinical Research Institutions (CRO) and their potential training courses on research for innovation in medical device sciences are not covered here.

***Table 4**: Notified Bodies (Europe)*

Name of Institution (examples*)	**Country**	www.team-nb.org
Team-NB Academy, Association of Notified Bodies	Belgium	www.team-nb.org
TÜV Süd Akademie	Germany	https://www.tuvsud.com/de-de/store/akademie
TÜV Rheinland LGA Products GmbH	Germany,	https://akademie.tuv.com/catalogsearch/result/index/?cat=503
TUV Rheinland Italia Srl	Italy	https://www.tuv.com/italy/en/open-seminars.html
TÜV NORD	Germany	https://www.tuev-nord.de/de/weiterbildung/themen/qm-medizinprodukte-und-gesundheitsversorgung/
DQS Medizinprodukte GmbH	Germany	https://www.dqs-med.de/unser-service/seminare
DEKRA Certification GmbH	Germany	https://www.dekra-akademie.de/qm-weiterbildung-medizinprodukte/
MDC/ medical device certification GmbH	Germany	https://www.mdc-ce.de/medizinprodukte/seminare.html
BSI Group The Netherlands B.V.	The Netherlands	https://www.bsigroup.com/en-GB/medical-devices/training/
GMED SAS	France	https://lne-gmed.com/knowledge-center/webinars
SGS UK, SGS Belgium	UK, Belgium	https://www.sgs.be/en/training-services
CE certiso	Hungary	https://cecertiso.hu/?page_id=13054
ECM/ Ente Certificazione Macchine Srl	Italy	www.entecerma.it
Kiwa Cermet Italia	Italy	https://www.kiwa.com/it/it/media/webinar/archivio/
IMQ/ Istituto italiano del marchio di qualita Spa.	Italy	https://www.imq.it/en/training
CERTIQUALITY Srl	Italy	https://www.certiquality.it/en/focus-on/training
ISS/ Istituto superior di sanita	Italy	https://www.iss.it/web/iss-en/training
NSAI/ National Standards Authority of Ireland	Ireland	https://www.nsai.ie/about/learning-centre/
SQS/ Swiss Association for Quality and Management Systems	Schweiz	https://www.sqs.ch/de/schulungen/medical
TÜV Austria	Austria	https://www.tuv-akademie.at/
SIQ	Slovenia	https://www.siq.si/izobrazevanje/program/#filter_cat=&sub_id=9327457C-D92E-E911-80D9-81EF3824CAA0
IMNB/ Intertek Medical Notified Body AB	Sweden	www.intertek.se
3EC International a.s.	Slovakia	https://www.3ec.sk/en/services/trainings/

* not intended to be exhaustive

Table 5: *Medical Device Industry and Consultancies*

Name of Institution (examples*)	Type of Institution	Country	Website Link
MedTech Europe	European Trade Association for the medical technology industry	Belgium	https://www.medtecheurope.org/new-medical-technology-regulations/training-and-education/
World Medical Device Organisation (WMDO)	Global network for medical device professionals in industry	USA, Switzerland Malaysia	https://wmdo.org/course-catalogue.aspx
Austromed	Austrian trade association for medical technology	Austria	https://www.austromed.org/akademie/seminare-ueberblick/
VDE/ Verband der Elektrotechnik Elektronik Informationstechnik e. V.	German trade association for medical technology	Germany	https://meso.vde.com/de/events/
mdlaw.eu	Obelis Group, Company specialised in training	Belgium	https://mdlaw.eu/webinars/
DIN Akademie	Beuth Verlag GmbH, Publisher	Germany	https://www.beuth.de/de/dinakademie/medizintechnik
GFQ Akademie	Company specialised in training	Germany	https://www.gfq.de/de#Seminaruebersicht
Trautmann Akademie	Consultancy	Germany	https://atrautmann.de/Schulung-MDR.htm
educo life sciences	Company specialised in training	UK	https://educolifesciences.com/medical-device-training/
easy medical device	Consultancy	Switzerland	https://school.easymedicaldevice.com/emd-course
GS1 Academy	Consultancy	Germany	https://www.gs1-germany.de/no_cache/gs1-academy/trainings/?tx_gs1seminars%5Bcategory%5D%5B80%5D=true#c1397
Meddev Solutions	Consultancy	UK, Ireland	https://www.meddevsolutions.co.uk/virtual classrooms
Management Forum	Falconbury Group: Company specialised in training	UK	https://management-forum.co.uk/product/overview/69-0/life-sciences
Oriel	Consultancy	USA, Europe	https://www.orielstat.com/courses/medical-device-RA-QA
Key2compliance	Consultancy	Sweden	https://key2compliance.com/public-courses
Qserve	Consultancy	The Netherlands	https://www.qservegroup.com/eu/en/events-en-training
mdpharmacourses.com	Consultancy	Switzerland	https://mdpharmacourses.com/product-category/regulatory/ https://mdpharmacourses.com/product-category/rd-and-technical/
Johner Institute	Consultancy	USA, Germany, New Zealand	https://www.johner-institute.com/training-seminars/seminars/medical-device-regulation/
SQT	Company specialised in training	Ireland	https://www.sqt-training.com/programmecats/life-sciences/
GCP-Service International	Company specialised in courses for Principal Investigators and other clinicians	Germany	https://www.gcp-service.com/pruefgruppenleiter-aufbauschulung-de/
Skill Net Ireland	National business support agency	Ireland	https://www.skillnetireland.ie/networks/irish-medtech-skillnet-2/

* not intended to be exhaustive

Table 6: *Clinical (Learned) Societies and Regulatory Affairs Societies*

Name of Institution (examples*)	Type of Institution	Country	Website Link
Clinical (Learned) Societies			
BioMed Alliance	NPO representing 36 leading European medical societies	Belgium	https://www.biomedeurope.org/regulatory-affairs/regulatory-affairs-and-medical-devices-task-force.html
EFGCP/ European Forum for Good Clinical Practice	EFGCP is a not-for-profit organisation established by, and for, those with interest in the development of medicines and medical technologies.	Belgium	EFGCP - European Forum for Good Clinical Practice
MAPS/ Medical Affairs Professional Society	NPO	USA	https://medicalaffairs.org/events/; https://medicalaffairs.org/le-masterclass-Zurich/
Medical congresses	Sessions at congresses, webinars or e-learning or internal meetings of committees related to regulatory affairs	EU	.....
Regulatory Affairs Societies			
RAPS/ Regulatory Affairs Professionals Society	Gobal organization for professionals involved in regulation of healthcare and related products; a neutral, non-lobbying NPO	USA, Europe	https://www.raps.org/education-events/e-learning/online-university-certificates/the-regulatory-affairs-certificate-medical-devices
TOPRA/ Organisation for Professionals in Regulatory Affairs	Organisation for professionals working in healthcare regulatory affairs.	UK, Europe	https://www.topra.org/TOPRA_Member/Resources/Medical_device_resources/TOPRA/TOPRA_Member/News_Folder/2017/Resources_for_Professionals.aspx?hkey=f62c313d-4b49-4f4e-a0b2-e71442329195
Deutsche Gesellschaft für Qualität (DGO)	NPO	Germany	https://shop.dgq.de/themen/weiterbildung-medizinprodukte
DIA/ Drug Information Association	Global organisation for professionals working in the life sciences	USA, China, Switzerland, India, Japan	https://www.diaglobal.org/en/course-listing#q=all/sort=relevance/page=0/region=

* not intended to be exhaustive

***Table 7**: Academic institutions and universities (Europe)*

Name of Institution (examples*)	Type of Institution	Country	Website Link	Academic degree
University of Hertfordshire in UK in coop with RAPS and TOPRA	University	UK	https://www.herts.ac.uk/study/schools-of-study/life-and-medical-sciences/departments/clinical-pharmaceutical-and-biological-sciences/pharmaceutical-and-regulatory-science	MSc Regulatory Affairs Medicines / Medical Devices
Cranfield University	University	UK	https://www.cranfield.ac.uk/	MSc Medical Technology Regulatory Affairs
University of Galway	University	Ireland	https://www.nuigalway.ie/courses/taught-postgraduate-courses/medical-technology-regulatory-affairs.html#	MSc Medical Technology Regulatory Affairs
Trinity College Dublin	University	Ireland	In development	Ms Medical Device Regulatory Affairs for Medical Devices
Friedrich-Alexander Universität Erlangen-Nürnberg - ZIMT/ The Central Institute of Medical Engineering	University	Germany	https://www.zimt.fau.eu/wissenschaft/medical-device-regulation-mdr2/	Ms Medical Engineer: Seminars on Regulatory Affairs
Universite de Franche Comte	University	France	https://isifc.univ-fcomte.fr/isifc-master-international/	Int. Master in Biomed Engineer: courses in Regulatory Affairs, etc.
Université Paris-Saclay	University	France	https://www.universite-paris-saclay.fr/en/education/master/pharmaceutical-science/m2-regulatory-affairs-health-industry	Ms in Regulatory Affairs of the Health industry
Polytech Lyon, co-habilitated with "l'Ecole Centrale de Lyon"	University	France	https://polytech.univ-lyon1.fr/formation/cycle-ingenieur/genie-biomedical/master-genie-biomedical	Affaires Techniques et Réglementaires des Dispositifs Médicaux (ATRDM) in English: Technical and Regulatory Affairs for Medical Devices
FH Technikum Wien	Fachhoch-schule	Austria	https://academy.technikum-wien.at/master-akademische-abschluesse/health-tech-management/	MBA, Health Tech Management, including regulatory affairs. Digital Health Solutions, Business Development
University for Continuing Education Krems/Donau University	University	Austria	https://www.donau-uni.ac.at/de/studium/eu-regulatory-affairs/inhalte-und-termine.html	EU Regulatory Affairs, CP (Certified Program) /MSc
KU Leuven	University	Belgium	https://onderwijsaanbod.kuleuven.be//2022/syllabi/e/H03I5AE.htm#activetab=doelstellingen_idp840784	Ms Biomeed Engineer - different lectures: Medical Equipment and Regulatory Affairs

* not intended to be exhaustive

3.2.2 Content and Mode of the advanced training

The content of advanced training and qualifications can be broadly assigned into three categories:

1. Seminars or courses (also virtual: webinars, videos) for **hands-on training** on specific tasks for the conduct of the conformity assessments of certain products before being placed on the European market (by notified bodies) or for submitting data and documents for the approval of products (by medical device companies): Those courses last usually several hours, single or a few couple of days as continuing education.
2. Clinicians receive a different type of training that is more hands on and applicable to their daily work in caring for patients or participating in health research related activities. There are for example sessions and **congresses and webinars**, and other CME and CPD related activities to better inform clinicians on regulatory affairs. Several European medical societies also have **regulatory affairs** committees or groups bringing together interested clinicians in this field. In addition, clinicians participating in the European Expert Panels for medical devices have received training to be able to contribute to the work of the panels. Overall results of our initial research show that educational opportunities for clinicians are still limited.
3. Regulators are organized in supranational organisations for professionals in regulatory affairs such as RAPS, TOPRA or DIA: these organisations also provide a full range of **postgraduate qualifications**, sometimes even offered in conjunction with a university **graduate master´s program**. Those courses or certification programs usually last longer and cover a comprehensive set of core modules complemented by elective module and courses.

Not mentioned and not offered in any of the advanced training and qualifications are (formalised) fellow- or internships for training-on-the-job in the respective institutions such as national competent authorities, organisations for accreditation of notified bodies or in notified bodies for clinicians or students.

Last but not least, there are numerous university programs “Regulatory Affairs” for medicines (as graduate program: University of Copenhagen/ Denmark, University of Bonn/ Germany etc.; as postgraduate programs: Medical University of Vienna/ Austria, etc.) not mentioned here, but only a handful such programs for medical devices. Additional to full university programs core module programs complemented by further specialised courses are offered.

Table 8: *Content and Mode of Advanced Training courses and qualifications*

Institutions	Topics offered	Mode of training
Notified Bodies	Multiple different courses on MDR/ IVDR: classifications, clinical data (evidence) and evaluation, data analysis and appraisal technical documentation, risk-management, Software (SMDR), Audits, Post-marketing surveillance, UDI, ISO, GMP, quality management, manufacturing, performance evaluation. Reporting. Regulatory affairs, legal issues, national requirements	Courses, seminars, webinars: A few hours or 1-3 days courses
Medical Device Industry & Consultancies	Multiple different courses on Design & Development of MDs, MD studies an study designs, literature search for MDs/IVDs MDR/ IVDR: classifications, clinical data (evidence) and evaluation, data analysis and appraisal technical documentation, risk-management, Software (SMDR), Audits, Post-marketing surveillance, UDI, ISO, GMP, quality management, manufacturing, performance evaluation. Reporting. Regulatory affairs, legal issues, national requirements, cybersecurity	Courses, seminars, webinars: A few hours or 1-3 days courses Medical device "university": E-Learning library
Clinical (Learned) Societies	GCP Training, evidence generation planning, engagement	No details provided
Regulatory Affairs Societies	RAPS: 4 core courses: Ethics, Global regulatory strategy, MDs: definition and lifecycle, Role of the regulatory professional + 5 elective courses RAPS training on a broad range of topics: Law, medical writing, regulatory affairs, project management, compliance, audits, risk management, GCP, GMP, understanding/managing clinical trials, MD/IVD regulation. TOPRA: Basics courses on medical devices Introductory course for new professionals to MD Regulatory Affairs Masterclasses (MSc Regulatory Affairs – Medical Devices) in coop with University of Hertfordshire DIA Regulatory Medical Affairs: medical statistics, benefit-risk assessment, literature searching	Courses for Regulatory Affairs Certificate (RAC) = internationally recognized certification program for regulatory affairs professionals Training 1 day 3 days 4 semesters several webinars courses: single days
Universities	Masterclasses with core curriculum and elective courses Comprehensive: Design, Development and Certification of Medical Devices; Clinical Evaluation of Medical Devices; Post-Market Surveillance and Vigilance for Medical Devices	4 semesters awarded with Master degree Single courses as part of Master in Biomed or Medical Engineering

3.3 Results of exploratory consultations with stakeholders (notified bodies, regulators) and BioMed Alliance exploratory survey

3.3.1 Exploratory consultations with Notified Bodies and regulators

The exploratory consultations were held with representatives from notified bodies and regulators. The main issues mentioned during the consultations were summarized in the Table 9.

***Table 9**: Main issues extracted from the exploratory consultations with notified bodies and regulators*

	Notified Bodies	**Regulators**
	• One representative from AFMPS • One representative from TÜV SÜD	• One former clinical investigation and evaluation (CIE) chair/member • One clinical manager, medical devices from HPRA • One representative from the joint assessment process of notified bodies (medical devices) at the European Commission
Questions/topics	**Answers: main issues**	**Answers: main issues**
Current training	Training is done **mainly internally**, but also **external vendors** are used. Each member has a training program including coaching, especially when joining. **There are three categories** of training: • Technical training (e.g. engineering, scientific knowledge; some fundamentals are expected), done internally • Regulatory training (regulatory frameworks/standards), done internally or externally • Process training (e.g. work flows, is very specific to each NB), done internally	Training courses **do not go into sufficient depth** (especially in the clinical field i.e. with regard to clinical investigation and related methods, outcome measurements etc.). **In depth training needed would be**: medical statistics, systematic literature search (according to PICO), different kind of clinical investigations, how to assess different study designs, how to assess if choice of clinical benefit and outcome parameters are appropriate, safety aspects/side effects, how to compare the acceptability of a benefit/risk ratio for products with the state of the art. Training courses cover **mostly strategy, but not the methodology** of clinical evaluations. At the regulator, there is an induction plan and on the job training. Difficult to find training for medical devices. Looked at RAPS, TOPRA, some companies, also **competent authorities** provided training for EC staff (bespoke training).
Training needs for own and other target/stakeholder groups	**Notified bodies, regulators and clinicians**: there should be a baseline or consensus on how to apply and interpret certain requirements. **Notified bodies and regulators** should have the same needs and thus the same kind of training (both consider medical device safety and performance requirements).	**Notified bodies**, **regulators and clinical experts** should in general be doing similar types of assessments. Employees from **designating authorities (also on European level)** and **members from ethics committees** (assess scientific content as well as appropriateness of the investigator/site) could benefit from training.

	Clinical experts should be trained in regulatory aspects needed for their job. Importance of required vigilance reporting from **clinicians** was highlighted to allow analyses by the authorities. At the **clinical level**, advanced skills must be acquired to carry out a clinical evaluation and if necessary call on external experts. Therapeutic fields: neurology, orthopaedics, cardiology, gynaecology. Non-clinical skills: technological groups. The **methodology** is essential to achieve consistency of services. Guidance from Competent Authorities for Medical Devices (CAMD) would likely be useful for CAs. **Risk management** (to be understood even beyond the standard), **classification** and **methods on how to write standards and regulations** (to help the understanding of how to read them) were outlined as training needs.	Specific training in clinical evaluation could be interesting for **ministries and agencies**, especially for those involved in market surveillance. **Market surveillance** is important (involves bringing in the clinical evaluation and assessing it). Training could cover **scientific aspects of the clinical evaluation** in the context of the description of the clinical investigation for the different professional groups (cardiologists, orthopaedics, diabetologists) across stakeholders (notified bodies, clinicians, regulators). **Training needs for notified bodies**: clinical areas such as active implantables, orthopaedics, cardiology. **Training needs for clinicians**: clinical expertise is there, but in some cases knowledge about regulatory science is missing or the actual understanding what conformity assessment means. Member states and the EC are required to set up implant registries. There could be a training need on **how to set up registries**. **There could be a training module on how to set up a structured dialogue**. Pre-clinical testing and structured dialogues: what kind of clinical data is needed (clinical data, literature data, technical data, biocompatibility data). Areas for current **training of EC staff**: • Clinical aspects of MD conformity assessment/clinical evidence • MD standards, harmonised standards • Classification and borderline • Corrective Action Preventive Action (CAPA) Training **Some competency areas mentioned**: sterilisation, pre-clinical evaluation, software, combination devices, tissues of cells of human origin, quality management system (QMS). Need to link it back into the regulatory science and conformity assessment itself.
Possible modalities for training	Not more training per se needed, but some topics can be **streamlined and focused** on. New regulations framed the educational requirements well so at this stage **no other requirements** in terms of training should be added (skills needed are defined in NANDO codes).	Training needs for notified bodies: additional **on the spot training** is needed, actual operational work they need to do, training in the methodologies, technologies, procedures. Maybe fund types of **internship for practical (operational type of) training**. Practical experience is needed.

		Would be helpful to have training material that the EC can audit the designated notified bodies against.

For notified bodies training is mostly done internally, although for regulatory sciences also external providers are used. Regulators mentioned that especially for methodologies of clinical evaluations training opportunities are lacking. Some in depth training is needed (see table above for suggested list of topics).

Notified bodies and regulators agreed that there should be similar training needs for notified bodies, regulators and clinical experts/clinicians, since they are performing similar types of assessments. Furthermore, both suggested that clinicians might need some training with regard to regulatory sciences. Clinical fields where advanced clinical skills were needed are e.g. neurology, orthopaedics, cardiology, gynaecology and diabetology. For clinicians, the importance of vigilance reporting was highlighted by notified bodies.

Notified bodies reported some specific areas where training is needed: risk management, classification and approaches/methods to use in the contribution to the creation of new standards and regulations. In addition, regulators indicated that training in how to set up registries or structured dialogues (MDCG 2022-14, point 15) is lacking. Other required competencies were sterilisation, pre-clinical evaluation, software, combination devices, tissues of cells of human origin and quality management system (QMS).

Notified bodies stated that educational requirements are assessed and reviewed on a regularly basis as required by their Competent Authority and regulations. Each notified body is putting in place an introductory plan for each new hired person – mostly by internal training. For the time being, Notified bodies´ staff can attend the training courses organised by "Team-NB Academy" (About us - Welcome to Team NB | Team NB (team-nb.org) that support them in dealing with the requirements of the new regulations in their assessments. A new tool "**Team-NB Experts Sessions**" was set up to ensure a better alignment and harmonisation through exchanges on (practical) case studies. Each year around 15 sessions on 10 differents topics are organized. In addition, **Experts Harmonisation Sessions** are organised, to allow senior experts of the subject matter to share their experience on « hot » topics to help answering challenges to conduct a conformity assessment. The objective is that attendees cascade the info into their organisation to reach all reviewers. These sessions are organised on a quaterly basis. More recently, to respond to the MDCG Position Paper Transition to the MDR and IVDR (MDCG 2022-14) that encourages notified bodies to strengthen the communication with manufacturers by different means, a first **webinar toward manufacturers** is under development and planned.

Regulators suggested that additional on the spot training is needed, since practical training is missing. This could be performed in form of internships etc.

3.3.2 Exploratory survey by BioMed Alliance

The BioMed Alliance conducted a short survey instead of exploratory interviews to ensure it would receive feedback from a maximum number of societies from different medical fields. Questions inquired whether societies follow developments in regulatory affairs, what sort of educational activities they organise in this field and what the training needs of clinicians are. Fourteen persons representing European medical and research societies completed the BioMed Alliance exploratory survey on societies' education in regulatory affairs:

Abbreviation	Organisation
EASD	European Association for the Study of Diabetes
EULAR	European Alliance of Associations for Rheumatology
EASL	European Association for the Study of the Liver
ESPGHAN	European Society for Pediatric Gastroenterology Hepatology and Nutrition
ESHRE	European Society of Human Reproduction and Embryology
EHA	European Hematology Association
ERS	European Respiratory Society
ESC	European Society of Cardiology
EAN	European Academy of Neurology
ERA	European Renal Association
EFORT	European Federation of National Associations of Orthopaedics and Traumatology
	Three unspecified organisations

Five organisations indicated that they follow developments around regulatory affairs with regard to medical devices (e.g. around the MDR), three organisations followed it a little, but not actively, and six organisations did not follow it. Some suggestions for particular actions that would help colleagues in their discipline to develop an interest in regulatory affairs were:

- Information sessions at congresses and meetings (mentioned four times)
- Adding it to the curriculum of residents in training (mentioned twice)
- Webinars (mentioned twice)
- Articles published in peer reviewed specialty journals
- Funding for educational activities

One organisation indicated that regulatory affairs is part of the curriculum for their respective specialty and thirteen organisations stated that it was not for theirs. It was also mentioned that regulatory affairs should be included in the curricula of medical students and then more in detail in the various medical specialties.

Some organisations reported that they organize educational activities on regulatory affairs (e.g. sessions during congresses, regulatory affairs courses, webinars, guidelines, documents). Two training opportunities for clinicians in the field of regulatory affairs for medical devices were mentioned: Training Course for the European Commission Expert Panels on Medical Devices and the Regulatory Affairs Certificate Program of the regulatory affairs professionals' society (RAPS). Some major training needs they perceived as necessary to help clinicians better understand the MDR were:

- How EU strategies and regulations are developed and how they can be amended
- The differences between the old and the new regulation. General information about the MDR and its consequences

- The daily impact of regulations. Implication of MDR for clinical practice, and e.g. how MDR is used for new and old implants.

3.4 Results of CORE-MD survey

Main results presented refer to 1) the background of survey respondents, 2) knowledge about regulatory affairs/sciences (clinicians only), 3) identified needs for methodological expertise and educational requirements (per employment category) and 4) training, training formats and modalities. Detailed survey results can be found in Appendix 4: Quantitative survey results.

Please note that these results refer to the CORE-MD survey participants only. Generalization to the respective stakeholder groups in general might be limited. See “limitations” section.

3.4.1 Demographics, occupation and education, training of survey respondents

Main employment

As already mentioned above, the main stakeholders with regard to the implementation of the MDR considered in this survey are notified bodies, regulators and clinicians. Therefore, the survey respondents were asked to select which of these three categories defined best their main employment, so that the analysis could identify potential differences between these groups. There was also the option to indicate “other” (later on described as “other employment category”). Some of the other employment options mentioned were in the fields of: research/engineering (twelve persons), industry (five persons), legal (five persons), patient organisation (two persons), and consultancy (two persons).

The majority of survey respondents were **clinicians** (68%, 278 persons) and around a seventh were **regulators** (14%, 58 persons). The remainder of respondents did belong to the groups of **notified bodies** (9%, 37 persons) and **other employment category** (9%, 36 persons). See Figure 5 below.

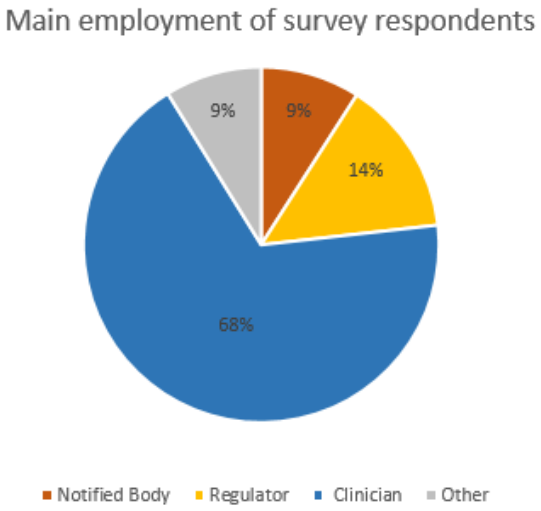


***Figure 5**:* Percentages of survey respondents per employment category

Second employment/affiliation, gender and country of current place of work (main employment)

Half of the clinicians (51%), around a fourth of notified bodies (24%) and of **regulators** (26%) and 31% of **other employment category** had a second employment.

The gender distribution of **notified bodies** was rather similar: 54% (20 persons) females and 46% males (17 persons). More than half of **regulators** were women (57%, 33 persons), a third was men (33%, 19 persons) and 10% refrained from declaring their gender. Vast majority of **clinicians** were male (69%, 191 persons), nearly a third was female (31%, 86 persons). For the **other employment category** half were female (50%, 18 persons), nearly half were male (44%, 16 persons) and 6% (two persons) opted to not state their gender.

Country of current place of work (main employment)
The countries from the EU and European Economic Area (EEA) were listed, in addition the option of "other country" was offered.

For **notified bodies**, the top two EU/EEA countries where respondents worked were Germany (19%, seven persons) and Poland (14%, five persons). For **regulators** these were Germany (22%, 13 persons) and Ireland (10%, six persons). Countries where **clinicians** worked were Germany (14%, 38 persons) and Croatia (10%, 28 persons). For **other employment category**, Belgium (19%, seven persons) and Netherlands (17%, six persons) were among the most selected EU/EEA countries. From the list of EU/EEA countries, no one chose Estonia, Liechtenstein and Slovakia.

In total 72 of 409 respondents (18%) indicated "other country", most of them clinicians (57 persons), nine notified bodies, one regulator and five persons from "other employment category". One to four persons per country participated from: Albania, Armenia, Australia, Azerbaijan, Colombia, Egypt, Ethiopia, Georgia, India, Indonesia, Iran, Israel, Japan, Jordan, Lebanon, Mongolia, Nigeria, North Macedonia, Pakistan, Peru, Russia, Saudi Arabia, Serbia, Syria, United Kingdom, Ukraine, United

States of America, Zambia. Ten persons (four clinicians and six notified bodies) indicated that their country of current place of work is Turkey and 17 persons (two notified bodies, 14 clinicians, one "other") indicated United Kingdom. One clinician indicated working from home from the USA for a notified body based in the Netherlands.

From those who selected "other country", six were part of an EU expert panel for the evaluation of medical devices or in-vitro diagnostics: one notified body (Turkey), one "other employment category" (Australia, Maltese citizen) and the remainder (four) were clinicians. There was one person each from Australia (Maltese citizen), USA, UK, Turkey, Azerbaijan, Zambia.

As indicated in the methods above, the answers from the respondents from all countries were included, but a sensitivity analysis for the six domains (including the skills) of the core competencies was performed. In total, 40 persons were excluded, this means that 369 were included in the sensitivity analysis.

- 1 notified body was excluded (from the USA) i.e. 3%
- 1 regulator was excluded (stated "rather not say" for the "other country") i.e. 2%
- 3 Other employment category (USA, Nigeria, Iran) i.e. 8%
- 35 Clinicians i.e. 12,6%

Stage of career

At least 50% or more of each employment category indicated that they are at senior or executive level. The highest number of respondents at entry-level was seen for regulators (17%, 10 persons). See Figure 6 below.

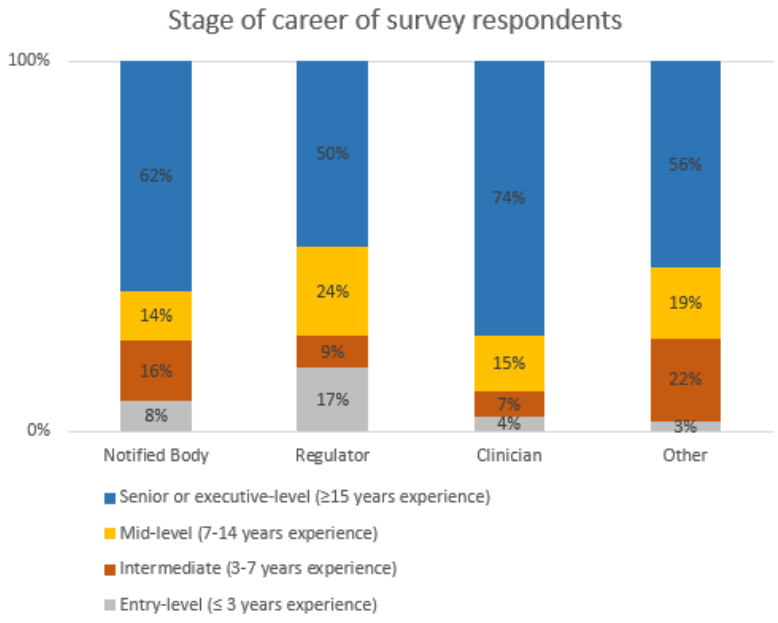


***Figure 6**:* Stage of career of survey respondents per employment category

EU expert panel

One **notified body** (3% of notified bodies) and one **regulator** (2% of regulators) participated each in one expert panel. Of the 64 **clinicians** (23% of clinicians) that are part of an EU expert panel, seven

were part of two EU expert panels. Eighteen **clinicians** participated in the screening panel (determines whether there is a need for a scientific opinion), twelve in the circulatory system panel, nine in the general and plastic surgery and dentistry panel, and eight in the neurology panel. No one from the survey respondents was part of an EU expert panel on endocrinology and diabetes. The distribution to the other panels can be found in Appendix 4.

Languages able to use in a professional working environment
Nearly all respondents indicated that they could use English in a professional working environment (97% of **notified bodies/**36 persons, 95% of **regulators/**55 persons, 97% of **clinicians**/271 persons, and all from **other employment category**/36 persons). Second most indicated language was German (24% of **notified bodies/**9 persons, 28% of **regulators/**16 persons, 25% of **clinicians**/69 persons, and 31% of **other employment category**/11 persons).

The survey allowed multiple selections. Nineteen **notified bodies** speak two languages, four notified bodies three languages and one notified body four languages. Twenty-five **regulators** can use two languages, five regulators three languages and one regulator four languages. For **clinicians**, 131 clinicians indicated two languages, 34 clinicians mentioned three languages, eight clinicians noted four languages and three clinicians stated five languages. From the "**other employment category**" 17 stated two languages, eight from this category mentioned three languages and one person even speaks six languages. In total, 78 persons indicated "other language", which corresponded to the "other countries" as listed above.

Highest educational level
In total three-quarter of all survey respondents indicated that they have a PhD, M.D. or doctorate (75%, 305 persons). Majority of PhD, M.D. or doctorate graduates could be found among the clinicians (88%, 245 persons), followed by other employment category (56%, 20 persons), notified bodies (49%, 18 persons) and regulators (38%, 22 persons). Twenty percent (80 persons) of all survey respondents owned a Master degree.

Educational background/specialty
For **notified bodies**, most mentioned specialties were engineering (43%, 16 persons) and human medicine (32%, twelve persons). For **regulators,** it was similar, 34% (20 persons) indicated engineering and 17% (ten persons) human medicine. Not surprisingly, 94% (262 persons) of **clinicians** stated human medicine as their specialty. The **other employment category** showed the following: 22% (eight persons) indicated engineering and nearly a fifth (19%, seven persons) stated "other specialty".

Of 278 **clinicians**, 16 did not indicate human medicine as their educational background/specialty. Specialties mentioned were dentistry, nursing, engineering and others. The definition of a clinician according to the Cambridge Dictionary is „someone, such as a doctor, who has qualifications in an area of very skilled health work.

Of those who selected human medicine, nearly a sixth of **notified bodies** (17%, two persons), a bit less than a third of **regulators** (30%, three persons), nearly all **clinicians** (96%, 251 clinicians), and a fifth of **other employment category** (20%, one person), stated that they practising clinicians.

Of all respondents that selected human medicine, nearly half indicated circulatory system (45%, 129 persons) as their main specialty, followed by neurology (14%, 40 persons) and "other specialties" (11%, 32 persons).

Vast majority of survey participants indicated a singly specialty each, although multiple selections were possible. Three notified bodies indicated two specialties each. Eight regulators indicated that they had two specialties each, three regulators stated three specialties each. Seven clinicians listed two specialties each, one clinician mentioned three specialities each. Two persons from "other employment category" indicated two specialties each.

Current employer (main employment) providing education or training in the field of medical device regulatory sciences

Vast majority of **clinicians** (81%, 226 persons), 60% (35 persons) of **regulators** and 64% (23 persons) of **other employment category** reported "no" to the question if their current employer did/does or will provide any education or training. Seventy percent (26 persons) of **notified bodies** indicated that the employer is currently offering training. See Figure 7 below.

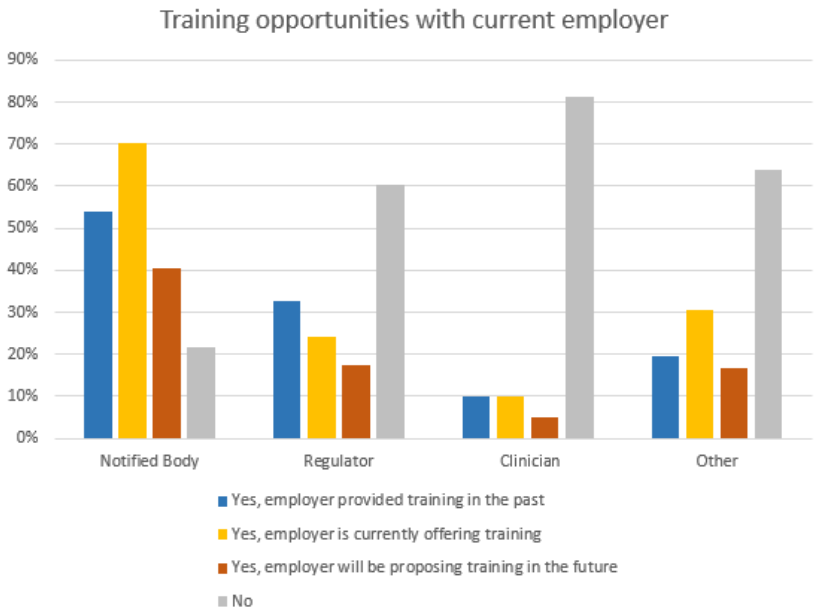


Figure 7: Past, current and future training opportunities with current employer

Attendance at medical device regulatory sciences education or training

More than half of **notified bodies** (68%, 25 persons) and of **other employment category** (64%, 23 persons) ever attended medical device regulatory sciences education or training. However, more than half of r**egulators** (53%, 31 persons) and **clinicians** (65%, 182 persons) did not. See Figure 8 below.

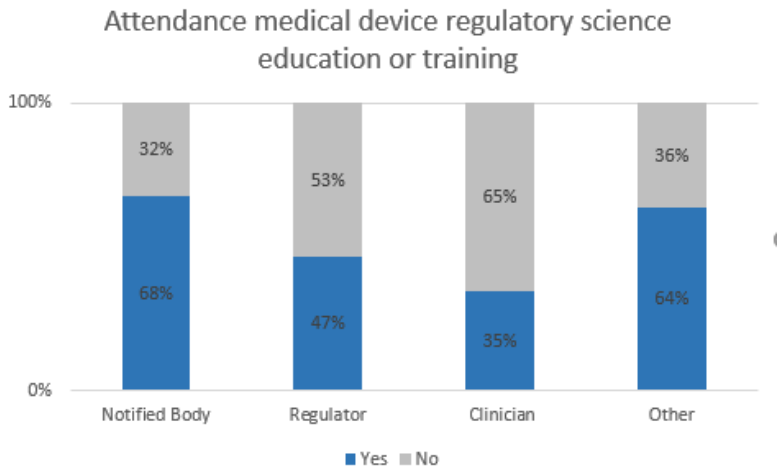


Figure 8: Any previous attendance of survey respondents at medical device regulatory sciences education or training

If the survey respondents selected "yes" to the above mentioned question, a follow up question was posed with regard to which education or training was attended. Multiple options could be selected. Majority of all respondents attended few hour webinars. However, the type of training that was attended by the different employment categories varied. See Figure 9 below.

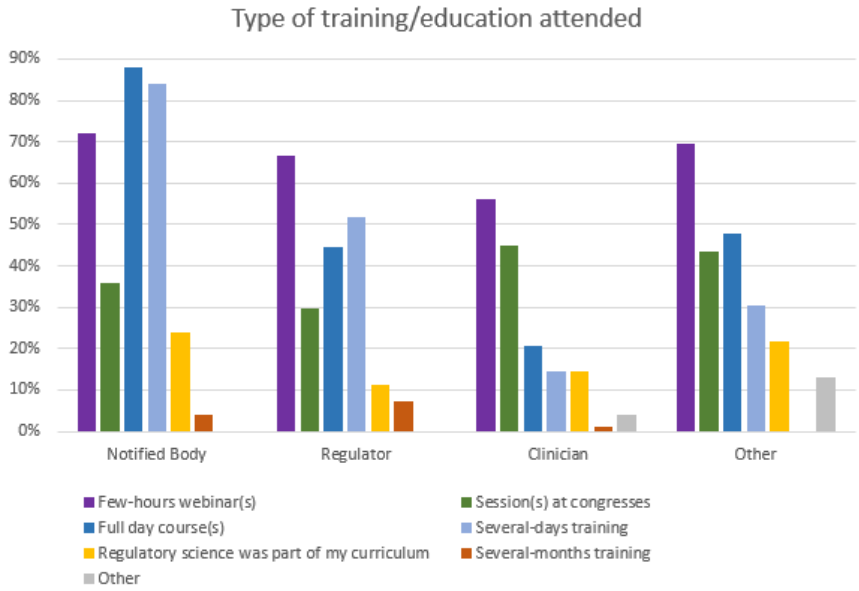


Figure 9: Training/education attended by survey respondents per employment category

Entity that provided training

Another follow up questions asked **which entity provided the training**. Multiple options could be selected.

In total, of all respondents that indicated that they ever attended a medical device regulatory science education or training, 40% (68 persons) stated that the training was provided by a regulatory agency. The other popular provider of training courses of the respondents were the employer (32%, 55 persons) and industry (30%, 52 persons). In Figure 10 below the entities were split up according to the employment category.

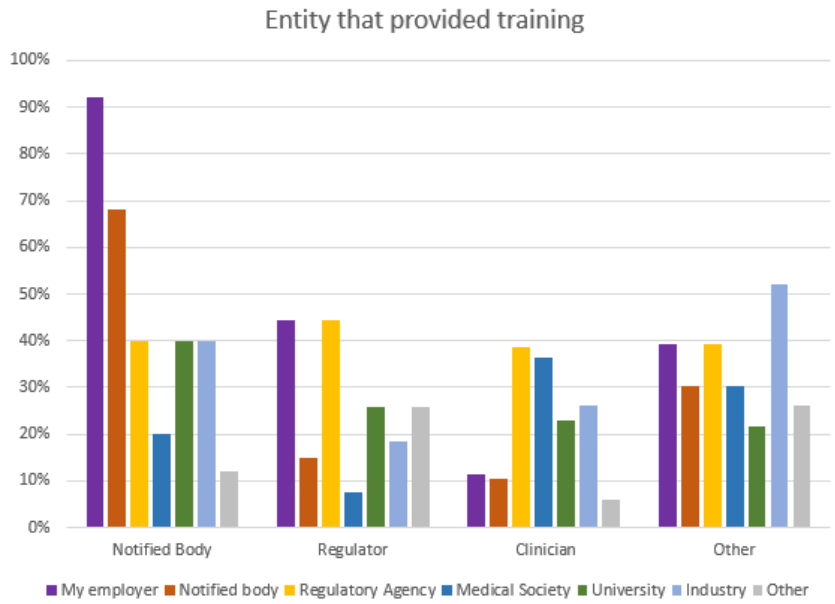


Figure 10: Entity that provided training of survey respondents per employment category

3.4.2 Knowledge about regulatory affairs/sciences - questions only for clinicians

For clinicians additional questions, which only showed up if the category “clinician” was selected as “main employment”, were added in order to identify their knowledge level about regulatory affairs/sciences in general.

Figure 11 below shows the knowledge of clinicians (who participated in the survey) about the regulatory system of medical devices.

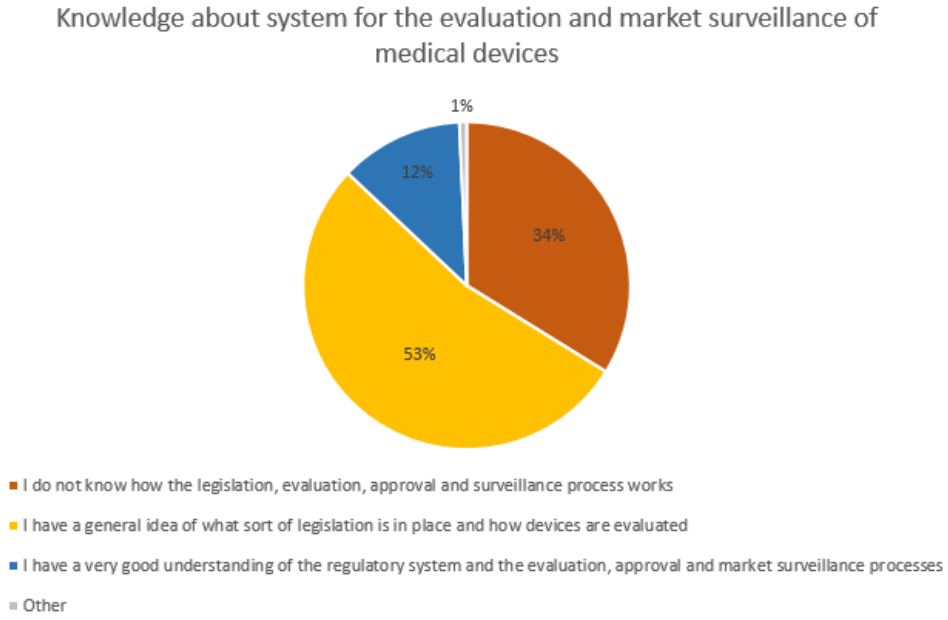


Figure 11: Clinician respondents´ knowledge about the regulatory system of medical devices

- Nearly two-thirds of the clinician respondents (65%, 182 persons) indicated that they have a general idea or a very good understanding of the legislation and regulatory system.
- Around a third (34%, 94 persons) declared that they did not know how the legislation, evaluation, approval and surveillance process works.

Figure 12 indicates the knowledge of clinicians (who participated in the survey) of who is responsible for demonstrating clinical effectiveness of a high-risk MD in the EU.

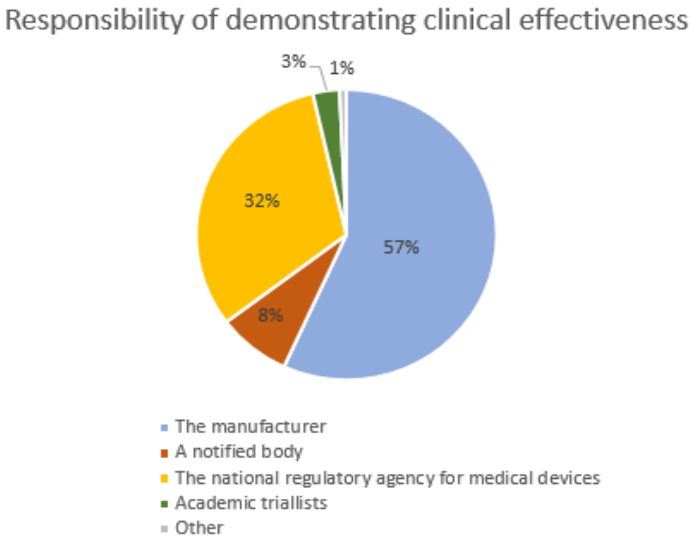


Figure 12: Clinician respondents´ knowledge of who is responsible for demonstrating clinical effectiveness of a high-risk MD in the EU.

- More than half of the clinician respondents (57%, 158 persons) stated that the manufacturer is responsible for demonstrating the clinical effectiveness.
- The remainder allocated this responsibility to the national regulatory agency (32%, 88 persons), notified bodies (8%, 22 persons), academic triallists (3%, 8 persons) or other (1%, 2 persons).

The responsibility of demonstrating clinical effectiveness lies with the manufacturer. They need to provide medical devices that work as intended, are safe and are clinically effective. Notified bodies and national regulatory agencies for medical devices are evaluating the data and documents they receive from the manufacturers.

Figure 13 demonstrates information sources used by clinicians, who participated in the survey, to verify the safety of a medical device. Multiple options could be selected.

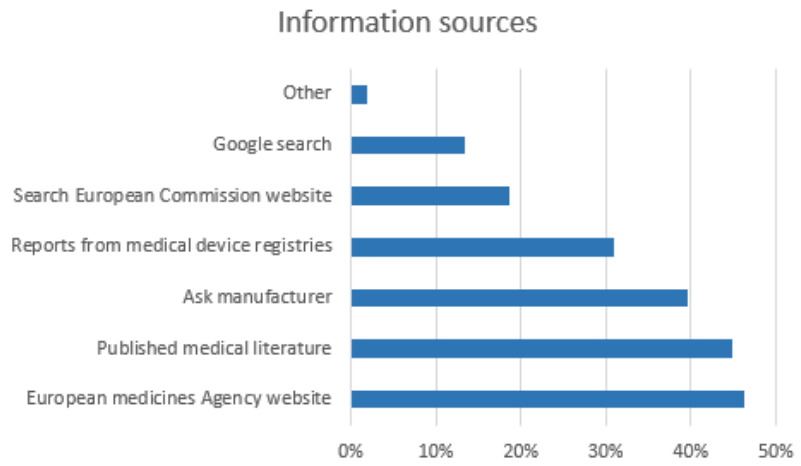


Figure 13: Clinician respondent's information sources to verify the safety of a medical device

- Nearly half of the clinician respondents used the EMA website (46%, 131 persons) and published medical literature (45%, 125 persons) as sources for information.
- Two percent of the clinician respondents (five persons) mentioned other sources such as EUDAMED, MAUDE database, Ministry of Health and national regulator.

Published medical literature and reports from medical device registries might be reliable information sources. However, depending on the type of device, other sources could also be helpful.

Figure 14 offers some insights into how clinicians, who participated in the survey, would report a concern around the safety of a medical device.

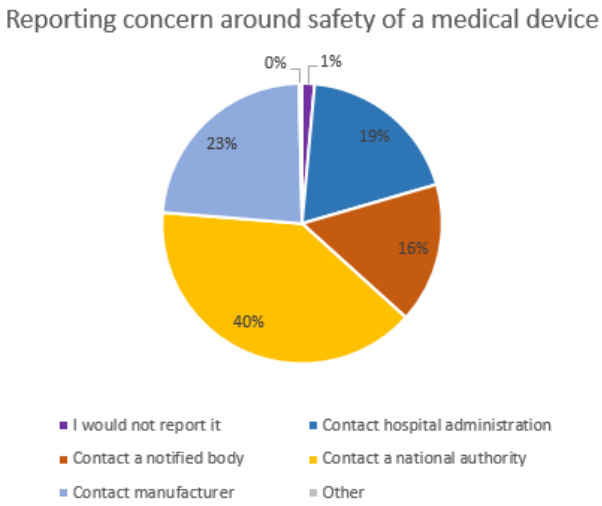


Figure 14: How clinician respondents would report a concern around the safety of a medical device

- Only 1% of the clinician respondents (four persons) would not report a concern around the safety of a device.
- The remainder of the clinician respondents would report it and the most selected body for sending the report to, is the national authority with 40% of the clinician respondents (110 persons).

Figure 15 shows the perception of clinicians (who participated in the survey) on how training on regulatory affairs and medical devices could help in daily work. Multiple options could be selected.

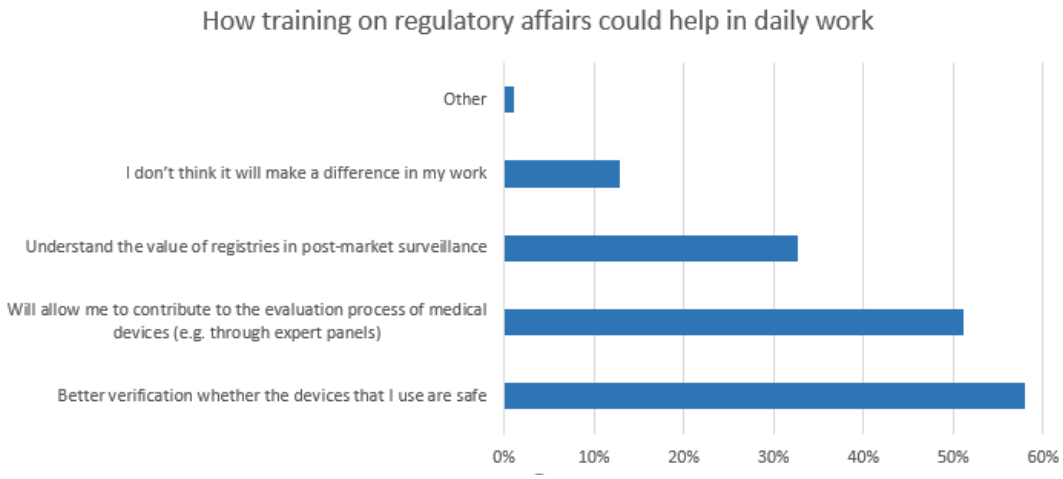


Figure 15: Clinician respondent´s perception on how training on regulatory affairs and medical devices could help in daily work

- More than half of the clinician respondents (58%, 161 persons) stated that training on regulatory affairs/sciences could help them to better verify the safety of the devices.
- Half of the clinician respondents (51%, 142 persons) also stated that it would allow them to participate in an evaluation process of a medical device.
- A third (33%, 91 persons) also indicated that it would help them in der understanding of the value of registries in post-market surveillance.
- Thirteen percent of clinician respondents (36 persons) stated that they do not think it will make a difference in their work, however, one of them also selected the option "Better verification whether the devices that I use are safe".
- One percent of clinician respondents (3 persons) answered with "other" and specified that regulatory affairs/sciences is not easy to understand for a person educated as a medical doctor, that health care professionals are not trained in medical devices compared to medicines and that it would help to better interpret the regulations.

3.4.3 Identified needs for methodological expertise and educational requirements (per stakeholder group)

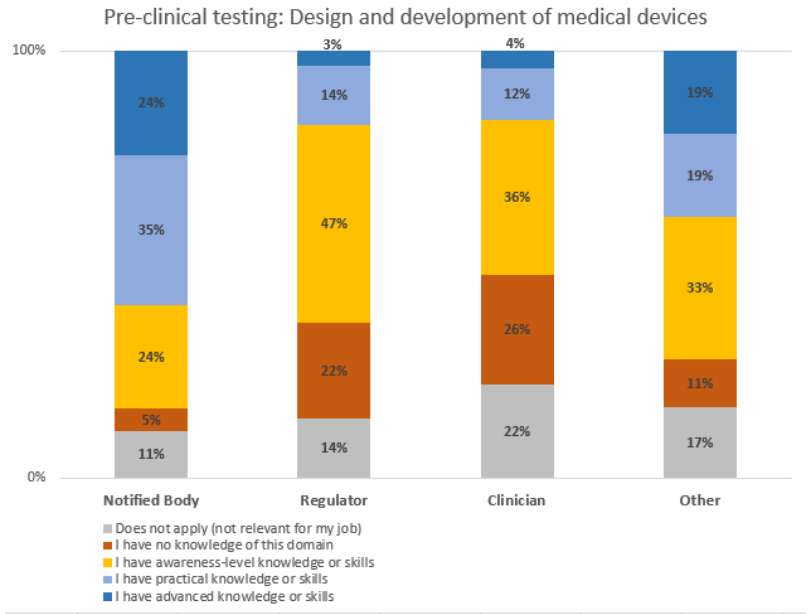
The core competencies were structured into **six domains** namely 1) pre-clinical testing, 2) drafting scientific, technical and clinical opinions and advices to manufacturers, 3) clinical investigation, 4) legal and regulatory for market access, 5) post-market surveillance, and 6) soft skills. Three of these domains listed **respective skills** (namely clinical investigation, legal/regulatory for market access and post-market surveillance), the other three domains (namely pre-clinical testing, scientific, technical and clinical opinions and advices to manufacturers and soft skills) did not specify any further skills.

Survey respondents were asked to select one of five options (see figures below). If option 1 – "does not apply (not relevant for my job)" was chosen, the respective skills of the domain were not shown. However, if someone selected option 2 "I have no knowledge of this domain", the respective skills were still shown, since the aim was to offer the respondents a chance to differentiate their knowledge further into specific skills. In some cases the respondents took the opportunity to provide distinct answers for the skills, in other cases the answer option 2 "I have no knowledge of this domain" was repeated for the skills.

The Figures show the different stakeholder groups, each adding up to a 100%. In order to calculate percentages for the skills, the sum for whom the respective domain was applicable was used (i.e. the number who selected option 2, 3, 4 or 5 in the respective domain question was used as a denominator).

1. **Domain → Pre-clinical testing (methodology and evaluation): Design and development of medical devices**

Figure 16 shows the level of knowledge or skills in the area of pre-clinical testing for notified bodies, regulators, clinicians and "other employment category", who participated in the survey, separately.



- In general, the group of **notified body respondents** showed the largest proportion of persons having practical (35%, 13 persons) and advanced knowledge (24%, 9 persons)
- **Clinician respondents** had the highest proportion of persons having no knowledge (26%, 71 persons) or for whom it was not applicable (22%, 61 persons)
- Also **22%** (13 persons) of **regulator respondents** do not have knowledge of this domain

***Figure 16**:* Results for the domain pre-clinical testing (methodology and evaluation): design and development of medical devices per employment category

2. **Domain → Drafting of a Scientific Advice to Manufacturers**

Figure 17 shows the level of knowledge or skills about drafting a scientific advice to manufacturers for notified bodies, regulators, clinicians and "other employment category", who participated in the survey, separately.

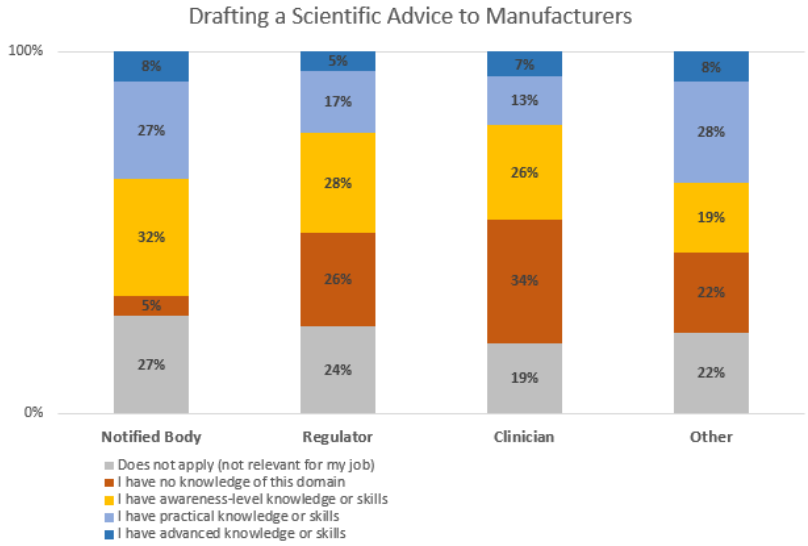


***Figure 17**:* Results for the domain drafting a scientific advice to manufacturers per employment category

- In general, **notified body respondents** and „**other employment category**" **respondents** had practical (27%, 10 persons; 28%, 10 persons) and advanced (8%, 3 persons for both groups each) knowledge or skills
- **Clinician respondents** had the highest proportion of persons having no knowledge (34%, 95 persons), followed by **regulator respondents** (26%, 15 persons)

3. Domain → Clinical investigation (methodology and evaluation)

Figure 18 shows the level of knowledge or skills about clinical investigation for notified bodies, regulators, clinicians and "other employment category", who participated in the survey, separately.

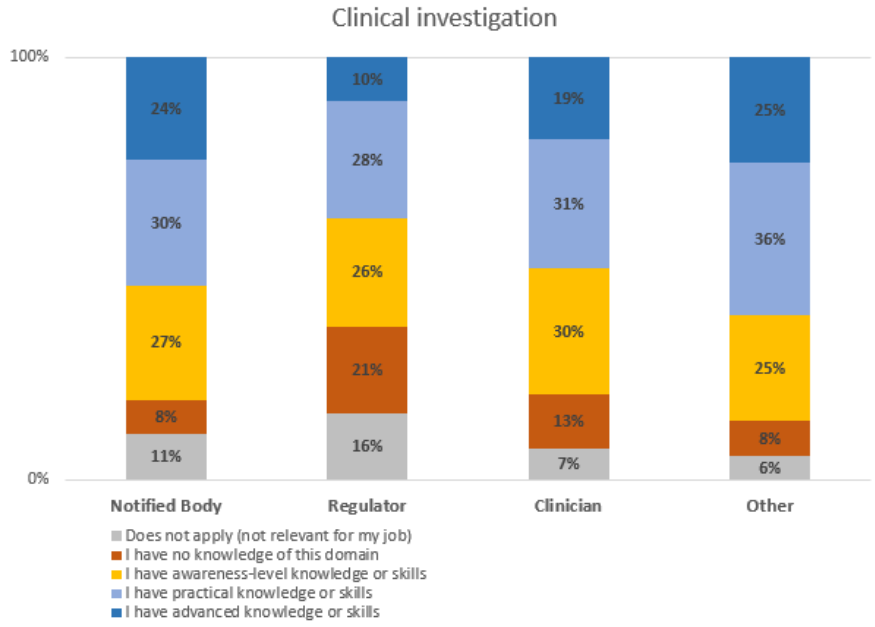


***Figure 18**:* Results for the domain clinical investigation (methodology and evaluation) per employment category

- Majority of **all groups** had awareness-level or practical knowledge
- Some **regulator respondents**, had no knowledge (21%, 12 persons)

This domain was further **subdivided into 14 skills**. Table 10 shows that 21-30% of **notified body respondents** had no knowledge in two skills: "Methods and time-points for patient involvement/ engagement" and "Clinical epidemiology".

Furthermore, 31-40% of **regulator respondents** indicated for five skills that they had no knowledge: "Concepts of unmet need in patient populations", "Methods and time-points for patient involvement/ engagement", "Choice of comparators", "Methods for the evaluation of specific high-risk medical devices", "Data analysis". For the skill "Clinical epidemiology" even over 41% stated that they had no knowledge. Also 21-30% of regulator respondents indicated seven different skills where they were lacking knowledge (see Table 10).

From **clinician respondents** 21-30% stated that they had no knowledge in (functional) Safety and performance assessment and 31-40% indicated this for "Use of data from equivalence" and "Methods for the evaluation of specific high-risk medical devices".

From the survey participants of the "**other employment category**", 21-30% said that they had no knowledge in "Concepts of unmet need in patient populations", "Methods and time-points for patient involvement/ engagement", "Methods for the evaluation of specific high-risk medical devices", "Clinical epidemiology" and "Data analysis".

Overall, 35% (131 persons) of **all survey participants** stated that they had no knowledge in "Methods for the evaluation of specific high-risk medical devices".

Table 10: Clinical investigation skills and the different levels of "**no knowledge**" per employment category

	Notified Body	Regulator	Clinician	Other
Study-designs and their advantages/ disadvantages	9% (3 persons)	24% (12 persons)	9% (24 persons)	12% (4 persons)
Concepts of unmet need in patient populations	15% (5 persons)	39% (19 persons)	15% (39 persons)	21% (7 persons)
Methods and time-points for patient involvement/ engagement	21% (7 persons)	39% (19 persons)	16% (41 persons)	21% (7 persons)
Choice of comparators (standard of care vs. Sham vs. Placebo)	15% (5 persons)	33% (16 persons)	12% (32 persons)	18% (6 persons)
Outcomes measurements and instruments (standardized and validated instruments)	15% (5 persons)	29% (14 persons)	16% (42 persons)	15% (5 persons)
Assessment of benefit-risk ratio and thresholds for acceptability	12% (4 persons)	24% (12 persons)	19% (50 persons)	15% (5 persons)
Use of data from equivalence (Biocompatibility standard)	9% (3 persons)	27% (13 persons)	33% (86 persons)	15% (5 persons)
(functional) Safety and performance assessment	6% (2 persons)	16% (8 persons)	25% (64 persons)	12% (4 persons)
Methods for the evaluation of specific high-risk medical devices (e.g. artificial intelligence, combination devices,	18% (6 persons)	35% (17 persons)	39% (100 persons)	24% (8 persons)

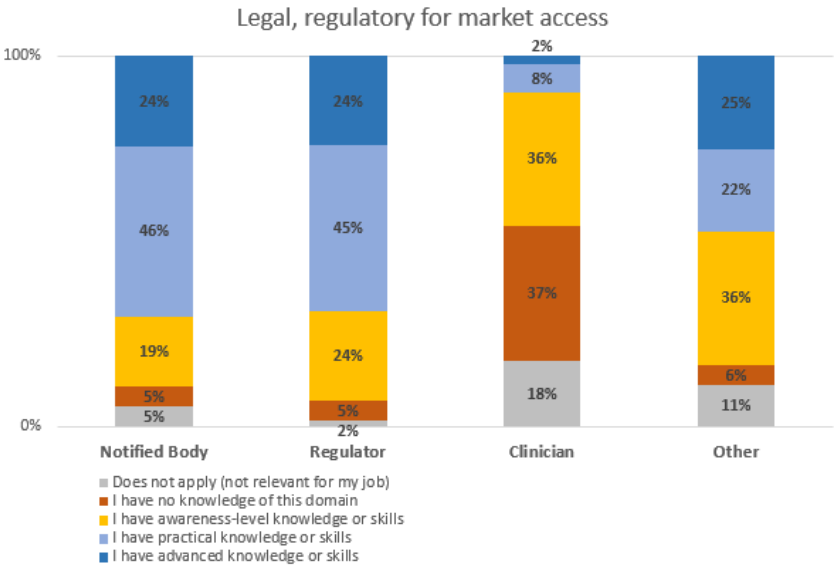
devices derived from tissues and cells of human origin)				
Systematic literature review (guidance for method and process)	6% (2 persons)	22% (11 persons)	9% (23 persons)	9% (3 persons)
Medical statistics (e.g. power calculation of trials, p-values)	15% (5 persons)	27% (13 persons)	12% (31 persons)	18% (6 persons)
Clinical epidemiology (data and sources for burden of disease, prevalence, incidence)	24% (8 persons)	41% (20 persons)	9% (22 persons)	24% (8 persons)
Data analysis (different for processing primary data)	12% (4 persons)	35% (17 persons)	16% (40 persons)	21% (7 persons)
Ethics in clinical trials (e.g. recruitment, patient´s consent, information on uncertainties)	9% (3 persons)	24% (12 persons)	7% (19 persons)	9% (3 persons)

Levels of "no knowledge" per group of survey participants (there were 4 other answer possibilities such as "does not apply (not relevant for my job)", "I have awareness-level knowledge or skills", "I have practical knowledge or skills", "I have advanced knowledge or skills" – these are not shown in the table, but can be found in Appendix 3 and Appendix 4)

	0-10%
	11-20%
	21-30%
	31-40%
	over 41%

4. Domain → Legal, regulatory for market access

Figure 19 shows the level of knowledge or skills about legal, regulatory for market access for notified bodies, regulators, clinicians and "other employment category", who participated in the survey, separately.



- **Clinician respondents** were lacking knowledge about legal and regulatory issues (37%, 102 persons)

***Figure 19**:* Results for the domain legal, regulatory for market access per employment category

The fourth domain was further **subdivided into six skills**. Table 11 shows that 21-30% of **regulator** and of **clinician respondents** had no knowledge in "Good clinical practice (GCP)".

From **clinician respondents** 31-40% were lacking knowledge about the Medical Device Regulation and about classification of devices. Furthermore, over 41% of clinician respondents did not have skills in "Good manufacturing practice (GMP)", risk management and Quality Management System.

Table 11: *Legal, regulatory for market access* skills and the different levels of "**no knowledge**" per employment category

	Notified Body	**Regulator**	**Clinician**	**Other**
Medical Device Regulation: requirements, procedures, implementation, update on regulatory developments	n.a.	4% (2 persons)	33% (75 persons)	n.a.
Classification of devices (esp. borderline devices)	3% (1 person)	5% (3 persons)	40% (91 persons)	6% (2 persons)
Quality Management System - ISO 13485	n.a.	7% (4 persons)	51% (117 persons)	13% (4 persons)
Good clinical practice (GCP) - ISO14155	11% (4 persons)	23% (13 persons)	26% (60 persons)	9% (3 persons)
Good manufacturing practice (GMP) - ISO 13485	3% (1 person)	16% (9 persons)	48% (111 persons)	13% (4 persons)
Risk management - ISO 14971	n.a.	12% (7 persons)	45% (103 persons)	16% (5 persons)

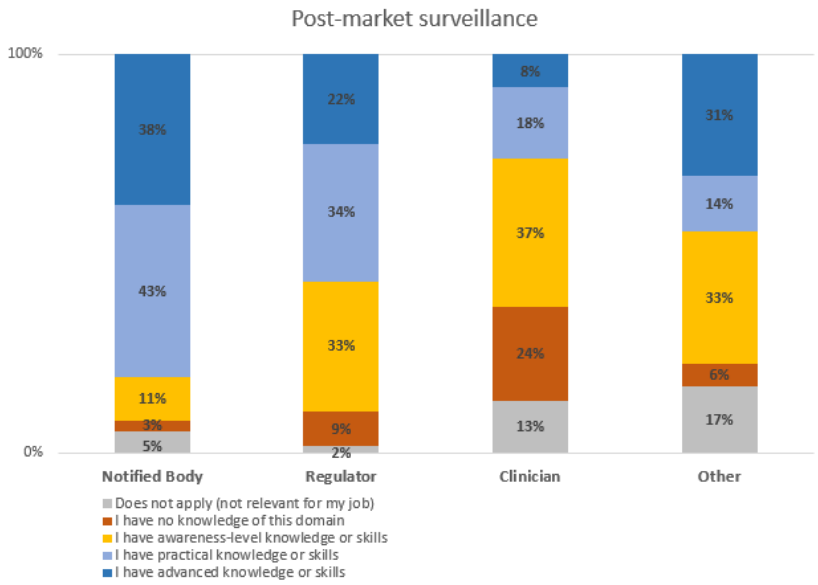
n.a.: not applicable

Levels of "no knowledge" per group of survey participants (there were 4 other answer possibilities such as "does not apply (not relevant for my job)", "I have awareness-level knowledge or skills", "I have practical knowledge or skills", "I have advanced knowledge or skills" – these are not shown in the table, but can be found Appendix 3 and Appendix 4)

	1-10%
	11-20%
	21-30%
	31-40%
	over 41%

5. Domain → Post-market surveillance

Figure 20 shows the level of knowledge or skills about post-market surveillance for notified bodies, regulators, clinicians and "other employment category", who participated in the survey, separately.



- **Notified body** and **regulator respondents** had practical (43%, 16 persons; 34%, 20 persons) and advanced (38%, 14 persons; 22%, 13 persons) knowledge
- **Clinicians** respondents were lacking knowledge about post-market surveillance (24%, 66 persons), followed by **regulator respondents** (9%, 5 persons)

***Figure 20**: Results for the domain post-market surveillance per employment category*

The fifth domain was further **subdivided into five skills**. Table 12 shows that over 41% of **clinician respondents** did not have any knowledge in "Drafting a Post-Launch Plan", "Collection of vigilance data" or in "types of Post-market surveillance data". Also 31-40% of clinician respondents were lacking knowledge in "Registers and post launch evidence generation" and in "Post-market clinical follow-up) plans and evaluation reports".

Furthermore 31-40% of **regulator respondents** had no knowledge in "Drafting a Post-Launch Plan" and 21-30% did not have knowledge in "Collection of vigilance data", "Post-market clinical follow-up plans and evaluation reports" or "Types of Post-market surveillance data".

***Table 12:** Post-market surveillance skills and the different levels of "**no knowledge**" per employment category*

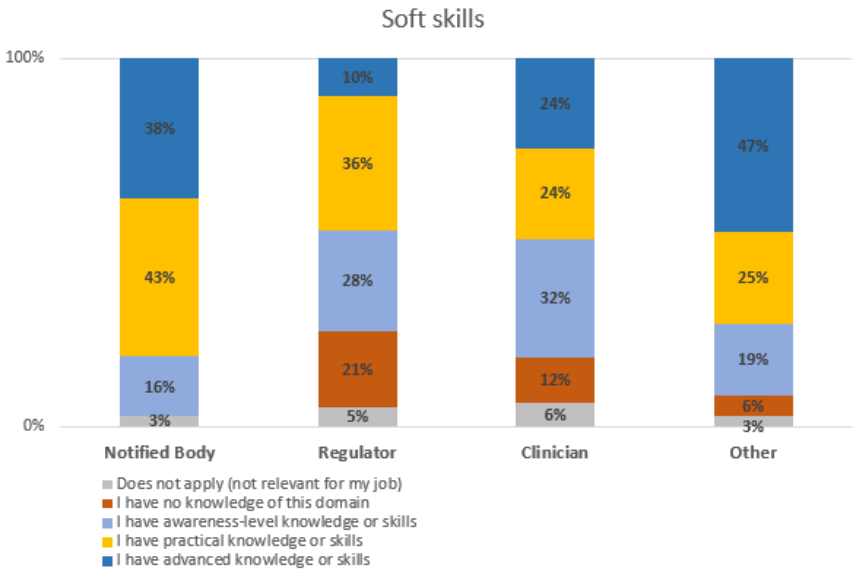
	Notified Body	Regulator	Clinician	Other
Registers and post launch evidence generation (types of registers, data collections)	11% (4 persons)	19% (11 persons)	33% (79 persons)	7% (2 persons)
Drafting a Post-Launch Plan	17% (6 persons)	37% (21 persons)	50% (122 persons)	17% (5 persons)
Collection of vigilance data	6% (2 persons)	25% (14 persons)	42% (101 persons)	3% (1 person)
Post-market clinical follow-up (PMCF) plans and evaluation reports	6% (2 persons)	21% (12 persons)	40% (97 persons)	7% (2 persons)
Types of post-market surveillance (PMS) data	6% (2 persons)	25% (14 persons)	46% (111 persons)	17% (5 persons)

Levels of "no knowledge" per group of survey participants (there were 4 other answer possibilities such as "does not apply (not relevant for my job)", "I have awareness-level knowledge or skills", "I have practical knowledge or skills", "I have advanced knowledge or skills" – these are not shown in the table, but can be found in Appendix 3 and Appendix 4)

	1-10%
	11-20%
	21-30%
	31-40%
	over 41%

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

Figure 21 shows the level of knowledge about soft skills for notified bodies, regulators, clinicians and "other employment category", who participated in the survey, separately.



- Some **regulator respondents** were lacking soft skills (21%, 12 persons)
- Majority of all survey respondents (54%, 219 persons) had practical or advanced skills.

***Figure 21**:* Results for the domain soft skills (e.g. medical writing, project management) per employment category

The following **additional skills**, that were not part of the above list, and for which training might be needed, were mentioned by survey participants from:

- **Notified Bodies:** two persons mentioned one skill each: welding, post market clinical follow up protocol design
- **Regulators**: four persons listed one skill each: medical device combination products with medicinal products, biocompatibility and toxicology for the assessment of safety of devices, unmet need in patient population versus relevance of medical device/novelty/added benefit, trials involving companion diagnostics.
- **Clinicians**: three persons listed one skill each: appropriate patient involvement in scientific advice process, ISO 17025 - advanced knowledge, online course/certification in cardiac devices - if applicable. A technician/nurse mentioned: how a pacemaker or ICD works, discriminator, tachycardia and bradycardia, how to program a device and troubleshooting.
- **Other employment category**: seven persons listed one skill each: in silico trials - advanced knowledge, clinical evaluation and risk-benefit analysis principles, tips for drafting/templates to complete the file for the notified body, level of responsibilities under MDR: manufacturer,

distributor, user, notified body, competent authority, hospital; write a CEP and CER (clinical evaluation plan and report).

The survey also asked about the **top three skills in which the respondents would like to have training over the next three to five years.** Respondents could select each skill as a first, second or third choice. Therefore, skills could show up multiple times, depending on how often they were selected as a first/second/third choice.

Notified body respondents named the following skills

- as a first choice: Assessment of benefit-risk ratio and thresholds for acceptability (19%, 7 persons), Pre-clinical testing (methodology and evaluation) Design and development of medical devices (14%, 5 persons), 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) (14%, 5 persons)
- as a second choice: Assessment of benefit-risk ratio and thresholds for acceptability (19%, 7 persons), Pre-clinical testing (methodology and evaluation) Design and development of medical devices (11%, 4 persons), Concepts of unmet need in patient populations (11%, 4 persons)
- as a third choice: Drafting a Scientific Advice to Manufacturers (11%, 4 persons), then 7 skills are listed with 8% (3 persons) each

Regulator respondents named the following skills

- as a first choice: Assessment of benefit-risk ratio and thresholds for acceptability (21%, 12 persons), Pre-clinical testing (methodology and evaluation) Design and development of medical devices (16%, 9 persons)
- as a second choice: Assessment of benefit-risk ratio and thresholds for acceptability (14%, 8 persons), Outcomes measurements and instruments (standardized and validated instruments) (12%, 7 persons)
- as a third choice: Assessment of benefit-risk ratio and thresholds for acceptability (14%, 8 persons), Use of data from equivalence (Biocompatibility standard) (12%, 7 persons)

Clinician respondents named the following skills

- as a first choice: Study-designs and their advantages/ disadvantages (21%, 57 persons), Assessment of benefit-risk ratio and thresholds for acceptability (14%, 40 persons)
- as a second choice: Assessment of benefit-risk ratio and thresholds for acceptability (13%, 37 persons), Drafting a Scientific Advice to Manufacturers (11%, 30 persons), Choice of comparators (standard of care vs. Sham vs. Placebo) (11%, 30 persons)
- as a third choice: Assessment of benefit-risk ratio and thresholds for acceptability (15%, 41 persons), Study-designs and their advantages/ disadvantages (12%, 33 persons)

Other employment category respondents named the following skills

- as a first choice: Medical Device Regulation: requirements, procedures, implementation, update on regulatory developments (19%, 7 persons), Assessment of benefit-risk ratio and thresholds for acceptability (17%, 6 persons)

- as a second choice: Concepts of unmet need in patient populations (14%, 5 persons), Use of data from equivalence (Biocompatibility standard) (14%, 5 persons), Classification of devices (esp. borderline devices) (14%, 5 persons)
- as a third choice: 4 skills are indicated each with 8% (3 persons) namely Methods and time-points for patient involvement/ engagement, Assessment of benefit-risk ratio and thresholds for acceptability, Use of data from equivalence (Biocompatibility standard), Good clinical practice (GCP) - ISO14155

Summary of top three skills in which the survey respondents would like to have training over the next three to five years:

- **All stakeholder groups** mentioned "**Assessment of benefit-risk ratio and thresholds for acceptability**" among their first, second and/or third choice for training opportunities.
- 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**.
- For **clinicians**, study-designs and their advantages/ disadvantages was the most frequently mentioned skill as a first choice
- For the **other employment category**, "Medical Device Regulation: requirements, procedures, implementation, update on regulatory developments" was the skill that was indicated the most as a first choice.

Results of sensitivity analysis:

As indicated in the methods section, the results of the six domains of the core competencies were re-analysed excluding a selected number of participants. The maximum difference in the results was 2% (for each answer possibility, for all employment categories) for the domains drafting a scientific advice to manufacturers and soft skills. For the domains pre-clinical testing, clinical investigation and post-market surveillance the maximum difference was 3% (for each answer possibility, for all employment categories). For the domain legal, regulatory for market access, the maximum difference was 4% for the answer "I have advanced knowledge or skills" within the "other employment category, for the other answer possibilities and employment categories it was less. In summary, for some answer possibilities no change was seen and even if there was a change, the overall meaning of the results did not change.

Furthermore, also the skills of the three domains (the remainder of the domains did not list any skill) were re-analysed. However, since the results of the skills depend on the answers of the respective domain(s) (if they selected "does not apply", the questions on the skills were not shown), the comparability of the answers from the original analysis with the sensitivity analysis is limited. A specific focus was given to the answer possibility "I have no knowledge of this domain": for notified bodies, results varied about 1% maximum; same applies for regulators (except for quality management system where the difference was 2%); for clinicians, the maximum difference was 4% and for "other employment category" a maximum of 5% difference was seen - except for post-market clinical follow-up (PMCF) plans and evaluation reports where the difference was 11%). Also for this sensitivity analysis, the general results on training needs did not change to a notable extent.

3.4.4 Training, training formats and modalities

Respondents could select one or more groups (notified bodies, regulators, clinicians) for which they perceived training needs. Every group selected their own group as having the highest need for training. In total 72% of survey respondents (296 persons) indicated that the highest need for training was for clinicians, which was followed by 48% (197 persons) for regulators and 41% (169 persons) for notified bodies. Only 1% (4 persons) of all respondents indicated that there is no training needed for any of the three groups. See Figure 22 below.

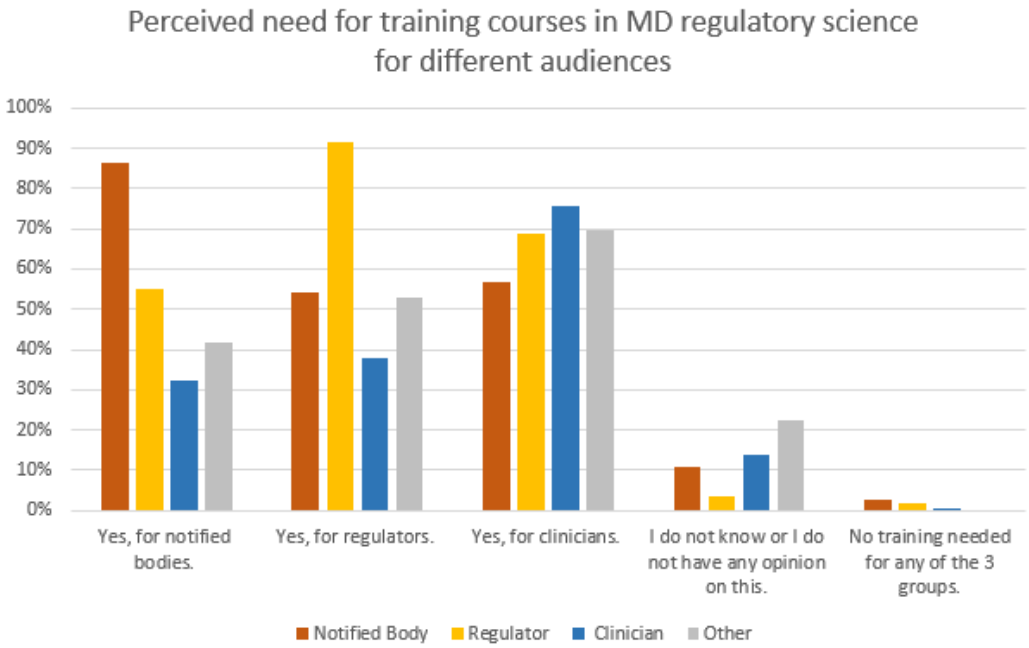


Figure 22: Perceived training needs for notified bodies, regulators and clinicians

The follow up question on the preferred format of the training (for those who selected "yes" for any of the three stakeholder groups) allowed multiple selections. In total, the offered options were selected in a similar frequency which ranged from 44% of survey respondents (142 persons) for practical training on the job (advanced internships in organisations and mentoring programs) up to 50% (159 persons) for training in single days. However, the different groups had slightly different preferences. **Notified body respondents** favored training in single days over the year and **regulator respondents** preferred lifelong upskilling and reskilling as well as block training modules. The most frequent selected option by **clinician respondents** was training in single days over the year, although the frequency of selected options was rather similar. See Figure 23 below.

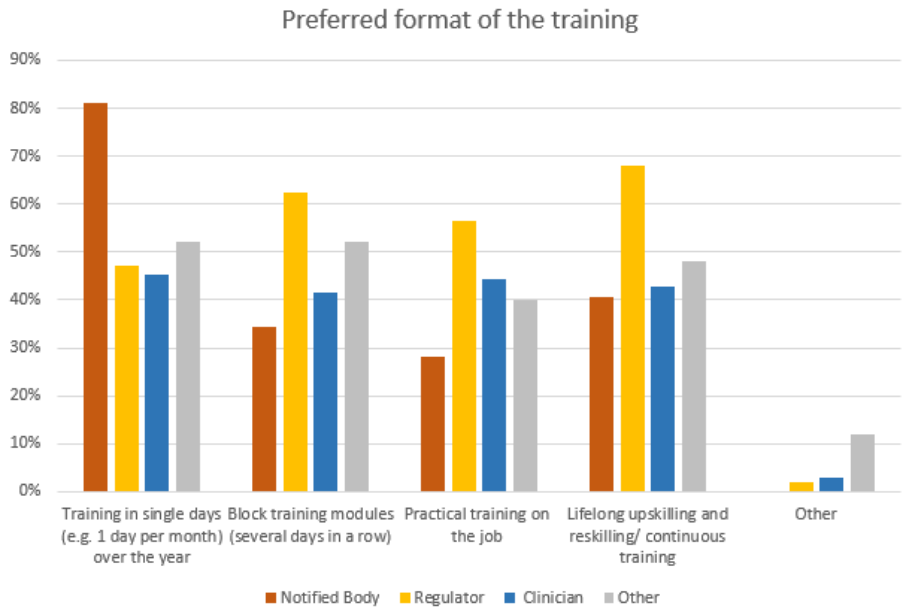


***Figure 23**: Preferred training format by notified bodies, regulators, clinicians and other employment category survey respondents*

Other suggestions for training formats were: initial block training (for 2-3 days), then refresher for 1 day or 1/2 day every (two) months; 1 day per year; on demand webinars; e-learnings and self-scheduled on-line learning modules. It was also noted that the format would vary hugely depending on target audience.

All survey respondents received the question on the preference regarding the composition of the training group. Only one option could be selected. Around a third of every group (notified body, regulator, clinician, other employment category), that participated in the survey, preferred training dedicated to the specific target group. In total, 15% of all survey respondents (63 persons) favored training across the target groups. A high percentage of survey respondents, in particular 40% of clinician respondents, did not have an opinion on this. The smallest percentage of every group (in case of Notified Bodies it was equal with training across target groups) stated that it depends on the topic/module. See Figure 24 below.

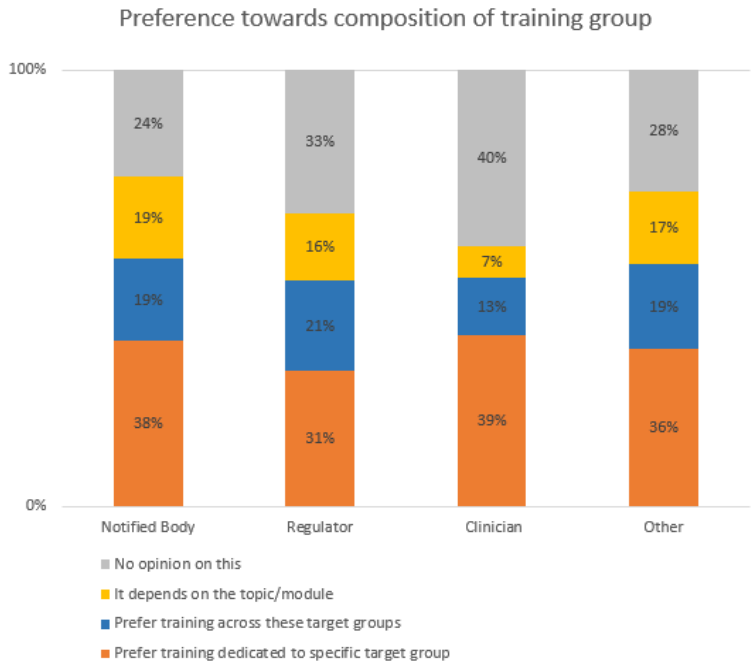


***Figure 24**:* Preference of notified bodies, regulators, clinicians and other employment category survey respondents regarding composition of training group

If a preference was given, the follow up questions revealed some explanations for the chosen preference for the composition of the group.

In general, all four groups (notified bodies, regulators, clinicians, other employment category) of survey respondents, indicated similar explanations as to why they prefer to have training **dedicated to the specific target group**. In summary these are:

- The target groups have different needs, language, background knowledge and competencies. The approach and focus of the training might differ as well.
- Generic/general training is not considered useful. The training should be applicable to daily practice with relevant examples and should be matched with processes the specific target group is using.
- It would provide an opportunity to level up with peers and to exchange experiences. There is a preference to train together with colleagues, who have the same task.

However, a regulator mentioned that perhaps regulators and notified bodies could have the same training. It was also indicated that it would be good for all groups to interact together from time to time.

One clinician stated that many regulators have little or no clinical experience, so they would benefit from understanding the clinical context of their decisions, while many clinicians have no experience regarding the basis for regulatory approvals. It was mentioned that the training for clinicians shall fit to their daily activities and the level of involvement in the specific area.

One clinician suggested that clinicians need a specific approach for every specialty group (e.g. mechanical ventilator users).

One respondent from the "other employment category" mentioned that clinicians need to be aware of the obligations to manufacturers and users under the MDR and be able to support clinical investigations as well as first-in-human studies.

Also, the arguments for a training **across the four groups** (notified bodies, regulators, clinicians, other employment category) were similar:

- Stakeholders should ideally be trained together for a better understanding of each other's viewpoints and perspectives (regulatory and clinical/practical aspects, to create a full picture) and to allow for an (interdisciplinary) exchange of experiences and knowledge sharing. It might also initiate or strengthen cooperation across the different groups.
- Harmonization of the assessment of the clinical evaluations of the medical devices and of respective views was mentioned. All the links in the chain should have a similar point of view so that consensus (about the most practical way to do things) could be reached.

A notified body stated that there are similar levels of knowledge and needs across notified bodies, competent authorities, and persons responsible for regulatory compliance (PRRC).

A regulator mentioned the need to understand the process as a whole because different groups did not cooperate in the past and they are not familiar with work and obstacles each group has.

A clinician mentioned that there is a need to understand participant's perspectives: end-user, patient, device regulator, research and development science, manufacturer/commercial realities. It might help de-fragment the knowledge in the medical device area.

One respondent from the" other employment category" highlighted as a reason for training across the four groups that the MDR is the same for everyone.

In general, the four groups (notified bodies, regulators, clinicians, other employment category) of survey respondents mentioned the following reasons why the format of the training (if separate or across stakeholders) should **depend on the topic/training**:

- Topics for training can be generic or specific. Some topics may only be relevant for specific groups and some topics could be applicable to more groups. There could be a basic training across the groups (if needed) and specific training with a focus on the need for specific groups. Some elements might be common, but other elements might be specific to the roles and responsibilities of the respective group.
- The basic knowledge of the groups is different. For each group different levels of knowledge and/or skills on different topics could be helpful.

A participant from a notified body commented that most regulatory topics can be covered for multiple types of audiences, but certain areas need a focus on the job role itself. It was highlighted that the implementation of the regulation is very important, not just the theory of the text. Some topics are not applicable for all audiences, e.g. giving scientific advice does not apply for notified bodies.

A regulator indicated that for some topics, such as pre-clinical testing or statistics, it would be recommended distinguishing between technical and clinical background.

A clinician mentioned that if the course is online, the training could be split into specific target groups, if the training is in person it could be across the groups, then the training and discussion contributes to the understanding of the objectives of the different groups.

A clinician stated that some parts are not relevant or only relevant for clinicians. There might be specific topics for clinicians, because every department has different kind of medical devices.

Here it was suggested as well that notified bodies and regulators most often can be one target group while clinicians have a somewhat different scope of interest.

Further comments by survey respondents made on educational requirements

Note: The comments made by individual survey respondents – domains/skills that are not extensively covered or explicitly mentioned above - were summarized for the sake of readability in the Table 13 below.

***Table 13**:* Additional comments from survey respondents on educational requirements

Suggested topics
Field of safety: • Understanding at the basic level the electrical, electromagnetic, radiologic, biological and chemical safety aspects and requirements • Clinical risk, hazards, harms, mitigation, identification, reporting • Toxicological assessments • Usability studies: key for the safe use of MDs. Training for all involved (clinicians, experts, regulators, notified bodies and industry) in how safe and performing medical devices are developed is key for a good functioning regulatory system • Training on (often mandatory) adverse event reporting to authorities and manufacturers
Field of legal/regulatory: • Understanding novelty • Harmonised standards • How to set up a QMS • Benchmarking • Update on the MDCG guidance documents • Suggestion that notified body clinicians should be first taught auditing/review of CERs skills (following MedDev 2.7.1 Rev 4 Section 12) and then how to write a CER (following Meddev 2.7.1 Rev 4 sections 1 - 11)
Areas of MDs: • Delivery Devices for Advanced Therapy Medicinal Products (ATMPs) • Nanomaterials • Advanced training for clinicians participating in product implementation, development and research. Special need for small groups of patients (like children and congenital heart disease patients) who must be treated with many devices used off-label.

Field of IT: • Cybersecurity • Software review • Specificity for artificial intelligence based softwares • Modern medical architectures application and approach for the assessment of high -risk MDs.
Other: • Long term device registries • Researchers often propose new methods that may involve use of medical devices. To offer specific training for academic researchers on this. • Physiological principles, physical and mechanical principles, materials, implantation indication, benefits and follow up checks of the device therapy. Sleep disorder breathing and sleep disorders.
Mode of training
• Notified bodies, regulators to undergo training on regular monthly basis. • Refreshment training on different implants / high-risk devices would be helpful. To have a monthly virtual meeting (2-4 hours) focusing on a specific device type, a risk-based approach, which requires a short-deadline planning.
• To start at the university (basic training) and add more specific curricula later • The manufacturer of the medical device must provide training and safety information about the product • National authorities should be much more active in this area. They are the ones often doing the interpretation and instructions to notified bodies so they should do the education and not commercial companies.
• Training and educational requirements should be either free or affordable

4. Discussion

In a recent position paper of the Medical Device Coordination Group (MDCG) capacity building for the transition to the MDR and IVDR is recognized and emphasized [32]. Capacity building comprises not only good knowledge on the legislation (MDR, IVDR), regulatory policies and instruments as well as MDCG-guidances, covered under the umbrella term of "Regulatory Affairs", but also more in-depth and specific knowledge on advanced methodologies for the evaluation of medical devices in preclinical and clinical investigations and post-market surveillance evaluations. The development of new methodologies for better regulation is often referred to as "Regulatory Science", defined as "the science of developing and validating new standards and tools to evaluate and assess the benefit/risk of medical devices and IVDs, facilitating sound and transparent regulatory decision making" [33]. Increasing the efficiency of the regulatory system and improving its effectiveness on the basis of scientific research results [33] is of great importance for the successful implementation of the MDR and IVDR.

To support this endeavor it is the intention to develop recommendations for advanced education and training courses. The aim of this roadmap is to survey present training needs of stakeholders (notified bodies, regulators and clinicians) and to develop recommendations for educational contents of advanced training courses for these professionals.

4.1 Summary of findings

In summary, these CORE-MD survey results indicate that **regulators and clinicians** might need training in pre-clinical testing (methodology and evaluation), drafting a scientific advice to manufacturers and post-market surveillance. **Clinicians**, who contribute to the regulation of medical devices in their role to ensure that the devices they use in clinical practice are safe or who contribute to expert panels or in clinical trials, are in need of a different knowledge level. They might lack skills regarding legal, regulatory knowledge for market access. **All stakeholder groups** (especially regulators, followed by clinicians and then notified bodies) might need training in some skills related to clinical investigation (methodology and evaluation).

A review of published literature (manual search only) on skills in regulatory science, a landscape overview of existing advanced educational programs, exploratory consultations with stakeholders and an extensive survey laid the basis for a comprehensive **list of domains and skills.** These domains and skills along the lifecycle of a medical device might form the starting point for specific curricula. The creation of the list was facilitated through gathering input from all three stakeholder groups. Differences in skills between the three stakeholder groups could be identified. Also, the open question where survey respondents could add additional skills (that were missing in the list of domains and skills), did only reveal a limited number of further topics (but may equally be an indicator of fatigue/time pressure). The same applies to the open question about further comments on educational requirements, where the survey respondents mainly clarified and further outlined skills and related training needed.

4.2 Interpretation and possible knowledge gaps

The question about **knowledge on regulatory affairs/sciences to clinician respondents** revealed that only 12% had a very good understanding of the regulatory system and 34% did not know how the legislation and related processes work. The majority though had a general idea. This shows room for improvement and clinicians, who participated in the survey, saw the value of training on regulatory affairs/sciences: more than half of them stated that such training could help them to better verify the safety of the devices and that it would allow them to participate in an evaluation process of a medical device. One could argue that some of them might be interested in taking on a role in regulatory processes, which might be important due to the increasing need for qualified personnel as indicated by the MDR. However, 13% of clinician respondents stated that they do not think it will make a difference in their work, so clearly some information sharing and awareness raising is needed. Another question to clinicians also showed that some education and explanation might be needed around the responsibility of demonstrating the clinical effectiveness.

When discussing the training needs, one may want to further **differentiate between possible different subgroups**, which is specifically relevant for the group of clinicians. For example, clinicians working for notified bodies need to comply with certain educational requirements and work experience, which are already defined in Annex VII of the MDR. Clinicians involved in clinical trials and research need to have specific knowledge on trial methodologies and also clinicians not specifically dedicated to such activities need to have at least a basic understanding of collection of post market surveillance data (including vigilance data). Any offers for training and education must be for the specific stakeholder groups and their tasks in the regulatory process to be capable to fulfill their roles and assignments professionally.

One can discuss if there is a true **lack of regulatory science training**, if there is a lack of willingness to participate in such training (e.g. due to possible absence of understanding of its importance), or if there are certain barriers that can be removed for attendance at such training. Also, the circumstances need to be taken into account: any suggested schedule for training should be feasible for the respective stakeholder group.

It should be noted that the interpretation of the results of the survey participants in the "**other employment category**" is limited due to its heterogeneity. However, in any case the focus of the analysis was on notified bodies, regulators and clinicians, and not on any other stakeholder group. In any case, the analysis might show that other groups have different knowledge levels and different strategies might be needed to cover their needs.

4.3 Limitations

CORE-MD survey

The results must be interpreted in the context of the following limitations:

Since this CORE-MD survey was **self-administered**, the respondents could have put themselves into a wrong category (notified body, regulator, clinician, other employment category) or the persons from the "other employment category" could have been better placed into one of the three main categories. However, no re-categorisation was performed, since this would not have been

methodologically correct and the analysis was done on the results provided by the respondents without any modification.

Participation in the survey was **voluntary**. (Self) selection bias might be present, since only those interested in the topic participated in the survey. Those respondents that are more confident with the assessment of high-risk medical devices and/or who have knowledge about the MDR (e.g. clinicians that contribute to expert panels might have distort the answers positively), might be more likely to complete the survey, than those with less knowledge/skills. Furthermore, respondents could have presented their answers more positively than they actually are and results might not truly reflect the educational status of the respondents. However, this CORE-MD survey could be completed anonymously, which should have counteracted these issues.

The conclusions are **limited by the range of individuals** responding in each organization: since esp. the group of clinicians responding to the survey were heterogeneous a generalization should be done with caution.

Some discussion arose whether a differentiation needs to be done with regard to survey participants from **countries**, where the MDR is not applicable. To counteract this issue a **sensitivity analysis** was performed with regard to the core competencies (domains), which did not show any change of the overall meaning of the results. It could also be argued that survey respondents that selected “no knowledge of this domain” should not have received the subsequent questions on skills. However, the intention was to get more nuanced responses, since different skills were listed and respective responses could vary. Anyways, this hampered the comparability of the results of the skills from the original analysis with the sensitivity analysis, since these obviously depended on the respective results of the core competencies (domains).

It needs to be considered that the knowledge gaps mentioned are based on previous education and experience and **generalization** to the respective stakeholder group in general might be limited. The survey sample size varied quite a lot among the different stakeholder groups, which needs to be taken into account when interpreting and comparing the results among these groups. The results esp. of the stakeholder group “clinicians” have to be treated with caution due to the highly amorphous nature of the group and of stakeholder group “notified bodies” due to the potential lack of clinical background.

Moreover, the **analysis** of the survey results was not performing different statistical approaches e.g. hypothesis testing, since basic analysis in Microsoft Excel was considered sufficient. The aim was to evaluate in general the training needs of the different stakeholder groups and not to conduct any correlation analysis or to go into depth with different profiles of survey respondents.

The survey was only available in **English**, which should not have posed an obstacle, since one can assume that persons working in the field of science are able to use English in a professional working environment.

5. Conclusion: recommendations and outlook

As mentioned in Figure 22, nearly all survey respondents stated that they see a need for training courses in medical device regulatory science for the three stakeholder groups. The highest need for training was indicated for **clinicians** (72%), which was followed by **regulators** (48%) and **notified bodies** (41%). This also corresponds to the result that more than half of **clinician respondents** (65%) and r**egulator respondents** (53%) never attended medical device regulatory science education or training (for notified bodies it was 32%). Furthermore, vast majority of **clinician respondents** (81%), 64% of **other employment category respondents** and 60% of **regulator respondents** reported that their current employer neither did/does nor will provide any education or training (for notified bodies it was 22%).

To summarize, the survey showed "real gaps" (defined by critical skill needed by a stakeholder to do their job correctly), and "ideal" gaps (defined by additional nice to have skills).

The "real" gaps identified are:

- For **clinicians**, a distinction should be made between those clinicians who mainly work in clinical care and those who want to actively contribute to the approval of safe and effective medical devices, e.g. through their roles working in clinical trials, medical devices expert panels or notified bodies. Clinicians mainly performing clinical care duties may only need a basic knowledge of the regulatory system to be able to for example flag safety issues with medical devices and to provide high-level contributions where necessary. Persons with clinical training that choose to play an active role in the regulatory system, and who's daily work is more centered on regulatory affairs, may need additional and more elaborate training on clinical and post-market surveillance trial methodologies for participation in clinical investigations (as clinical trialists) and in conformity assessment (as medical experts). Internships with Notified Bodies and regulators (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.
- for **notified bodies**, regular training courses on new MDCG-guidances and on advanced methodologies to assess clinical data esp. in highly specific medical areas (Artificial Intelligence, Robotics, …).

A gap ideally to be filled for all three stakeholder groups are the additional modules and specializations.

Finally, based on the overview of perceived needs for Regulatory Science, the analysis of the landscape of existing training and educational courses, the exploratory interviews and the survey the CORE-MD consortium calls for action aiming at capacity-building in favor of increasing the efficiency of the regulatory system for safe and effective medical devices and improving its effectiveness.

The following recommendations are put forward:

5.1 Recommendations

Recommendation 1: Needs-based (modular) Curriculum

Based on our findings and inspired by STARS [28, 29, 34] we propose a modular curriculum that can be adapted to the training needs of the three stakeholder groups encompassing a Core Set of training complemented by modules for further specialization (see in Figure 25). The modular composition of such a curriculum would offer tailored educational elements for the respective tasks of the three stakeholder groups to fulfill them in a highly professional manner. It will also take into account the existing knowledge that persons already have and will be targeted to match the skills that they need in their daily job.

Training or education 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.).

- An academic curriculum or degree could be applicable to all stakeholder groups e.g. MSc medical device regulatory sciences, similar to pharmaceutical regulatory science/affairs. There could be core-domains that are relevant for all stakeholder groups and that could be complemented by specific domains.
    - Special attention should be given to methodology and evaluation, since current training opportunities mainly focus on procedural aspects.
    - In total three-quarter of all CORE-MD survey respondents indicated that they have a PhD, M.D. or doctorate. Most mentioned specialties were human medicine and engineering. The training needs that can be seen from the results, might indicate that certain topics are not sufficiently covered.
- Hands-on experience, training on the job and re-skilling of professionals 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)
    - In this CORE-MD survey, at least 50% or more of each employment category indicated that their stage of career is at senior or executive level. It should be made as easy as possible for professionals to attend further training (e.g. flexible schedules, online courses)

Target groups for Recommendation 1: Regulators, Notified Bodies, Clinicians contributing to regulation

Measures to proceed:

1. Raise awareness by broad dissemination to academic umbrella organisation (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.

The recommendations below include the domains/skills for which at least 20% of the respective stakeholder group indicated "no knowledge" (**in bold**) or which they stated as top priority in the question "top three skills in which one would like training over the next three to five years".

Recommendations for **notified bodies**

Notified Body ⧗

Topics to focus on:

- Pre-clinical testing (methodology and evaluation)
- Clinical investigation (methodology and evaluation): "Assessment of benefit-risk ratio and thresholds for acceptability", **"Methods and time-points for patient involvement/ engagement"** and **"Clinical epidemiology"**
- Training for **each new MDCG guidance** document to raise awareness and understanding of the guide

Recommendations for **regulators**

Regulator 🏛

Topics to focus on:

- **Pre-clinical testing (methodology and evaluation)**
- **Drafting a scientific advice to manufacturers**
- **Clinical investigation (methodology and evaluation): "Assessment of benefit-risk ratio and thresholds for acceptability" and further skills**
- **Legal, regulatory for market access: "Good clinical practice (GCP) - ISO14155"**
- **Post-market surveillance (all skills)**
- **Soft skills**

Recommendations for **clinicians**

Clinician ♡

Topics to focus on:

- **Pre-clinical testing (methodology and evaluation)**
- **Drafting a scientific advice to manufacturers**
- Clinical investigation (methodology and evaluation): "Assessment of benefit-risk ratio and thresholds for acceptability", "study-designs and their advantages/ disadvantages", **(functional) Safety and performance assessment, "Use of data from equivalence", "Methods for the evaluation of specific high-risk medical devices".**
- **Legal, regulatory for market access (all skills)**
- **Post-market surveillance (all skills)**

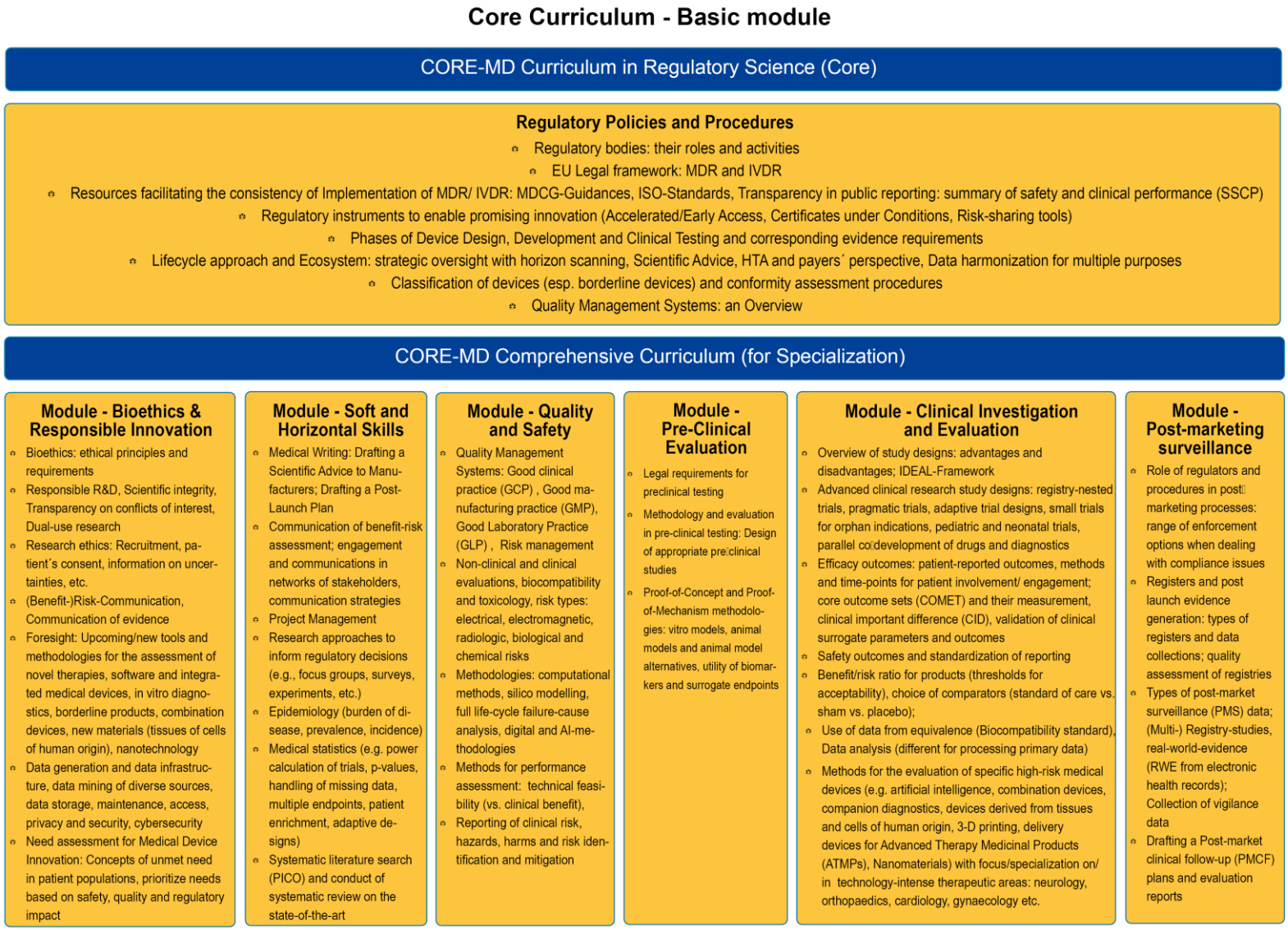


Figure 25: CORE-MD Curriculum in Regulatory Science for Medical Device

Recommendation 2: Training-on-the Job: Internship Program for Clinical Reviewers

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 for Recommendation 2: 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 and submit a proposal for the development of regulatory practice-relevant curricula (Recommendation 1) and Training-on-the Job programs (Recommendation 2).

Examples for training-on-the-job activities at TGA and FDA/ CDRH:

TGA[1] (Therapeutic Goods Administration, Australia): There is no formal training programme at TGA for medical officers, although training/ supervision requirements are documented in the TGA QMS. The clinical assessors are all medical doctors and are exposed to a broad variety of tasks, including types of medical devices and types of regulatory issue, throughout the device life-cycle, i.e. post market vigilance as well as pre-authorisation review. A large part of “on the job training” is having escalation protocols and ensuring that these are well utilised; this includes longer-serving staff, staff with subject matter knowledge and the ability to source expert opinion, maintaining involvement in that advice.

CDRH[2] (Center for Devices and Radiological Health at Food and Drug Administration/ FDA): Reviewer Certification Program (*see* Boxes below)

[1] Simon L. Singer, Principal Medical Adviser, Medical Devices Authorisation Branch, Medical Devices and Product Quality Division | Health Products Regulation Group, Australian Government, Department of Health and Aged Care, email-correspondence

[2] Kenneth J. Cavanaugh, Deputy Director, OHT2: Office of Cardiovascular Devices, Office of Product Evaluation and Quality, CDRH | Food and Drug Administration, email-correspondence

Good Practice Model at FDA

The training – called Reviewer Certification Program - applies to all new reviewers, including but not limited to medical officers, and consists of the following:

- At least 30 online real-time or recorded courses
- Passing post-course assessments with an average score of 80% or higher
- Completing evaluations of each course to get input on how they can be improved
- Completing a capstone activity, which ties all the core coursework together using mock applications to review and present to cohort

Core Courses (35 hours, deliver by internal experts)

Course	Description/Objective
Orientation	One-hour overview presentation on administrative and technical content of the Reviewer Certification Program
Your Role in Supporting Medical Device Innovation	Brief overview on both understanding the confidential resources for resolving regulatory grievances and medical device innovations to the patients' needs
Introduction to Total Product Life Cycle (TPLC)	Overview of the current organizational structure, strategic priorities and essentials of premarket and postmarket compliance
Premarket Program: 510(k) & 513(g)	Introduction to two types of premarket submissions common to lower-risk medical devices
Conducting a 510(k) Review	Describes the scope of 510(k) reviews and the purpose of consults (i.e. technical expert reviews such as those performed by medical officers), including how "to think" through the review
Basics of Writing Consult Requests & Consult Reviews	Understand the premarket review process, define roles and responsibilities and write effective reviews
Basic Clinical Trials & IDEs	Defining clinical trials, regulatory context and when IDEs (request for approval for new clinical trial) are needed
Q-Submissions & the Presubmission Program	Overview of the various Q-submission (consultation) types and understanding the review process
Documenting a Premarket Review	Overview of documents that are used when forming recommendations as a lead reviewer and why the admin file is important
Use of the Submission Memo & Report Template (SMART) for Premarket Reviews	Introduction of macro-enabled Microsoft word document template used to review various medical device submission types
Premarket Programs: PMA & HDE	An overview of Class 3 (highest-risk) medical devices and types of premarket submissions
Conducting a PMA Annual Report	Understanding components of an annual report and how to evaluate them
Premarket Review Clinic	Interactive practice session involving simulated review of a 510(k), including applying benefit-risk principles and writing deficiencies in the recommended way
Regulatory Basics	Describes the source and effect of law, regulation and guidance
Least Burdensome Provisions & Principles: Finding a Balance	General overview of Least Burdensome practices (asking for the appropriate amount of information at the appropriate time)
MDUFA V	Discussion of FDA and Industry agreement in the most recent Medical Device User Fee Agreement commitment letter
Requests for Information in Premarket Review: The Basics	How to request information from companies, to communicate how our concern relates to the regulatory decision, provide directions to submitters, and document the analysis
Basics of Standards in Premarket Review	Discussion of how standards became integral to the CDRH mission and how they are used

Using IT Systems in Premarket Review	States the purpose of each system in the premarket process, including how systems interact
Standards Overview	Defines standards and how they are applied, including differences between horizontal and vertical standards
Standards Resources and Premarket Use	Provides resources on how to find recognized standards and discusses how standards are used in premarket submissions
Overview of Freedom of Information (FOI)	Provides an overview of the FOI Act (which allows the US public to request access to certain types of non-public information from the government)
DeNovo Classification	Describes the legal basis for the DeNovo pathway and process (by which lower-risk devices can be marketed even though no comparable predicate exists)
General Biocompatibility Guidance	Goal is to provide clarity and update on evaluation and testing within a risk management process
Medical Device Corrections & Removals (Recalls)	Introduces definitions, regulations and overall review process, including standard operation procedures (SOPs) and benefit-risk considerations
Promotion, Advertising and Labeling Review	Overview of regulatory misconduct, such as research misconduct, triage process and close-out recommendations
Establishment Inspection Report & Potential Outcomes	Provides an understanding of the Establishment Inspection Report (the document resulting from inspections of manufacturing and clinical sites), including review and decision
Allegations	Covers what allegations are (complaints about a manufacturer or sponsor), where they come from and how they are received, including how to approach such assignments
Quality & Compliance Program	Broad overview of the compliance and quality (manufacturing and post-market quality assurance) program and compare the two as it relates to CDRH mission

Once this core coursework is completed, reviewers can choose to take "advanced" classes if desired and relevant to their duties. These are typically taught by external experts:

Advanced Topics in Clinical Investigations	IDE submissions, regulations and review process, including other regulations and resources related to clinical trials
Critical Thinking and Decision Making	Discuss thought-optimized processing as it applies to roles at work
Effective Communication	Increase effectiveness in delivering clear, concise communication, both internally and externally
Introduction to Medical Device Law	Learn the key laws, regulations, cases, and policies and how they apply to work
Master Deficiency Writing	Improve ability to write deficiencies that are clear, concise, and in the appropriate format
Master Technical Writing	Teaches the basic elements of plain writing and how to use them to write succinct, well-written technical documents
Evaluating Patient-Reported Outcomes (PROs) in Submissions	How to determine if a PRO is used correctly in a study or clinical trial and how to determine the validation of a PRO measure to ensure it has been used appropriately in a submission
Overview of CDRH Signal Management	Understanding CDRH's process for identifying post-market safety signals and communicating appropriate information to the public

While it's not part of the actual training program, new reviewers (including medical officers) typically are assigned a mentor with whom they work closely over the first 6 – 12 months to provide additional informal instructions, provide a check of their work prior to submitting it, etc.

Recommendation 3: EU Network Training Centers for Capacity Building and Harmonization of Curricula

The further development of a Network for Capacity Building coordinated by the Technical EU NTC Office (at EMA) for the creation of a European-wide network for the national Competent Authorities (NCA) has the objectives (analogue to the EU NTC developed for Drug Regulators, hma.eu) to improve the quality, consistency and efficiency of the work of the MD 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 development of regulation of medical devices. EU NTC has the following tasks:

- Development of competency matrix, development of curriculum and harmonisation of educational and training materials for the implementation of the MDR/ IVDR
- Central platform for training in Regulatory Affairs and Regulatory Science in Europe (e.g. Training and Continuing Education | FDA)
- Contact point for internships/rotation-programs and training-on-the job (of clinicians in notified bodies or regulators, similar to FDA/ TGA) (Network of Experts Program: Connecting the FDA with External Expertise | FDA)

Target groups for Recommendation 3: Regulators, Notified Bodies, Clinicians contributing to regulation

Measures to proceed:

1. Facilitate exchange among Competent Authorities and national regulators on EU NTC on medical devices initiatives.
2. Support EU NTC on medical devices at EMA to identify the most urgent topics for training of Competent Authorities staff members.

Actors (EMA EU NTC team, Team NB-Academy, Universities, Applied Universities) in the network might contribute to the curriculm with offering specific elements (***see* Table 2)**:

Table 14: EU NTC curriculum for national drug authorities as of 2023)[3]

Curriculum Topic (Expert Body)	Online Courses	Face to face courses	Webinars
Pharmacovigilance (PRAC)	36	11	18
Quality (QWP)	31	12	21
Telematics (/ Network Portfolio)	27	3	8
Regulatory (CMDh, EMA)	21	1	33
Veterinary (CVMP, WP)	20	20	4
Non-Clinical (SWP)	17	4	4
Internal Audits (WGQM)	12	0	1
Paediatric (PDCO)	8	0	16
ATMP (CAT)	9	2	5
Product Information (SmPC AG)	5	0	Several
Clinical Trials - *ACT EU*	3	9	6
GCP (GCP IWP)	2	5	1
Methodology / Biostatistics (BSWP)	3	2	2
Big Data - *tender launch 2022*	3	0	3
Herbal (HMPC)	3	1	2

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

Recent years have shown an increasing need for the involvement of clinicians in regulatory affairs, to ensure that clinical input is taken into account in the system and in health policy making. To name just a few examples, the Expert Panels for Medical Devices have been established[4], cooperation on Joint Health Technology Assessment is increasing and policy makers are dependent on clinicians for their knowledge and experience in working directly with medical technologies in patient care, for instance through representation in different stakeholder fora[5]. Nonetheless, many clinicians only have a basic understanding of the system for regulatory affairs, the way in which the devices and medicines they use are approved, post-market surveillance procedures and how clinicians can contribute to regulatory affairs. The survey showed that more than a third (34%) of clinicians, do not know how the legislation, evaluation, approval and surveillance process works. This number is likely to be even higher among the wider group of clinicians across Europe, as there may be a certain bias in the results of the survey due to a high number of Members of Medical Devices Expert Panels that replied and due to the way in which respondents were contacted (e.g. through BioMed Alliance and European Medical Societies). In addition, more than half of the clinicians (58%, 161 persons) stated that training on regulatory affairs/sciences could help them to better verify the safety of the devices. The main part of the job of clinicians is focused around clinical care but they would need a basic knowledge of regulatory affairs, e.g. to advise policy makers and to flag potential issues with the

[3] Sheila Kennedy (EU NTC office at EMA): Background to Curriculum Development under the EU NTC, presentation.

[4] For more information see: https://health.ec.europa.eu/medical-devices-expert-panels/overview_en

[5] Clinicians are involved in different stakeholder fora including the Medical Devices Coordination Group, HERA Civil Society Forum, Health Technology Assessment Stakeholder Forum, European Medicines Agency Healthcare Professionals Working Party etc.

health technologies that they use. They often already have a heavy workload, and they would not have the necessary time to follow some of the elaborate courses that are proposed for e.g. regulators and notified bodies. Instead, we would propose a more flexible approach for clinicians with a combination of different training models.

Target groups for Recommendation 4: Clinicians not yet contributing to regulation

Measures to proceed:

1. Development of sessions on regulatory affairs in curricula in medical schools and professional medical speciality training programmes.
2. Development of information materials, online training and webinars for sessions in medical congresses and CME-related activities

5.2 Roadmap for Implementation of Recommendations

Next steps are to consider the above mentioned results and to implement the subsequent recommendations. The target audiences as stated in the introduction could be responsible for initiating the discussions and for executing the action points outlined in Figure 26.

*There is a tendency that training should be dedicated to the specific target group. However, it was also suggested that notified bodies and regulators could be combined in one target group. In any case, training across the stakeholders could enhance understanding of each other's viewpoints and allow for an exchange of experiences, which might be done on certain occasions. Depending on the stakeholder group and stage of career, different schedules and extent of training might be needed.

Figure 26: Action points towards implementation of recommendations

Among the measures proposed some can be realized soon, others need more time to prepare:

Short term measuers (1-3 Years)

1. Dissemination of CORE-MD document to relevant actors (Federation Applied Universities, Universities) for raising awareness on educational and training needs.
2. Identification of EC-grants and development of a proposal for the development of regulatory practice-relevant curricula (Recommendation 1) and Training-on-the Job programs (Recommendation 2).
3. Development of information materials, online training and webinars for sessions in medical congresses and CME-related activities.
4. Facilitate exchange among Competent Authorities and national regulators on EU NTC on medical devices initiatives.
5. Support EU NTC on medical devices at EMA to identify the most urgent topics for training of Competent Authorities staff members.

Mid-term measures (3-5 years)

1. Interconnection of existing academic programmes for a mutual recognition of modules.
2. Identification and coordination of interested parties to take stewardship in training-on-the-job activities
3. Development of such Training-on-the Job programs among interested parties.
4. Development of sessions on regulatory affairs in curricula in medical schools.

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Appendix 1: Exploratory survey by BioMed Alliance

Survey on Education in Regulatory Affairs - CORE-MD

This short survey assesses what sort of training or education exists within your medical field and specialty association, to inform healthcare professionals about regulatory science and affairs, particularly in the context of the EU Medical Device Regulation.

It will help to identify needs for the development of methodological expertise and educational requirements for the assessment of high-risk medical devices, in relation to task 4.3 of the CORE-MD project. The results will contribute to an overview of educational activities in the field of regulatory affairs, across the major medical specialties in Europe. It may also be used to advise about training for members of EU Expert Panels on medical devices.

CORE–MD is a European Union Horizon 2020 project, that will run from April 2021 until March 2024. It will review methods for evaluating high-risk medical devices, in order to translate expert evidence into advice for EU regulators and to recommend an appropriate balance between innovation, safety, and clinical effectiveness. The BioMed Alliance is a partner in the project.

1. Does your society follow developments around regulatory affairs in relation to medical devices? (e.g. around the EU Medical Device Regulation) Please give details.
    a. Textbox
2. Does your society organise educational activities on regulatory affairs? (provide examples, details & links where applicable)
    a. Sessions at congresses (textbox)
    b. Regulatory affairs courses (textbox)
    c. Webinars (textbox)
    d. Documents (position papers, articles in journals etc.) (textbox)
    e. Guidelines (textbox)
    f. Other (textbox)
3. Is education on regulatory science part of the curriculum for your specialty?
    a. Yes (tick box)
    b. No (tick box)
    c. Comments/specifications/links (textbox)
4. Are you aware of other training opportunities for doctors in the field of regulatory affairs for medical devices? (please provide examples & links)
    a. Training (textbox)
    b. Courses (textbox)
    c. Guidance (textbox)
    d. Fellowships (textbox)
    e. Other (textbox)
5. What particular actions would help colleagues in your discipline to develop an interest in regulatory affairs?
    a. Textbox

6. Which major training needs do you perceive as necessary to help clinicians better understand the MDR?
    a. Textbox
7. Could you please provide us with the name and e-mail address for a relevant contact person within your society that we could follow up with, if necessary?
    a. Textbox

Thank you for contributing to this survey.
Further details about CORE-MD are available at www.core-md.eu

Appendix 2: CORE-MD Survey

Educational requirements for the assessment of high-risk MD

The aim of this survey is to identify the needs for methodological expertise and educational requirements for the assessment of high-risk medical devices, specifically in the context of the EU Medical Device Regulation. The results will be summarized in a Roadmap that is created within the "Coordinating Research and Evidence for Medical Devices" (CORE-MD) Project.

CORE–MD is a European Union Horizon 2020 project that runs from April 2021 until March 2024. It reviews methods for evaluating high-risk medical devices, in order to translate expert evidence into advice for EU regulators and to recommend an appropriate balance between innovation, safety, and clinical effectiveness.

Your participation in the current survey is very important to us and crucial to help identify the needs for education and training related to the assessment of high-risk medical devices. In the survey, we kindly ask you to share information about your professional background and skill set. There are around 25 survey questions and the responses take about 10-15 minutes (will add approximate duration later) in total.

The Austrian Institute for Health Technology Assessment (AIHTA), an academic non-profit institute, is leading this survey together with the European Association for Medical Devices of Notified Bodies (Team-NB). The survey is set up via the EU Survey tool and data collection is coordinated by AIHTA.

We guarantee that the data provided will be kept completely anonymous and treated confidentially in strict accordance with national and European data protection legislation. The information you provide to us will be used for purely scientific purposes. If you have any questions about the storage and processing of the data, please refer to our privacy notice here: https://aihta.at/page/datenschutzerklaerung/en
This project has received funding from the European Union's Horizon 2020 research and innovation program under grant agreement No 965246.

Demographics

* Question 1	Response (choose one option)
Please select your **gender**	1. Female 2. Male 3. Other 4. Rather not say

* Question 2	Response (choose one option)
Please select the country of your current place of work (main employment)	1. Austria 2. Belgium 3. Bulgaria 4. Croatia 5. Republic of Cyprus 6. Czech Republic 7. Denmark 8. Estonia 9. Finland 10. France 11. Germany 12. Greece 13. Hungary 14. Iceland 15. Ireland 16. Italy 17. Latvia 18. Liechtenstein 19. Lithuania 20. Luxembourg 21. Malta 22. Netherlands 23. Norway 24. Poland 25. Portugal 26. Romania 27. Slovakia 28. Slovenia 29. Spain 30. Sweden 31. Switzerland 32. Other *[free text]*

Occupation and education

* Question 3	Response (choose one option)
At which **stage of your career** are you?	1. Entry-level (≤ 3 years experience) 2. Intermediate (3-7 years experience) 3. Mid-level (7-14 years experience) 4. Senior or executive-level (≥15 years experience)

* Question 4	Response (choose one option)
Which of these 3 categories defines best your **main employment**?	1. Clinician 2. Notified Body 3. Regulator 4. Other *[free text]*

* Question 5	Response (choose one option)
If you have a **second employment/affiliation**: Which of these 3 categories defines it best?	1. Clinician 2. Notified Body 3. Regulator 4. Other *[free text]* 5. Not applicable

* Question 6	Response
Please provide your exact professional job title	*[free text]*

* Question 7	Response (choose one option)
Are you a member of an **EU expert panel for the evaluation of medical devices or in-vitro diagnostics (IVDs)**?	1. Yes 2. No

Only if response to question 7 was 1. "yes"

* Question 7a	Response (choose all that apply)
If yes, which **EU expert panel?**	1. Screening panel - determines whether there is a need for a scientific opinion 2. Orthopaedics, traumatology, rehabilitation, rheumatology 3. Circulatory system 4. Neurology 5. Respiratory system, anaesthesiology, intensive care 6. Endocrinology and diabetes 7. General and plastic surgery and dentistry 8. Obstetrics and gynaecology, including reproductive medicine 9. Gastroenterology and hepatology 10. Nephrology and urology 11. Ophthalmology 12. In vitro diagnostic medical device

* Question 8	Response (choose all that apply)
In your perception, which **languages** are you able to use in a professional working environment (e.g. for training, as working language)?	1. English 2. German 3. Spanish 4. Italian

	5. French 6. Dutch 7. Polish 8. Other *[free text]*

* **Question 9**	**Response (choose one option)**
What is your **highest educational level**?	1. High school graduate 2. Bachelor 3. Master 4. PhD, MD or Doctorate

* **Question 10**	**Response (choose all that apply)**
Please state your **educational background/specialty**	1. Human Medicine: *If 1.: Practising Clinician (yes or no)* 2. Veterinary Medicine 3. Dentistry 4. Biology 5. Chemistry 6. Physics 7. Pharmacy 8. Engineering 9. Law 10. Other *[free text]*

Only if response to question 10 was 1. "Human Medicine"

* **Question 10a**	**Response (choose one option)**
Please state your main specialty in human medicine	1. Orthopaedics, traumatology, rehabilitation, rheumatology 2. Circulatory system 3. Neurology 4. Respiratory system, anaesthesiology, intensive care 5. Endocrinology and diabetes 6. General and plastic surgery and dentistry 7. Obstetrics and gynaecology, including reproductive medicine 8. Gastroenterology and hepatology 9. Nephrology and urology 10. Ophthalmology 11. Other *[free text]*

* **Question 11**	**Response (choose one option)**
Please briefly describe your area of practice	*[free text]*

Knowledge on regulatory affairs

NOTE: The next 5 questions (A-E) are only shown for clinicians i.e. if they select "clinicians" in question 4 – "Which of these 3 categories defines best your **main employment**?"

* **Question A**	**Response (choose one option)**
Do you know how the system for the evaluation and market surveillance of medical devices works?	1. I do not know how the legislation, evaluation, approval and surveillance process works 2. I have a general idea of what sort of legislation is in place and how devices are evaluated 3. I have a very good understanding of the regulatory system and the evaluation, approval and market surveillance processes 4. Other: *[free text]*

* **Question B**	**Response (choose one option)**
In the European Union, demonstrating the clinical effectiveness of a high-risk medical device is the responsibility of:	1. The manufacturer 2. A notified body 3. The national regulatory agency for medical devices 4. Academic triallists 5. Other: *[free text]*

* **Question C**	**Response (choose all that apply)**
If you want to verify whether a device that you want to use is safe, where would you look for information?	1. Ask manufacturer 2. Search European Commission website 3. European Medicines agency website 4. Google search 5. Published medical literature 6. Reports from medical device registries. 7. Other: *[free text]*

* **Question D**	**Response (choose one option)**
If you have a concern around the safety of a medical device, how would you report this?	1. I would not report it 2. Contact hospital administration 3. Contact a notified body 4. Contact a national authority 5. Contact manufacturer 6. Other: *[free text]*

* **Question E**	**Response (choose all that apply)**
How do you think additional training on regulatory affairs & medical devices could help you in your daily work?	1. Better verification whether the devices that I use are safe 2. Will allow me to contribute to the evaluation process of medical devices (e.g. through expert panels)

	3. Understand the value of registries in post-market surveillance 4. I don't think it will make a difference in my work 5. Other *[free text]*

Training

* **Question 12**	**Response**
Did/does/will your **current employer** (main employment) provide any **education or training** in the field of medical device regulatory science*?	1. Yes, employer provided training in the past *[free text]* 2. Yes, employer is currently offering training *[free text]* 3. Yes, employer will be proposing training in the future *[free text]* 4. No

*In the context of this survey, we use the following definition for the term **regulatory science**:
Regulatory science is the application of the scientific method to improve the development, review, and oversight of new drugs, biologics, and devices that require regulatory approval prior to dissemination.
Specifically we are interested in the **medical device regulatory science**.
Reference: Institute of Medicine. 2012. *Strengthening a Workforce for Innovative Regulatory Science in Therapeutics Development: Workshop Summary*. Washington, DC: The National Academies Press. https://www.ncbi.nlm.nih.gov/books/NBK92887/

Question 13	**Response**
* Did you **ever attend** medical device regulatory science education or training?	1. Yes 2. No

Only if response to question 13 was 1. "yes"

* **Question 13a**	**Response (choose all that apply)**
What have you attended in the past 3 years?	1. Session(s) at congresses 2. Few-hours webinar(s) 3. Full day course(s) 4. Several-days training 5. Several-months training 6. Regulatory science was part of my curriculum 7. Other *[free text]*

* **Question 13b**	**Response (choose all that apply)**
Which entity provided the training?	1. My employer 2. Notified body 3. Regulatory Agency 4. Medical Society 5. University 6. Industry 7. Other *[free text]*

Core competencies and training needs

Competency: an important skill that is needed to do a job, the ability to do something well (Cambridge dictionary)

NOTE: We now have **one table/matrix** with the headers/domains (written in bold) – see question 14. If a header/domain is answered with answer 2, 3, 4 or 5, the individual skills are shown in **different tables/matrix** – see question 15.

* **Question 14**	**Response (Choose one option for each domain)**
Please indicate your **individual level of need for training** around each domain **Domains from table 1 are listed in a table/matrix**	1. Does not apply (not relevant for my job) 2. I have no knowledge of this domain 3. I have awareness-level knowledge or skills 4. I have practical knowledge or skills 5. I have advanced knowledge or skills

* **Question 15**	**Response (Choose one option for each skill)**
Please indicate your **individual level of need for training** around each skill **Skills from table 1 are listed in a table/matrix. If option 1 from Question 14 was selected for a domain, respective skills are not shown in question 15**	1. Does not apply (not relevant for my job) 2. I have no knowledge of this domain 3. I have awareness-level knowledge or skills 4. I have practical knowledge or skills 5. I have advanced knowledge or skills

* **Question 16**	**Response**
From this list, please rank the **top three** skills in which you would like training over the next three to five years **All skills from question 14/15 are shown in a table/matrix including an "other *[free text]" option*.**	1. First choice 2. Second choice 3. Third choice

Table 1

Domains and skills (along the lifecycle of a medical device)
Pre-clinical testing (methodology and evaluation)
Design and development of medical devices
Drafting a Scientific Advice to Manufacturers
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 vs. Sham vs. Placebo)
Outcomes measurements and instruments (standardized and validated instruments)
Assessment of benefit-risk ratio and thresholds for acceptability

Use of data from equivalence (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 (different for processing primary data)
Ethics in clinical trials (e.g. recruitment, patient´s consent, information on uncertainties)
Legal, regulatory for market access
Medical Device Regulation: requirements, procedures, implementation, update on regulatory developments
Classification of devices (esp. borderline devices)
Quality Management System - ISO 13485
Good clinical practice (GCP) - ISO14155
Good manufacturing practice (GMP) - ISO 13485
Risk management - ISO 14971
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 (PMCF) plans and evaluation reports
Types of post-market surveillance (PMS) data
Soft skills (e.g. medical writing, project management)

Question 17	**Response**
If any skill(s) was missing from the list, please add it here and explain your individual level of need for training around this skill	*[free text]*

Training formats and modalities

* **Question 18**	**Response (choose all that apply)**
In your opinion, is there a need for **training courses** in medical device regulatory science for the following audiences?	1. Yes, for notified bodies. 2. Yes, for regulators. 3. Yes, for clinicians. 4. I do not know or I do not have any opinion on this. 5. No training needed for any of the 3 groups.

Only if response to question 18 was 1. "yes" (yes for NB, yes for regulators, or yes for clinicians)

* **Question 18a**	**Response (choose all that apply)**
What **format** should the training be?	1. Training in single days (e.g. 1 day per month) over the year 2. Block training modules (several days in a row)

	3. Practical training on the job (advanced internships in organisations and mentoring programs) 4. Lifelong upskilling and reskilling/ continuous training 5. Other *[free text]*

* **Question 19**	**Response (choose one option)**
Do you have any preference on whether training should be **specific** for the respective target group (clinicians, regulators, notified bodies) or if it should be offered **across** these target groups?	1. No opinion on this 2. Prefer training dedicated to specific target group If 2, please explain *[free text]* 3. Prefer training across these target groups If 3. please explain *[free text]* 4. It depends on the topic/module If 4, please explain *[free text]*

Question 20	**Response (free text)**
If you have any **further comments on** educational requirements for the assessment of high-risk MD, which are not covered above, please state them here	*[free text]*

Question 21	**Response (free text)**
If you agree to be contacted in case of **follow up – or clarification questions**, please provide your email address.	*[free text]*

Question 22	**Response (free text)**
If you are interested in the **results of the survey**, please provide your email address.	*[free text]*

* means mandatory questions

Appendix 3: Figures on results of skills about clinical investigation; legal, regulatory for market access; and Post-market surveillance

Domain: Clinical investigation (methodology and evaluation)

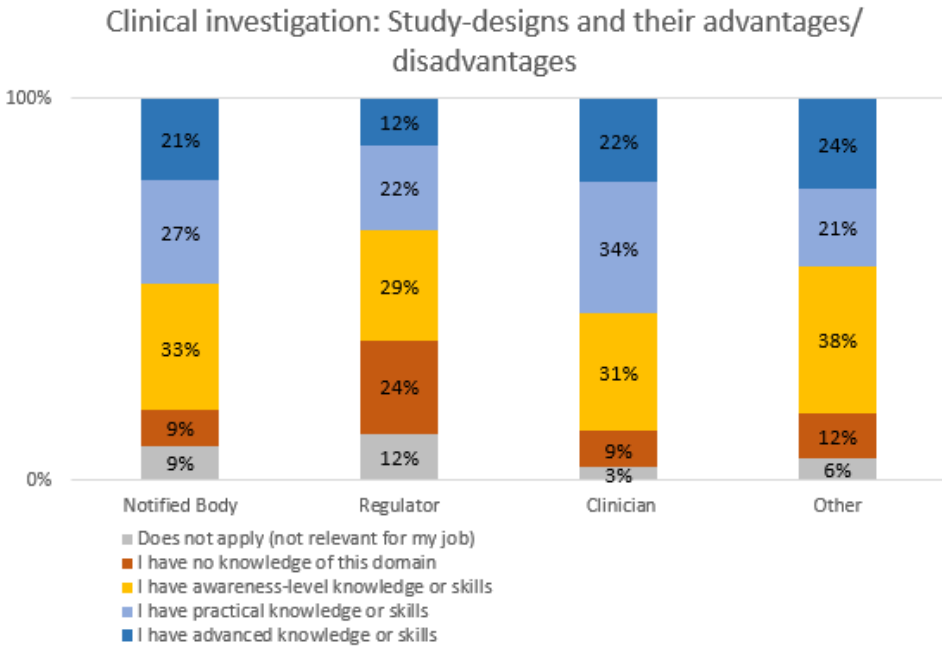

Figure A 1: Results of skill: study-designs and their advantages/disadvantages per employment category

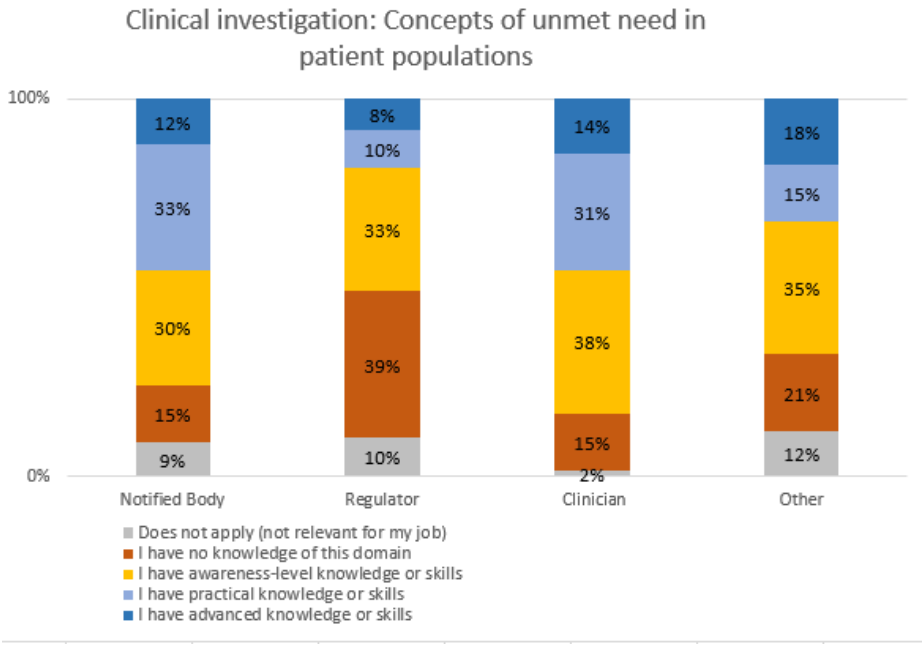

Figure A 2: Results of skill: concepts of unmet need in patient populations per employment category

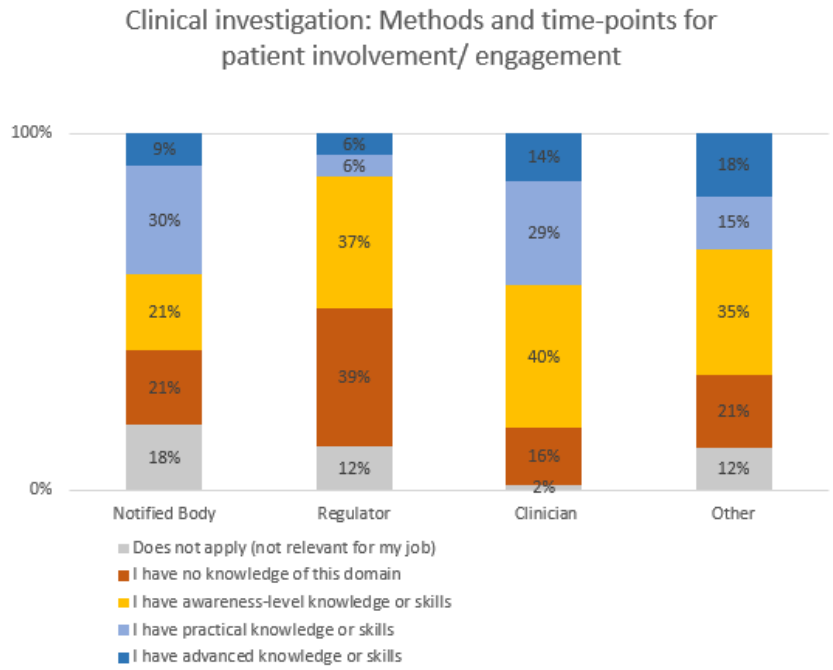

Figure A 3: Results of skill: methods and time-points for patient involvement/ engagement per employment category

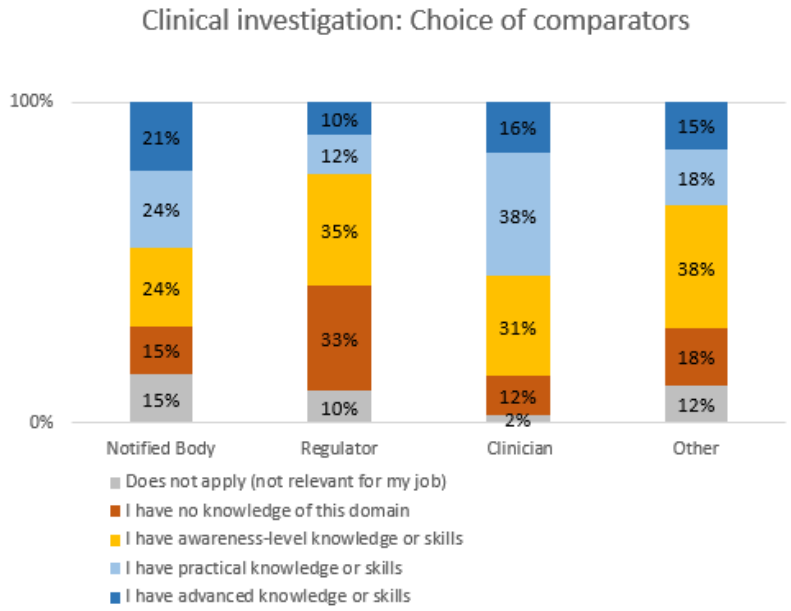

***Figure A 4**:* Results of skill: choice of comparators (standard of care vs. sham vs placebo) per employment category

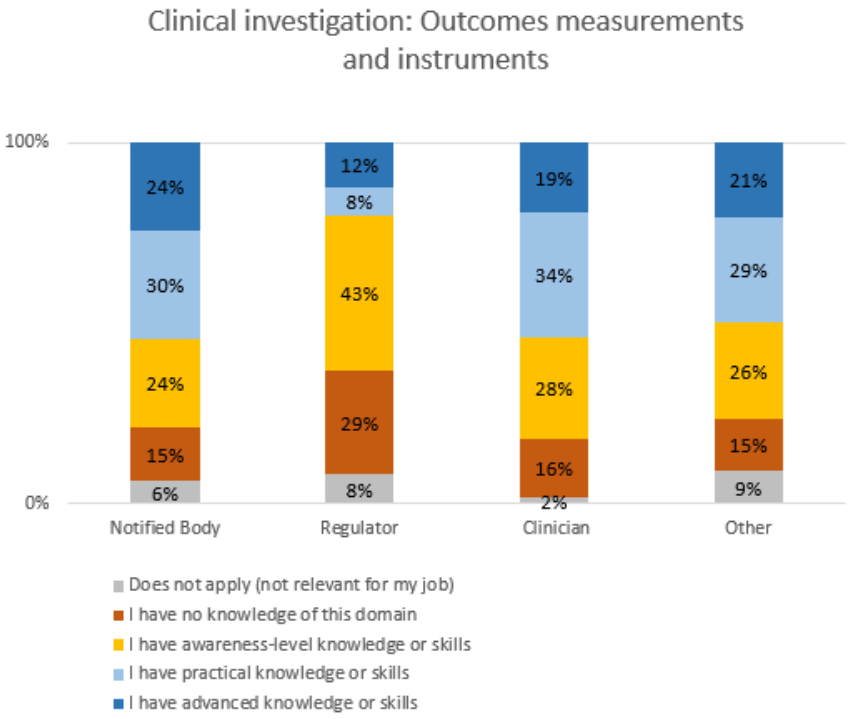

***Figure A 5**:* Results of skill: outcomes measurements and instruments (standardized and validated instruments) per employment category

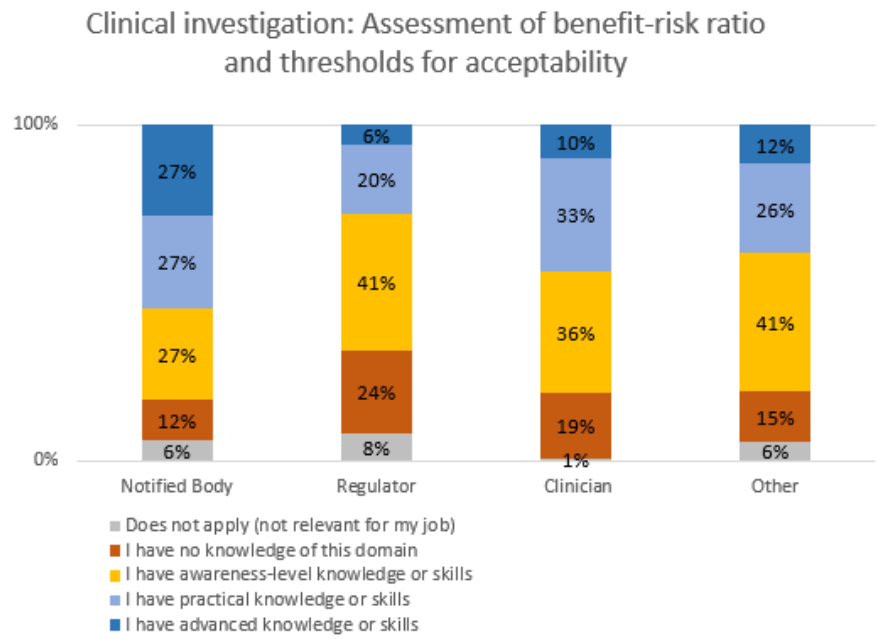

Figure A 6: Results of skill: assessment of benefit-risk ratio and thresholds for acceptability per employment category

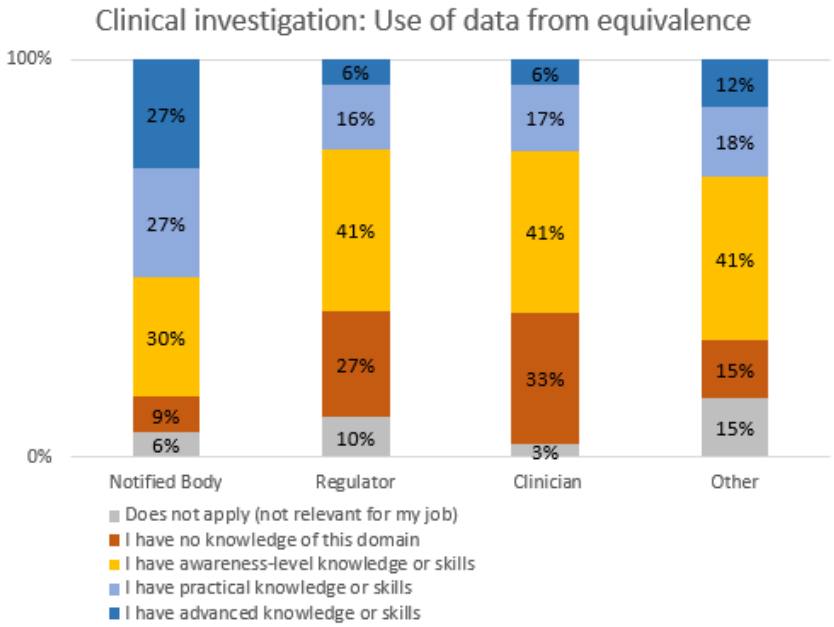

Figure A 7*:* Results of skill: use of data from equivalence (biocompatibility standard) per employment category

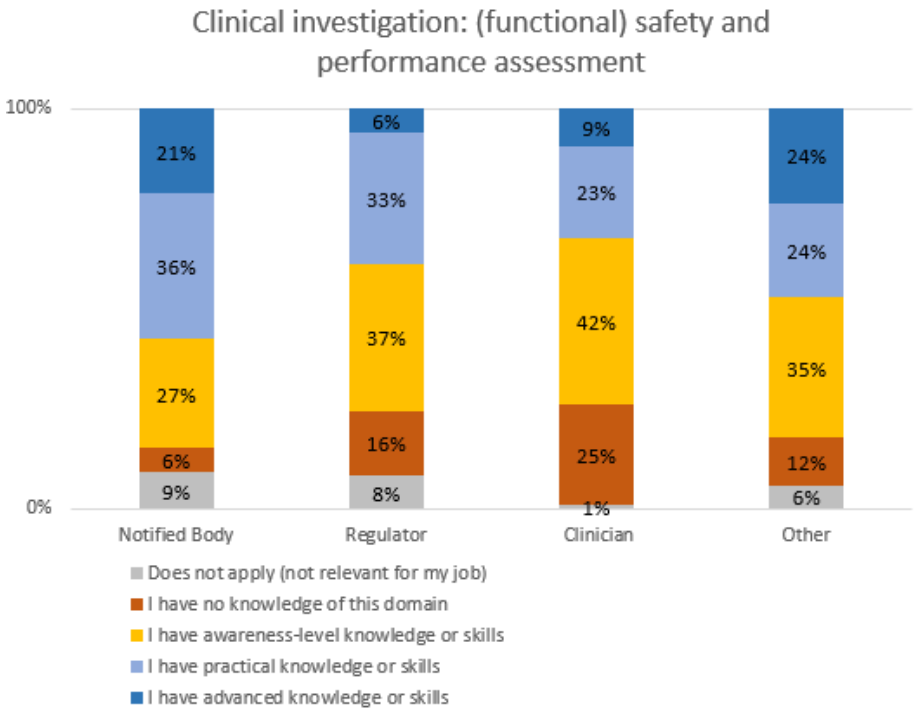

***Figure A 8**:* Results of skill: (functional) safety and performance assessment per employment category

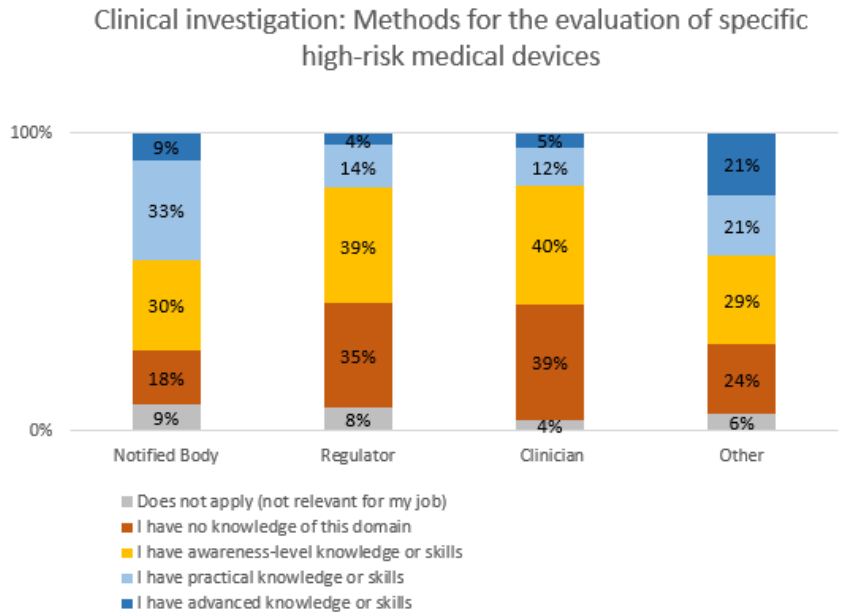

Figure A 9: Results of skill: methods for the evaluation of specific high-risk medical devices per employment category

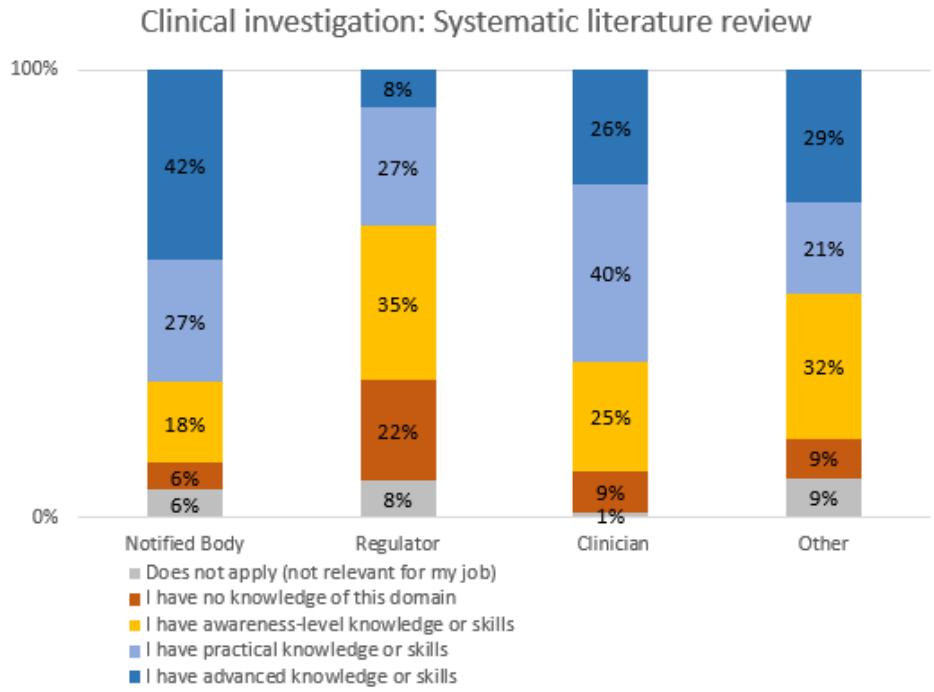

Figure A 10: Results of skill: systematic literature review (guidance for method and process) per employment category

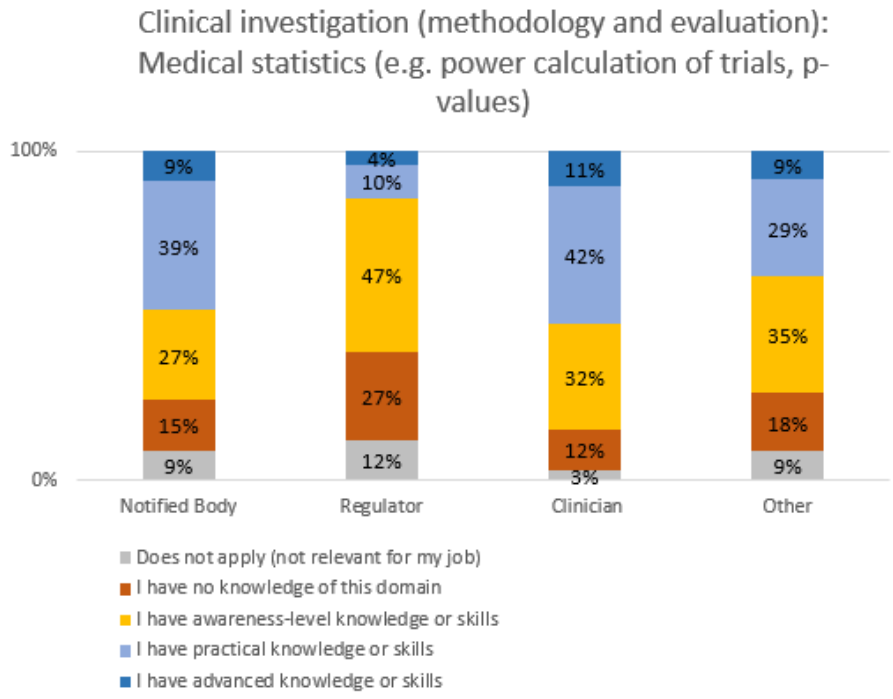

Figure A 11: Results of skill: medical statistics (e.g. power calculation of trials, p-values) per employment category

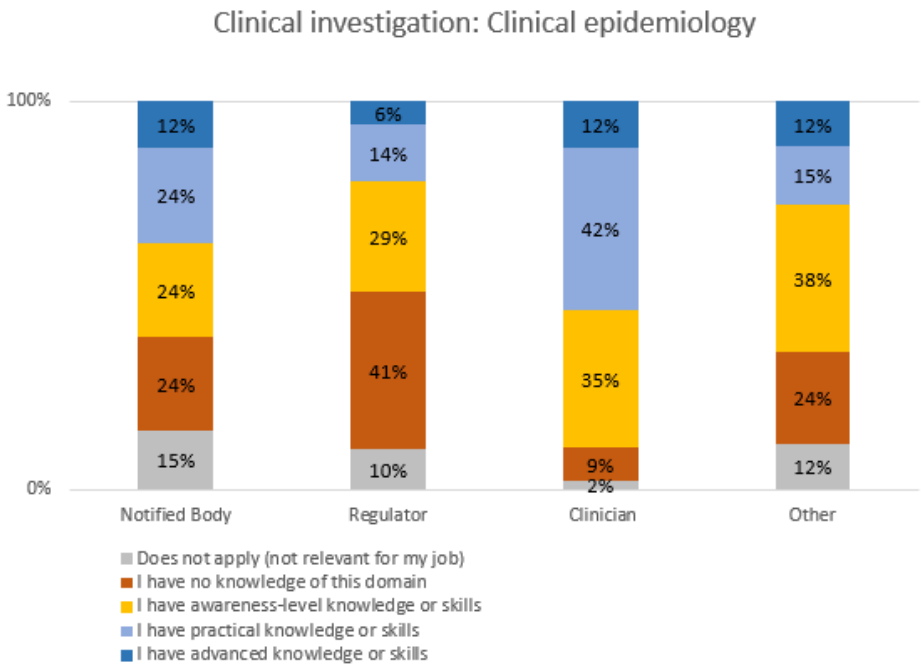

Figure A 12: Results of skill: clinical epidemiology (data and sources for burden of disease, prevalence, incidence) per employment category

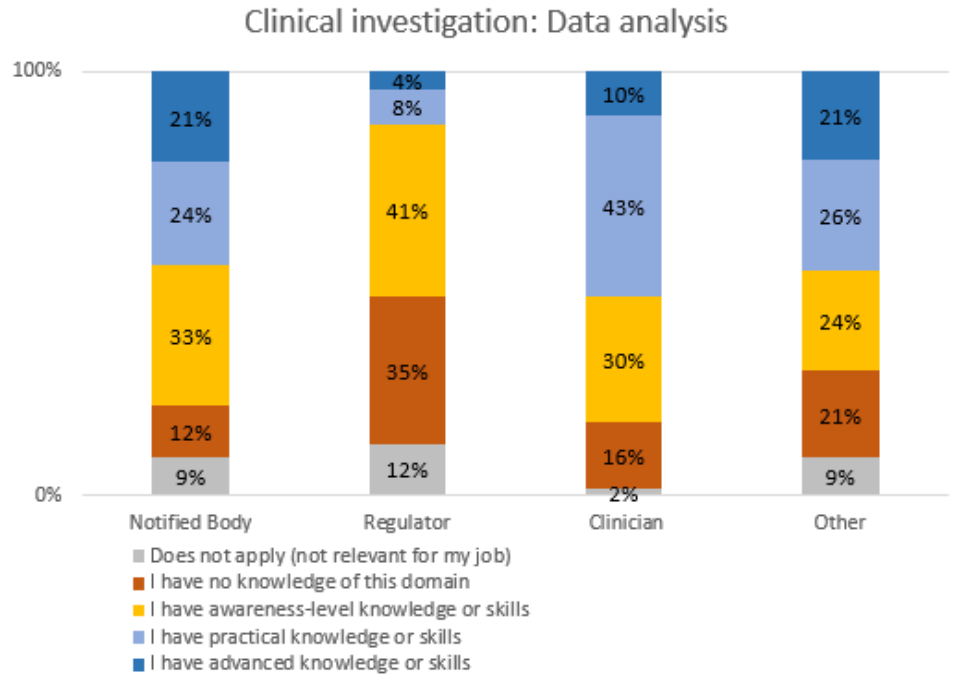

Figure A 13: Results of skill: data analysis (different for processing primary data) per employment category

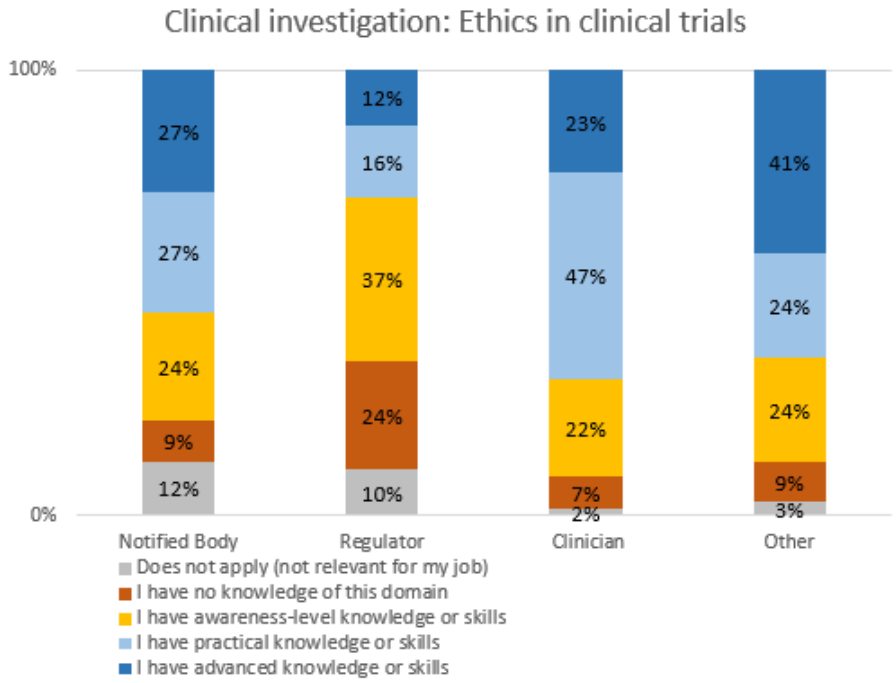

Figure A 14: Results of skill: ethics in clinical trials (e.g. recruitment, patient´s consent, information on uncertainties) per employment category

Legal, regulatory for market access

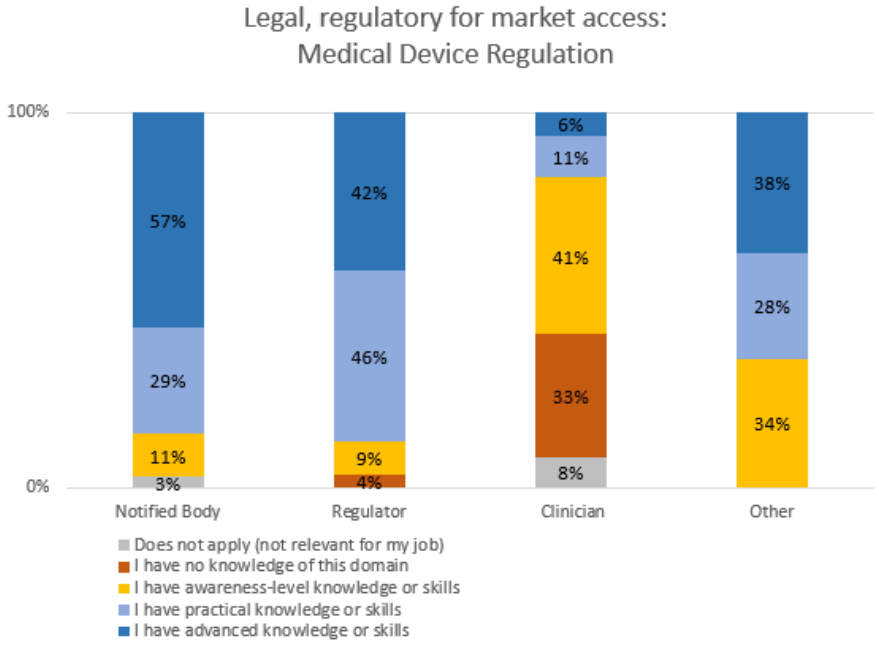

Figure A 15: Results of skill: Medical Device Regulation: requirements, procedures, implementation, update on regulatory developments per employment category

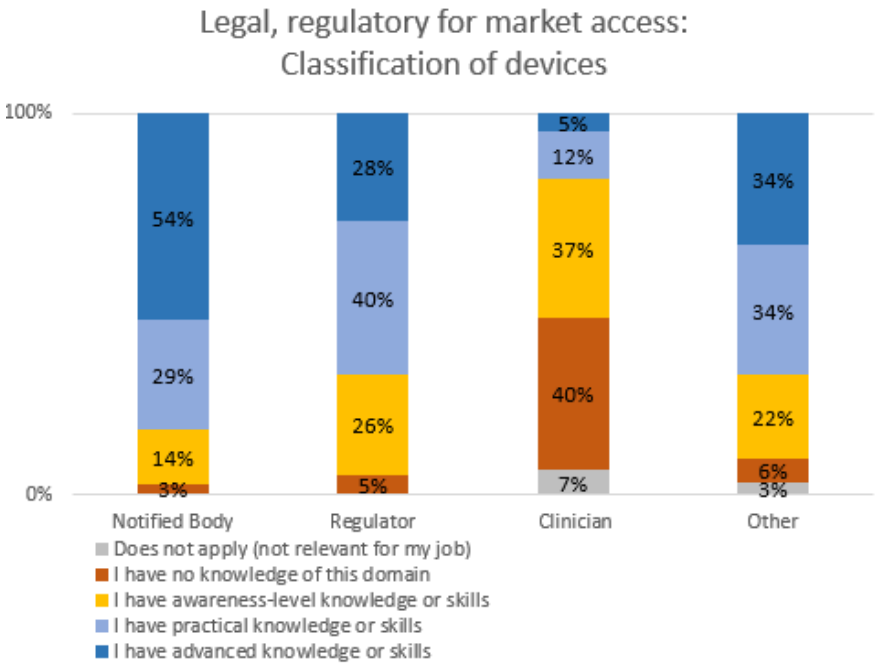

Figure A 16: Results of skill: classification of devices (esp. borderline devices) per employment category

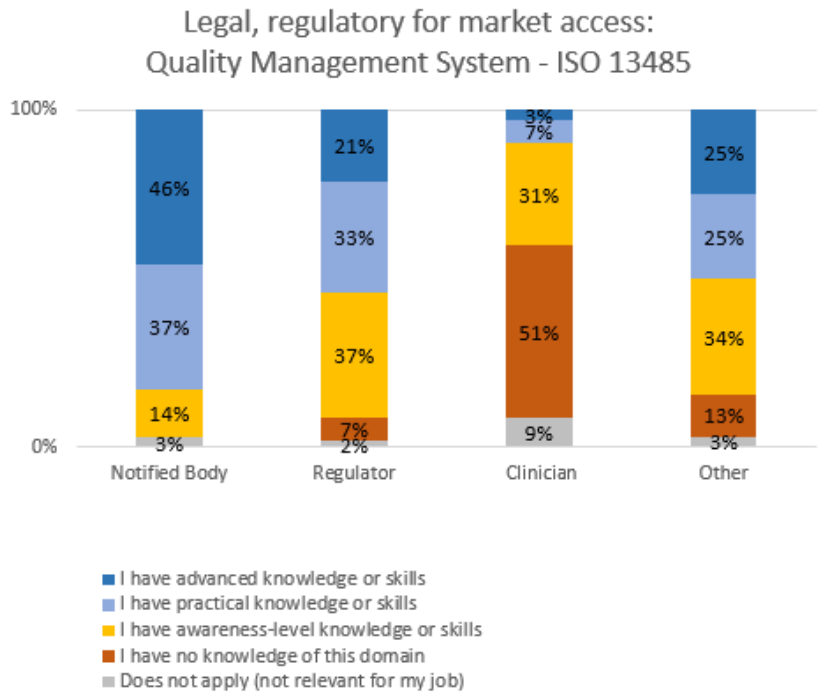

Figure A 17: Results of skill: Quality Management System (QMS) - ISO 13485 per employment category

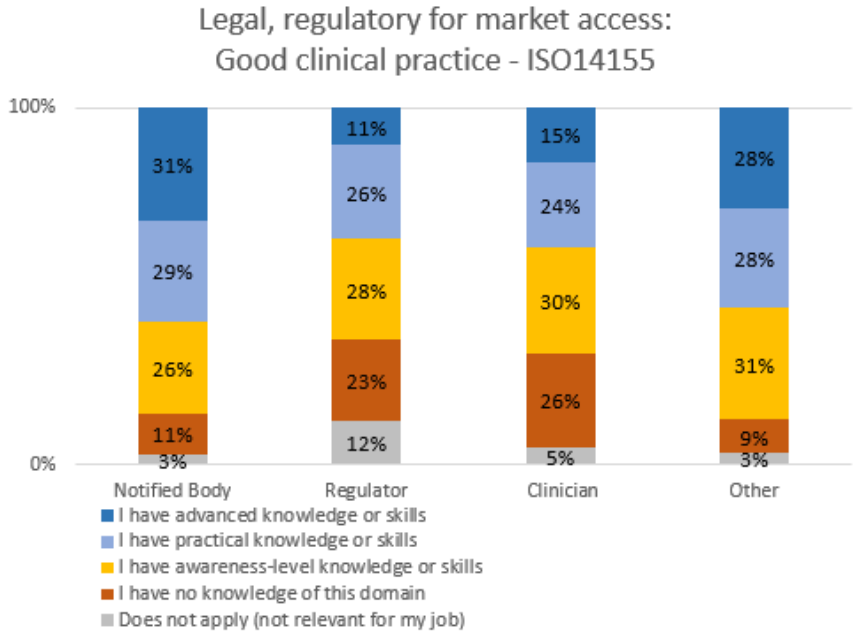

***Figure A 18**:* Results of skill: Good clinical practice (GCP) - ISO14155 per employment category

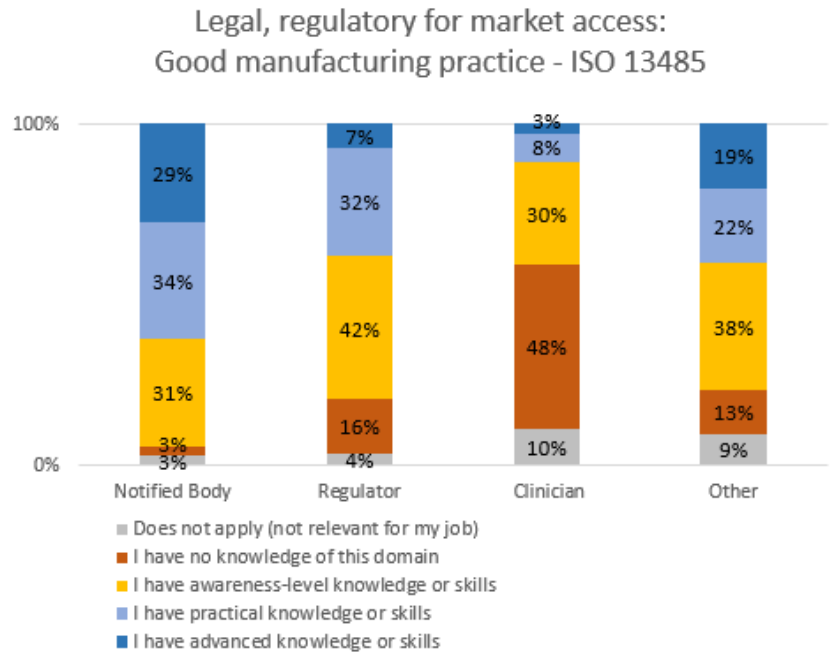

Figure A 19: Results of skill: Good manufacturing practice (GMP) - ISO 13485 per employment category

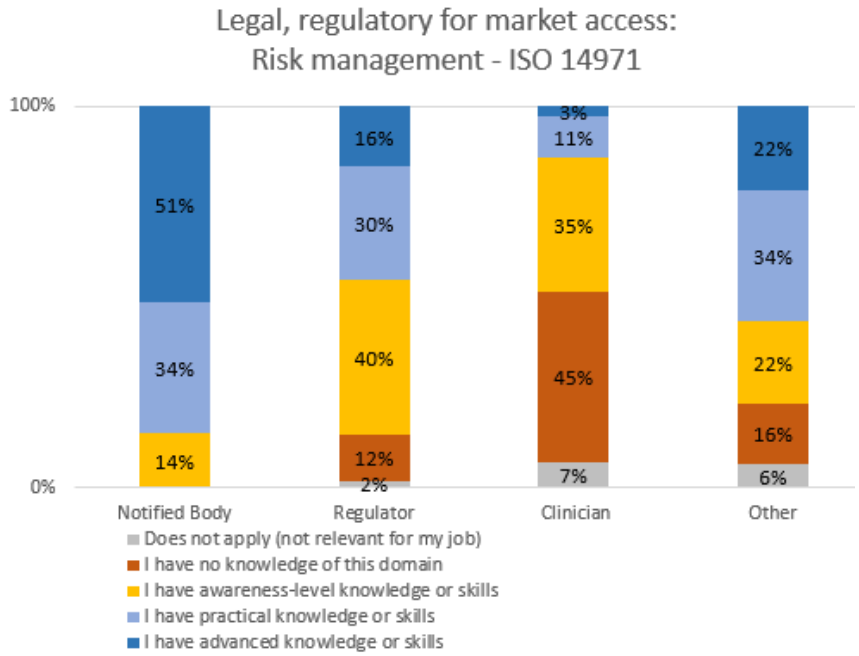

Figure A 20: Results of skill: Risk management - ISO 14971 per employment category

Post-market surveillance

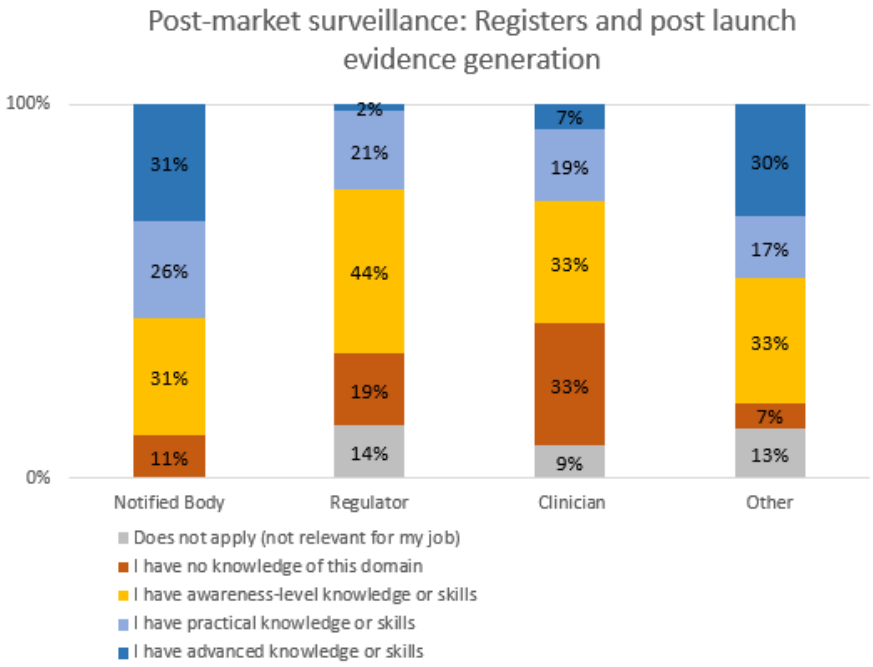

Figure A 21: Results of skill: Registers and post launch evidence generation (types of registers, data collections) per employment category

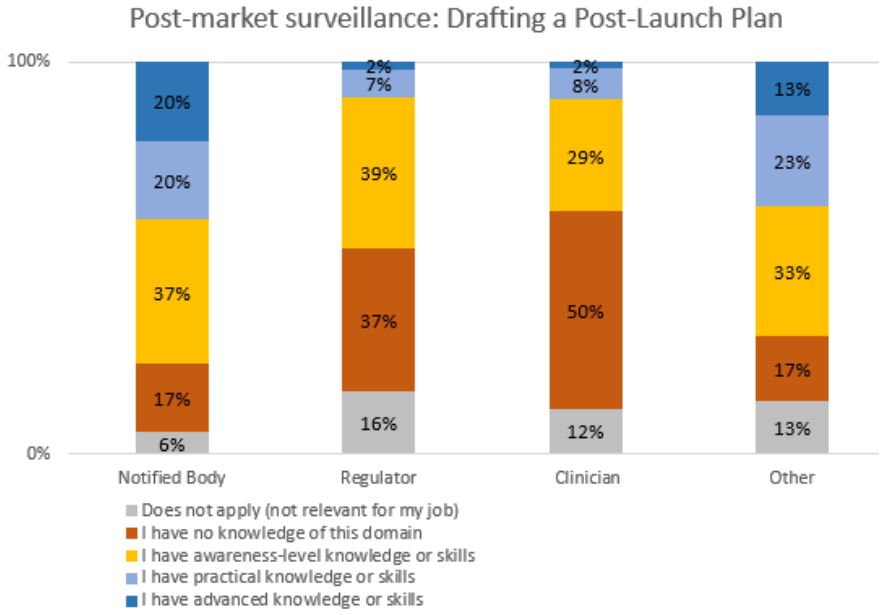

Figure A 22: Results of skill: Drafting a Post-Launch Plan per employment category

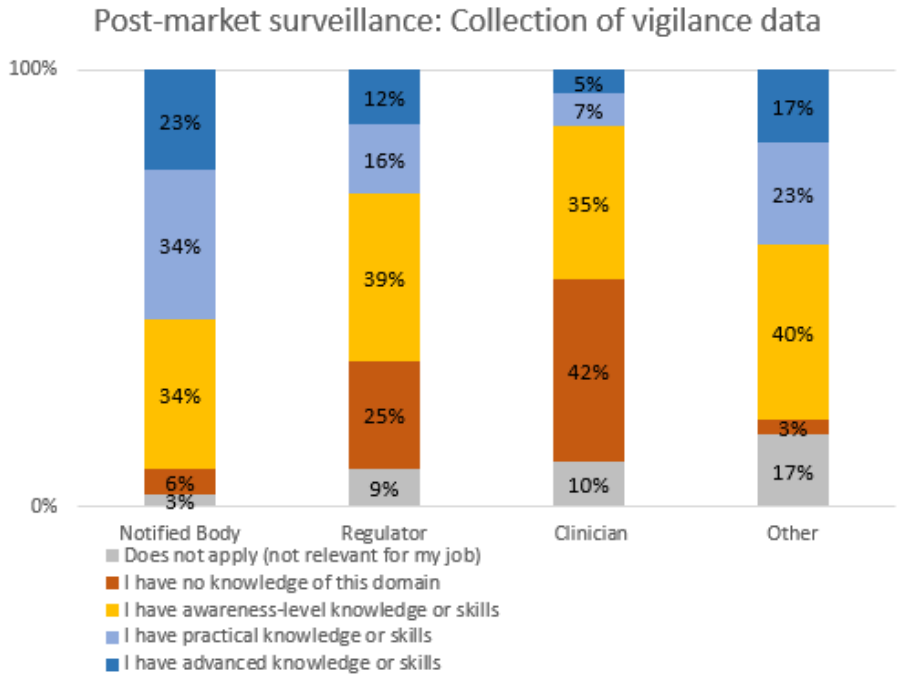

Figure A 23: Results of skill: Collection of vigilance data per employment category

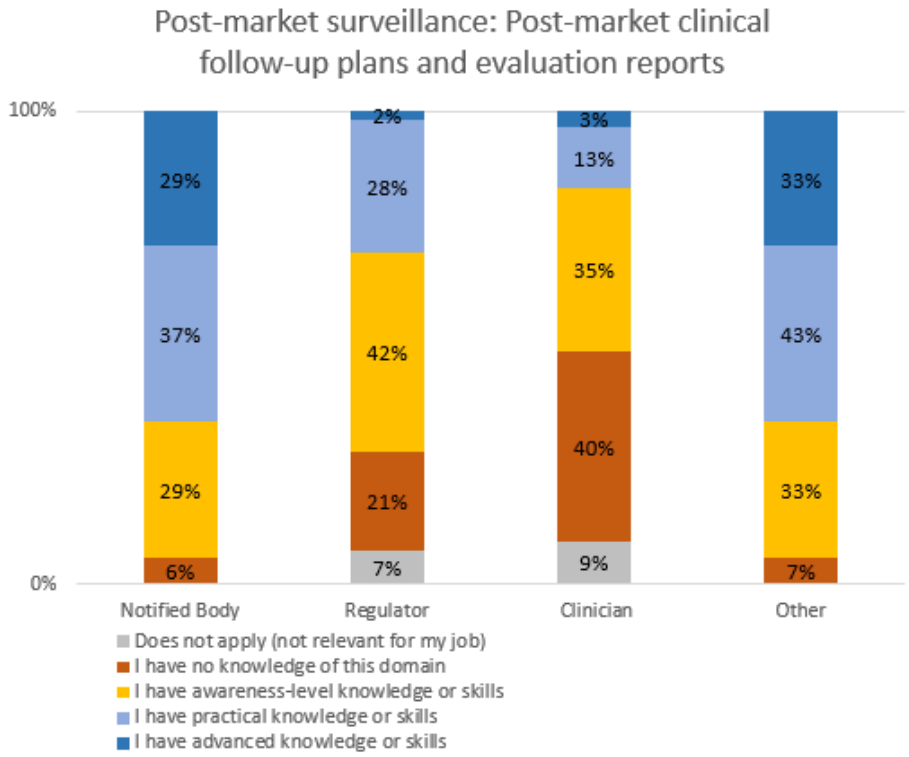

Figure A 24: Results of skill: post-market clinical follow-up (PMCF) plans and evaluation reports per employment category

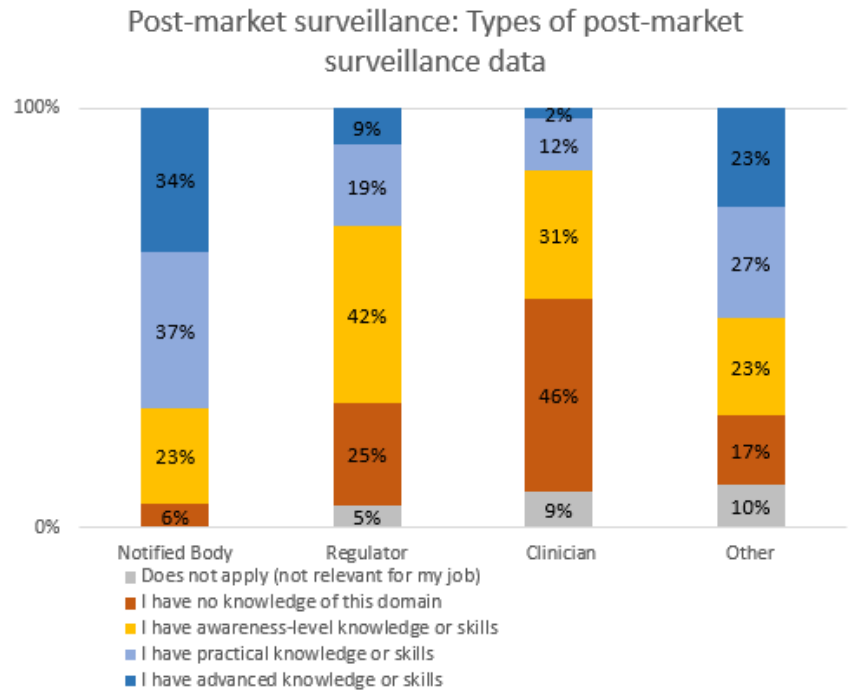

Figure A 25: Results of skill: types of post-market surveillance (PMS) data per employment category

Appendix 4: Quantitative survey results

	Notified Body	%	Regulator	%	Clinician	%	Other	%	Total	%
DEMOGRAPHICS										
Gender										
Female	20	54%	33	57%	86	31%	18	50%	157	38%
Male	17	46%	19	33%	191	69%	16	44%	243	59%
Other	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.
Rather not say	n.a.	n.a.	6	10%	1	<1%	2	6%	9	2%
Total (per employment category)	**37**	**9%**	**58**	**14%**	**278**	**68%**	**36**	**9%**	**409**	100%
Country of current place of work (main employment)										
Austria	n.a.	n.a.	1	2%	6	2%	n.a.	n.a.	7	2%
Belgium	2	5%	2	3%	14	5%	7	19%	25	6%
Bulgaria	n.a.	n.a.	n.a.	n.a.	5	2%	n.a.	n.a.	5	1%
Croatia	n.a.	n.a.	1	2%	28	10%	1	3%	30	7%
Czech Republic	n.a.	n.a.	3	5%	2	1%	n.a.	n.a.	5	1%
Denmark	n.a.	n.a.	3	5%	5	2%	n.a.	n.a.	8	2%
Finland	n.a.	n.a.	2	3%	n.a.	n.a.	n.a.	n.a.	2	<1%
France	n.a.	n.a.	n.a.	n.a.	11	4%	2	6%	13	3%
Germany	7	19%	13	22%	38	14%	4	11%	62	15%
Greece	1	3%	n.a.	n.a.	10	4%	n.a.	n.a.	11	3%
Hungary	3	8%	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	3	1%
Iceland	n.a.	n.a.	2	3%	n.a.	n.a.	n.a.	n.a.	2	<1%
Ireland	1	3%	6	10%	2	1%	n.a.	n.a.	9	2%
Italy	3	8%	4	7%	27	10%	3	8%	37	9%
Latvia	n.a.	n.a.	n.a.	n.a.	1	<1%	n.a.	n.a.	1	<1%
Lithuania	n.a.	n.a.	1	2%	n.a.	n.a.	n.a.	n.a.	1	<1%
Luxembourg	n.a.	n.a.	1	2%	n.a.	n.a.	n.a.	n.a.	1	<1%

	Notified Body	%	Regulator	%	Clinician	%	Other	%	Total	%
Malta	n.a.	n.a.	1	2%	1	<1%	n.a.	n.a.	2	<1%
Netherlands	2	5%	n.a.	n.a.	13	5%	6	17%	21	5%
Norway	1	3%	1	2%	4	1%	n.a.	n.a.	6	1%
Poland	5	14%	n.a.	n.a.	6	2%	1	3%	12	3%
Portugal	n.a.	n.a.	2	3%	11	4%	n.a.	n.a.	13	3%
Republic of Cyprus	1	3%	n.a.	n.a.	4	1%	n.a.	n.a.	5	1%
Romania	1	3%	5	9%	9	3%	n.a.	n.a.	15	4%
Slovenia	n.a.	n.a.	3	5%	4	1%	n.a.	n.a.	7	2%
Spain	1	3%	1	2%	10	4%	1	3%	13	3%
Sweden	n.a.	n.a.	5	9%	2	1%	3	8%	10	2%
Switzerland	n.a.	n.a.	n.a.	n.a.	8	3%	3	8%	11	3%
Other	9	24%	1	2%	57	21%	5	14%	72	18%
OCCUPATION AND EDUCATION										
Stage of career										
Entry-level (≤ 3 years experience)	3	8%	10	17%	11	4%	1	3%	25	6%
Intermediate (3-7 years experience)	6	16%	5	9%	19	7%	8	22%	38	9%
Mid-level (7-14 years experience)	5	14%	14	24%	42	15%	7	19%	68	17%
Senior or executive-level (≥15 years experience)	23	62%	29	50%	206	74%	20	56%	278	68%
Second employment/affiliation										
Clinician	4	11%	8	14%	71	26%	1	3%	84	21%
Notified Body	3	8%	1	2%	6	2%	n.a.	n.a.	10	2%
Regulator	n.a.	n.a.	3	5%	17	6%	1	3%	21	5%
Other *[free text]*	2	5%	3	5%	47	17%	9	25%	61	15%
Not applicable	28	76%	43	74%	137	49%	25	69%	233	57%
Member of an **EU expert panel for the evaluation of medical devices or in-vitro diagnostics**										
Yes	1	3%	1	2%	64	23%	4	11%	70	17%
No	36	97%	57	98%	214	77%	32	89%	339	83%
EU expert panel										
Screening panel - determines whether there is a need for a scientific opinion	n.a.	n.a.	n.a.	n.a.	18	28%	1	25%	19	27%

	Notified Body	%	Regulator	%	Clinician	%	Other	%	Total	%
Orthopaedics, traumatology, rehabilitation, rheumatology	n.a.	n.a.	n.a.	n.a.	6	9%	2	50%	8	11%
Circulatory system	n.a.	n.a.	1	100%	12	19%	n.a.	n.a.	13	19%
Neurology	n.a.	n.a.	n.a.	n.a.	8	13%	n.a.	n.a.	8	11%
Respiratory system, anaesthesiology, intensive care	1	100%	n.a.	n.a.	1	2%	n.a.	n.a.	2	3%
Endocrinology and diabetes	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.
General and plastic surgery and dentistry	n.a.	n.a.	n.a.	n.a.	9	14%	n.a.	n.a.	9	13%
Obstetrics and gynaecology, including reproductive medicine	n.a.	n.a.	n.a.	n.a.	3	5%	n.a.	n.a.	3	4%
Gastroenterology and hepatology	n.a.	n.a.	n.a.	n.a.	2	3%	n.a.	n.a.	2	3%
Nephrology and urology	n.a.	n.a.	n.a.	n.a.	5	8%	n.a.	n.a.	5	7%
Ophthalmology	n.a.	n.a.	n.a.	n.a.	3	5%	n.a.	n.a.	3	4%
In vitro diagnostic medical device	n.a.	n.a.	n.a.	n.a.	4	6%	1	25%	5	7%
Languages able to use in a professional working environment (e.g. for training, as working language)										
English	36	97%	55	95%	271	97%	36	100%	398	97%
German	9	24%	16	28%	69	25%	11	31%	105	26%
Spanish	4	11%	2	3%	20	7%	2	6%	28	7%
Italian	2	5%	3	5%	38	14%	2	6%	45	11%
French	1	3%	3	5%	40	14%	8	22%	52	13%
Dutch	n.a.	n.a.	2	3%	18	6%	9	25%	29	7%
Polish	5	14%	1	2%	7	3%	n.a.	n.a.	13	3%
Other *[free text]*	10	27%	12	21%	50	18%	6	17%	78	19%
Highest educational level										
High school graduate	1	3%	2	3%	5	2%	1	3%	9	2%
Bachelor	6	16%	2	3%	6	2%	1	3%	15	4%
Master	12	32%	32	55%	22	8%	14	39%	80	20%
PhD, M.D. or Doctorate	18	49%	22	38%	245	88%	20	56%	305	75%
Educational background/specialty										
Human Medicine	12	32%	10	17%	262	94%	5	14%	289	71%
Veterinary Medicine	n.a.	n.a.	1	2%	n.a.	n.a.	1	3%	2	<1%

	Notified Body	%	Regulator	%	Clinician	%	Other	%	Total	%
Dentistry	1	3%	1	2%	4	1%	1	3%	7	2%
Biology	3	8%	7	12%	5	2%	5	14%	20	5%
Chemistry	1	3%	7	12%	1	<1%	2	6%	11	3%
Physics	2	5%	n.a.	n.a.	1	<1%	1	3%	4	1%
Pharmacy	1	3%	17	29%	1	<1%	2	6%	21	5%
Engineering	16	43%	20	34%	2	1%	8	22%	46	11%
Law	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	6	17%	6	1%
Other *[free text]*	4	11%	9	16%	11	4%	7	19%	31	8%
If Human Medicine: Practising Clinician										
Yes	2	17%	3	30%	251	96%	1	20%	257	89%
No	10	83%	7	70%	11	4%	4	80%	32	11%
Main specialty in human medicine										
Circulatory system	3	25%	1	10%	124	47%	1	20%	129	45%
Endocrinology and diabetes	n.a.	n.a.	1	10%	1	<1%	n.a.	n.a.	2	1%
Gastroenterology and hepatology	n.a.	n.a.	n.a.	n.a.	12	5%	n.a.	n.a.	12	4%
General and plastic surgery and dentistry	2	17%	1	10%	8	3%	n.a.	n.a.	11	4%
Nephrology and urology	n.a.	n.a.	n.a.	n.a.	30	11%	n.a.	n.a.	30	10%
Neurology	1	8%	1	10%	37	14%	1	20%	40	14%
Obstetrics and gynaecology, including reproductive medicine	n.a.	n.a.	n.a.	n.a.	3	1%	n.a.	n.a.	3	1%
Ophthalmology	n.a.	n.a.	n.a.	n.a.	3	1%	n.a.	n.a.	3	1%
Orthopaedics, traumatology, rehabilitation, rheumatology	4	33%	n.a.	n.a.	12	5%	1	20%	17	6%
Respiratory system, anaesthesiology, intensive care	n.a.	n.a.	n.a.	n.a.	9	3%	1	20%	10	3%
Other	2	17%	6	60%	23	9%	1	20%	32	11%
Questions only for clinicians - KNOWLEDGE ON REGULATORY AFFAIRS										
Question A: Knowledge about system for the evaluation and market surveillance of medical devices										
I do not know how the legislation, evaluation, approval and surveillance process works	n.a.	n.a.	n.a.	n.a.	94	34%	n.a.	n.a.	n.a.	n.a.

	Notified Body	%	Regulator	%	Clinician	%	Other	%	Total	%
I have a general idea of what sort of legislation is in place and how devices are evaluated	n.a.	n.a.	n.a.	n.a.	148	53%	n.a.	n.a.	n.a.	n.a.
I have a very good understanding of the regulatory system and the evaluation, approval and market surveillance processes	n.a.	n.a.	n.a.	n.a.	34	12%	n.a.	n.a.	n.a.	n.a.
Other: *[free text]*	n.a.	n.a.	n.a.	n.a.	2	1%	n.a.	n.a.	n.a.	n.a.
Question B: In the European Union, demonstrating the clinical effectiveness of a high-risk medical device is the responsibility of:										
The manufacturer	n.a.	n.a.	n.a.	n.a.	158	57%	n.a.	n.a.	n.a.	n.a.
A notified body	n.a.	n.a.	n.a.	n.a.	22	8%	n.a.	n.a.	n.a.	n.a.
The national regulatory agency for medical devices	n.a.	n.a.	n.a.	n.a.	88	32%	n.a.	n.a.	n.a.	n.a.
Academic triallists	n.a.	n.a.	n.a.	n.a.	8	3%	n.a.	n.a.	n.a.	n.a.
Other: *[free text]*	n.a.	n.a.	n.a.	n.a.	2	1%	n.a.	n.a.	n.a.	n.a.
Question C: If you want to verify whether a device that you want to use is safe, where would you look for information										
Ask manufacturer	n.a.	n.a.	n.a.	n.a.	110	40%	n.a.	n.a.	n.a.	n.a.
Search European Commission website	n.a.	n.a.	n.a.	n.a.	52	19%	n.a.	n.a.	n.a.	n.a.
European Medicines agency website	n.a.	n.a.	n.a.	n.a.	131	46%	n.a.	n.a.	n.a.	n.a.
Google search	n.a.	n.a.	n.a.	n.a.	37	13%	n.a.	n.a.	n.a.	n.a.
Published medical literature	n.a.	n.a.	n.a.	n.a.	125	45%	n.a.	n.a.	n.a.	n.a.
Reports from medical device registries.	n.a.	n.a.	n.a.	n.a.	86	31%	n.a.	n.a.	n.a.	n.a.
Other: *[free text]*	n.a.	n.a.	n.a.	n.a.	5	2%	n.a.	n.a.	n.a.	n.a.
Question D: If you have a concern around the safety of a medical device, how would you report this										
I would not report it	n.a.	n.a.	n.a.	n.a.	4	1%	n.a.	n.a.	n.a.	n.a.
Contact hospital administration	n.a.	n.a.	n.a.	n.a.	53	19%	n.a.	n.a.	n.a.	n.a.
Contact a notified body	n.a.	n.a.	n.a.	n.a.	45	16%	n.a.	n.a.	n.a.	n.a.
Contact a national authority	n.a.	n.a.	n.a.	n.a	110	40%	n.a.	n.a.	n.a.	n.a.
Contact manufacturer	n.a.	n.a.	n.a.	n.a.	65	23%	n.a.	n.a.	n.a.	n.a.
Other: *[free text]*	n.a.	n.a.	n.a.	n.a.	1	<1%	n.a.	n.a.	n.a.	n.a

	Notified Body	%	Regulator	%	Clinician	%	Other	%	Total	%
Question E: How do you think additional training on regulatory affairs & medical devices could help you in your daily work										
Better verification whether the devices that I use are safe	n.a.	n.a.	n.a.	n.a.	161	58%	n.a.	n.a.	n.a.	n.a.
Will allow me to contribute to the evaluation process of medical devices (e.g. through expert panels)	n.a.	n.a.	n.a.	n.a.	142	51%	n.a.	n.a.	n.a.	n.a.
Understand the value of registries in post-market surveillance	n.a.	n.a.	n.a.	n.a.	91	33%	n.a.	n.a.	n.a.	n.a.
I don't think it will make a difference in my work	n.a.	n.a.	n.a.	n.a.	36	13%	n.a.	n.a.	n.a.	n.a.
Other *[free text]*	n.a	n.a.	n.a.	n.a.	3	1%	n.a.	n.a.	n.a.	n.a.
TRAINING										
Did/does/will your current employer (main employment) provide any education or training in the field of medical device regulatory science										
Yes, employer provided training in the past *[free text]*	20	54%	19	33%	28	10%	7	19%	74	18%
Yes, employer is currently offering training *[free text]*	26	70%	14	24%	28	10%	11	31%	79	19%
Yes, employer will be proposing training in the future *[free text]*	15	41%	10	17%	14	5%	6	17%	45	11%
No	8	22%	35	60%	226	81%	23	64%	292	71%
Did you ever attend medical device regulatory science education or training										
Yes	25	68%	27	47%	96	35%	23	64%	171	42%
No	12	32%	31	53%	182	65%	13	36%	238	58%
What have you attended in the past 3 years										
Session(s) at congresses	9	36%	8	30%	43	45%	10	43%	70	41%
Few-hours webinar(s)	18	72%	18	67%	54	56%	16	70%	106	62%
Full day course(s)	22	88%	12	44%	20	21%	11	48%	65	38%
Several-days training	21	84%	14	52%	14	15%	7	30%	56	33%
Several-months training	1	4%	2	7%	1	1%	n.a.	n.a.	4	2%
Regulatory science was part of my curriculum	6	24%	3	11%	14	15%	5	22%	28	16%
Other *[free text]*	n.a.	n.a.	n.a.	n.a.	4	4%	3	13%	7	4%

	Notified Body	%	Regulator	%	Clinician	%	Other	%	Total	%
Which entity provided the training										
My employer	23	92%	12	44%	11	11%	9	39%	55	32%
Notified body	17	68%	4	15%	10	10%	7	30%	38	22%
Regulatory Agency	10	40%	12	44%	37	39%	9	39%	68	40%
Medical Society	5	20%	2	7%	35	36%	7	30%	49	29%
University	10	40%	7	26%	22	23%	5	22%	44	26%
Industry	10	40%	5	19%	25	26%	12	52%	52	30%
Other *[free text]*	3	12%	7	26%	6	6%	6	26%	13	8%
CORE COMPETENCIES AND TRAINING NEEDS										
Individual level of need for training around each domain: **Pre-clinical testing (methodology and evaluation): Design and development of medical devices**										
Does not apply (not relevant for my job)	4	11%	8	14%	61	22%	6	17%	79	19%
I have no knowledge of this domain	2	5%	13	22%	71	26%	4	11%	90	22%
I have awareness-level knowledge or skills	9	24%	27	47%	101	36%	12	33%	149	36%
I have practical knowledge or skills	13	35%	8	14%	34	12%	7	19%	62	15%
I have advanced knowledge or skills	9	24%	2	3%	11	4%	7	19%	29	7%
Sum for whom applicable	33	n.a.	50	n.a.	217	n.a.	30	n.a.	330	81%
Individual level of need for training around each domain: **Drafting a Scientific Advice to Manufacturers**										
Does not apply (not relevant for my job)	10	27%	14	24%	54	19%	8	22%	86	21%
I have no knowledge of this domain	2	5%	15	26%	95	34%	8	22%	120	29%
I have awareness-level knowledge or skills	12	32%	16	28%	73	26%	7	19%	108	26%
I have practical knowledge or skills	10	27%	10	17%	37	13%	10	28%	67	16%
I have advanced knowledge or skills	3	8%	3	5%	19	7%	3	8%	28	7%
Sum for whom applicable	27	n.a.	44	n.a.	224	n.a.	28	n.a.	323	79%
Individual level of need for training around each domain: **Clinical investigation (methodology and evaluation)**										
Does not apply (not relevant for my job)	4	11%	9	16%	20	7%	2	6%	35	9%
I have no knowledge of this domain	3	8%	12	21%	36	13%	3	8%	54	13%

	Notified Body	%	Regulator	%	Clinician	%	Other	%	Total	%
I have awareness-level knowledge or skills	10	27%	15	26%	83	30%	9	25%	117	29%
I have practical knowledge or skills	11	30%	16	28%	85	31%	13	36%	125	31%
I have advanced knowledge or skills	9	24%	6	10%	54	19%	9	25%	78	19%
Sum for whom applicable	**33**	n.a.	**49**	n.a.	**258**	n.a.	**34**	n.a.	**374**	91%
Individual level of need for training around each domain: **Legal, regulatory for market access**										
Does not apply (not relevant for my job)	2	5%	1	2%	49	18%	4	11%	56	14%
I have no knowledge of this domain	2	5%	3	5%	102	37%	2	6%	109	27%
I have awareness-level knowledge or skills	7	19%	14	24%	100	36%	13	36%	134	33%
I have practical knowledge or skills	17	46%	26	45%	21	8%	8	22%	72	18%
I have advanced knowledge or skills	9	24%	14	24%	6	2%	9	25%	38	9%
Sum for whom applicable	**35**	n.a.	**57**	n.a.	**229**	n.a.	**32**	n.a.	**353**	86%
Individual level of need for training around each domain: **Post-market surveillance**										
Does not apply (not relevant for my job)	2	5%	1	2%	36	13%	6	17%	45	11%
I have no knowledge of this domain	1	3%	5	9%	66	24%	2	6%	74	18%
I have awareness-level knowledge or skills	4	11%	19	33%	103	37%	12	33%	138	34%
I have practical knowledge or skills	16	43%	20	34%	50	18%	5	14%	91	22%
I have advanced knowledge or skills	14	38%	13	22%	23	8%	11	31%	61	15%
Sum for whom applicable	**35**	n.a.	**57**	n.a.	**242**	n.a.	**30**	n.a.	**364**	89%
Individual level of need for training around each domain: **Soft skills (e.g. medical writing, project management)**										
Does not apply (not relevant for my job)	1	3%	3	5%	18	6%	1	3%	23	6%
I have no knowledge of this domain	n.a.	n.a.	12	21%	34	12%	2	6%	48	12%
I have awareness-level knowledge or skills	6	16%	16	28%	90	32%	7	19%	119	29%
I have practical knowledge or skills	16	43%	21	36%	68	24%	9	25%	114	28%
I have advanced knowledge or skills	14	38%	6	10%	68	24%	17	47%	105	26%
Sum for whom applicable	36	n.a.	55	n.a.	260	n.a.	35	n.a.	386	94%
Individual level of need for training around each skill within the domain "Clinical investigation (methodology and evaluation)": **Study-designs and their advantages/ disadvantages**										

	Notified Body	%	Regulator	%	Clinician	%	Other	%	Total	%
Does not apply (not relevant for my job)	3	9%	6	12%	9	3%	2	6%	20	5%
I have no knowledge of this domain	3	9%	12	24%	24	9%	4	12%	43	11%
I have awareness-level knowledge or skills	11	33%	14	29%	80	31%	13	38%	118	32%
I have practical knowledge or skills	9	27%	11	22%	89	34%	7	21%	116	31%
I have advanced knowledge or skills	7	21%	6	12%	56	22%	8	24%	77	21%
Individual level of need for training around each skill within the domain "Clinical investigation (methodology and evaluation)": **Concepts of unmet need in patient populations**										
Does not apply (not relevant for my job)	3	9%	5	10%	4	2%	4	12%	16	4%
I have no knowledge of this domain	5	15%	19	39%	39	15%	7	21%	70	19%
I have awareness-level knowledge or skills	10	30%	16	33%	98	38%	12	35%	136	36%
I have practical knowledge or skills	11	33%	5	10%	80	31%	5	15%	101	27%
I have advanced knowledge or skills	4	12%	4	8%	37	14%	6	18%	51	14%
Individual level of need for training around each skill within the domain "Clinical investigation (methodology and evaluation)": **Methods and time-points for patient involvement/ engagement**										
Does not apply (not relevant for my job)	6	18%	6	12%	4	2%	4	12%	20	5%
I have no knowledge of this domain	7	21%	19	39%	41	16%	7	21%	74	20%
I have awareness-level knowledge or skills	7	21%	18	37%	103	40%	12	35%	140	37%
I have practical knowledge or skills	10	30%	3	6%	75	29%	5	15%	93	25%
I have advanced knowledge or skills	3	9%	3	6%	35	14%	6	18%	47	13%
Individual level of need for training around each skill within the domain "Clinical investigation (methodology and evaluation)": **Choice of comparators (standard of care vs. Sham vs. Placebo)**										
Does not apply (not relevant for my job)	5	15%	5	10%	6	2%	4	12%	20	5%
I have no knowledge of this domain	5	15%	16	33%	32	12%	6	18%	59	16%
I have awareness-level knowledge or skills	8	24%	17	35%	80	31%	13	38%	118	32%

	Notified Body	%	Regulator	%	Clinician	%	Other	%	Total	%
I have practical knowledge or skills	8	24%	6	12%	99	38%	6	18%	119	32%
I have advanced knowledge or skills	7	21%	5	10%	41	16%	5	15%	58	16%
Individual level of need for training around each skill within the domain "Clinical investigation (methodology and evaluation)": **Outcomes measurements and instruments (standardized and validated instruments)**										
Does not apply (not relevant for my job)	2	6%	4	8%	4	2%	3	9%	13	3%
I have no knowledge of this domain	5	15%	14	29%	42	16%	5	15%	66	18%
I have awareness-level knowledge or skills	8	24%	21	43%	73	28%	9	26%	111	30%
I have practical knowledge or skills	10	30%	4	8%	89	34%	10	29%	113	30%
I have advanced knowledge or skills	8	24%	6	12%	50	19%	7	21%	71	19%
Individual level of need for training around each skill within the domain "Clinical investigation (methodology and evaluation)": **Assessment of benefit-risk ratio and thresholds for acceptability**										
Does not apply (not relevant for my job)	2	6%	4	8%	2	1%	2	6%	10	3%
I have no knowledge of this domain	4	12%	12	24%	50	19%	5	15%	71	19%
I have awareness-level knowledge or skills	9	27%	20	41%	94	36%	14	41%	137	37%
I have practical knowledge or skills	9	27%	10	20%	86	33%	9	26%	114	30%
I have advanced knowledge or skills	9	27%	3	6%	26	10%	4	12%	42	11%
Individual level of need for training around each skill within the domain "Clinical investigation (methodology and evaluation)": **Use of data from equivalence (Biocompatibility standard)**										
Does not apply (not relevant for my job)	2	6%	5	10%	8	3%	5	15%	20	5%
I have no knowledge of this domain	3	9%	13	27%	86	33%	5	15%	107	29%
I have awareness-level knowledge or skills	10	30%	20	41%	105	41%	14	41%	149	40%
I have practical knowledge or skills	9	27%	8	16%	43	17%	6	18%	66	18%
I have advanced knowledge or skills	9	27%	3	6%	16	6%	4	12%	32	9%
Individual level of need for training around each skill within the domain "Clinical investigation (methodology and evaluation)": **(functional) Safety and performance assessment**										

	Notified Body	%	Regulator	%	Clinician	%	Other	%	Total	%
Does not apply (not relevant for my job)	3	9%	4	8%	3	1%	2	6%	12	3%
I have no knowledge of this domain	2	6%	8	16%	64	25%	4	12%	78	21%
I have awareness-level knowledge or skills	9	27%	18	37%	108	42%	12	35%	147	39%
I have practical knowledge or skills	12	36%	16	33%	59	23%	8	24%	95	25%
I have advanced knowledge or skills	7	21%	3	6%	24	9%	8	24%	42	11%
Individual level of need for training around each skill within the domain "Clinical investigation (methodology and evaluation)": **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)**										
Does not apply (not relevant for my job)	3	9%	4	8%	10	4%	2	6%	19	5%
I have no knowledge of this domain	6	18%	17	35%	100	39%	8	24%	131	35%
I have awareness-level knowledge or skills	10	30%	19	39%	103	40%	10	29%	142	38%
I have practical knowledge or skills	11	33%	7	14%	32	12%	7	21%	57	15%
I have advanced knowledge or skills	3	9%	2	4%	13	5%	7	21%	25	7%
Individual level of need for training around each skill within the domain "Clinical investigation (methodology and evaluation)": **Systematic literature review (guidance for method and process)**										
Does not apply (not relevant for my job)	2	6%	4	8%	3	1%	3	9%	12	3%
I have no knowledge of this domain	2	6%	11	22%	23	9%	3	9%	39	10%
I have awareness-level knowledge or skills	6	18%	17	35%	64	25%	11	32%	98	26%
I have practical knowledge or skills	9	27%	13	27%	102	40%	7	21%	131	35%
I have advanced knowledge or skills	14	42%	4	8%	66	26%	10	29%	94	25%
Individual level of need for training around each skill within the domain "Clinical investigation (methodology and evaluation)": **Medical statistics (e.g. power calculation of trials, p-values)**										
Does not apply (not relevant for my job)	3	9%	6	12%	8	3%	3	9%	20	5%
I have no knowledge of this domain	5	15%	13	27%	31	12%	6	18%	55	15%
I have awareness-level knowledge or skills	9	27%	23	47%	83	32%	12	35%	127	34%

	Notified Body	%	Regulator	%	Clinician	%	Other	%	Total	%
I have practical knowledge or skills	13	39%	5	10%	108	42%	10	29%	136	36%
I have advanced knowledge or skills	3	9%	2	4%	28	11%	3	9%	36	10%
Individual level of need for training around each skill within the domain "Clinical investigation (methodology and evaluation)": **Clinical epidemiology (data and sources for burden of disease, prevalence, incidence)**										
Does not apply (not relevant for my job)	5	15%	5	10%	6	2%	4	12%	20	5%
I have no knowledge of this domain	8	24%	20	41%	22	9%	8	24%	58	16%
I have awareness-level knowledge or skills	8	24%	14	29%	91	35%	13	38%	126	34%
I have practical knowledge or skills	8	24%	7	14%	108	42%	5	15%	128	34%
I have advanced knowledge or skills	4	12%	3	6%	31	12%	4	12%	42	11%
Individual level of need for training around each skill within the domain "Clinical investigation (methodology and evaluation)": **Data analysis (different for processing primary data)**										
Does not apply (not relevant for my job)	3	9%	6	12%	4	2%	3	9%	16	4%
I have no knowledge of this domain	4	12%	17	35%	40	16%	7	21%	68	18%
I have awareness-level knowledge or skills	11	33%	20	41%	77	30%	8	24%	116	31%
I have practical knowledge or skills	8	24%	4	8%	111	43%	9	26%	132	35%
I have advanced knowledge or skills	7	21%	2	4%	26	10%	7	21%	42	11%
Individual level of need for training around each skill within the domain "Clinical investigation (methodology and evaluation)": **Ethics in clinical trials (e.g. recruitment, patient´s consent, information on uncertainties)**										
Does not apply (not relevant for my job)	4	12%	5	10%	4	2%	1	3%	14	4%
I have no knowledge of this domain	3	9%	12	24%	19	7%	3	9%	37	10%
I have awareness-level knowledge or skills	8	24%	18	37%	56	22%	8	24%	90	24%
I have practical knowledge or skills	9	27%	8	16%	120	47%	8	24%	145	39%
I have advanced knowledge or skills	9	27%	6	12%	59	23%	14	41%	88	24%
Individual level of need for training around each skill within the domain "Legal, regulatory for market access": **Medical Device Regulation:**										

	Notified Body	%	Regulator	%	Clinician	%	Other	%	Total	%
requirements, procedures, implementation, update on regulatory developments										
Does not apply (not relevant for my job)	1	3%	n.a.	n.a.	19	8%	n.a.	n.a.	20	6%
I have no knowledge of this domain	n.a.	n.a.	2	4%	75	33%	n.a.	n.a.	77	22%
I have awareness-level knowledge or skills	4	11%	5	9%	95	41%	11	34%	115	33%
I have practical knowledge or skills	10	29%	26	46%	26	11%	9	28%	71	20%
I have advanced knowledge or skills	20	57%	24	42%	14	6%	12	38%	70	20%
Individual level of need for training around each skill within the domain "Legal, regulatory for market access": **Classification of devices (esp. borderline devices)**										
Does not apply (not relevant for my job)	n.a.	n.a.	n.a.	n.a.	15	7%	1	3%	16	5%
I have no knowledge of this domain	1	3%	3	5%	91	40%	2	6%	97	27%
I have awareness-level knowledge or skills	5	14%	15	26%	84	37%	7	22%	111	31%
I have practical knowledge or skills	10	29%	23	40%	28	12%	11	34%	72	20%
I have advanced knowledge or skills	19	54%	16	28%	11	5%	11	34%	57	16%
Individual level of need for training around each skill within the domain "Legal, regulatory for market access": **Quality Management System - ISO 13485**										
Does not apply (not relevant for my job)	1	3%	1	2%	20	9%	1	3%	23	7%
I have no knowledge of this domain	n.a.	n.a.	4	7%	117	51%	4	13%	125	35%
I have awareness-level knowledge or skills	5	14%	21	37%	70	31%	11	34%	107	30%
I have practical knowledge or skills	13	37%	19	33%	15	7%	8	25%	55	16%
I have advanced knowledge or skills	16	46%	12	21%	7	3%	8	25%	43	12%
Individual level of need for training around each skill within the domain "Legal, regulatory for market access": **Good clinical practice (GCP) - ISO14155**										
Does not apply (not relevant for my job)	1	3%	7	12%	11	5%	1	3%	20	6%
I have no knowledge of this domain	4	11%	13	23%	60	26%	3	9%	80	23%
I have awareness-level knowledge or skills	9	26%	16	28%	68	30%	10	31%	103	29%
I have practical knowledge or skills	10	29%	15	26%	55	24%	9	28%	89	25%

	Notified Body	%	Regulator	%	Clinician	%	Other	%	Total	%
I have advanced knowledge or skills	11	31%	6	11%	35	15%	9	28%	61	17%
Individual level of need for training around each skill within the domain "Legal, regulatory for market access": **Good manufacturing practice (GMP) - ISO 13485**										
Does not apply (not relevant for my job)	1	3%	2	4%	24	10%	3	9%	30	8%
I have no knowledge of this domain	1	3%	9	16%	111	48%	4	13%	125	35%
I have awareness-level knowledge or skills	11	31%	24	42%	69	30%	12	38%	116	33%
I have practical knowledge or skills	12	34%	18	32%	19	8%	7	22%	56	16%
I have advanced knowledge or skills	10	29%	4	7%	6	3%	6	19%	26	7%
Individual level of need for training around each skill within the domain "Legal, regulatory for market access": **Risk management - ISO 14971**										
Does not apply (not relevant for my job)	n.a.	n.a.	1	2%	15	7%	2	6%	18	5%
I have no knowledge of this domain	n.a.	n.a.	7	12%	103	45%	5	16%	115	33%
I have awareness-level knowledge or skills	5	14%	23	40%	80	35%	7	22%	115	33%
I have practical knowledge or skills	12	34%	17	30%	25	11%	11	34%	65	18%
I have advanced knowledge or skills	18	51%	9	16%	6	3%	7	22%	40	11%
Individual level of need for training around each skill within the domain "Post-market surveillance": **Registers and post launch evidence generation (types of registers, data collections)**										
Does not apply (not relevant for my job)	n.a.	n.a.	8	14%	21	9%	4	13%	33	9%
I have no knowledge of this domain	4	11%	11	19%	79	33%	2	7%	96	26%
I have awareness-level knowledge or skills	11	31%	25	44%	79	33%	10	33%	125	34%
I have practical knowledge or skills	9	26%	12	21%	47	19%	5	17%	73	20%
I have advanced knowledge or skills	11	31%	1	2%	16	7%	9	30%	37	10%
Individual level of need for training around each skill within the domain "Post-market surveillance": **Drafting a Post-Launch Plan**										
Does not apply (not relevant for my job)	2	6%	9	16%	28	12%	4	13%	43	12%
I have no knowledge of this domain	6	17%	21	37%	122	50%	5	17%	154	42%
I have awareness-level knowledge or skills	13	37%	22	39%	69	29%	10	33%	114	31%
I have practical knowledge or skills	7	20%	4	7%	19	8%	7	23%	37	10%

	Notified Body	%	Regulator	%	Clinician	%	Other	%	Total	%
I have advanced knowledge or skills	7	20%	1	2%	4	2%	4	13%	16	4%
Individual level of need for training around each skill within the domain "Post-market surveillance": **Collection of vigilance data**										
Does not apply (not relevant for my job)	1	3%	5	9%	25	10%	5	17%	36	10%
I have no knowledge of this domain	2	6%	14	25%	101	42%	1	3%	118	32%
I have awareness-level knowledge or skills	12	34%	22	39%	85	35%	12	40%	131	36%
I have practical knowledge or skills	12	34%	9	16%	18	7%	7	23%	46	13%
I have advanced knowledge or skills	8	23%	7	12%	13	5%	5	17%	33	9%
Individual level of need for training around each skill within the domain "Post-market surveillance": **PMCF (Post-market clinical follow-up) plans and evaluation reports**										
Does not apply (not relevant for my job)	n.a.	n.a.	4	7%	22	9%	n.a.	n.a.	26	7%
I have no knowledge of this domain	2	6%	12	21%	97	40%	2	7%	113	31%
I have awareness-level knowledge or skills	10	29%	24	42%	84	35%	10	33%	128	35%
I have practical knowledge or skills	13	37%	16	28%	31	13%	13	43%	73	20%
I have advanced knowledge or skills	10	29%	1	2%	8	3%	10	33%	29	8%
Individual level of need for training around each skill within the domain "Post-market surveillance": **Types of PMS (Post-market surveillance) data**										
Does not apply (not relevant for my job)	n.a.	n.a.	3	5%	21	9%	3	10%	27	7%
I have no knowledge of this domain	2	6%	14	25%	111	46%	5	17%	132	36%
I have awareness-level knowledge or skills	8	23%	24	42%	74	31%	7	23%	113	31%
I have practical knowledge or skills	13	37%	11	19%	30	12%	8	27%	62	17%
I have advanced knowledge or skills	12	34%	5	9%	6	2%	7	23%	30	8%
Top three skills in which you would like training over the next three to five years: First choice										
Pre-clinical testing (methodology and evaluation) Design and development of medical devices	5	14%	9	16%	28	10%	4	11%	46	11%
Drafting a Scientific Advice to Manufacturers	2	5%	2	3%	28	10%	2	6%	34	8%
Study-designs and their advantages/ disadvantages	3	8%	5	9%	57	21%	3	8%	68	17%
Concepts of unmet need in patient populations	2	5%	1	2%	23	8%	n.a.	n.a.	26	6%

	Notified Body	%	Regulator	%	Clinician	%	Other	%	Total	%
Methods and time-points for patient involvement/ engagement	n.a.	n.a.	n.a.	n.a.	4	1%	2	6%	6	1%
Choice of comparators (standard of care vs. Sham vs. Placebo)	n.a.	n.a.	3	5%	8	3%	n.a.	n.a.	11	3%
Outcomes measurements and instruments (standardized and validated instruments)	n.a.	n.a.	1	2%	35	13%	4	11%	40	10%
Assessment of benefit-risk ratio and thresholds for acceptability	7	19%	12	21%	40	14%	6	17%	65	16%
Use of data from equivalence (Biocompatibility standard)	3	8%	4	7%	13	5%	n.a.	n.a.	20	5%
(functional) Safety and performance assessment	1	3%	4	7%	1	<1%	2	6%	8	2%
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)	5	14%	5	9%	9	3%	4	11%	23	6%
Systematic literature review (guidance for method and process)	n.a.	n.a.	n.a.	n.a.	2	1%	n.a.	n.a.	2	<1%
Medical statistics (e.g. power calculation of trials, p-values)	2	5%	1	2%	4	1%	n.a.	n.a.	7	2%
Clinical epidemiology (data and sources for burden of disease, prevalence, incidence)	n.a.	n.a.	n.a.	n.a.	2	1%	1	3%	3	1%
Data analysis (different for processing primary data)	n.a.	n.a.	1	2%	1	<1%	n.a.	n.a.	2	<1%
Ethics in clinical trials (e.g. recruitment, patient´s consent, information on uncertainties)	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.
Medical Device Regulation: requirements, procedures, implementation, update on regulatory developments	4	11%	3	5%	13	5%	7	19%	27	7%
Classification of devices (esp. borderline devices)	n.a.	n.a.	1	2%	n.a.	n.a.	n.a.	n.a.	1	<1%
Quality Management System - ISO 13485	n.a.	n.a.	1	2%	n.a.	n.a.	1	3%	2	<1%
Good clinical practice (GCP) - ISO14155	n.a.	n.a.	1	2%	2	1%	n.a.	n.a.	3	1%
Good manufacturing practice (GMP) - ISO 13485	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.
Risk management - ISO 14971	n.a.	n.a.	2	3%	1	<1%	n.a.	n.a.	3	1%
Registers and post launch evidence generation (types of registers, data collections)	n.a.	n.a.	n.a.	n.a.	2	1%	n.a.	n.a.	2	<1%
Drafting a Post-Launch Plan	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.

	Notified Body	%	Regulator	%	Clinician	%	Other	%	Total	%
Collection of vigilance data	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.
PMCF (Post-market clinical follow-up) plans and evaluation reports	2	5%	1	2%	n.a.	n.a.	n.a.	n.a.	3	1%
Types of PMS (Post-market surveillance) data	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.
Soft skills (e.g. medical writing, project management)	1	3%	1	2%	4	1%	n.a.	n.a.	6	1%
Other	n.a.	n.a.	n.a.	n.a.	1	<1%	n.a.	n.a.	1	<1%
Top three skills in which you would like training over the next three to five years: Second choice										
Pre-clinical testing (methodology and evaluation) Design and development of medical devices	4	11%	2	3%	18	6%	n.a.	n.a.	24	6%
Drafting a Scientific Advice to Manufacturers	2	5%	2	3%	30	11%	1	3%	35	9%
Study-designs and their advantages/ disadvantages	2	5%	4	7%	26	9%	1	3%	33	8%
Concepts of unmet need in patient populations	4	11%	1	2%	24	9%	5	14%	34	8%
Methods and time-points for patient involvement/ engagement			1	2%	18	6%	2	6%	21	5%
Choice of comparators (standard of care vs. Sham vs. Placebo)	1	3%	1	2%	30	11%	n.a.	n.a.	32	8%
Outcomes measurements and instruments (standardized and validated instruments)	1	3%	7	12%	29	10%	2	6%	39	10%
Assessment of benefit-risk ratio and thresholds for acceptability	7	19%	8	14%	37	13%	2	6%	54	13%
Use of data from equivalence (Biocompatibility standard)	2	5%	5	9%	19	7%	5	14%	31	8%
(functional) Safety and performance assessment	1	3%	4	7%	5	2%	1	3%	11	3%
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)	2	5%	1	2%	7	3%	2	6%	12	3%
Systematic literature review (guidance for method and process)	1	3%	1	2%	4	1%	1	3%	7	2%
Medical statistics (e.g. power calculation of trials, p-values)	2	5%	3	5%	3	1%	n.a.	n.a.	8	2%
Clinical epidemiology (data and sources for burden of disease, prevalence, incidence)	1	3%	n.a.	n.a.	1	<1%	n.a.	n.a.	2	0%

	Notified Body	%	Regulator	%	Clinician	%	Other	%	Total	%
Data analysis (different for processing primary data)	n.a.	n.a.	1	2%	2	1%	1	3%	4	1%
Ethics in clinical trials (e.g. recruitment, patient´s consent, information on uncertainties)	n.a.	n.a.	n.a.	n.a.	1	<1%	1	3%	2	<1%
Medical Device Regulation: requirements, procedures, implementation, update on regulatory developments	n.a.	n.a.	1	2%	7	3%	1	3%	9	2%
Classification of devices (esp. borderline devices)	n.a.	n.a.	1	2%	1	<1%	5	14%	7	2%
Quality Management System - ISO 13485	n.a.	n.a.	1	2%	1	<1%	1	3%	3	1%
Good clinical practice (GCP) - ISO14155	2	5%	4	7%	4	1%	n.a.	n.a.	10	2%
Good manufacturing practice (GMP) - ISO 13485	n.a.	n.a.	1	2%	1	<1%	1	3%	3	1%
Risk management - ISO 14971	n.a.	n.a.	3	5%	4	1%	n.a.	n.a.	7	2%
Registers and post launch evidence generation (types of registers, data collections)	n.a.	n.a.	1	2%	1	<1%	1	3%	3	1%
Drafting a Post-Launch Plan	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.
Collection of vigilance data	n.a.	n.a.	2	3%	1	<1%	n.a.	n.a.	3	1%
PMCF (Post-market clinical follow-up) plans and evaluation reports	2	5%	1	2%	1	<1%	2	6%	6	1%
Types of PMS (Post-market surveillance) data	2	5%	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	2	<1%
Soft skills (e.g. medical writing, project management)	n.a.	n.a.	1	2%	2	1%	1	3%	4	1%
Other	1	3%	1	2%	1	<1%	n.a.	n.a.	3	1%
Top three skills in which you would like training over the next three to five years: Third choice										
Pre-clinical testing (methodology and evaluation) Design and development of medical devices	n.a.	n.a.	6	10%	24	9%	2	6%	32	8%
Drafting a Scientific Advice to Manufacturers	4	11%	4	7%	32	12%	2	6%	42	10%
Study-designs and their advantages/ disadvantages	3	8%	4	7%	33	12%	2	6%	42	10%
Concepts of unmet need in patient populations	2	5%	2	3%	20	7%	2	6%	26	6%
Methods and time-points for patient involvement/ engagement	3	8%	4	7%	20	7%	3	8%	30	7%
Choice of comparators (standard of care vs. Sham vs. Placebo)	2	5%	1	2%	12	4%	2	6%	17	4%

	Notified Body	%	Regulator	%	Clinician	%	Other	%	Total	%
Outcomes measurements and instruments (standardized and validated instruments)	3	8%	4	7%	22	8%	2	6%	31	8%
Assessment of benefit-risk ratio and thresholds for acceptability	1	3%	8	14%	41	15%	3	8%	53	13%
Use of data from equivalence (Biocompatibility standard)	2	5%	7	12%	29	10%	3	8%	41	10%
(functional) Safety and performance assessment	n.a.	n.a.	2	3%	n.a.	n.a.	1	3%	3	1%
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)	3	8%	n.a.	n.a.	6	2%	n.a.	n.a.	9	2%
Systematic literature review (guidance for method and process)	n.a.	n.a	n.a.	n.a.	3	1%	n.a.	n.a.	3	1%
Medical statistics (e.g. power calculation of trials, p-values)	3	8%	1	2%	8	3%	2	6%	14	3%
Clinical epidemiology (data and sources for burden of disease, prevalence, incidence)	n.a.	n.a.	n.a.	n.a.	4	1%	n.a.	n.a.	4	1%
Data analysis (different for processing primary data)	n.a.	n.a.	2	3%	1	<1%	n.a.	n.a.	3	1%
Ethics in clinical trials (e.g. recruitment, patient´s consent, information on uncertainties)	n.a.	n.a.	n.a.	n.a.	2	1%	2	6%	4	1%
Medical Device Regulation: requirements, procedures, implementation, update on regulatory developments	1	3%	n.a.	n.a.	6	2%	1	3%	8	2%
Classification of devices (esp. borderline devices)	n.a.	n.a.	n.a.	n.a.	3	1%	1	3%	4	1%
Quality Management System - ISO 13485	n.a.	n.a.	1	2%	1	<1%	n.a.	n.a.	2	<1%
Good clinical practice (GCP) - ISO14155	3	8%	n.a.	n.a.	4	1%	3	8%	10	2%
Good manufacturing practice (GMP) - ISO 13485	3	8%	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	3	1%
Risk management - ISO 14971	n.a.	n.a.	5	9%	n.a.	n.a.	2	6%	7	2%
Registers and post launch evidence generation (types of registers, data collections)	1	3%	1	2%	1	<1%	1	3%	4	1%
Drafting a Post-Launch Plan	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.
Collection of vigilance data	n.a.	n.a.	1	2%	n.a.	n.a.	n.a.	n.a.	1	<1%
PMCF (Post-market clinical follow-up) plans and evaluation reports	1	3%	2	3%	2	1%	n.a.	n.a.	5	1%
Types of PMS (Post-market surveillance) data	n.a.	n.a.	1	2%	2	1%	n.a.	n.a.	3	1%

	Notified Body	%	Regulator	%	Clinician	%	Other	%	Total	%
Soft skills (e.g. medical writing, project management)	n.a.	n.a.	1	2%	1	<1%	1	3%	3	1%
Other	2	5%	1	2%	1	<1%	1	3%	5	1%
TRAINING FORMATS AND MODALITIES										
Need for training courses in medical device regulatory science for the following audiences										
Yes, for notified bodies.	32	86%	32	55%	90	32%	15	42%	169	41%
Yes, for regulators.	20	54%	53	91%	105	38%	19	53%	197	48%
Yes, for clinicians.	21	57%	40	69%	210	76%	25	69%	296	72%
I do not know or I do not have any opinion on this.	4	11%	2	3%	38	14%	8	22%	52	13%
No training needed for any of the 3 groups.	1	3%	1	2%	2	1%	n.a.	n.a.	4	1%
Format of the training										
Training in single days (e.g. 1 day per month) over the year	26	81%	25	47%	95	45%	13	52%	159	50%
Block training modules (several days in a row)	11	34%	33	62%	87	41%	13	52%	144	45%
Practical training on the job (advanced internships in organisations and mentoring programs)	9	28%	30	57%	93	44%	10	40%	142	44%
Lifelong upskilling and reskilling/ continuous training	13	41%	36	68%	90	43%	12	48%	151	47%
Other *[free text]*	n.a.	n.a.	1	2%	6	3%	3	12%	10	3%
Preference on whether training should be specific for the respective target group (clinicians, regulators, notified bodies) or offered across these target groups										
No opinion on this	9	24%	19	33%	112	40%	10	28%	150	37%
Prefer training dedicated to specific target group	14	38%	18	31%	109	39%	13	36%	154	38%
Prefer training across these target groups	7	19%	12	21%	37	13%	7	19%	63	15%
It depends on the topic/module	7	19%	9	16%	20	7%	6	17%	42	10%

n.a. = not applicable

Table A 1: Quantitative survey results of 409 respondents (note: no qualitative answers are described in the table)

CORE-MD

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CORE-MD

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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