CT·LUSO CLINICAL TRIALS IN PORTUGUESE-SPEAKING AFRICAN COUNTRIES

CT-Luso

Ethics and Regulatory Capacity Building Partnership for Clinical Trials in Portuguese-speaking African Countries

Project 101145790

WP4 – Interdisciplinary and cross-sectoral education

Deliverable 4.2 – "The Ethical and Legal Requirements for the Development of Scientific and Clinical Research": Training Programme Results

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Due date: 31 July 2025

EDCTP

List of Acronyms and Abbreviations

ALLEA - European Federation of Academies of Sciences and Humanities

ANARME, I.P – National Medicines Regulatory Authority, I.P

AO – Angola

BSc – Bachelor's degree

CESIC – Health Ethics Committee for Scientific Research

CNBS – National Committee for Bioethics in Health

CNEPS – National Ethics Committee for Health Research of Cape Verde

CNEPS – National Health Research Ethics Committee of Guinea-Bissau

CV – Cape Verde

ECTS – European Credit Transfer and Accumulation System

EMA – European Medicines Agency

ERIS – Independent Health Regulatory Authority

Fem. – Female

FFUL – Faculty of Pharmacy, University of Lisbon

GB – Guinea-Bissau

GCP – Good Clinical Practices

ICH – International Council for Harmonization

IHMT – Institute of Hygiene and Tropical Medicine

INASA – National Institute of Public Health

INFARMED, I.P. – National Authority of Medicines and Health Products, I.P.

INIS – National Institute of Health Research

INSA – National Institute of Health Doutor Ricardo Jorge

INSP – National Institute of Public Health

ISO - International Organization for Standardization

M – Module(s)

MSc – Master's degree

MZ – Mozambique

NMS – NOVA Medical School

PSAC – Portuguese-speaking African Countries

PSB – Bandim Health Project

PhD – Doctor of Philosophy

STP – São Tomé and Príncipe

UniCV – University of Cape Verde

WHO – World Health Organization

WP4 – Work Package 4

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1. Summary

This report, identified as D2.4, presents the results of Task 4.2 (WP4), which focuses on evaluating of the Training Programme — a comprehensive, and interdisciplinary educational project addressing the ethical and regulatory requirements in biomedical research, with a particular emphasis on the development of clinical trials in Portuguese-Speaking African Countries (PSAC).

The Training Programme was specifically designed for all professionals who may engage research activities, including members of Ethics Committees, National Regulatory Authorities, senior and junior researchers (both medical and non-medical), project managers, and university lecturers.

The Programme's objective of reaching a broad and diverse audience was fully achieved. While the initial target was 120 trainees, 303 applications were approved, and 234 trainees successfully completed the training. Among the trainees, there was notable diversity in academic backgrounds, professional profiles, and institutions of origin – most linked to research – with a balanced distribution of age groups and genders.

The team of trainers comprised outstanding professionals with widely recognised academic and professional expertise in their respective fields. Their intellectual background and professional experience were crucial in ensuring the high quality of the training, maintaining rigorous and demanding standards throughout the programme.

The trainees' performance was highly positive overall: over 90% achieved final grades of "Good" or higher (on a scale from "Poor" to "Excellent"), and around 70% reached the "Very Good" or "Excellent" levels, with an average score of 80 out of 100. Importantly, no trainees failed, largely due to a recovery plan implemented to support those requiring additional assistance. Cases of non-completion were primarily due to various reasons, mostly of a personal nature and unrelated to academic performance.

Anonymous evaluations completed by trainees for each module of the Training Programme assessed a wide range of aspects, including the relevance of the content, pedagogical quality, and alignment with professional needs. Formal aspects, such as session length, scheduling, and the availability of materials, were also assessed. Satisfaction levels reached 90% or higher for most modules, with only two modules receiving slightly lower ratings. On a scale from 1 to 5, average satisfaction scores for individual parameters ranged from 3.9 to 4.8, with average module satisfaction ranged from 4.4 to 4.6.

In the final evaluation of the Training Programme, based on an anonymous survey, 94% of trainees rated the training as "Very Good" or "Excellent", and 91% reported a direct and significant impact on their professional activity, rating it as "High" or "Very High".

In summary, the Training Programme generated a significant impact from two complementary perspectives. Firstly, it far exceeded the initial target of 120 trainees, with 234 trainees successfully completing the programme, demonstrating both strong interest in the course and commitment to its completion. The excellent evaluation results suggest enduring medium- and long-term benefits in ethical and regulatory capacity-building and in strengthening individual and institutional competencies. Secondly, trainees reported an immediate positive impact on their professional practice through the Training Programme's evaluation process.

2. Introduction

The Training Programme "Ethical and Legal Requirements for the Development of Scientific and Clinical Research" constitutes the first level of training within the CT-Luso Project. It is an interdisciplinary and thematically broad initiative, framed within internationally recognised ethical and legal principles, and aims to build capacity in biomedical research and clinical trials in Portuguese-Speaking African Countries (PSAC) – Work Package 4 (WP4).

The Training Programme lasted six months, running from 3 December 2024 to 3 June 2025, and comprised a total of 111 hours (105 hours of training and 6 hours of assessment). The training is accredited by the NOVA Medical School (NMS) of the NOVA University of Lisbon and by the Faculty of Pharmacy of the University of Lisbon (FFUL). Successful completion of the Training Programme corresponds to the award of 12 European Credit Transfer and Accumulation System (ECTS) credits. However, accreditation process was carried out independently by the two faculties: 10 ECTS were granted by NMS, corresponding to the completion of the first five modules, and 2 ECTS were granted by FFUL, following completion of module six. To obtain accreditation, trainees were assessed at the end of each module.

The two faculties jointly planned the Training Programme, including the definition of content and the allocation of trainers for each session, and subsequently submitted it to their respective Scientific Councils for accreditation approval. This process was developed in close collaboration with the Project's coordination and management team, which facilitated the joint work between the various entities and individuals involved and ensured all necessary conditions for delivering the training online. This included the design of a user-friendly Zoom platform; technical support trainees and trainers in accessing and navigating the sessions and training materials; timely dissemination of information about each session; and continuous clarification of queries. In addition, an e-learning platform was also created to support the training, serving both as a content repository and as the tool for conducting assessments (Deliverable 4.1 of the Project).

The intended audience for the training included but was not limited to: Regulators (members of National Regulatory Authorities and Research Ethics Committees), senior and junior Researchers, Doctors and other health professionals, University lecturers, and professionals from other fields. Eligibility criteria required candidates to hold a university degree and to have a background broadly related to clinical research, including Pharmaceutical Sciences/Pharmacy, Life Sciences, Biology and related areas, Medicine, Nursing, Psychology, Sociology, as well as Administration and Management. This broad academic

eligibility was aligned with the Project's goal of training professionals for the development of biomedical research and clinical trials in the PSAC. A more detailed description of the profile of the trainees who completed the programme is provided in Section 5.1.

The Training Programme was widely disseminated through a public notice (Annex 1) by the Project's partner institutions and by relevant institutions active in the Portuguese-speaking world, both in Portugal and in the PSAC, including Embassies, Ministries of Health, Foundations and Institutes for Cooperation, Universities, and Professional Societies. Each institution was asked to promote the Training Programme both internally and externally to reach a broad and diverse audience. Dissemination also took place through various digital channels, such as email and the Project website, with a dedicated promotional leaflet (Annex 2) produced and shared in both digital and printed versions, where appropriate.

The application period ran from 15 October to 15 November 2024, followed by a trainee selection process carried out by an appointed jury. The jury consisted of the project coordinators, M. Patrão Neves and Helder Mota Filipe, the Consultant, Maria Alexandra Ribeiro, and the Scientific Lead, Esperança Sevene. Results were announced at the end of November. A total of 356 applications were received, of which 336 met the established eligibility criteria. Once the application period ended, eligible candidates were contacted to confirm their intention to participate in the training, and 303 individuals confirmed their attendance. The Training Programme therefore began with 303 enrolled trainees.

3. Training Programme description

The full Training Programme, including thematic areas and number of sessions, as well as the respective trainers and guest speakers involved, is presented in Annex 3.

This main objective of the Training Programme was to promote and enhance of theoretical and practical skills, equipping professionals in the field of biomedical research and clinical trials. This capacity-building is grounded in internationally recognised ethical and legal principles, ensuring responsible and safe practices in compliance with global regulatory standards. At the same time, it aims to stimulate critical thinking, foster autonomy in research, and encourage the application of knowledge in real-world scientific contexts.

In this context, the Training Programme was designed to cover six major thematic areas – the Modules (M) – corresponding to sub-tasks 4.1.1 to 4.1.6 of Work Package 4 of the Project:

M1 – Science and Ethics: their relationship.

M2 – Research integrity and good clinical practice requirements.

M3 – International bioethics institutions and guidelines for research and health-related practices.

M4 – Public health issues and infectious diseases.

M5 – Biobanks and responsible research involving humans, fauna and flora, and patentable innovation.

M6 – Regulatory affairs.

Each module consisted of three to five theoretical-practical sessions, each lasting three to four hours, concluding with a thematic workshop lasting two hours. The theoretical-practical sessions consisted of lectures for content delivery, along with some exercises to consolidate learning, under the responsibility of the trainers involved. The workshops were highly practical and interactive sessions, involving a professional from each of the PSAC, who was asked to deliver a brief oral presentation on the state of the art in their country regarding the topic under discussion. This was followed by a discussion among all panel members, moderated by a representative of the Project coordination team or another designated trainer. In some workshops, depending on the specific topic, the trainer from Portugal was also asked to provide context on the situation in Portugal. In the case of the workshop in Module 6, a regulatory contextualisation at both European and African levels was included.

The sessions were delivered online via Zoom, on Tuesdays and Thursdays, between 3 p.m. and 7 p.m. (GMT), totalling 111 hours (including 1 hour of assessment by module). A schedule was made available to structure the sessions and facilitate organisation for both trainees and trainers. This schedule included all sessions, workshops, and assessments (Annex 4).

The trainers and PSAC professionals invited to the workshops were carefully selected based on their strong academic backgrounds, recognised professional competence, and proven experience relevant to the topics of each module.

The trainers team comprised 24 Portuguese trainers from various academic institutions, some of which were partners of the Project, such as NOVA Medical School (NMS) and the Faculty of Pharmacy of the University of Lisbon (FFUL), research and health institutes such as the National Institute of Health Doutor Ricardo Jorge (INSA), and Regulatory Authorities such as the National Authority of Medicines and Health Products, I.P. (INFARMED, I.P.). In addition, 31 professionals from the PSAC were invited, based on their academic and professional

profile, also representing Regulatory Authorities, academic institutions, research centres, and other relevant organisations. A total of 234 trainees completed the entire Training Programme (all six modules), and one additional trainee completed only Module 6, relating to Regulatory Affairs.

Based on the general objectives of the Training Programme, specific learning objectives were defined for each of the six major thematic areas, that constituted the modules of the training.

Below we present the specific learning objectives for each module, according to their respective topics, along with the content of each session (corresponding to one training day) and the related thematic workshop, also identifying the trainers involved and the dates of each activity.

3.1. Module 1 – Science and Ethics: Their Relationship

Table 1 *- Learning Objectives of Module 1 (M1)*

Learning Objectives – M1	
Session 1	**Science, Technology and Ethics** – Understand the genealogy and evolution of the relationship between Science, Technology and Ethics. – Systematise the role of ethics within the scope of Science and Technology. – Understand the key factors that led to the emergence of Applied Ethics (Bioethics) in Biomedicine. – Identify the initial themes of Bioethics and trace their development to the present day.
Session 2	**Applied Ethics to Biomedicine** – Identify real ethical dilemmas in biomedicine and analyse them considering bioethical theories. – Recognise how clinical situations influence the development of ethical principles. – Understand the main theoretical models of Bioethics and their core principles. – Understand the model of ethical analysis used in resolving biomedical cases.
Session 3	**Ethical Deliberation** – Understand the concept of an ethical dilemma. – Identify the fundamental requirements for ethical deliberation. – Understand how to justify and formalise an ethical decision in biomedical practice.
Workshop	**Fundamental Principles of Biomedicine in the PSAC**

Learning Objectives – M1	
	– Analyse the fundamental principles of biomedical practice in the PSAC, recognising how sociocultural and historical contexts shape the application of ethics, social responsibility, and health research in these countries.

3.1.1. Schedule, themes and trainers

Table 2 *- Schedule, themes and trainers of Module 1 (M1)*

Session	Date	Theme(s)	Duration (hours)	Trainer(s)
Session 1	3 December 2024	Science, Technology and Ethics	3	M. Patrão Neves
Session 2	10 December 2024	Applied Ethics to Biomedicine	3	M. Patrão Neves
Session 3	17 December 2024	Ethical Deliberation	3	M. Patrão Neves
Workshop	7 January 2025	Fundamental Principles of Biomedicine in the PSAC	3	Moderator: M. Patrão Neves Participants from the PSAC: – José António Reis – Mouhammed Djicó – Esperança Sevene – Eula Maquengo

3.2. Module 2 – Research Integrity and Good Clinical Practice Requirements

Table 3 *- Learning Objectives of Module 2 (M2)*

Learning Objectives – M2	
Session 1 and **Session 2**	**Scientific Integrity and Responsible Research Conduct** – Understand the fundamental principles of scientific integrity as defined by the ALLEA Code. – Recognise the importance of these fundamental principles in fostering a culture of ethical and rigorous research. – Apply the principles of responsible conduct in scientific research by identifying best practices in areas such as data management, authorship, publication, collaboration, and the prevention of misconduct (including plagiarism, falsification, and fabrication of results). – Recognise the implications of fraud or misconduct in both general and clinical scientific research.
Session 3	**Good Clinical Practice Requirements**

Learning Objectives – M2	
	– Contextualise the principles of good clinical practice in research as safeguards for participant rights and safety, as well as data quality. – Identify the main responsibilities regarding GCP of the various stakeholders involved in clinical research.
Session 4	**Communication in Science and Biomedical Research** – Develop the ability to communicate scientific content clearly, accessibly, and responsibly. – Recognise the public registration of clinical studies as an ethical commitment to science, society, and participants. – Understand the importance of publication and dissemination of clinical studies.
Workshop	**Scientific Integrity and Good Research Practices in the PSAC** – Promote critical understanding of the principles of scientific integrity and good research practices by empowering participants to recognise, prevent, and address misconduct, and to apply ethical standards at all stages of the scientific process.

3.2.1. Sessions, themes and trainers

Table 4 *- Schedule, themes and trainers of Module 2 (M2)*

Session	Date	Theme(s)	Duration (hours)	Trainer(s)
Session 1	9 January 2025	Scientific Integrity and Responsible Research Conduct – Part I	4	Maria Alexandra Ribeiro
Session 2	16 January 2025	Scientific Integrity and Responsible Research Conduct – Part II	4	Maria Alexandra Ribeiro
Session 3	23 January 2025	Good Clinical Practice Requirements: ICH-GCP and ISO Standards	4	Maria Alexandra Ribeiro
Session 4	30 January 2025	Communication in Science and Biomedical Research	4	– Maria Alexandra Ribeiro – António Granado
Workshop	4 February 2025	Scientific Integrity and Good Research Practices in the PSAC	2	Moderator: Maria Alexandra Ribeiro Participants from the PSAC: – Isabel Araújo – Cesário Martins – Vasco Muchanga

3.3. Module 3 – International Bioethics Institutions and Guidelines for Research and Health-Related Practices

***Table 5** - Learning Objectives of Module 3 (M3)*

Learning Objectives – M3	
Session 1 and **Session 2**	**Institutionalisation and Internationalisation of Bioethics** – Identify the main international bioethics organisations – Understand the nature, mission, and role of international bioethics organisations in defining global ethical standards – Analyse the normative and guiding function of international bioethics declarations – Recognise the relevance of international bioethics declarations in harmonising ethical principles in multicultural contexts – Understand the process of bioethics internationalisation and the consolidation of bioethics as an interdisciplinary and globally recognised field
Session 3	**Ethical Principles of Clinical Research** – Understand the main ethical principles that guide clinical research – Apply ethical principles in the design and assessment of clinical research projects – Recognise researchers' ethical responsibility to protect research participants – Identify ethical principles that are particularly relevant in contexts of economic, social, and health vulnerability
Session 4	**Clinical Research and Health Infrastructures** – Understand the different phases of the life cycle of a clinical study, the stakeholders involved, and their responsibilities – Identify the essential requirements for the operation of clinical trial centres – Understand national and international organisational models that support clinical research – Recognise the importance of clinical research infrastructures
Workshop	**Research Institutions in the PSAC** – Understand the role and challenges of research institutions in the PSAC, recognising their importance in strengthening science in local contexts and in promoting innovative solutions to the region's health and development issues

3.3.1. Schedule, themes and trainers

***Table 6** - Schedule, themes and trainers of Module 3 (M3)*

Session	Date	Theme(s)	Duration (hours)	Trainer(s)
Session 1	6 February 2025	Institutionalisation and Internationalisation of Bioethics – Part I	4	– M. Patrão Neves – Maria Alexandra Ribeiro

Session	Date	Theme(s)	Duration (hours)	Trainer(s)
Session 2	13 February 2025	Institutionalisation and Internationalisation of Bioethics – Part II	4	– M. Patrão Neves – Maria Alexandra Ribeiro
Session 3	20 February 2025	Ethical Principles of Clinical Research	4	Maria Alexandra Ribeiro
Session 4	27 February 2025	Clinical Research and Health Infrastructures	4	– Lúcia Domingues – Sara Maia
Workshop	5 March 2025	Research Institutions in the PSAC	2	Moderator: Emília Monteiro Participants from the PSAC: – Joana Paixão – Maria da Luz Lima – Francisco Samory Levy – Yardlene Sequeira

3.4. Module 4 – Public Health Issues and Infectious Diseases

Table 7 *- Learning Objectives of Module 4 (M4)*

Learning Objectives – M4	
Session 1 and **Session 2**	**Public Health** – Analyse the main ethical, legal, and political aspects that guide action in public health – Recognise the ethical and legal challenges in protecting collective health while safeguarding individual rights – Understand the foundations and strategies of public health planning, assessing the importance of epidemiological surveillance, prevention, and coordinated responses to outbreaks and health emergencies – Explore the role of infectious diseases and their vectors in public health – Recognise the importance of research, risk communication, and inter-institutional cooperation in the context of global public health
Session 3	**Epidemiology and Research** – Understand the fundamental concepts and main methods of epidemiology – Understand the influence of demographic, genetic, and environmental factors on disease distribution, assessing their interaction and impact on population health – Explore the principles of epidemiological surveillance and research – Identify strategies for monitoring, early detection, and response to outbreaks and emerging public health issues
Session 4 and **Session 5**	**Research Methods in Health** – Understand the fundamental concepts of clinical research that guide knowledge production in health

Learning Objectives – M4	
	– Distinguish the main types of clinical studies and their methodological designs, assessing the suitability of each model for different research questions – Recognise the particularities of experimental clinical studies regarding specific ethical, regulatory, and methodological requirements
Workshop	**Emerging Human and Animal Diseases** – Understand the factors that contribute to the emergence of human and animal diseases, recognising the importance of the "One Health" approach in the prevention, surveillance, and integrated response to global health threats.

3.4.1. Schedule, themes and trainers

Table 8 *- Schedule, themes and trainers of Module 4 (M4)*

Session	Date	Theme(s)	Duration (hours)	Trainer(s)
Session 1	6 March 2025	Public Health – I	4	Ana Paula Rodrigues
Session 2	13 March 2025	Public Health – II	4	Maria João Alves
Session 3	20 March 2025	Epidemiology and Research	4	Ana Rodrigues
Session 4	25 March 2025	Research Methods in Health – I	4	Emília Monteiro
Session 5	27 March 2025	Research Methods in Health – II	4	Emília Monteiro
Workshop	1 April 2025	Emerging Human and Animal Diseases	2	Moderator: M. Patrão Neves e Sofia Núncio Participants from the PSAC: – Maria Cecília Almeida – Lara Gómez – Inácio Alvarenga – Osvaldo Frederico – Adionilde Aguiar

3.5. Module 5 – Biobanks and Responsible Research Involving Humans, Fauna and Flora, and Patentable Innovation

***Table 9** - Learning Objectives of Module 5 (M5)*

	Learning Objectives – M5
Session 1	**Biobanks: Ethical, Legal, and Social Framework** – Understand the ethical, legal, and social framework surrounding biobanks – Identify the fundamental principles guiding the collection, storage, and use of biological samples and personal data for biomedical research purposes – Understand the role of informed consent and the responsible management of personal and sensitive information held in biobanks – Recognise the importance of biobanks as essential infrastructures for advancing biomedical research
Session 2	**Organisation of a Biobank: Planning and Management of Human Biological Samples** – Understand the process of planning, managing, and sharing human biological samples within a biobank – Recognise the importance of good practices and applicable ethical principles in the collection, storage, quality assurance, and access to information
Session 3	**Biological Sample Banks of Animal or Plant Origin and Biomedical Research** – Recognise the different approaches of international organisations regarding banks and repositories of biological samples – Learn about the Lusophone Network of Biobanks and Biological Collections, its stakeholders, challenges, and collaboration opportunities
Session 4	**Research, Innovation, and Development: Intellectual Property and Patents** – Understand the concepts of intellectual property, copyright, patents, and patentability requirements – Recognise the strategic role of intellectual property and patents in protecting scientific and technological innovation, as well as their importance for knowledge valorisation, sustainable development, and competitiveness in the global context
Workshop	**Research involving biological samples of animal and plant origin in biomedicine** – Understand the role of biobanks and scientific research in biodiversity conservation, improvement of human health, and sustainable development

3.5.1. Schedule, themes and trainers

***Table 10** - Schedule, themes and trainers of Module 5 (M5)*

Session	Date	Theme(s)	Duration (hours)	Trainer(s)
Session 1	3 April 2025	Biobanks: Ethical, Legal, and Social Framework	4	Célia Ventura

Session	Date	Theme(s)	Duration (hours)	Trainer(s)
Session 2	10 April 2025	Organisation of a Biobank: Planning and Management of Human Biological Samples	4	Maria Assunção
Session 3	17 April 2025	Biological Sample Banks of Animal or Plant Origin and Biomedical Research	4	Ana Paula Arez
Session 4	14 April 2025	Research, Innovation, and Development: Intellectual Property and Patents	4	Diogo Antunes
Workshop	5 May 2025	Research involving biological samples of animal and plant origin in biomedicine	2	Moderators: M. Patrão Neves e Lúcia Domingues Participants from the PSAC: – Bucar Indjai – Nidia Cangi Vaz – Miclay Carvalho – Maria Assunção

3.6. Module 6 – Regulatory Affairs

Table 11 *- Learning Objectives of Module 6 (M6)*

Learning Objectives – M6	
Session 1 and **Session 2**	**Principles of Regulation for Medicines and Health Products: The Role of Regulatory Authorities** – Understand the regulatory framework for European, North American, and ICH evaluation and decision-making procedures for the market authorisation of medicines and health products – Identify the different types of advanced therapy medicinal products. – Be familiar with the European regulatory framework relating to advanced therapies.
Session 3	**Clinical Trials with Medicinal products** – Identify the ethical and regulatory aspects of clinical trials with medicinal products – Understand the specifics of the European Clinical Trials Regulation and the associated information system. – Understand the European regulatory framework on clinical trial safety monitoring.
Session 4	**Risk Management System** – Identify the principles and methods for assessing and monitoring medicinal products safety – Recognise the role of pharmacovigilance and good practices in the early detection of adverse reactions and protection of public health – Understand the importance of post-authorisation studies and the surveillance of medical devices.

Learning Objectives – M6	
	– Identify risk management strategies for medical devices and their regulatory requirements to ensure safe and effective use.
Workshop	**International Regulatory Systems** – Identify the principles, structures, and challenges of international regulatory systems, recognising their role in protecting public health, promoting equity in access to medicinal products, and harmonising standards across countries and regions.

3.6.1. Schedule, themes and trainers

Table 12 *- Schedule, themes and trainers of Module 6 (M6)*

Session	Date	Theme(s)	Duration (hours)	Trainer(s)
Session 1	8 May 2025	Principles of Regulation for Medicinal Products and Health Products: The Role of Regulatory Authorities – Part I	4	– Beatriz Lima – Isabel Vieira
Session 2	15 May 2025	Principles of Regulation for Medicinal Products and Health Products: The Role of Regulatory Authorities – Part II	4	– Helena Ribeiro – Rosário Lobato – Olga Silva
Session 3	22 May 2025	Clinical Trials with Medicinal Products	4	– Cecília Lima – Leonor Nogueira
Session 4	29 May 2025	Risk Management System	4	– Carla Torre – Diogo Almeida
Workshop	3 June 2025	International Regulatory Systems	2	Moderators: Bruno Sepodes and Djamila Reis Participants from the PSAC: – Eduardo Tavares – Tânia Sitoie – Hironisia dos Santos

4. Training methodologies

The sessions were delivered online, via Zoom, initially in webinar format due to the high number of trainees (over 300) and the impossibility of predicting the level of spontaneous interventions. As the training progressed and written questions were received during each session, it became clear that the average number of questions would allow them to be addressed in real time. Therefore, from Module 4 onwards, the sessions were switched to a

meeting format, which allowed for greater interaction between trainees and trainers. All sessions were recorded and made available to the trainees on the e-learning platform created for this purpose (Deliverable 4.1 of the Project).

The training content for each session was prepared in advance by the responsible trainers, usually in the form of a PowerPoint presentation and supporting bibliography. All materials were made available on the e-learning platform after each session.

During the sessions, various strategies were used to encourage trainees' participation (initially in writing and later orally) and to promote content comprehension, included solving dilemmas through online voting, discussion of practical cases, collaborative slide building with trainees' suggestions, among others. Suggestions for improvement made by trainees were also taken into account, such as introducing more frequent breaks and providing additional opportunities for interaction during the sessions.

The workshops also took place online via Zoom, using a different methodology from the theoretical-practical sessions. As previously indicated, for each workshop a representative from each PSAC was invited, according to the thematic area and their professional profile. Each representative was asked to deliver a brief introductory oral presentation on the state of the art in their country regarding the topic under discussion. This was followed by a discussion among all panel members, moderated by a member of the Project coordination team or another designated participant. The Module 6 workshop followed a different dynamic. It began with two presentations by the moderators to provide an overview of the European and African Regulatory Systems, followed by contributions from representatives of the regulatory authorities of each country. The implementation of these varied methodologies enabled the development of different learning models and the enhancement of diverse competencies among the trainees.

5. Participants´ Profile

5.1. Trainees' Profile

This Training Programme brought together a diverse group of trainees from the PSAC (including a small number of trainees studying in Portugal). Their personal, academic, and professional profiles contributed significantly to the dynamics and overall success of the Training Programme, as will be demonstrated in Sections 6 and 7.

The average age of the trainees was 39 ± 10.5 years (mean ± standard deviation), ranging from 22 to 83 years, with the most frequent age (mode) being 30 years (N = 17). This is therefore a relatively young population, whose capacity-building is expected to foster the development of their countries of origin and support the training of future generations. Of the 234 trainees who completed the entire Training Programme, 120 were aged between 30 and 40 years, representing more than 51% of the trainees. Within this group, the majority were working in their home country, with only seven trainees (around 3%: two from Angola, two from Cape Verde, two from Mozambique and one from Guinea-Bissau) working in Portugal at the time of application. One trainee, originally from Angola, was working in Brazil. These data suggest that the impact of the Training Programme is likely to be felt not only in the short term but also in the medium and long term in the PSAC, by increasing the scientific and technical capacity of each country.

The following table (**Table 13**) presents the number of trainees by country, gender, and academic degree, as well as the totals by category (N = 235; including one trainee who completed only the module 6).

Table 13 *- Number and profile of trainees by country and by categories*

Country of Origin	N	Gender		Academic Degree		
		Fem.	Male	PhD	MSc	BSc
AO	44	26	18	3	15	26
CV	62	41	22	5	21	37
GB	28	6	5	5	12	11
MZ	89	42	47	6	27	56
STP	11	8	3	0	4	7
RW	1*	Fem.		BSc		
Total	235	124	111	19	79	137

Legend: Country: Angola – AO, Cape Verde – CV, Guinea-Bissau – GB, Mozambique – MZ, São Tomé and Príncipe – STP, and Rwanda – RW; Gender: Female – Fem. and Male – M; Academic Degree: PhD – Doctor of Philosophy, Master's – MSc, and Bachelor's – BSc. (*Trainee working in Mozambique.)

The Training Programme had the highest number of trainees from Mozambique and the lowest number from São Tomé and Príncipe, a distribution primarily related to the population size of each country. It may also reflect, among other country-specific factors, the maturity of research

institutions and the corresponding level of research development, as well as the dynamics of the National Regulatory Authority and the National Ethics Committee.

The country with the highest academic level among its trainees in the Training Programme was Guinea-Bissau, with approximately 18% of its trainees holding a PhD and working as senior health researchers. Cape Verde, on the other hand, had the largest percentage of trainees with a master's degree (approximately 34%) and 8% holding a PhD. Overall, in terms of academic qualifications, 41.7% of the 235 trainees held a master's or PhD by 15 November 2024 (the application date), with some trainees pursuing postgraduate studies at the time. It should also be highlighted that, although gender distribution was not an eligibility criterion, the overall composition of the trainees reflects a clear gender balance.

The profile of the trainees in terms of academic background and professional area (at the time of application) is presented in **Figure 1** and **Figure 2**, respectively. Some professionals perform roles in more than one sector, for example, higher education (lecturers) and research and/or ethics committees, as well as education and the National Regulatory Authority or other combinations, across different institutions, as presented in **Figure 3**.

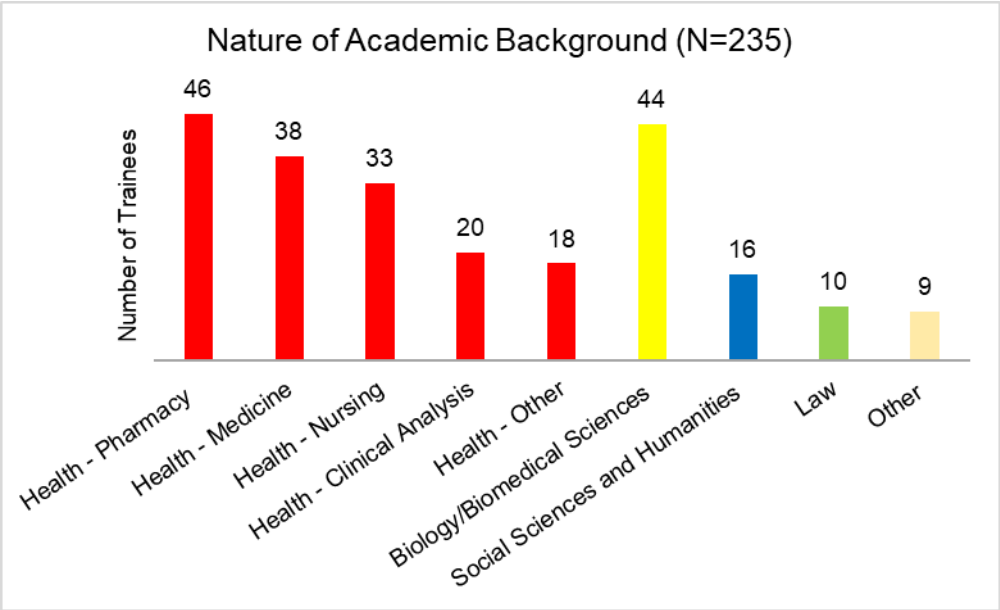


***Figure 1** - Academic background of trainees who completed the Training Programme (including the trainee who only completed M6).*
Social Sciences and Humanities include fields such as Psychology, Sociology, Public Administration, Law, and Anthropology. The category "Health – Other" encompasses trainees whose primary training is in health-related technical or scientific areas, such as nutrition, physiotherapy, speech therapy, epidemiology, or health technologies. The category "Other" includes fields such as Economics, Management, Chemical Engineering, Veterinary Medicine, Computer Science. (N=235)

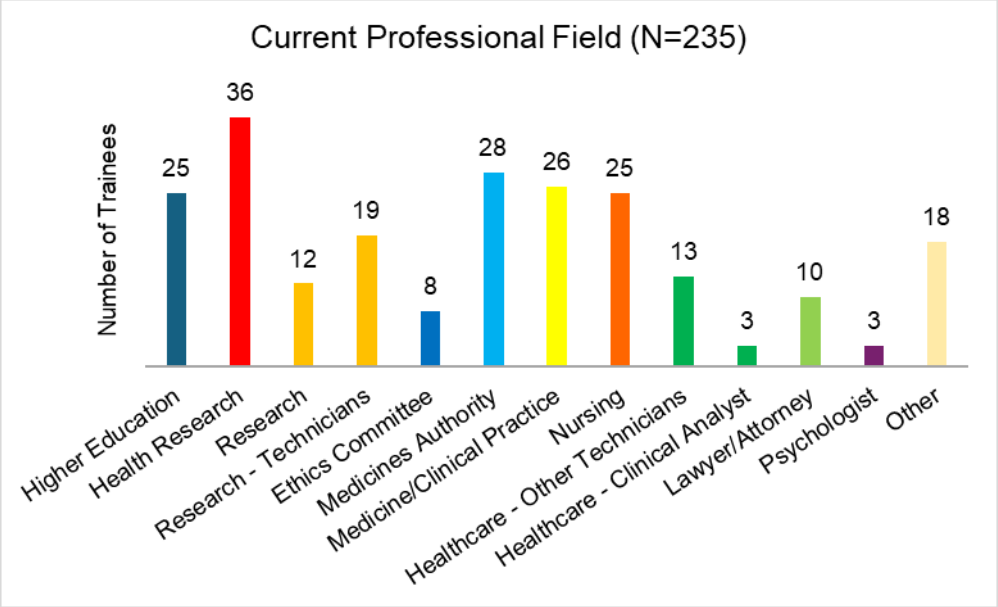


***Figure 2** - Professional field of trainees who completed the Training Programme (including the trainee who only completed M6).*

The category "Health – Other technical" mainly includes the same professionals referenced in **Figure 1**'s fields of study, such as nutrition, physiotherapy, speech therapy, epidemiology, health technologies, and medical imaging. The category "Other" comprises trainees whose professional areas include sociology, anthropology, economics, management, quality and biosafety, or those who are pursuing academic studies. (N=235)

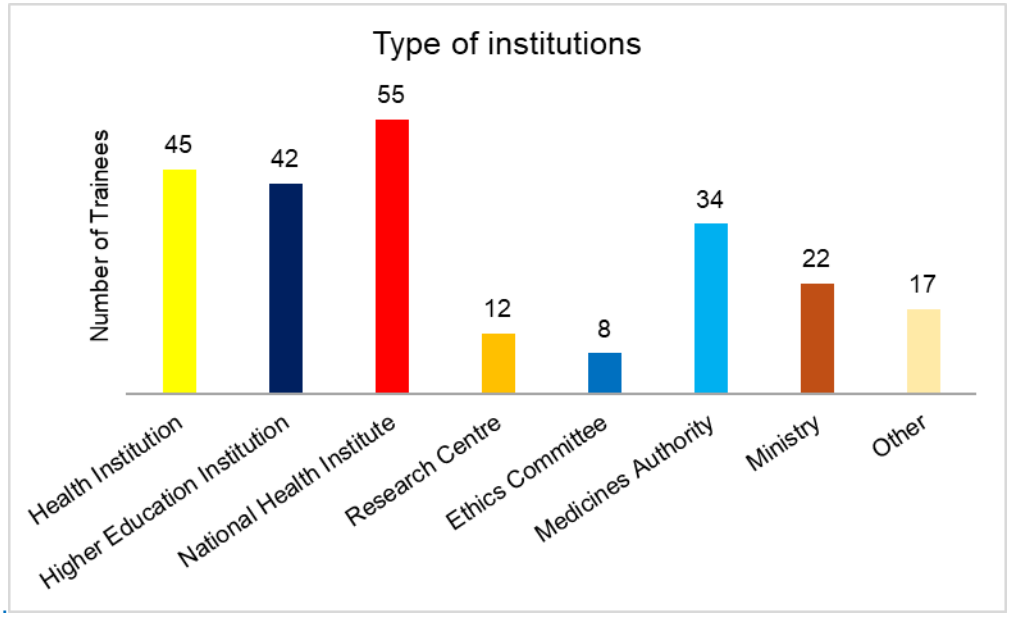


***Figure 3** - Type of institutions of the trainees who completed the Training Programme (including the trainee who completed only M6).*

The category "Other" includes Non-Governmental Organisations (NGOs), a foundation, a clinical analysis laboratory, and an undergraduate education institution.

Analysis of the figures on academic background and professional area shows that 67% of the trainees come from the health sector and about 17% from Biology and Biomedicine; only 6% are from the Social Sciences and Humanities. Most trainees work in the field of research (approximately 29% – N = 67), the same proportion as those working in the health/clinical sector. About 12% work for the National Regulatory Authorities, only 3% report being part of Ethics Committees, and 11% are university lecturers.

In terms of the institutions of origin, 23% came from the National Institute of Health, where the health research area is predominant, 19% from healthcare institutions (hospitals and/or clinics), followed by higher education institutions (18%), the National Regulatory Authority (15%) and Ministries (9%).

In summary, the profile of the trainees demonstrates broad diversity and inclusiveness in terms of age, gender, initial academic background, professional occupation, and represented institutions, fully reflecting the objectives defined for the target population of this Training Programme.

5.2. Trainers´ Profile´

To ensure the Training Programme´s pedagogical and scientific quality, trainers of recognised excellence and proven expertise in the relevant training area were selected. Their professional backgrounds and technical expertise guaranteed a high training standard. A simplified overview of the trainers involved in the lectures is presented below, together with those who contributed to the workshops. For each module's workshop, a representative from each of the PSAC was invited, in line with the theme of the workshop. Some of them were unable to attend the workshops due to last minute unforeseen professional commitments or technical difficulties.

The following table (**Table 14**) presents the number of trainers by country, their gender, and academic qualification, as well as the totals per each category, with a total of 47 trainers.

***Table 14** - Number and profile of trainers in the Training Programme, by country and by categories*

Country	N	Gender		Academic Degree		
		Fem.	Male	PhD	MSc	BSc
PT	24	18	6	19	4	1
AO	2	2	0	1	1	0
CV	6	4	2	3	1	1
GB	5	0	5	2	3	0
MZ	5	3	2	3	2	0
STP	5	3	2	1	2	2
Total	47	30	17	29	13	4

Legend: Country: Portugal – PT; Angola – AO, Cape Verde – CV, Guinea-Bissau – GB, Mozambique – MZ, São Tomé and Príncipe – STP; Gender: Female – Fem. and Male; Academic Degree: PhD – Doctor of Philosophy, Master's – MSc, and Bachelor's – BSc.

The trainers' profiles in terms of their academic background and current professional area are presented in the figures below (**Figure 4** and **Erro! A origem da referência não foi encontrada.**). Some professionals work across more than one sector – for example, Higher Education (University) and Research and/or Ethics Committees, but also Education and the National Regulatory Authority, or other combinations. Their institutional affiliations are detailed in the following table (**Table 15**).

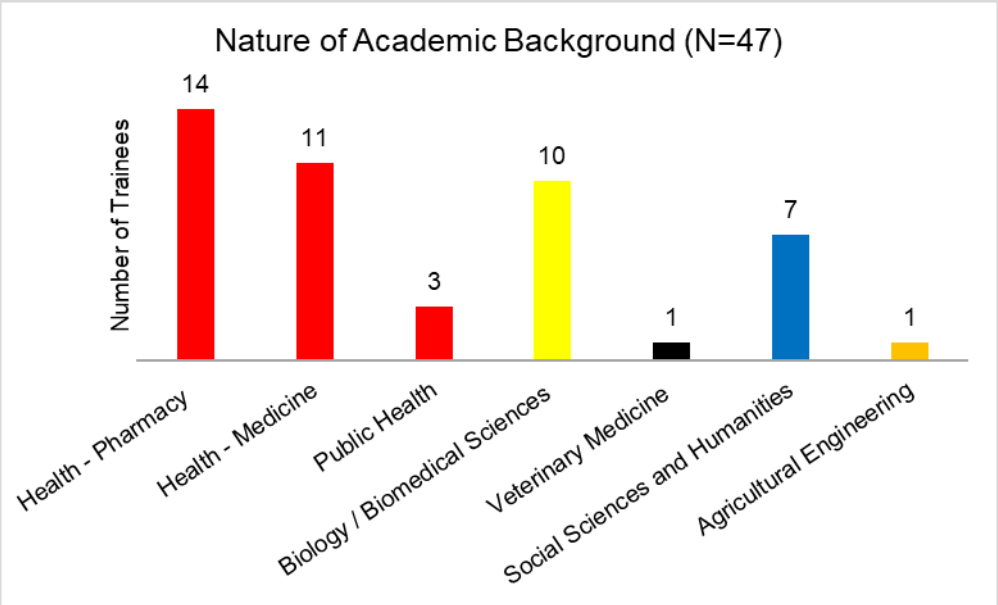


***Figure 4** - Academic Background of the trainers involved in the Training Programme (N=47)*

The Social Sciences and Humanities category includes one professional from each of the following fields: Philosophy, Psychology, Social Sciences, Sociology, Public Administration, Law, and Anthropology.

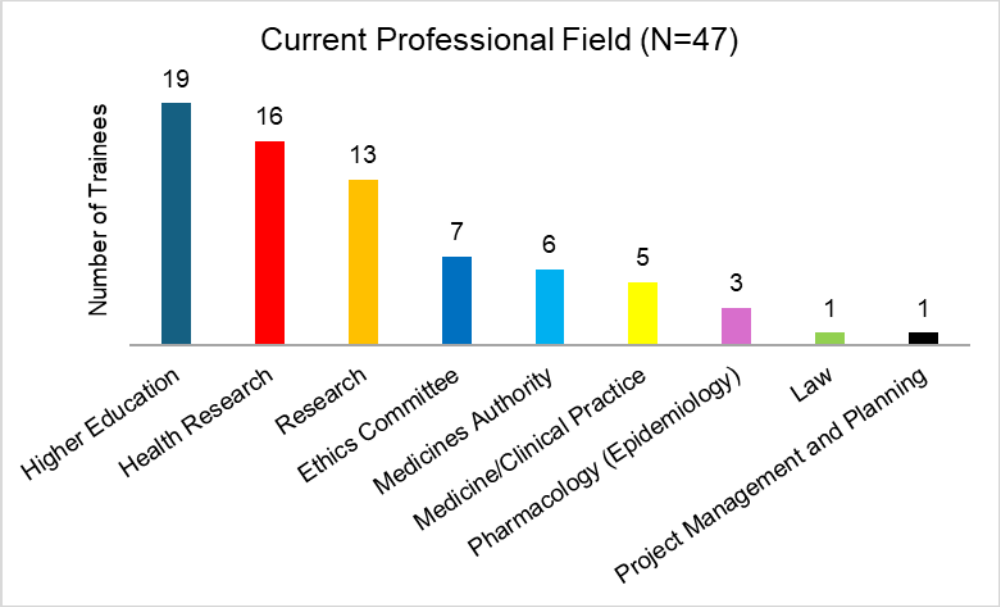


Figure 5 *- Current professional field of the trainers involved in the Training Programme. (N=47)*

Table 15 *- Type of institutions to which the trainers belong or with which they have professional affiliations*

Affiliated institutions of the trainers
Universities
National Institutes of Health
National and Reference Laboratories in the Health Sector
National Regulatory Authorities
National Ethics Committees
Research Institutes (Health/Agronomic and Technological)
Companies (or Private Companies, if you want to specify non-public sector)
International Organisations (EMA and WHO Africa)

Regarding the profile of the trainers, it can be concluded that the health sector is the most strongly represented area, with 28 professionals out of a total of 47 trainers (around 60%), and within the health field, 50% are pharmacists. Biology/Biomedical Sciences also constitute a well-represented group (like the number of medical doctors — about 22%), reflecting the

interconnection between these fields and health research, as well as their involvement in health regulation and Ethics Committees. This is, after all, the focus of capacity building within this Project and of the Training Programme itself. In addition to these two core regulatory areas, the university sector and research activities are also highly, which reflects the experience and the goal of establishing a body of trainers with high professional and academic standards – a fact also evident in their academic degree (**Table 14**): 29 of the 47 trainers hold a PhD and 13 hold a Master's degree. The same table presents that 30 trainers were female and 17 males. The selection criteria for trainers were based primarily on institutional affiliation – with a preference for trainers from the two universities awarding ECTS – and on academic and professional competence or career trajectory, rather than gender.

In conclusion, the academic and professional profile of the trainers reflects their recognised excellence, a decisive factor for the success of the Training Programme, as highlighted by the trainees and explored in detail in Section 7 of this report.

6. Results achieved by the trainees

6.1. Assessment Methods

The assessment consisted of a multiple-choice test for each module, comprising from 12 to 20 questions, each with five answer options. The tests were conducted online on the day of each workshop. Trainees were able to access the platform to take the test from 5:00 p.m. (GMT) on the test date and could do so until 2:00 p.m. (GMT) the following day, to accommodate professional commitments, time zones, and internet access constraints. Once accessed, the duration of the test was fixed for all trainees, lasting between 30 and 60 minutes (with an additional 10 minute tolerance), depending on the number of questions – which varied according to the number of hours of each module – as presented in the table below (**Table 16**).

Table 16 *- Schedule, number of questions and duration of tests for Modules 1 to 6*

	Test' Date	**Number of questions (test duration)**
M1	Tuesday, 7 January	12 (40 minutes)
M2	Tuesday, 4 February	16 (50 minutes)

	Test' Date	Number of questions (test duration)
M3	Wednesday, 5 March	16 (50 minutes)
M4	Tuesday, 1 April	20 (60 minutes)
M5	Tuesday, 6 May	16 (50 minutes)
M6	Tuesday, 3 June	20 (60 minutes)

To obtain accreditation of the 12 ECTS, each trainee was required to pass all modules. Considering the possibility that trainees might not be able to sit the exam on the scheduled date or might fail it, they were given the opportunity to complete a short-written recovery assignment (approximately 2,500 characters) on the topic of the respective module.

In this assignment, trainees were required to identify and present the most useful content taught, in relation to their training and professional practice. The assignments were assessed by the trainers responsible for the Training Programme, drawing on their scientific and professional expertise, using a qualitative assessment grid which was then converted to a percentage scale. Assignments were classified as 'not passed' (< 50%) or 'pass' (≥ 50%), according to the classification ranges presented in **Table 17**.

***Table 17** - Qualitative and quantitative assessment categories of the trainees*

Not passed	Passed				
	Poor	Fair	Good	Very Good	Excellent
< 50%	50-55%	56-65%	66-75%	76-89%	90-100%

All trainees who attended the training until the end but did not sit tests for certain modules, or did not submit the written resit assignment, were invited to complete their training through oral assessments. These followed the same structure as the written remedial assignments (identifying and presenting the most relevant content taught for their training and professional practice) and used the same assessment criteria.

In the context of the assessment plan and considering only the trainees who completed the Training Programme, a total of 1268 tests, 172 resit assignments and 35 oral assessments were carried out, distributed by module as presented in **Table 18**.

***Table 18** - Total number of tests, resit assignments and oral tests (oral resit work), by module*

	Tests	Resit Assignment	Oral Assessments
M1	231	15	1
M2	212	23	1
M3	204	36	3
M4	203	41	8
M5	207	20	9
M6	211	37	13

Each trainee's final grade was calculated based on their test grade, resit assignment grade or oral assessment grade, as applicable, for each module. All trainees who passed all modules were awarded 10 ECTS by the NOVA Medical School (NMS) of the NOVA University of Lisbon and 2 ECTS by the Faculty of Pharmacy of the University of Lisbon (FFUL) and received the corresponding certificates.

The assessment results and the method for calculating the grades (on a scale from 1 to 100), by module and by trainee, are presented in the following section.

6.2. Assessment results by module and by trainee

Of the 303 trainees who began the training, 69 withdrew or did not complete their assessments. The cases of non-completion were mainly due to difficulties in reconciling the training with professional and/or personal commitments (6 trainees formally communicated their withdrawal) or because they lost continuity, having consecutively missed the assessment of one or more modules.

Therefore, 234 trainees successfully completed and passed all modules of the Training Programme, obtaining the planned 12 ECTS. Additionally, one other trainee obtained only 2 ECTS credits from FFUL, related to Module 6 – Regulatory Affairs, as they did not complete all modules (M1 to M6) accredited by NMS. The grade awarded to each trainee correspond to the grade obtained in the written test and, in cases of assessment by remedial assignment (or oral assessment), the grade corresponds to the lower level of the qualitative assessment scale (50%, 56%, 66%, 76% or 90%), as presented in the previous table (**Table 17**).

The following section presents the assessment results by module and by trainee. For the purposes of presenting the results, only the 234 trainees who completed the entire Training Programme were included. Additionally, for Module 6, the average grades are presented, including the trainee who completed only this module.

The following table (**Table 19**) presents the average results obtained by the total number of trainees who completed all training modules (N = 234), as well as the standard deviation and the most frequent grade (mode) for each module. It also presents the trainees' overall average (the mean of the average grades obtained by each trainee across all modules, M1 to M6), together with its standard deviation and mode.

***Table 19** - Average grades (on a scale from 1 to 100) of trainees by module, and overall average grades of trainees.*

	M1	M2	M3	M4	M5	M6	Trainees
Mean	78	86	76	79	89	75	80
Standard Deviation	13,6	13,3	14,7	16,6	12,7	15,4	9,7
Mode	83	94	88	100	100	88	90
Min - Max	50-100						53-97

Legend: Results of the average grades (on a scale from 1 to 100) obtained by the trainees for each module (M) and the trainees´ overall average, with their respective standard deviations and modes (N=234)

From the previous table, it can be observed that the average scores per module ranged from 75 points (M6) and 89 points (M5), with the most frequent score in these modules being 100 points. Regarding Module 6, considering the grade of 50 points obtained by the trainee who only successfully completed this module, the average and standard deviation change (rounded to one and two decimal places, respectively) from 74.6% and 15.35% (for the 234 trainees) to 74.5% and 15.40%, with no impact on the mode.

The average final grades of the trainees were clearly positive, at 80 points out of 100, with the most frequent grade being 90 points (N = 11) and a standard deviation of 9.7 points.

Figure 6, presented below, illustrates the distribution of trainee grades by grade intervals according to the assessment scale from "Poor" to "Excellent" (as presented in **Table 17**, section 6.1), allowing for comparison across the different modules.

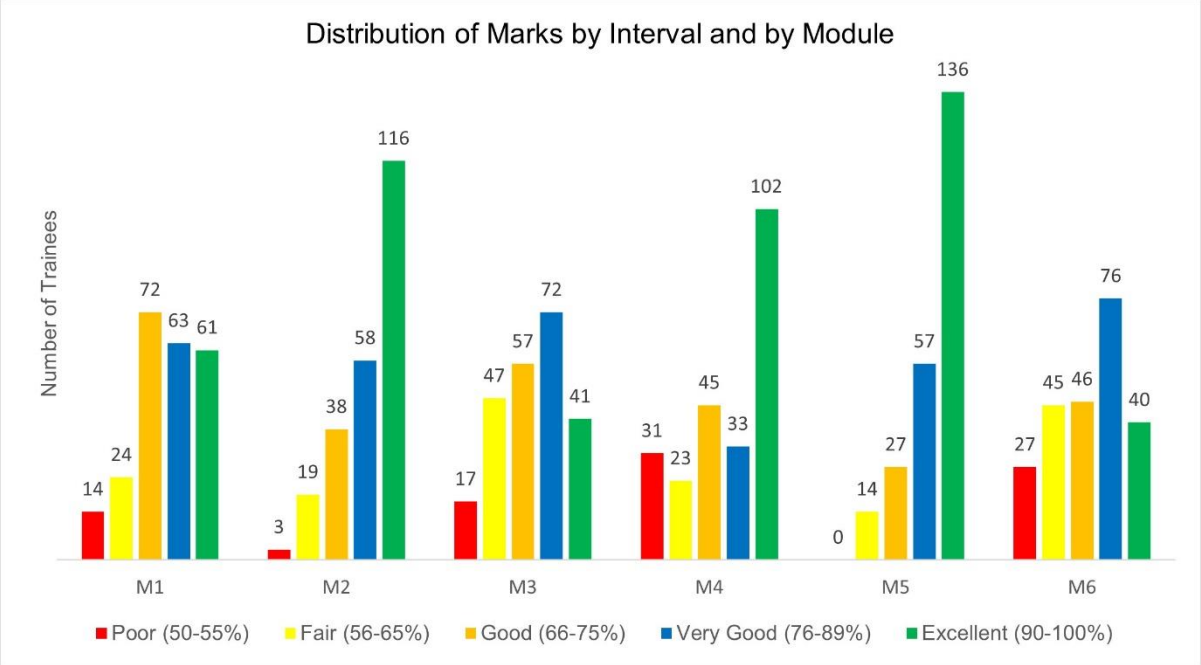


***Figure 6** - Distribution of the trainees' grades, grouped by classification intervals, for each module (M)..*
Distribution of the trainees' grades, by interval, according to the classification scale from 'Poor' to 'Excellent' (as presented in **Table 17**), for each module. (N=234)

Analysis of

Figure 6 regarding trainee performance by module, reveals that Modules 2 and 5 recorded the highest overall grades. In both cases, there is an almost complete absence of assessments at the "Poor" level and a significant frequency of "Excellent" grades, with over 100 trainees (out of a total of 234) falling within this range. On the other hand, Modules 1, 3, and 6 present a distribution of grades that approximates normality, although with a right skew. This pattern indicates a greater concentration of trainees in the "Good" category (in the case of M1) and "Very Good" category (in M3 and M6).

Thus, the low incidence of "Poor" grades across all modules, combined with the high presence of "Excellent" grades in some, and the predominant levels of "Very Good" and "Good" in the others, appears to reflect a solid foundation of assimilated content and acquired learning, highlighting the overall success of the trainees' results.

Figure 7, presented next, illustrates the distribution of trainees' final average grades by assessment interval, according to the grading scale from "Poor" to "Excellent" (as presented in **Table 17**, section 6.1).

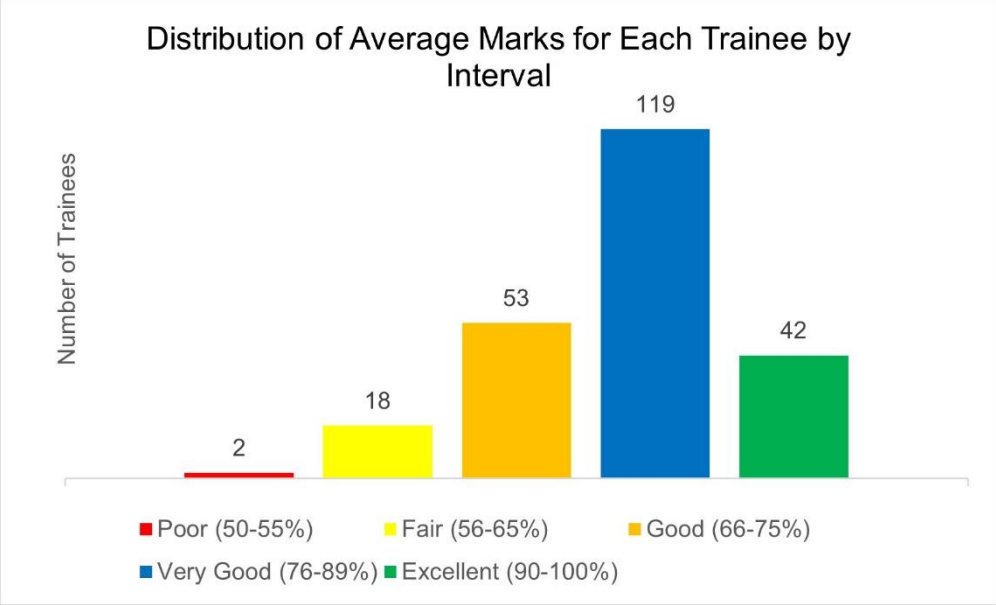


***Figure 7** - Distribution of trainees' global average grades, by classification interval.*
Distribution of the average grades obtained by the trainees across all modules, by interval, according to the classification from 'Poor' to 'Excellent' (as presented in **Table 17**). (N=234)

The results presented in **Figure 7** presents that the average performance of the trainees across the six modules was clearly positive. Over 90% of the trainees achieved final averages at or above the "Good" level (on a scale from "Poor" to "Excellent"), with over 69% reaching the "Very Good" and "Excellent" rating levels.

In conclusion, the results obtained by the trainees suggest not only a consistent training path aligned with the pedagogical objectives of the Training Programme but also demonstrate the overall quality of the trainees, whose engagement significantly contributed to the success of the training process and the outcomes achieved.

7. Assessment of the Training Programme

7.1. Assessment by module and improvement strategies

To monitor and continuously improve the Training Programme throughout the 6 months of training, an assessment survey was developed and distributed to trainees at the end of each module. This tool enable data to be collected on trainees' satisfaction levels regarding several aspects of the training, and opportunities for improvement to be identified. To promote continuous improvement, trainees were asked to provide suggestions to all modules, except

last one, the 6. From Module 1 onwards, trainees were also asked to indicate whether their suggestions had been implemented or not.

The survey was made available by email to all trainees after the end of each module. A second request to complete it was sent during the first session of the following module. Additional reminders were also sent by email to encourage completion. The survey remained anonymous and allowed only one submission per trainee.

Trainees were asked to rate their level of satisfaction on a scale from 1 to 5 (with 1 being "Not satisfied" and 5 being "Very satisfied") for different aspects of the Training Programme (questions 1 to 17), to answer "Yes" or "No" to questions 19 and 20, and to provide suggestions for improvement through an open-text response (question 21). **Table 20** below presents a summary of the survey questions. The complete survey is included in Annex 5.

Table 20 *– Module´s Survey*

Module´s Survey
1. Prior information about the Training Programme, schedule, timetable and support materials. (Only used for the M1 and M2).
2. Prior information about accessing the e-learning platform. (Only used for the M1 and M2).
3. Clarification of trainees' questions before the start of the Training Programme (Used for M1 and M2)/ of the Module (Used for M3 to M6).
4. Structure of the Training: lectures and a workshop per module
5. Duration of the intensive sessions (one day per week).
6. Organisation and structure of the content in relation to the module topic.
7. Content´s Interest
8. Suitability of the content in relation to individual knowledge level.
9. Clarity of trainer presentation.
10. Trainer – trainee interaction: clarification of questions and participation, considering the number of trainees and the asynchronous methodology.
11. Training Support materials: PowerPoint presentations.
12. Activities and dynamics used during the sessions.
13. Appropriateness of the final assessment (multiple-choice test).
14. Availability of training content (PowerPoint and session recordings).
15. Ease of access to session´s materials.
16. Answering trainees' logistical questions.
17. Overall satisfaction with the module.
18. Contribution of content to personal development.
19. Contribution of content to professional practice.
20. Do you consider that improvements were made from one module to the next (taking suggestions into account)?
21. Suggestions for improvement (Used for M1 to M5) / What would you like to saw improved? (Used for M6).

Table 21 presents, for each of the questions (1 to 17 in **Table 20**), the average rating given by trainees regarding their level of satisfaction with each module, as well as the number of trainees who responded to the survey for each of the six modules (M1 to M6).

Table 21 *- Average trainee ratings for questions 1 to 17, by module*

	M1 N=188	**M2** N=133	**M3** N=136	**M4** N=76	**M5** N=169	**M6** N=214
Prior information about the Training Programme*	4,7	4,6	N/A	N/A	N/A	N/A
Information about the e-learning platform*	4,7	4,7	N/A	N/A	N/A	N/A
Clarifications before the start of the Training Programme/of the module°	4,3	4,4	4,4	4,4	4,5	4,4
Structure of the sessions	4,5	4,4	4,4	4,4	4,5	4,4
Duration of the sessions	4,1	3,9	4,0	4,0	4,0	4,0
Content´s organisation and structure	4,5	4,4	4,4	4,4	4,5	4,4
Relevance of the content	4,7	4,7	4,7	4,8	4,7	4,5
Suitability of the content	4,5	4,5	4,4	4,5	4,4	4,3
Clarity of delivery	4,6	4,5	4,5	4,6	4,5	4,4
Trainer–trainee interaction	4,1	4,3	4,2	4,4	4,5	4,4
Training materials: presentations	4,6	4,6	4,5	4,6	4,6	4,5
Activities/dynamics during sessions	4,1	4,1	4,3	4,3	4,4	4,3
Suitability of the final assessment	4,6	4,7	4,5	4,6	4,7	4,5
Availability of training content	4,7	4,7	4,7	4,6	4,7	4,6
Ease of access to session content	4,6	4,7	4,7	4,8	4,7	4,7
Response to logistical queries	4,3	4,5	4,4	4,5	4,5	4,5
Overall satisfaction with the module	4,6	4,5	4,4	4,5	4,6	4,4
Contribution to personal development	4,7	4,6	4,5	4,6	4,7	4,5
Contribution to professional practice	4,6	4,6	4,5	4,7	4,6	4,4

* N/A (Not applicable, because these two questions were only asked in M1 and M2). • (Question asked in M1 and M2); ° (Question asked in M3 to M6).

The data in **Table 21** presents that the trainees' level of satisfaction with the various aspects of the training is very positive across all modules. The evaluations were measured on a scale from 1 to 5, with the lowest average score being 3.9, relating to the duration of the sessions

in Module 2, and the highest average score being 4.8, relating to the ease of access to session content, in Module 4.

Analysis of the results for Question 17 (**Table 20**), which relates to overall satisfaction with each module, presents satisfaction levels above 90% for the majority, except for Modules 3 and 6, which recorded slightly lower satisfaction rates of 88% and 87%, respectively.

Taking into account the capacity-building objectives defined within the scope of this Project, Figure 8 compares, across the six modules delivered (M1 to M6), the average responses to questions 18 and 19 (**Table 20**). These questions assessed the contribution of the training to trainees' personal development and professional activity, as summarised in **Table 21**.

The results present a very positive average evaluation, with the lowest score (4.4) concerning the contribution to professional practice in Module 6. This module, dedicated to Regulatory Affairs (related with medicines and clinical trials), covers a very specific area and therefore was expected to have less impact on the professional activity of most trainees, given their professional profiles. Conversely, the highest average score (4.7) was observed for professional practice in Module 4, and for personal development in Modules 1, 2 and 5. These results can be compared below, in **Figure 8**..

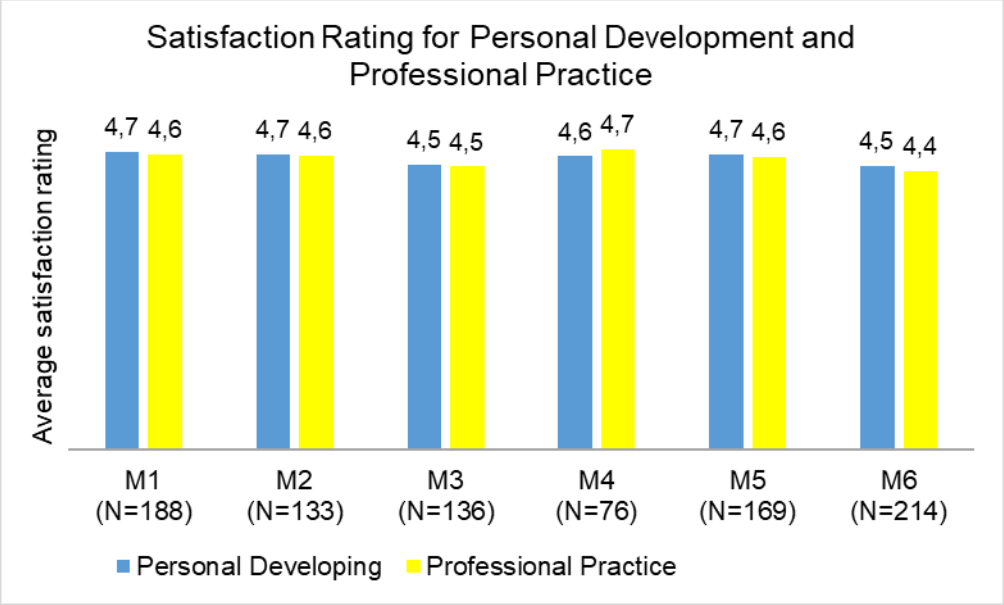


***Figure 8** - Comparison of the Training Programme's contribution to personal and professional development by Module (M1 to M6).*

Average of the trainees' responses to questions 18 and 19 (as presented in **Table 20** and **Table 21**) by module.

From the data in **Figure 8**, we can see that Modules 3 and 6 received the lowest overall ratings, although there appear to be no significant differences between them and the other modules. Additionally, the contribution to personal development was slightly higher than the contribution to professional practice in all modules, except for Module 4. Once again, these differences seem to be of little significance in terms of the overall impact of the Training Programme across the various thematic areas (modules).

To provide a more detailed analysis of trainees' satisfaction with the assessment survey questions (**Table 20**), the overall results are presented graphically below for each of the six modules (Figures 9 to 14). Each bar represents the percentage distribution of responses on a scale from 1 to 5, for each question within each module.

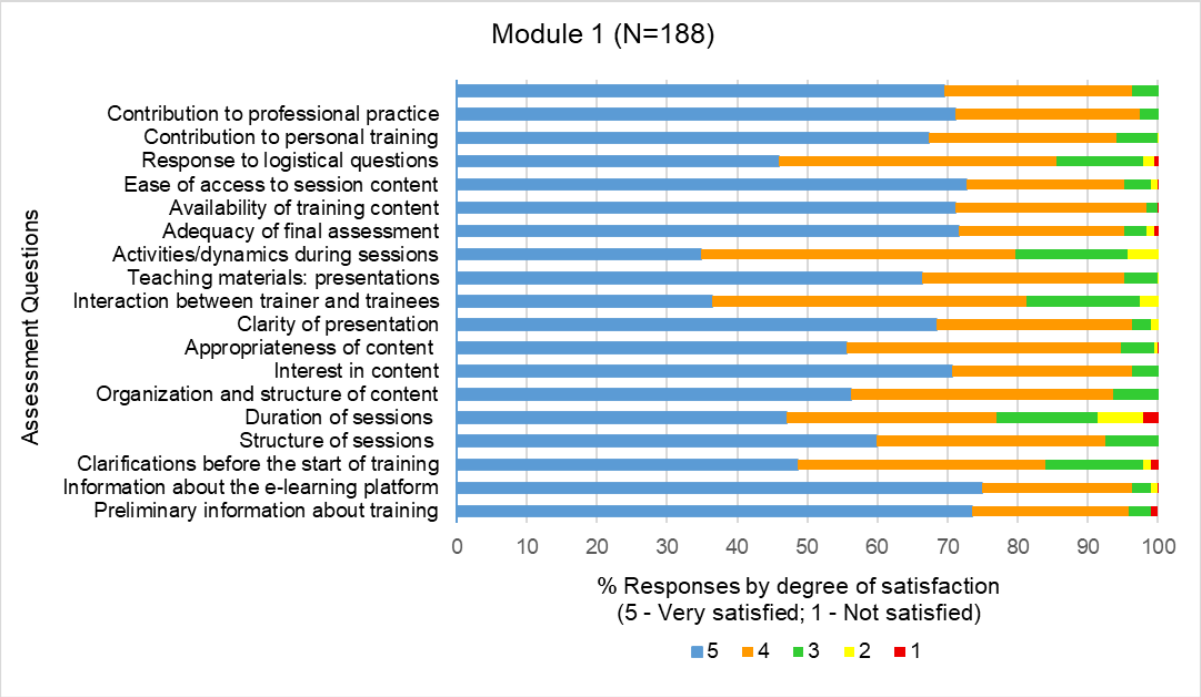


Figure 9 *- Results of the Training Programme assessment for Module 1 (N=188).*

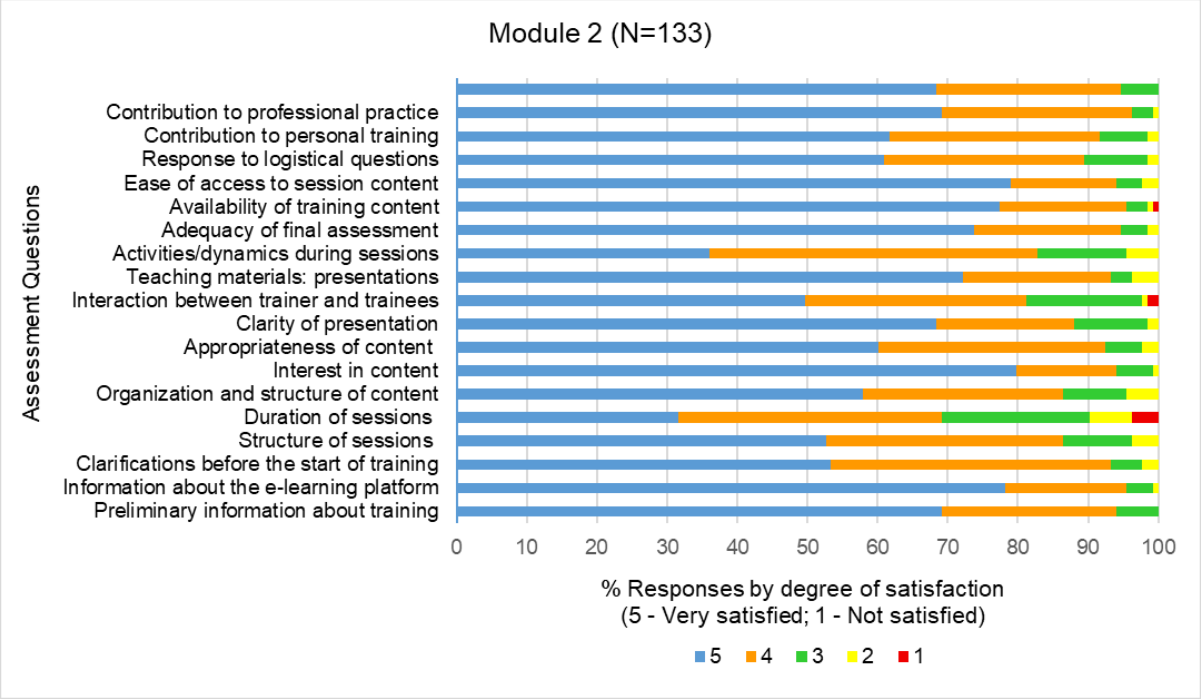


Figure 10 *- Results of the Training Programme assessment for Module 2 (N=133).*

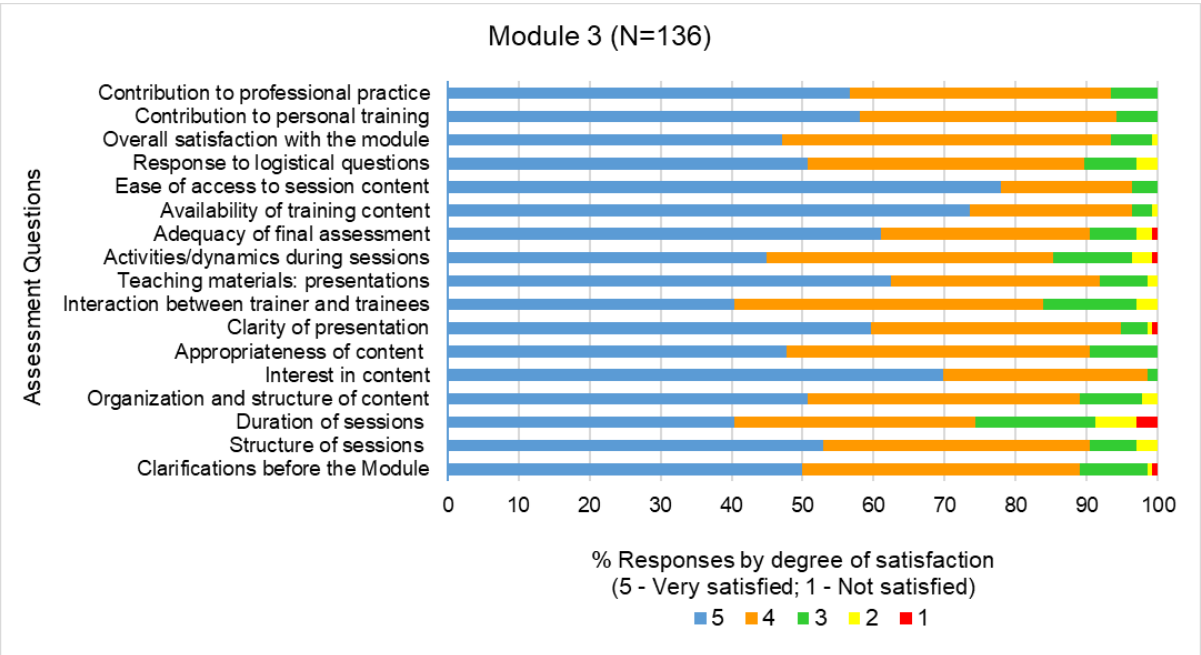


Figure 11 *- Results of the Training Programme assessment for Module 3 (N=136).*

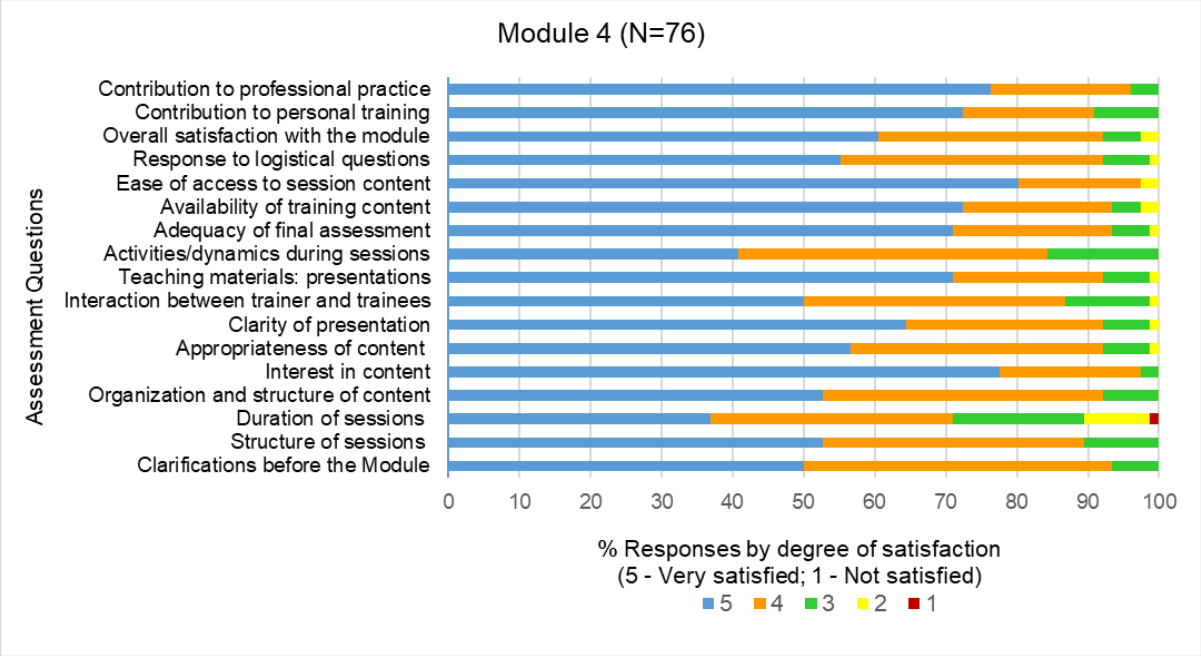


Figure 12 *- Results of the Training Programme assessment for Module 4 (N=76).*

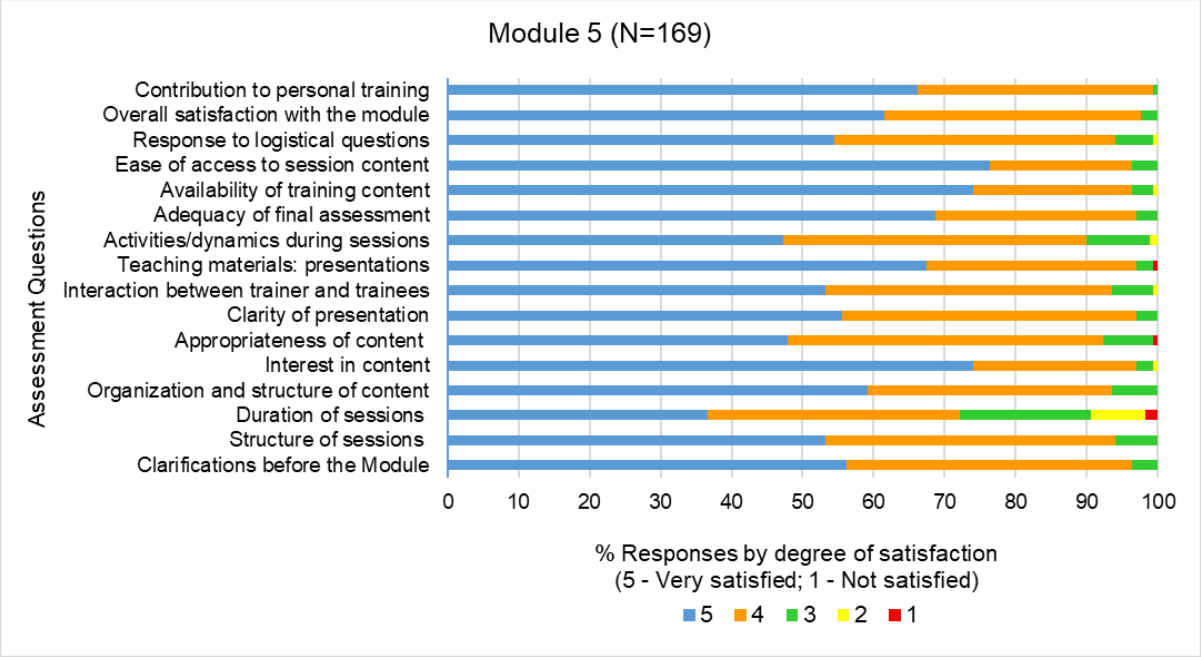


Figure 13 *- Results of the Training Programme assessment for Module 5. (N=169)*

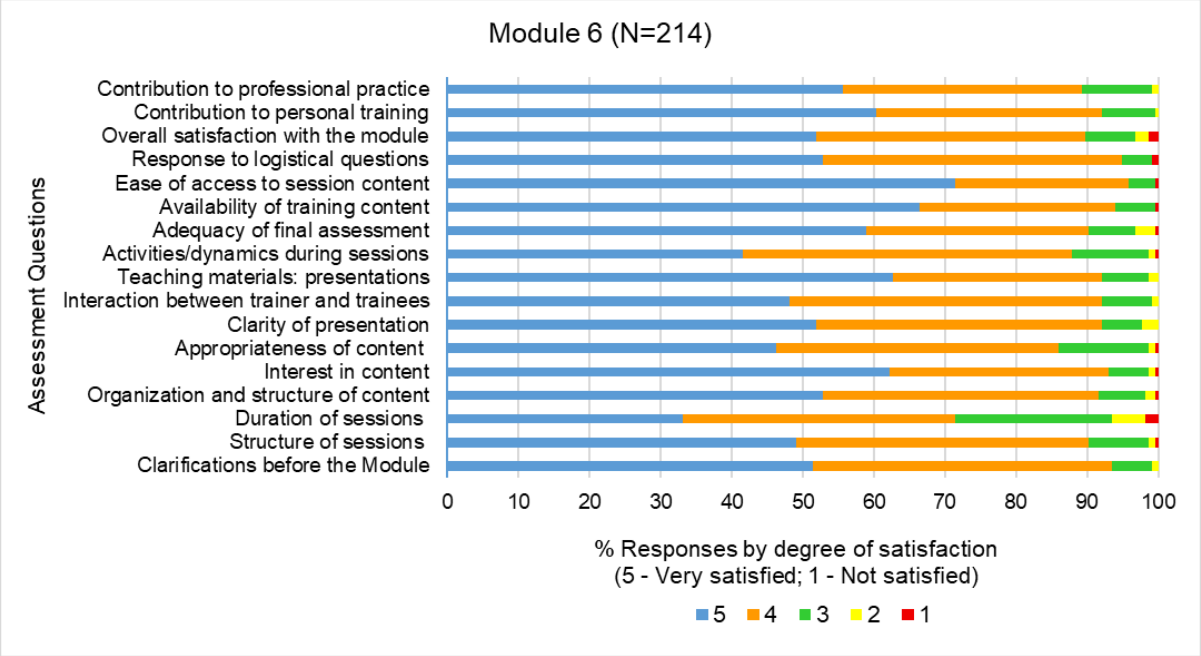


Figure 14 *- Results of the Training Programme assessment for Module 6. (N=214)*

The figures above present that, overall, the trainees' level of satisfaction with the training was highly positive, with the ratings of "Very satisfied" and "Satisfied" (blue and orange bars, respectively) predominating across most of the aspects assessed in all modules. It is noteworthy that only a few questions received a "Dissatisfied" rating (red bars), mainly regarding the duration of the sessions, with a greater incidence in Module 2 compared to the others. In Module 4, this was the only parameter to receive a "Dissatisfied" rating.

Regarding the final assessment parameter – *Suggestions for Improvement* – a total of 221 suggestions were received across all six modules, based on 916 completed surveys (some trainees made more than one suggestion). Negative comments were converted into improvement suggestions, while positive comments and proposals for additional thematic training were excluded from this analysis. The suggestions obtained were grouped into thematic categories. **Table 22** presents the consolidated results by category, distinguishing between those related to training and those related to assessment by module. Only categories with at least six training suggestions and at least four assessment suggestions are presented. For each module, the total number of surveys answered is indicated, as well as the total number of suggestions for improvement and their relative percentage; for each category, the total number of occurrences across all modules is indicated.

***Table 22** - Trainees' suggestions for improvement by category and module, and total number of trainees who made the same suggestion*

	M1	M2	M3	M4	M5	M6	TOTAL
Total surveys completed by module	188	133	136	76	169	214	916
Total number of suggestions for improvement, by module (% of total suggestions by module)	16 (8,5)	50 (37,6)	35 (25,7)	31 (40,8)	34 (20,1)	55 (25,7)	221
Regarding Training:							
Increase/improve interaction with trainees.	6	19	9	4	4	11	53
Reduce the duration of sessions/number of sessions per week.	3	12	7	4	10	14	50
Reduce/simplify the content of presentations.	-	3	1	3	2	9	18
Make the content available more promptly	-	-	3	2	7	1	13
Increase the number and/or length of breaks.	2	2	2	2	-	-	8
Change to sessions twice a week.	-	1	-	4	-	3	8
Provide presentations before sessions.	-	1	3	2	1	--	7
Provide sources of information for additional reference.	2	-	2	1	-	1	6
Regarding Assessment:							
Increase time allowed for the assessment / reduce number of questions.	1	1	1	1	2	1	7
Improve questions.	-	1	1	1	-	2	5
Extend the deadline for completing the test.	-	1	-	-	2	1	4

Analysis of **Table 22** allows for a comparison of the types (categories) and number of improvement suggestions made for each module, as well as identifying, for each category, the module where trainees most frequently made suggestions, along with the total number of suggestions across all six modules.

Regarding the number and/or relative percentage of suggestions, it is noted that Module 4, followed by Module 2, gathered the highest number and percentage of total improvement suggestions per module. Conversely, Module 1 recorded the lowest number and percentage of suggestions.

With respect to the most frequently suggested improvements throughout the entire Training Programme (with more than 10 trainees presenting the same suggestion in some modules), two main categories stand out: 1) "Increase/improve interaction with trainees", and 2) "Reduce the duration/number of training sessions." The first category was suggested 19 times in Module 2 and 11 times in Module 6, corresponding to 38% and 20% of the suggestions for these modules, respectively. This same suggestion represented for 26% of the total suggestions related to Module 3. The second category was mentioned 14 times in Module 6 (26% of total suggestions), 12 times in Module 2 (24%), and 10 times in Module 5 (29%). Together, across all modules, suggestions to "Increase/improve interaction with trainees" and "Reduce the duration/number of sessions" represent approximately 47% of all improvement suggestions.

Finally, although representing less than 10% of all suggestions, the category "Reduce/simplify presentation content" (N=18) was particularly frequent in Module 6 compared to other modules.

Suggestions to shorten the duration/number of training sessions and simplify/reduce content make up about 31% of total improvement suggestions. Suggestions related to assessment were less frequent but generally called for greater flexibility and clarity in assessment questions. At the end of each module, improvement suggestions were always reviewed, and any implemented changes were monitored throughout the next module. Thus, from the first assessment survey (Module 1) and throughout the Training Programme, new learning strategies were implemented, and trainees' suggestions were always welcomed, considered relevant, and duly implemented whenever possible. All the trainers from Modules 2 to 6 were informed and encouraged to adopt methodologies aimed at making sessions more dynamic and better suited to trainees' needs and real contexts. On the other hand, the nature and demands of the Training Programme – considering the defined objectives and the number of ECTS to be awarded – determined the total number of training hours. The number of hours per session and the number of sessions per week were set to concentrate the training into the fewest possible days, thus better accommodating trainees' professional and personal lives.

It is also worth noting that the suggestion to release presentations in advance was not implemented due to pedagogical and strategic reasons. Despite the efforts made, ensuring the timely availability of materials on the e-learning platform occasionally proved challenging, as it depended on the timely submission of presentations by trainers.

To assess trainees' perceptions on whether improvements based on their suggestions were implemented from one module to the next, question 20 was included in the Training Assessment Survey (**Table 20**), to which trainees responded "Yes" or "No." The results for each module is presented below, in **Figure 15**.

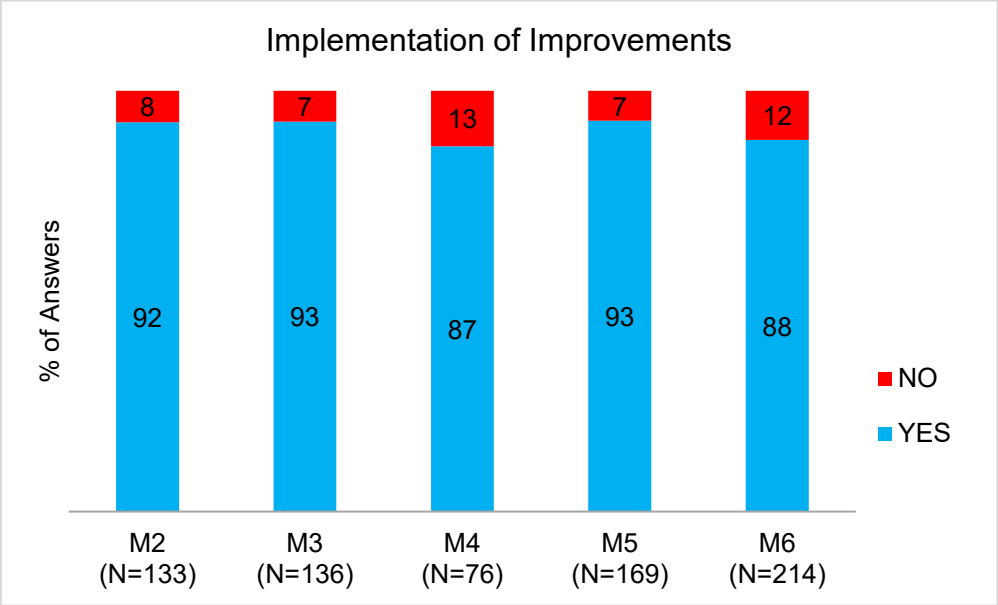


***Figure 15** - Percentage distribution of the 'Yes' and 'No' responses regarding the trainees' perception of the implementation of improvements from one module to the next, based on their suggestions.*

Analysis of **Figure 15** presents a generally positive perception among trainees, with average percentages over 87% across all modules regarding the implementation of improvements throughout the training programme. Nevertheless, these improvements appear to have been less effective in M4 and M6 compared to M3 and M5, respectively.

7.2. Results of the trainee survey at the end of the Training Programme

Once the module-by-module assessment of the Training Programme had been completed, it was considered relevant to carry out an overall assessment of the programme. For this purpose, a final survey was developed and sent by email to all trainees on 5 June 2025, remaining open for responses until 3 July 2025. Follow-up reminder emails were sent to encourage participation. The survey was anonymous and allowed only one submission per trainee. A total of 70 responses were collected.

The three questions addressed in the survey, together with their response categories, are presented below, along with the results for Questions 1 and 2, presented in **Figure 16** and **Figure 17**, respectively.

Table 23 *- Training Programme Survey*

Training Programme Survey
1. How would you rate the Training Programme overall? (0 - Not satisfactory; 1 - Somewhat satisfactory; 2 - Satisfactory; 3 - Good; 4 - Very good; 5 - Excellent)
2. How would you rate the direct impact that the Training Programme had on your professional practice? (0 - None; 1 - Minimal; 2 - Reasonable; 3 - Moderate; 4 - High; 5 - Very high)
3. If it had any impact, please specify what it was. (Free text)

***Figure 16** - Distribution of the responses regarding the overall rating of the Training Programme.*
Categories 0, 1, and 2 received no responses from trainees. (N=70)

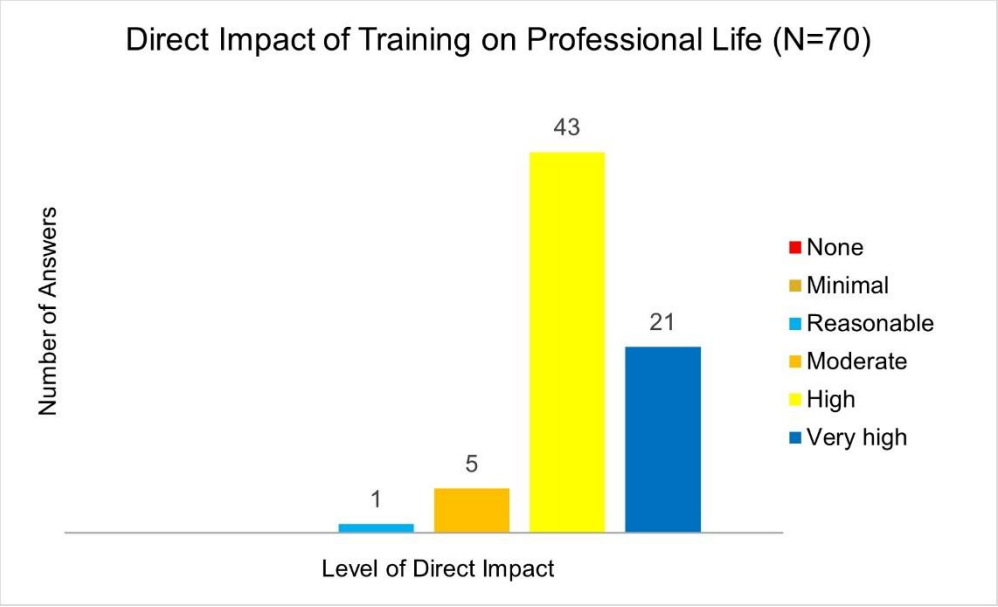


***Figure 17** - Distribution of the responses regarding the direct impact of the Training on each trainee's professional life.*
Categories 0, 1, and 2 received no responses from trainees. (N=70).

Analysis of **Figure 16** and **Figure 17** presents that, in line with the module-by-module assessments, the overall assessment of the Training Programme was also very positive, with 94% of trainees rating it as "Very Good" or "Excellent". Regarding the direct impact on each

trainee's professional practice – consistent with what was observed in the analysis of remedial work – 91.4% indicated a "High" or "Very High" impact.

To understand the nature of the training's direct impact on trainees' professional practice more broadly (Question 3 in **Table 23**), a qualitative analysis was carried out and organised by category. The categories presented were derived from a systematic review of the trainees' responses, with reference to the Project's goals – particularly the ethical and regulatory capacity building in the context of clinical trials – the WP4 training objectives, and the different perspectives of the trainees according to their professional area. None of the impacts described were grouped under more than one category. For each category, an approximate number of mentions is provided, totalling 86 references.

***Table 24** - Qualitative analysis, by category, of training impact on trainees' professional practice*

Nature of the impact of the training programme on professional practice.	
Ethics and Bioethics Training: taking a more ethical stance in scientific research, particularly in clinical studies and trials, with a focus on informed consent.	26
Regulatory training (and applicable legislation).	9
Increased knowledge: greater scientific and technical training, efficiency, professionalism and critical thinking.	16
Different perspectives:	
– **Indivi**dual (and/or as a member of the Ethics Committee): improving the assessment (and approval) of research projects, promoting better protection for participants, and improving the quality of ethical approvals issued.	8
– **Regulatory Authorities**: pharmacovigilance; streamlining procedures and integrating the global regulatory system; promoting safer approvals.	2
– **Postgraduate Education** (doctoral projects and related research): improving the study, particularly in consent and protection of the most vulnerable populations.	2
– **Clinical practice and public health surveillance**: improve ethical practices; predictive modelling and the use of artificial intelligence (AI) (particularly in countries where the risks of bias and digital exclusion are higher)	3
– **Research institutions:** – Increased awareness of responsibilities. – Promotion of a culture of scientific integrity. – Improvement of research project assessment procedures. – Improvement of procedures related to research, from its design to the dissemination of result – Improvement of coordination with Ethics Committees and alignment of practices with international standards. – Raising awareness among colleagues about the importance of ethical compliance research (even in laboratory or observational studies)	11

Nature of the impact of the training programme on professional practice.	
– Considering resources collectively and institutionally, rather than as private property.	
− **Higher Education and Training**: Integrating learning and improving teaching at university and for healthcare professionals.	2
– **Others:** − Understanding the role of Ethics Committees in the clinical research (1) − Implementation of biobanks/sample repositories. (1) − Protection of sensitive data (particularly in conditions of limited technological resources). (1) − Research with secondary data and sensitive data (including genetic research). (3) − Medical devices. (1)	7

Analysis of **Table 24**, which specifies the type of direct impact the training had on trainees' professional practice, presents that the most frequently mentioned category was ethical and bioethical capacity building (30% of references), followed by increased general knowledge (19%), and regulatory capacity building (11%).

Considering the impact from the perspective of trainees' professional areas, a significant share of respondents are linked to research activities (28%), whether at an individual level (or as reviewers, members of Ethics Committees), within postgraduate study programmes, at research institutions, or through the use of secondary and/or sensitive data (including genetic data) in scientific projects (N=24). Professional impact within research institutions accounts for 13% of references, followed by specific impacts at the individual level or as members of Ethics Committees, which account for 9%.Although less frequently cited, in addition to other impacts classified as "Other" in **Table 24**, it is worth highlighting the reference to clinical practice and public health surveillance, which, although mentioned by only three trainees, is relevant given that the main objective of the training was to build capacity in scientific research in general and in the health sector in particular.

8. Conclusion

A key objective of this Training Programme was to train a large and diverse group of professionals and build qualified critical mass to advance scientific and clinical research in the Portuguese-Speaking African Countries (PSAC). This objective was fully achieved, with results far exceeding the initial Project targets: although 120 participants were originally planned, the Training Programme enrolled 303 trainees, 234 of whom successfully completed all modules.

The trainees' educational backgrounds – covering areas such as Medicine, Pharmaceutical Sciences, Biology, Biomedicine, and with a strong representation of health technicians – reflect and fulfil the objectives of diversification and breadth. Their interest, commitment and quality of performance were remarkable, as demonstrated by the excellent overall evaluation results.

The competence, efficiency and dedication of the trainers, combined with the training strategies used, proved decisive for the success of the Training Programme. Their ability to adapt to trainees' needs, scientific rigour, methodological innovation, and technical and human quality contributed to achieving the defined objectives, amplifying the impact of the training beyond what was initially foreseen. Solid short-term results were generated, as well as lasting impacts, all aligned with the Programme's objectives.

The impacts of the Training Programme are evident and occur at two complementary levels:

- Institutional and strategic impact. The completion of the entire Training Programme by 234 professionals far exceeded the initial targets. The awarding of 12 ECTS credits demonstrates and consolidates the competencies acquired, anticipating sustained medium- and long-term benefits, both in local ethical, regulatory and technical capacity-building and in the promotion of high-quality research in the PSAC;
- Direct and immediate professional impact. As reported by trainees, the Training Programme is already producing effects in their professional practice, fostering greater awareness, critical thinking, and the effective application of the knowledge acquired.

Trainees' level of satisfaction with the Training Programme was clearly positive, reflecting not only the quality of the training structure and the relevance of the content, but also its alignment with the real professional needs of the trainees. This recognition, together with the suggestions for improvement put forward, validates the training model adopted and provides a solid

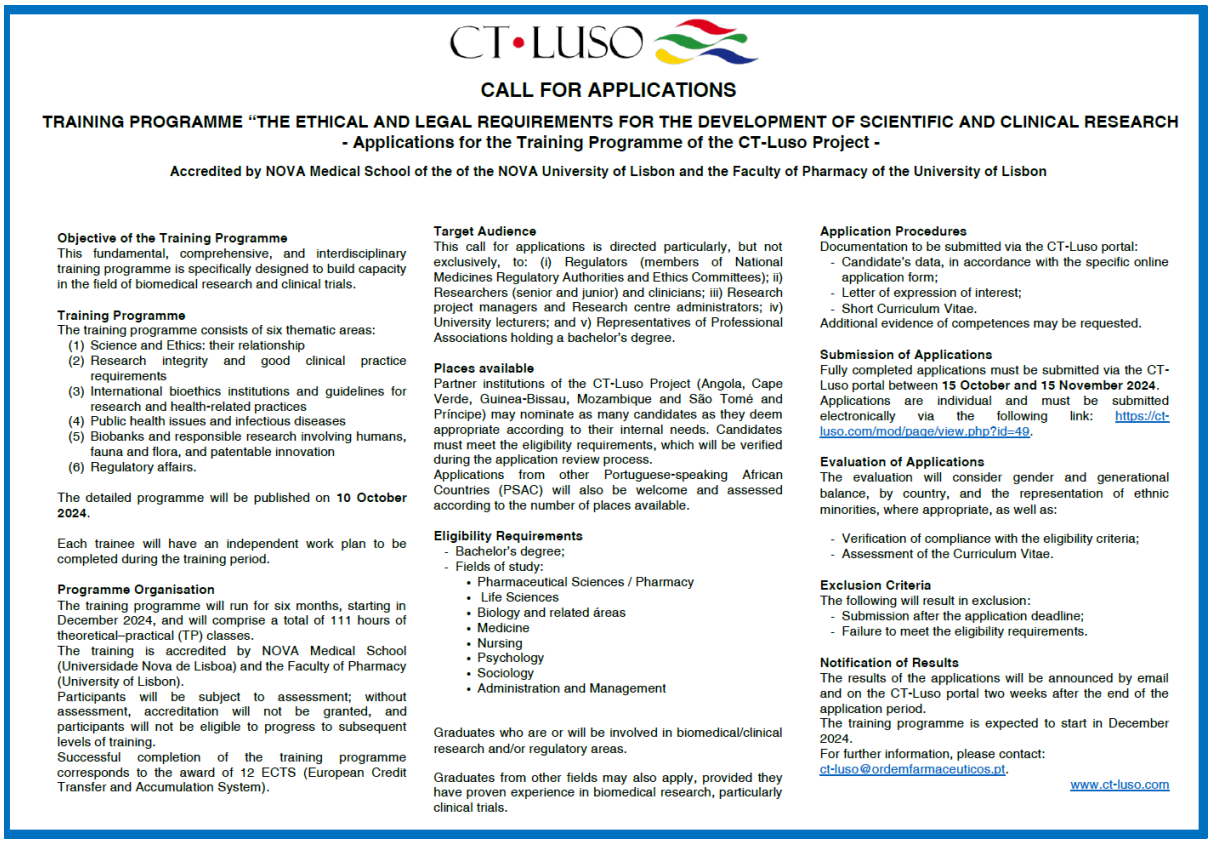
foundation for the evolution of the Project's training component. This already foresees the development of specialised and targeted actions, tailored to the different professional profiles of the trainees, further enhancing the Project's impact on ethical and regulatory capacity-building for biomedical research, particularly in clinical trials in the PSAC.

In summary, the high number of professionals who successfully completed the Training Programme, the strong representation from each of the five African partner countries, and the diversity of educational and professional profiles represent a strategic step forward in strengthening ethical and regulatory capacity in Lusophone Africa. This contributes to consolidating a pool of qualified human resources in research. Furthermore, as most trainees are professionally involved in research, particularly in the field of health research, the relevance of the programme and its ability to generate cross-cutting impact on the scientific systems of the five African partner countries is evident.

Annexes

Annex 1

Training Programme Call for Applications



CT·LUSO

CALL FOR APPLICATIONS

TRAINING PROGRAMME "THE ETHICAL AND LEGAL REQUIREMENTS FOR THE DEVELOPMENT OF SCIENTIFIC AND CLINICAL RESEARCH - Applications for the Training Programme of the CT-Luso Project -

Accredited by NOVA Medical School of the of the NOVA University of Lisbon and the Faculty of Pharmacy of the University of Lisbon

Objective of the Training Programme
This fundamental, comprehensive, and interdisciplinary training programme is specifically designed to build capacity in the field of biomedical research and clinical trials.

Training Programme
The training programme consists of six thematic areas:
(1) Science and Ethics: their relationship
(2) Research integrity and good clinical practice requirements
(3) International bioethics institutions and guidelines for research and health-related practices
(4) Public health issues and infectious diseases
(5) Biobanks and responsible research involving humans, fauna and flora, and patentable innovation
(6) Regulatory affairs.

The detailed programme will be published on **10 October 2024**.

Each trainee will have an independent work plan to be completed during the training period.

Programme Organisation
The training programme will run for six months, starting in December 2024, and will comprise a total of 111 hours of theoretical–practical (TP) classes.
The training is accredited by NOVA Medical School (Universidade Nova de Lisboa) and the Faculty of Pharmacy (University of Lisbon).
Participants will be subject to assessment; without assessment, accreditation will not be granted, and participants will not be eligible to progress to subsequent levels of training.
Successful completion of the training programme corresponds to the award of 12 ECTS (European Credit Transfer and Accumulation System).

Target Audience
This call for applications is directed particularly, but not exclusively, to: (i) Regulators (members of National Medicines Regulatory Authorities and Ethics Committees); ii) Researchers (senior and junior) and clinicians; iii) Research project managers and Research centre administrators; iv) University lecturers; and v) Representatives of Professional Associations holding a bachelor's degree.

Places available
Partner institutions of the CT-Luso Project (Angola, Cape Verde, Guinea-Bissau, Mozambique and São Tomé and Príncipe) may nominate as many candidates as they deem appropriate according to their internal needs. Candidates must meet the eligibility requirements, which will be verified during the application review process.
Applications from other Portuguese-speaking African Countries (PSAC) will also be welcome and assessed according to the number of places available.

Eligibility Requirements
- Bachelor's degree;
- Fields of study:
  - Pharmaceutical Sciences / Pharmacy
  - Life Sciences
  - Biology and related áreas
  - Medicine
  - Nursing
  - Psychology
  - Sociology
  - Administration and Management

Graduates who are or will be involved in biomedical/clinical research and/or regulatory areas.

Graduates from other fields may also apply, provided they have proven experience in biomedical research, particularly clinical trials.

Application Procedures
Documentation to be submitted via the CT-Luso portal:
- Candidate's data, in accordance with the specific online application form;
- Letter of expression of interest;
- Short Curriculum Vitae.

Additional evidence of competences may be requested.

Submission of Applications
Fully completed applications must be submitted via the CT-Luso portal between **15 October and 15 November 2024**.
Applications are individual and must be submitted electronically via the following link: https://ct-luso.com/mod/page/view.php?id=49.

Evaluation of Applications
The evaluation will consider gender and generational balance, by country, and the representation of ethnic minorities, where appropriate, as well as:

- Verification of compliance with the eligibility criteria;
- Assessment of the Curriculum Vitae.

Exclusion Criteria
The following will result in exclusion:
- Submission after the application deadline;
- Failure to meet the eligibility requirements.

Notification of Results
The results of the applications will be announced by email and on the CT-Luso portal two weeks after the end of the application period.
The training programme is expected to start in December 2024.
For further information, please contact:
ct-luso@ordemfarmaceuticos.pt.

www.ct-luso.com

Annex 2
Programme Brochure (In Portuguese)

Annex 3
Training Programme

CONTENTS and SCHEDULE – ASSESSMENT METHODS	No. of hours: 111

Training Programme: Tuesdays and Thursdays; starting at 15:00 GMT.

Sessions: Theoretical-practical Sessions + Workshops

Assessment:
The assessment consists of a multiple-choice test for each module, composed of 12 to 20 questions, each with 5 answer options, to be taken online and starting in the last hour of the workshop day. The duration will be 30 to 60 minutes (with a 10-minute grace period), depending on the number of questions in the test.
The trainee must pass all modules. If a trainee does not pass a module, they will be invited to complete a short recovery assignment (approximately 2,500 characters) about that module. The final assessment – pass or fail – will be conducted by the deadline of 31 July.

Accreditation: 12 ECTS (NOVA Medical School (NMS) of the NOVA University of Lisbon + Faculty of Pharmacy of the University of Lisbon (FFUL)

1. Science and Ethics: Their Relationship

1.1. *(3 December 2024, 3hrs)* Science, Technology and Ethics

- The relationship between Ethics, Science and Technology: a historical retrospective
- Ways of intervention of ethics in the field of Science and Technology
- The emergence of Applied Ethics: genealogy and evolving challenges of ethics applied to biomedicine (bioethics)

1.2. *(10 December 2024, 3hrs)* Applied Ethics to Biomedicine

- From practice to theory
- Some models of Bioethics theorisation: core principles
- Ethical analysis: between principles, norms and cases

1.3. *(17 December 2024, 3hrs)* Ethical Deliberation

- Notion of Dilemma
- Requirements for Deliberation
- Confirmation of the decision

Trainer (all sessions): *M. Patrão Neves | University of the Azores | Academic Background: Philosophy*

1.4. *(7 January 2025, 3hrs)* ***Workshop*** about Fundamental Principles of Biomedicine in the PSAC

Moderator: *M. Patrão Neves*

Participants from the PSAC:

- *Cape Verde: José António Reis | National Ethics Committee for Health Research of Cape Verde (CNEPS) | Academic background: Psychology*

- *Guinea-Bissau: Mouhammed Djicó | National Health Research Ethics Committee of Guinea-Bissau (CNEPS) | Academic background: Social Sciences*
- *Mozambique: Esperança Sevene | National Committee for Bioethics in Health (CNBS) | Academic background: Medicine*
- *São Tomé and Príncipe: Eula Maquengo | Health Ethics Committee for Scientific Research (CESIC) | Academic background: Medicine*

Assessment Test

2. Research Integrity and Good Clinical Practice Requirements

2.1. *(9 and 16 January 2025, 4hrs)* Scientific Integrity and Responsible Research Conduct

Trainers: *M. Patrão Neves and Maria Alexandra Ribeiro | NOVA Medical School (NMS) | Academic background: Biology and Bioethics*

2.2. *(23 January 2025, 4hrs)* Good Clinical Practice Requirements: ICH-GCP and ISO Standards

Trainer: *Maria Alexandra Ribeiro*

2.3. *(30 January 2025, 4hrs)* Communication in Science and Biomedical Research

- Communicating Science
- Registration of Clinical Studies
- Publication and Dissemination of Research Results

Trainers: *Maria Alexandra Ribeiro and António Granado | Faculty of Social and Human Sciences (FSCH) | Academic background: Modern Languages and Literatures*

2.4. *(04 February 2025, 3hrs)* **Workshop** about Scientific Integrity and Good Research Practices in the PSAC

Moderator: *Maria Alexandra Ribeiro*

Participants from the PSAC:

- *Cape Verde: Isabel Araújo | University of Cape Verde (UniCV) | Academic background: Biomedicine*
- *Guinea-Bissau: Cesário Martins | Bandim Health Project (PSB) | Academic background: Medicine*
- *Mozambique: Vasco Muchanga | Faculty of Medicine, Eduardo Mondlane University | Academic background: Sociology*

Assessment Test

3. International Bioethics Institutions and Guidelines for Research and Health-Related Practices

3.1. *(6 and 13 February 2025, 4hrs)* Institutionalisation and Internationalisation of Bioethics

- The different bodies: nature and function
- The key international declarations

Trainers: *M. Patrão Neves e Maria Alexandra Ribeiro*

3.2. *(20 February 2025, 4hrs)* Ethical Principles of Clinical Research

Trainer: *Maria Alexandra Ribeiro*

3.3. *(27 February 2025, 4hrs)* Clinical Research and Health Infrasctuctures

- Life cycle of a clinical study
- Requirements of trial centres, support structures and quality management
- National and international organisational models: the example of an academic CRO

Trainers: *Lúcia Domingues | NMS | Academic background: Biomedicine and Sara Maia | NMS | Academic background: Biomedical sciences*

3.4. *(5 March 2025, 3hrs)* **Workshop** about Research Institutions in the PSAC

Moderator: *Emília Monteiro | NMS | Academic background: Medicine*

Participants from the PSAC:

- *Angola: Joana Paixão | National Institute of Health Research (INS) | Academic background: Epidemiology*
- *Cape Verde: Maria da Luz Lima | National Institute of Public Health (INSP) | Academic background: Medicine*
- *Guinea-Bissau: Francisco Samory Levy | National Institute of Public Health (INASA) | Academic background: Medicine*
- *São Tomé and Príncipe: Yardlene Sequeira | National Reference Laboratory for Tuberculosis and COVID-19 | Academic background: Clinical Analysis and Public Health*

Assessment Test

4. Public Health Issues and Infectious Diseases

4.1. *(6 and 13 March 2025, 4hrs)* Public Health

- Ethical, legal and political aspects in public health
- Foundations and strategies for action and planning in public health
- Infectious diseases and vectors – the REVIVE example

Trainers: *Ana Paula Rodrigues | National Institute of Health Doutor Ricardo Jorge (INSA) | Academic background: Medicine and Maria João Alves | INSA | Academic background: Microbiology*

4.2. *(20 March 2025)* Epidemiology and Research

- Introduction and methods in epidemiology
- Demographic, genetic and environmental factors in disease distribution
- Epidemiological surveillance and reserach

Trainer: *Ana Rodrigues | NMS | Academic background: Medicine*

4.3. *(25 and 27 March 2025, 4hrs)* Research Methods in Health

- General concepts and definitions in clinical research
- Types of clinical studies and study design
- Specific features of experimental clinical studies involving medicinal products, devices, nutrition and surgery

Trainer: *Emília Monteiro*

4.4. *(01 April 2025, 3hrs)* **Workshop** about Emerging Human and Animal Diseases

Moderator: *M. Patrão Neves and Sofia Núncio | INSA | Academic background: Biology*

Participants from the PSAC:

- *Angola: Maria Cecília Almeida | Ministry of Health | Academic background: Medicine*
- *Cape Verde: Lara Gómez | Jean Piaget University of Cape Verde | Academic background: Biology*
- *Guinea-Bissau: Inácio Alvarenga | World Health Organization (WHO) | Academic background: Medicine*
- *Mozambique: Osvaldo Frederico | National Institute of Health (INS) | Academic background: Veterinary Medicine*
- *São Tomé and Príncipe: Adionilde Aguiar | Ministry of Health – National Reference Laboratory for TB/HIV and COVID-19 – Health Delegate and CUF (Portugal) | Academic background: Medicine*

Assessment Test

5. Biobanks and Responsible Research Involving Humans, Fauna and Flora, and Patentable Innovation

5.1. *(03 April 2025, 4hrs)* Biobanks: Ethical, Legal, and Social Framework

- European Regulatory System
- Informed consent and privacy
- The importance of biobanks for biomedical research

Trainer: *Célia Ventura | INSA | Academic background: Clinical Analysis and Public Health*

5.2. *(10 April 2025, 4hrs) Organisation of a Biobank: Planning and Management of Human Biological Samples*

- Collection, processing and storage of biological samples
- Sample and data management in the biobank
- Quality management, access, use and sharing of biobank samples

Trainer: *Maria Assunção | NMS | Academic background: Molecular Cell Biology*

5.3. *(17 April 2025, 4hrs)* Biological Sample Banks of Animal or Plant Origin and Biomedical Research

Trainer: *Ana Paula Arez | Institute of Hygiene and Tropical Medicine (IHMT) | Academic background: Biology*

5.4. *(24 April 2025, 4hrs)* Research, Innovation, and Development: Intellectual Property and Patents

Trainer: *Diogo Antunes | Inventa International S.A | Academic background: Law*

5.5. *(6 May 2025, 3hrs)* ***Workshop*** about Research involving biological samples of animal and plant origin in biomedicine

Moderators: *M. Patrão Neves and Lúcia Domingues*

Participants from the PSAC:

- *Guinea-Bissau: Bucar Indjai | National Institute of Studies and Research (INEP) | Academic background: Anthropology*
- *Mozambique: Nidia Cangi Vaz | Eduardo Mondlane University | Academic background: Biology*

- *São Tomé and Príncipe: Miclay Carvalho | Agronomic and Technological Research Centre of São Tomé and Príncipe | Academic background: Agronomic Engineering*

Assessment Test

6. Regulatory Affairs

6.1. *(08 and 15 May 2025, 4hrs)* Principles of Regulation for Medicinal Products and Health Products: The Role of Regulatory Authorities

- European and Portuguese Regulatory Systems
- Marketing authorisation procedures
- Medicinal products and health products: medicinal products, traditional herbal medicinal products (including cannabis-based medicinal products), generic medicinal products and biosimilars, advanced therapy medicinal products, cosmetics, food supplements and plant - based functional foods

Trainers: *Beatriz Lima | Faculty of Pharmacy, University of Lisbon (FFUL) | Academic Background: Pharmaceutical Sciences; Isabel Vieira | INFARMED, I.P | Academic Background: Pharmaceutical Sciences; Helena Ribeiro | FFUL | Academic Background: Academic Background; Rosário Lobato | FFUL | Academic Background: Pharmaceutical Sciences e Olga Silva | FFUL | Academic Background: Pharmaceutical Sciences*

6.2. *(22 May 2025, 4hrs)* Clinical Trials with Medicinal Products

- Ethical and regulatory aspects
- The European approval system

Trainers: *Cecília Lima | INFARMED, I.P | Academic Background: Pharmaceutical Sciences e Leonor Nogueira | INFARMED, I.P. | Academic Background: Pharmaceutical Sciences*

6.3. *(29 May 2025, 4hrs) Risk Management System*

- Evaluation and safety monitoring of medicinal products and pharmacovigilance
- Post-authorisation studies and monitoring of medical devices

Trainers: *Diogo Almeida | FFUL | Background: Pharmaceutical Sciences; Carla Torre | FFUL | Academic Background: Pharmaceutical Sciences*

6.4. *(03 june 2025, 3hrs) Workshop about International Regulatory Systems*

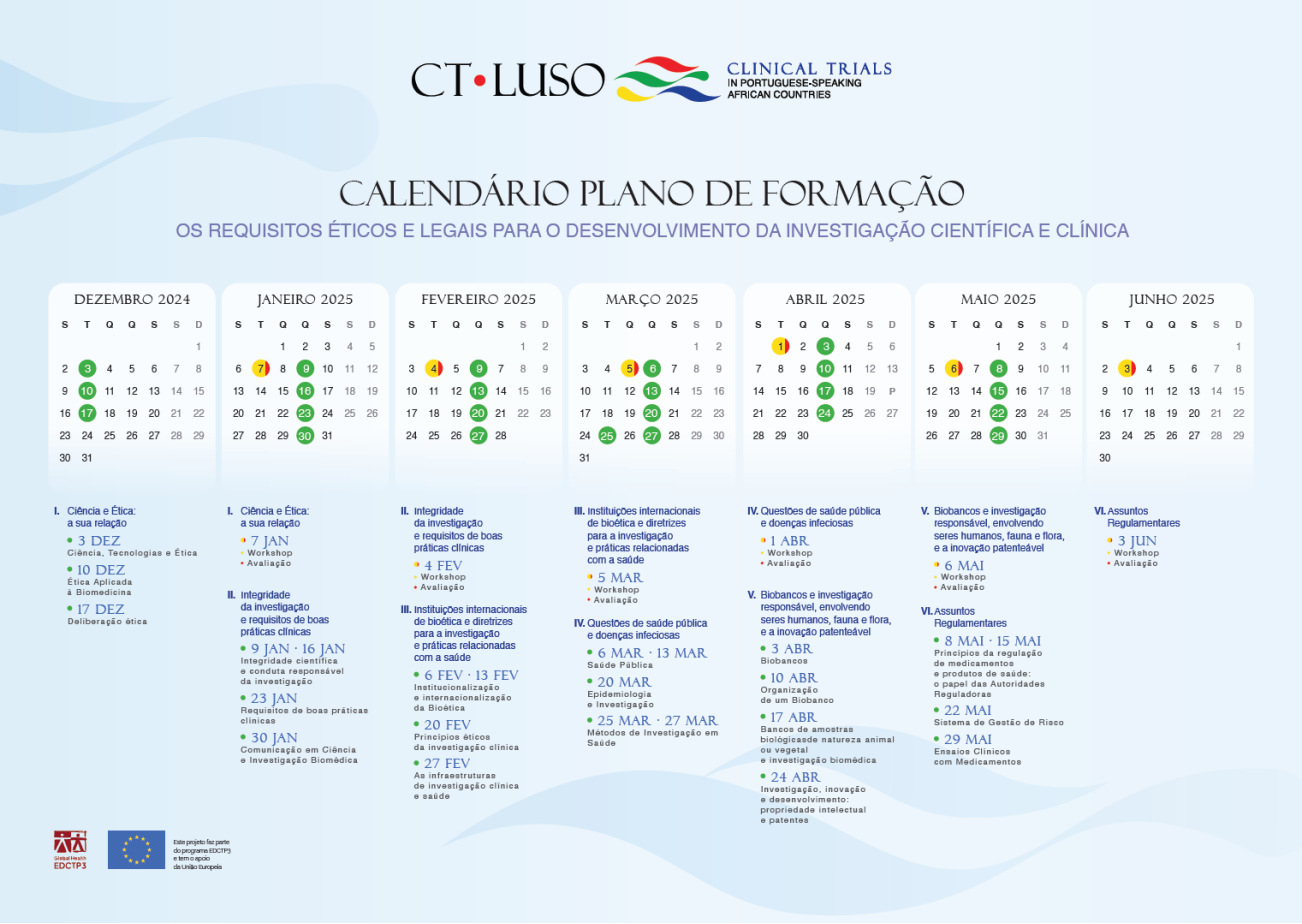
Moderation: *Bruno Sepodes | European Medicines Agency (EMA) | Academic Background: Pharmaceutical Sciences e Djamila Reis | OMS | Academic Background: Pharmaceutical Sciences*

Participants from the PSAC:

- *Cape Verde: Eduardo Tavares | Independent Health Regulatory Authority (ERIS) | Academic Background: Pharmaceutical Sciences*
- *Mozambique: Tânia Sitoie | National Medicines Regulatory Authority (ANARME, I.P.) | Academic Background: Pharmaceutical Sciences*
- *São Tomé and Príncipe: Hironisia dos Santos | Ministry of Health of São Tomé and Príncipe | Academic Background: Pharmaceutical Sciences*

Assessment Test

Annex 4
Timetable (In Portuguese)



Annex 5
Survey (Assessment of the Training Programme)

Assessment of Module X – Module Name

Dear trainees,

This survey is designed to evaluate **Module X** of the Training Programme *"The Ethical and Legal Requirements for the Development of Scientific and Clinical Research"* in its administrative and training aspects.

Completing it will take approximately two minutes, and we appreciate everyone's participation, as your feedback will help improve future modules.

Please rate the following aspects of Module X on a scale from **1 (minimum)** to **5 (maximum)**.

Thank you very much for your contribution.

Section 1 - Organisation of Sessions (Administration)

Please rate the following aspects related to the advance organisation of the sessions, from 1 (minimum) to 5 (maximum):

1. Provision of prior information about the course, timetable and supporting materials (Training Programme and schedule)[1]
2. Provision of prior information about access to the e-learning platform[1]
3. Clarification of questions raised by trainees before the start of the training/ the module

Section 2 - Module X Sessions (Training)

Please rate the following aspects related to the delivery of the sessions, from **1 (minimum)** to **5 (maximum)**.

1. Structure of the sessions – X theoretical sessions and 1 workshop
2. Duration of the sessions – intensive format, delivered one day per week
3. Organisation and structure of the content in relation to the module topic
4. Relevance of the content
5. Suitability of the content in relation to your level of knowledge of the topics
6. Clarity of delivery
7. Trainer – trainee interaction – clarification of questions, opportunities for participation (considering the conditions: approximately 300 trainees and via Zoom)
8. Supporting training materials – PowerPoint presentations
9. Activities and dynamics used during the sessions
10. Appropriateness of the final assessment – multiple-choice test

Section 3 – Post-Session Organisation (Administration)

Please rate the following aspects related to the organisation after the sessions, from **1 (minimum)** to **5 (maximum).**

1. Availability of training materials – presentations and session recordings
2. Ease of access to the materials
3. Response to trainees' logistical questions

Section 4 – Overall Assessment of Module X (Administration and Training)

Please rate the following aspects related to your overall assessment of Module X sessions, from **1 (minimum)** to **5 (maximum)**, except for the last question, which is open-ended.

1. Overall satisfaction with Module X
2. Contribution of the content to your training
3. Contribution of the content to your professional practice
4. Do you consider that improvements were made from Module X to Module X, based on trainees' suggestions?[2]
5. Suggestions for improvement for future modules[3] / What would you like to saw improved?[4] (open-ended)

[1] Questions included only in the surveys for M1 and M2.
[2] Question included from M2 onwards.
[3] Question asked in the survey for M1 to M5.
[4] Question changed in M6 survey.