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 4.3 – Complementary Training Programme

31 July 2025

Index

Thematic contextualisation

At the conclusion of the training course "The Ethical and Legal Requirements for the Development of Scientific and Clinical Research", foreseen under Work Package 4 (WP4) *"Interdisciplinary and Intersectoral Training"*, which began in December 2024 and was completed in June 2025, the coordination team of CT-Luso decided to organise a complementary distance (online) training programme, consisting of a series of webinars, intended:

(1) To further develop and deepen some of the topics covered in the course by subdividing broader themes into more specific issues;
(2) To reinforce the training provided by selecting new, related topics whose study may contribute to enhancing the trainees' educational qualification.

To this end, and following a trainee-centred training approach, the CT-Luso coordination team consulted all course participants to identify the key topics to prioritise in the complementary training programme.

Prospective consultation

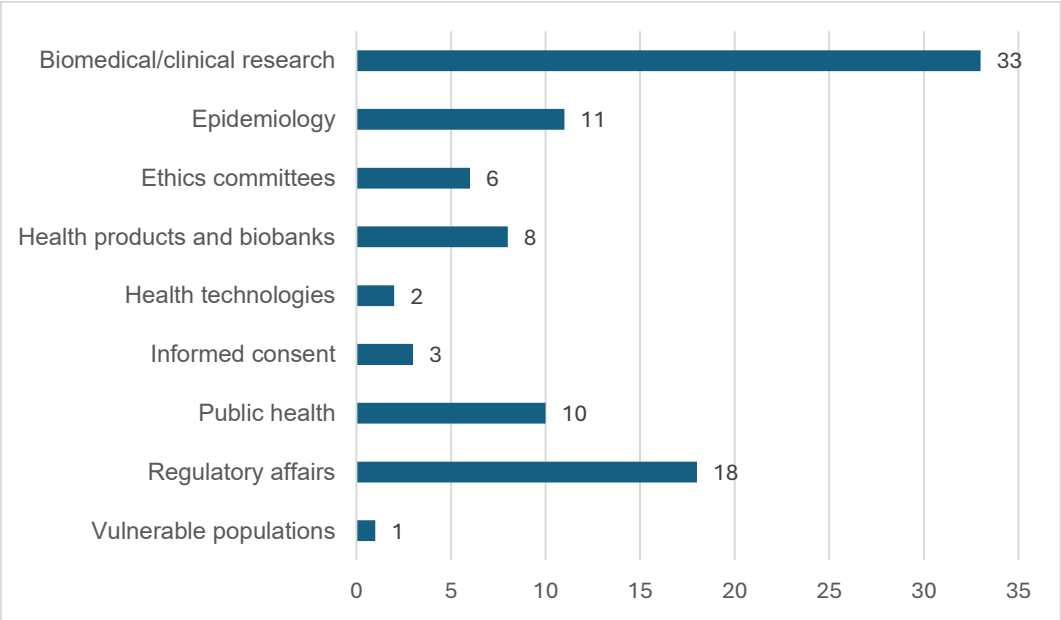
The prospective consultation was formally carried out through an online survey (Annex 1), made available during the first week of June (from the 4th to the 7th), which included two open-ended questions:

(1) "Among the topics covered in the Training Programme, which one(s) would you like to see further developed?"
(2) "Among the topics covered in the Training Programme, which one(s) would you like to see further developed?"

Both questions requested the specification "from which perspective or focusing on which subtopics?".

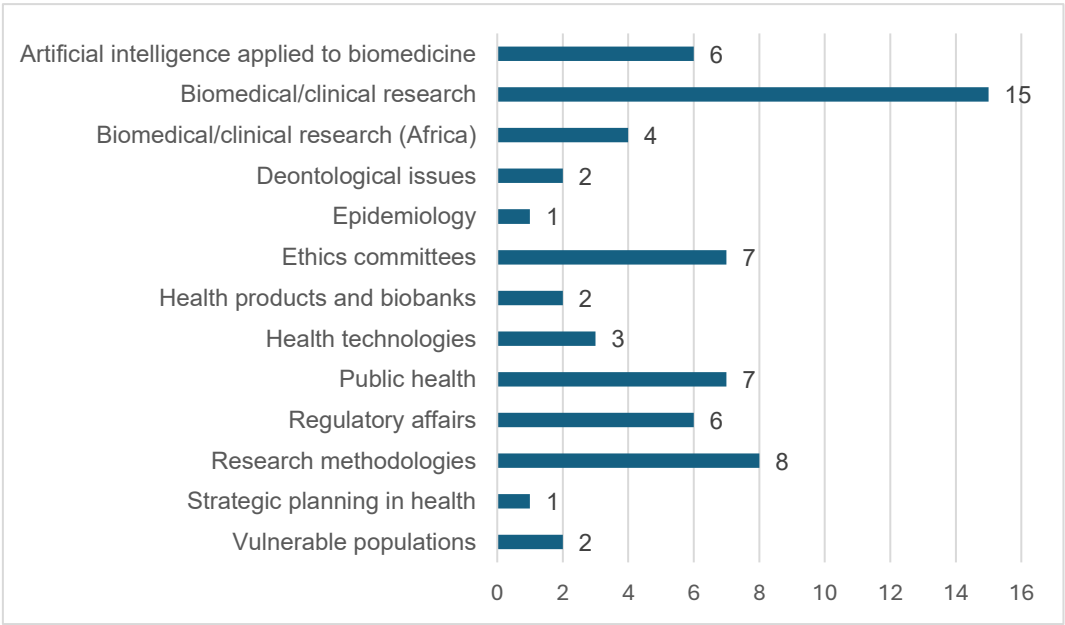
Seventy trainees participated, and their responses are summarised below. (Figure 1 and Figure 2).

***Figure 1** - Suggested topics for additional training (Question 1: 'Among the topics covered in the Training Programme, which one(s) would you like to see further developed?')*



Regarding the first question (Figure 1), the topic of "Biomedical/Clinical Research" stands out in the responses, receiving more than twice the level of interest expressed compared to the second most frequently mentioned topic, "Regulatory Affairs," followed by "Public Health" issues, particularly "Epidemiology."

***Figure 2** - Suggested topics for additional training (Question 2 – Which topic(s), currently absent from the Training Programme, would you like to be addressed?)*



Regarding the second question (**Figure 2**), the topic of "Biomedical/Clinical Research" is once again highlighted in the responses, showing twice the level of interest compared to the second most frequently mentioned topic, "Research Methodologies," followed by "Public Health" issues and those related to "Ethics Committees."

Although the first question is retrospective in nature and the second prospective, the convergence in responses to both is unsurprising, as they refer to thematic categories whose subtopics vary depending on whether they were covered during the course. In any case, the strong thematic alignment between the answers to the first and second questions clearly indicates the topics to be prioritised in the Continuing Training Programme.

It should be noted that a significant number of respondents (approximately 10%) considered the training, in general, to be highly enriching in terms of the diversity and depth of subjects covered and, therefore, did not suggest specific thematic developments or new topics for study.

In addition to considering the results of this formal consultation, informal feedback was also considered through oral sharing of trainees' opinions in various contexts, namely during question & answer sessions and workshops throughout the course delivery, as well as in written form through the appraisal of successive modules and the final overall course evaluation.

Both the formal and informal consultation processes converged in identifying the themes that trainees wish to see prioritised in the Continuing Training Programme.

Webinar Planning and Scheduling

Based on a quantitative and qualitative analysis of the surveys received, general thematic categories were established, grouping together a variety of proposed subtopics.

This work resulted in the following Programme and its corresponding Schedule (Table 1):

Table 1 *- Webinar Planning and Scheduling*

Date	Theme
October 2025	**Clinical and Non-Clinical Research:** Scientific methodologies and professional integrity. Good Clinical Practices. The role of Ethics Committees.
November 2025	**Regulatory Affairs in Africa:** International (ethical-legal) regulation, the African Medicines Agency, and harmonisation in the Portuguese-speaking African Countries. The particular case of drug and medical device approval.
January 2026	**Public Health and Epidemiology:** Epidemiological Surveillance, Neglected Tropical Diseases, Emergency management.
February 2026	**Clinical Research in Vulnerable Populations:** Standards regulating the inclusion of vulnerable populations in research. Community Engagement and Data Protection. Informed Consent and Health Literacy.
March 2026	**Regulatory Affairs and Clinical Trials:** Regulatory Authorities. Innovation, Risk Management and Safety. Pharmacovigilance.
April 2026	**Innovation in Health:** Transplantation, Genetic therapies, Artificial Intelligence, and Digital health products (software as a medical device). Equity in access to medicines.
May 2026	**Biomedical Research and Traditional Medicines:** Research involving animals (laboratory animal facilities) and focused on plant-based (botanical) products.

Annexes

Annex 1 – Survey Form

Introduction

"The purpose of this questionnaire is to identify additional training needs. Given the academic, scientific, and professional diversity of those who have completed the Training Course *"The Ethical and Legal Requirements for the Development of Scientific and Clinical Research"*, from five different countries, it is very likely that there are still topics which, according to each trainees' profile, would be of interest to explore in the future. CT-Luso will organise a series of webinars focused on the topics most frequently requested by you in the questionnaire below. Following your evaluations of each individual Module, it is now important to also assess the Training Course as a whole, and for that we kindly request your collaboration.

Part 1 – Specialised Complementary Training (open-ended responses)

1. Among the topics covered in the Training Programme, which one(s) would you like to see further developed?

1.1. From which perspective or focusing on which subtopics?

2. Which topic(s), currently absent from the Training Programme, would you like to see addressed?

2.1. From which perspective or focusing on which subtopics?

Part 2 – Overall Evaluation of the Training (select only one option)

1. How would you rate the Training Course overall?

Response options: 0 - Not satisfactory / 1 - Slightly satisfactory / 2 – Satisfactory / 3 – Good / 4 - Very good / 5 – Excellent

2. How would you rate the direct impact that the Training Course has had on your professional practice?

Response options: 0 - Not satisfactory / 1 - Slightly satisfactory / 2 – Satisfactory / 3 – Good / 4 - Very good / 5 – Excellent

3. If it had any impact, please specify what it was.

Thank you very much for your collaboration!

The CT-Luso Coordination Team

Annex 2 – "Among the topics covered in the Training Programme, which one(s) would you like to see further developed? From which perspective or focusing on which subtopics?"

Topic (original)	Topic (categorised)	Subtopic (original)	Subtopic (categorised)
Research integrity and Good Clinical Practice requirements	Biomedical/Clinical research	Science communication	Science communication
Health research	Biomedical/Clinical research	Clinical trials: practical cases	Clinical Trials
Plant-based medicines	Health products and biobanks	Development of the presented topics	Scientific papers
Regulatory affairs	Regulatory Affairs	Innovation and current challenges	Innovation
Scientific research	Biomedical/Clinical research	Improvement in the preparation of a scientific paper	Scientific papers
Regulatory and ethical issues in animal facilities and transport of animal samples	Regulatory Affairs	For the field of entomology	Entomology in Regulatory Affairs
Working with adolescents in malaria studies requires heightened attention to the ethical aspects of informed consent, especially when cultural, educational, or linguistic barriers exist. Furthermore, there are significant practical and ethical challenges in managing sensitive data in locations with limited infrastructure and less established legal frameworks.	Ethics Committees; Epidemiology; Vulnerable Populations; Informed Consent	1. Perspective of Justice and Equity in Research and Investigation on Vulnerable Populations (adolescents, communities with low educational levels, areas with limited access to healthcare). Informed consent adapted to the sociocultural and linguistic context. Fair distribution of research benefits, such as subsequent access to medicines.	Research in Vulnerable Populations; Informed Consent; Equity in Access to Medicines; GDPR; Safety and Risk Management

Topic (original)	Topic (categorised)	Subtopic (original)	Subtopic (categorised)
I also consider it essential to discuss more thoroughly the role of local ethics committees, their capacity building, and the mechanisms to ensure that scientific and clinical research truly respects the rights and dignity of participants, regardless of their socioeconomic context.		2. Perspective of Data Protection and Privacy Practical application of the GDPR in contexts with limited institutional capacity. Guarantees of anonymity in health and genetic data. Data sharing with other countries/institutions: risks and protective measures. 3. Perspective on Clinical Trials and Ethical Oversight Requirements for clinical trials in locations with fragile infrastructure. Capacity building of local Ethics Committees (IRBs/ECs). Reporting of adverse reactions (ADRs/SUSARs) and investigator responsibilities.	
1. Public health issues and infectious diseases. 2. International bioethics institutions and guidelines for health-related research and practices.	Epidemiology; Ethics Committees	1. All subtopics 2. All subtopics	N/A
Scientific research methods in health	Biomedical/Clinical research	Epidemiological methods	Epidemiology
In my opinion, some modules could be developed further: 2,3 e 6.	Biomedical/Clinical research; Ethics Committees; Regulatory Affairs	Topics focused on the area of clinical research	Biomedical/Clinical research

Topic (original)	Topic (categorised)	Subtopic (original)	Subtopic (categorised)
Epidemiological studies and ethical principles in clinical trials or clinical research	Epidemiology	Research methodology and types of studies	Research methodologies
Organ transplantation and gene therapies within the bioethical framework	Health Technologies	Bioethics	Bioethics
Incorporation of digital technologies Use of e-consent, remote monitoring, and digital tools. Decentralised clinical trials. Challenges and benefits of digitalisation.	Health Technologies; Informed Consent	Perspective of the Technology and Data Professional. Greater interest in: Electronic Data Capture (EDC) systems Information security Decentralised clinical trials and process digitalisation	Innovation; informed consent; GDPR
Regulation of Clinical Research aimed at integrating and facilitating the creation and development of the regulatory sector in PSAC as a foundational milestone for clinical research across Africa	Regulatory Affairs	Facilitate the creation and development of the regulatory framework for clinical research in the PSAC	Ethical-legal harmonisation in the PSAC
Ethical Principles; Epidemiology and Research; Research Regulation; Clinical Research; Science and Research Communication	Epidemiology; Biomedical/Clinical Research; Regulatory Affairs	Ethical regulation; Drug approval	Ethical regulation Drug approval
I would like a more in-depth discussion of the role of Ethics Committees and the scope of informed consent in the conduct of clinical trial studies and research.	Ethics Committees; Informed Consent	From a more technical-legal perspective	Responsibilities of Ethics Committees
Regulation in clinical trials	Regulatory Affairs	Aspects to consider in the implementation of clinical trial regulation	Regulatory Affairs in Clinical Trials

Topic (original)	Topic (categorised)	Subtopic (original)	Subtopic (categorised)
Biobank	Health products and biobanks	Deepen the topics discussed	N/A
1 – Public Health Issues 2 – Research Integrity and Good Clinical Practice Requirements	Public Health; Biomedical/Clinical Research	1 - Public Health, Epidemiology, and Health Research Methods 2 - Scientific Integrity and Responsible Research Conduct, Requirements of Good Clinical Practice, and Biomedical Research	Epidemiology; Research Methodologies; GCP
Research Methods	Biomedical/Clinical research	Research and development	Research Methodologies
Ethical principles of clinical research and planning in public health: a comparison	Biomedical/Clinical research	...	GCP; Public Health Planning
Health products	Health products and biobanks	Medical devices and in vitro diagnostics	Medical Devices; In Vitro Diagnostics
Clinical trials with medicines: monitoring and safety	Biomedical/Clinical research	Pharmacovigilance	Pharmacovigilance
Infectious disease and public health issues	Epidemiology; Public Health	Subtopics such as ethics in the implementation of health policies, equity in access to care, confidentiality and informed consent in vaccination campaigns, as well as ethical issues involving outbreak management and communication with the public. These topics help to reflect on the moral dilemmas and social responsibilities in the field of public health.	Public health planning; Bioethics

Topic (original)	Topic (categorised)	Subtopic (original)	Subtopic (categorised)
Research Ethics	Biomedical/Clinical research	Non-clinical research	Non-clinical research
Clinical trials with medicinal products	Biomedical/Clinical research	Pharmacovigilance	Pharmacovigilance
I would like the processes related to GCP inspection to be included.	Regulatory Affairs	How to conduct an inspection in clinical trials – at the initiation, during, and at the conclusion – covering the attitudes the inspector should maintain as well as the considerations the inspected party must consider avoiding non-compliance Planning and management of human biological samples	Regulatory affairs in clinical trials; GCP
Biobanks	Health products and biobanks	Planning and management of human biological samples	Organisation and management of biobanks
Principles of health product regulation	Health products and biobanks	Plant-based products The presentation of this topic was very brief due to time constraints. Given the relevance of this subject, I suggest its inclusion in future programmes.	Plant-based health products
Legal requirements for the regulation and supervision of clinical trials; Management of clinical trial authorisation applications at regulatory authorities; Evaluation of clinical trial dossiers at regulatory authorities;	Biomedical/Clinical research; Regulatory Affairs	Regulation and supervision of clinical trials	Regulatory affairs in clinical trials

Topic (original)	Topic (categorised)	Subtopic (original)	Subtopic (categorised)
Inspections of clinical trials by regulatory authorities			
I would like the topic of ethical and scientific risk assessment in clinical research projects to be explored in greater depth. Although it has been addressed, I believe its complexity warrants a more thorough examination, including practical examples adapted to different institutional contexts.	Biomedical/Clinical research	It would be useful to deepen: The practical application of ethical risk management tools, including risk matrix models and real case studies. The role of Ethics Committees in contexts with structural limitations (such as in the PSAC). Ethical decision-making in public health emergencies, such as epidemics and outbreaks, where it is not always possible to follow all formal procedures.	Regulatory affairs in clinical trials; Responsibilities of ethics committees; Clinical matters; Public health planning
Good Clinical Practices, like ISO standards; Medical device trials	Regulatory Affairs	European regulation and national legislation	International regulation
Scientific integrity in research	Biomedical/Clinical research	Focusing on research conduct	Regulatory affairs in clinical trials
Scientific integrity and responsible research conduct, Public health issues and infectious diseases	Biomedical/Clinical research	Ethical, legal, and political aspects in public health; Fundamentals and strategies for action and planning in public health	Bioethics; Science communication
Regulatory Affairs	Regulatory Affairs	Sessions 1 and 2 – Principles of drug and health product regulation: the role of regulatory authorities	Role of Regulatory Authorities
Ethics in emergency contexts	Public health	Pandemics	Pandemics
I would like the topic of ethics in biobank management to be explored in greater depth	Health products and biobanks	I propose a deeper exploration from the perspective of practical	Informed Consent; GDPR

Topic (original)	Topic (categorised)	Subtopic (original)	Subtopic (categorised)
		challenges and real-world dilemmas, focusing on the following subtopics: Informed consent in multicultural and low-literacy contexts. Benefit-sharing with donor communities. Confidentiality protection in the age of big data and AI.	
All the topics were relevant.	N/A	On ethical-legal issues: Informed consent	Informed consent
Drug regulation	Regulatory Affairs	Legislative initiatives in clinical research for drug development as the entry point for these issues	Regulatory affairs in clinical trials
Traditional medicines, novel foods, and cosmetics	Health products and biobanks	Indiscriminate use and public health guidance (the severe damage caused by hair dyes, extensions, and artificial nails to users)	Regulation of Health and Cosmetic Products
- Ethical and legal requirements for scientific and clinical research development - Health research methods. - Clinical trials	Biomedical/Clinical research; Regulatory Affairs	Applied or experimental studies (applied research)	Applied research
Public health	Public health	N/A	N/A
- Ethical and legal requirements for developing scientific and clinical research in evolving regulatory landscapes; - Pharmaceutical trials in resource-constrained settings	Biomedical/Clinical research	Applied research	Applied research

Topic (original)	Topic (categorised)	Subtopic (original)	Subtopic (categorised)
Research integrity and good clinical practice requirements, the institutionalisation of bioethics, public health planning, and the theme on bioethics communication	Biomedical/Clinical research; Comissões de Ética	With a focus on the realities of our countries, where policies are still in development and knowledge dissemination remains weak	Research in Vulnerable Populations; Organisation and management of biobanks
Module 3	Comissões de Ética; Biomedical/Clinical research	Scientific development	N/A
Module 4: Public Health and Infectious Diseases	Epidemiology; Public Health	Strengthening health systems for infectious disease prevention, surveillance and response with focus on equity and universal coverage; Priority subtopics for in-depth analysis: -Integrated epidemiological surveillance and rapid outbreak response; - Universal immunisation and preventive health coverage; - Social determinants of health in infectious diseases; - Public health emergency management - Climate change and emerging infectious diseases; - Community approach and social participation.	Public health planning; epidemiological surveillance; climate change; community engagement
Public health issues and infectious diseases	Epidemiology; Public Health	Fundamentals and action strategies and public health planning; Epidemiological surveillance and research.	Public Health Planning; Epidemiological Surveillance

Topic (original)	Topic (categorised)	Subtopic (original)	Subtopic (categorised)
Module 4; Module 6: Regulatory affairs; - Session 4: Clinical trials with medicinal products	Regulatory Affairs; Biomedical/Clinical research	Session 1 - Principles of drug and health product regulation role of regulatory authorities	Role of Regulatory Authorities
Approach to types of study	Biomedical/Clinical research	There was more discussion about quantitative studies, qualitative studies could also be discussed	Research methodologies
Research integrity and Good Clinical Practice requirements Public health issues and infectious diseases	Biomedical/Clinical research; Public Health	1. Science communication and biomedical research. 2. Fundamentals and strategy for action and planning in public health	Science communication; Public Health Planning
Final module. It was very specific to the field of medicinal products, which made it very difficult to fully understand for those not directly involved in that area.	Regulatory Affairs	I wouldn't specify, as the entire module was challenging for me.	N/A
Research integrity and Good Clinical Practice requirements Public health issues and infectious diseases	Biomedical/Clinical research; Public Health; Epidemiology	1.1. Good Clinical Practice requirements. 1.2. Communication in science and biomedical research. 2.1. Public health. 2.2. Epidemiology and research. 2.3. Health research methods.	GCP; Science communication; Public Health Planning; Research methodologies
In project design, the participation of each collaborator	Biomedical/Clinical research	From the perspectives of information and specimen exchange between countries, the possible existing sanctions, and the supervision criteria for participants in African countries, considering the issue of	International regulation; Research in vulnerable populations

Topic (original)	Topic (categorised)	Subtopic (original)	Subtopic (categorised)
		multiculturalism, since culture is not always science.	
Research guidelines; Ethics; Clinical trials.	Regulatory Affairs; Biomedical/Clinical research	More in-depth and with accreditation.	N/A
Institutionalisation and internationalisation of bioethics	Regulatory Affairs	Regulatory aspects of clinical trials	Regulatory affairs in clinical trials
Biobanks	Health products and biobanks	Human biobanks, conflicts of interest among entities regarding issues such as human cloning	Bioethics
Regulatory Affairs	Regulatory Affairs	From a legal perspective, encompassing the entire life cycle of a medicinal product—from research and development to the post-marketing phase (pharmacovigilance).	Regulatory affairs in clinical trials
Module 6 – Regulatory Affairs	Regulatory Affairs	Session 3 – Safety Monitoring and Risk Management: Essential in Pharmacovigilance	Safety and risk management; Pharmacovigilance
The topic of conflicts of interest in scientific and clinical research is fundamental but could be further developed. It would be valuable to explore best practices for identifying, managing, and disclosing various types of conflicts (financial, academic, personal), as well as how these conflicts can impact research integrity and public trust.	Biomedical/Clinical research	I would like the topic of Informed Consent to be explored in greater depth from the perspective of challenges faced by vulnerable populations. Specifically, focusing on the subtopics of: Communication strategies adapted to ensure understanding across different levels of literacy and cognitive abilities. Consent models for minors and the involvement of parents or guardians.	Informed consent; Science communication; Innovation

Topic (original)	Topic (categorised)	Subtopic (original)	Subtopic (categorised)
		Consent in emergency situations or in research contexts involving individuals unable to provide direct consent. Use of new technologies and their ethical and legal implications.	

Caption: GCP – Good Clinical Practice; GDPR – General Data Protection Regulation; PSAC – Portuguese-speaking African Countries

Annex 3 - "Which topic(s), currently absent from the Training Programme, would you like to see addressed? From which perspective or focusing on which subtopics?"

Topic (original)	Topic (categorised)	Subtopic (original)	Subtopic (categorised)
Clinical research in Africa	Biomedical/Clinical research (Africa)	Implementation of clinical studies in Africa	Biomedical/Clinical research (Africa)
Professional ethics	Deontological issues	Personal integrity and conscientious objection	Personal integrity and conscientious objection
Development of research protocols/projects	Research methodologies	Postgraduate studies	Postgraduate studies
Artificial intelligence and its regulation in healthcare	AI applied to biomedicine	Artificial intelligence and digital health products (software as a medical device)	AI applied to health products
Bioethics	Ethics Committees	Informed consent	Informed consent
Research involving live animal models	Biomedical/Clinical research	Entomological focus and trials in non-human mammals	Research in entomology/non-human mammals
I would like the program to address topics that are still underexplored but highly relevant for researchers working in low-income and vulnerable settings, such as: The ethics of research in emergency contexts and epidemic outbreaks. The decolonisation of science and the role of local communities in scientific decision-making	Vulnerable populations; Clinical/biomedical research; AI applied to biomedicine; Health literacy	It is recommended that the training programme incorporate a more applied and context-sensitive ethical approach, focusing on the real challenges faced by researchers working in vulnerable settings, during public health emergencies, and when using emerging technological tools. This approach emphasises social justice, local scientific sovereignty, and the researcher's responsibility in	Clinical/biomedical research (Africa); Ethical frontiers of science; AI applied to health research

Topic (original)	Topic (categorised)	Subtopic (original)	Subtopic (categorised)
The ethical challenges of applying artificial intelligence and predictive models in public health Additionally, I consider it essential to include subjects like ethical community engagement and responsible communication of scientific results in contexts with limited access to information.		addressing the new ethical frontiers of science.	
Scientific research	Biomedical/Clinical research	Greater emphasis on scientific research	N/A
It could be discussed the project management perspective within the African context; in other words, we should address more topics focused on African countries.	Biomedical/Clinical research (Africa)	Subtopic: the challenges faced from project writing to project implementation.	Biomedical/Clinical research (Africa)
The research process	Biomedical/Clinical research	Health	N/A
I would like them to provide a more detailed and thorough explanation of the clinical research process, as there are significant gaps in this area, even among academics.	Biomedical/Clinical research	From a professional perspective.	Clinical/biomedical research from a professional perspective
Research methodology	Research methodology	Scientific research in health	N/A
Organ and tissue donation	Health technologies	Bioethics	Bioethics

Topic (original)	Topic (categorised)	Subtopic (original)	Subtopic (categorised)
Practical training in monitoring activities. How to conduct visits for: Site Initiation Visit (SIV); Routine Monitoring Visit (RMV); Close-Out Visit (COV); How to review Case Report Forms (CRFs), source documents, protocol deviations, and adverse event reports	Biomedical/Clinical research	How to effectively supervise the research team; What the investigator should expect (or require) from monitoring visits; How to appropriately respond to findings from monitoring and inspections; Understanding what constitutes "good supervision" under GCP.	Clinical Trial Monitoring
Integration of clinical research based on phytotherapy (natural medicine), considering that, according to official data, 67% of the population in the PSAC still rely on traditional medicine due to insufficient access to conventional medicine. It would be valuable to address these issues, seeking comprehensive solutions to the challenges of medicinal healthcare in the PSAC and in the rest of Africa.	Biomedical/Clinical research; Health products and biobanks	Address issues related to clinical research based on traditional medicine, seeking definitive solutions for Africa	Traditional medicine
Research management platforms; Research monitoring	Biomedical/Clinical research	Type of information	Data Management; Clinical Trial Monitoring
Considering the reality in Angola and the absence of formal regulation regarding clinical trials, it would be valuable to address a topic focused on international guidelines related to clinical trials.	Regulatory Affairs	From legal and technical perspectives.	Ethical-legal framework

Topic (original)	Topic (categorised)	Subtopic (original)	Subtopic (categorised)
Ethics in the preparation of research projects	Ethics Committees	Ethical issues and budget	Financial issues
Scientific research methods	Biomedical/Clinical research	All themes	Research Methodologies
Criminalisation of irregular acts in research	Regulatory Affairs	Conducting clinical research outside legally approved standards	Criminalisation of Misconduct
Relationship between Deontology and Ethics	Deontological Issues	...	Deontological Issues
Vaccines	Public health	Trial, Production and Control	Vaccines
Aspects related to Artificial Intelligence	AI applied to Biomedicine	Human production or cloning	Human Production/Cloning
Topics such as social justice in the distribution of healthcare resources, the impact of public policies on social vulnerability, and the ethics of using emerging technologies – such as artificial intelligence in healthcare – would also be highly relevant.	Vulnerable populations; AI applied to biomedicine	Public policies and social responsibility: ethical analysis of governmental decisions and their impact on the most vulnerable populations. Emerging technologies in healthcare: ethical use of artificial intelligence, big data, and telemedicine, including issues of privacy and consent. Social impact of health interventions: how public health actions affect different social and cultural groups, promoting inclusion and respect for diversity.	Public Policies and Social Responsibility; Social impact of health interventions

Topic (original)	Topic (categorised)	Subtopic (original)	Subtopic (categorised)
Ethical principles in non-laboratory settings	Biomedical/Clinical research	Qualitative research	Research Methodologies
Topics related to regulatory inspection and supervision	Regulatory Affairs	Take into account the global context for conducting clinical trials, with the aim of training inspectors capable of supporting the entire clinical trial process in compliance with regulations and ethical considerations.	Clinical Trial Monitoring; Human Resources Training
Quantitative data for public health research	Biomedical/Clinical research; Public health	Quantitative research with practical exercises	Research Methodologies
It would be relevant to include the topic of clinical and scientific research in contexts of institutional fragility and international cooperation, with a special focus on the realities of developing countries.	Biomedical/Clinical research (Africa)	I suggest that the topic be addressed from the following perspectives: Challenges and best practices to ensure scientific and ethical integrity in resource-limited settings; Management of international research partnerships, including legal, cultural, and operational aspects; Social responsibility and communication of results to the community, especially in projects involving vulnerable populations.	Challenges of biomedical/clinical research (Africa); International partnerships; Science communication
Scientific Writing Applied Statistics Development of Research/Scientific Projects	Biomedical/Clinical research; Research Methodologies	Support in developing skills to write articles, reports, and research projects clearly and objectively; Data analysis and interpretation of scientific results	Scientific papers

Topic (original)	Topic (categorised)	Subtopic (original)	Subtopic (categorised)
I would like future training programmes to cover topics such as bioethics applied to forensic genetics, protection of genetic data and privacy, and international regulation of forensic research, with a practical focus on population studies and DNA databases. These contents would be highly relevant to the forensic reality in Cape Verde.	Biomedical/Clinical research	No	N/A
Organise webinars on Research Ethics Committees (RECs), Grant Proposal Writing, and Scientific Writing.	Ethics Committees	Organise short courses and webinars	N/A
Cost of medicines in Angola or Africa and their impacts: Critical analysis and proposals for optimisation toward sustainable access.	Biomedical/Clinical research (Africa)	Price cap theory; Health economics; Tax effects.	Price cap theory; Health economy
A missing topic that I consider important is the quality management and accreditation of biobanks, as well as technological innovation applied to sample preservation.	Health products and biobanks	I would like the topic to be addressed with a focus on: • International standards (such as ISO 20387); • Good laboratory practices and quality control; • Digitalisation and the use of biobank management systems (LIMS); • Sustainability and long-term funding models	Regulation; GCP; Management systems; Funding
Research methodology	Research methodology	Bioethics	Bioethics

Topic (original)	Topic (categorised)	Subtopic (original)	Subtopic (categorised)
Fortunately, I participated in all of them. However, I still suggest regular training (every two years), especially for us Africans, whose reality in the development, regulation, and management of pharmaceuticals and medicines is still in its infancy. Therefore, it is essential and truly necessary to have all possible support to better understand these subjects and apply them effectively.	Regulatory Affairs	From the perspective that knowledge is meant to be shared and not kept hidden, it calls upon the world regarding the development, regulation, and management of pharmaceuticals and medicines.	Development, regulation, and management of medicines
In vitro fertilisation	Health Technologies	Wide coverage	In vitro fertilisation
Methods or procedures for the disposal of animals, medicines, and medical devices used in clinical trials involving living beings	Biomedical/Clinical research	From the perspective of public health safety	Public health
Public health	Public health	Utilisation	N/A
Methods or procedures for the disposal of animals, medicines, and medical devices used in clinical trials involving living beings	Biomedical/Clinical research	Public health safety	Safety
I am satisfied with all the topics covered; however, I feel that there should be more practical exercises tailored to the realities of the countries.	N/A	I don't think it's necessary to add any new topics; rather, we should explore how artificial intelligence can serve as a beneficial tool for research.	AI applied to health research
Scientific research methods	Research methodology	I did not understand	N/A

Topic (original)	Topic (categorised)	Subtopic (original)	Subtopic (categorised)
Management and strategic planning in health systems	Strategic planning in health	Strategic and Evidence-Based Planning Leadership in Health and Human Resource Management Financing and Sustainability of Health Systems Evaluation of Health Policies and Programme	Evidence-based planning; Leadership in health; Financing; Sustainability of health systems; Evaluation of health policies and programmes
Environmental health and determinants of human health	Public health	Strategy and actions for improving environmental sanitation	Environmental sanitation
Scientific methodology	Research methodologies	Clinical analysis laboratory	Clinical analysis laboratory
Ethics of research in public health emergency situations	Public health	Explore real cases and best ethical practices in health crisis situations (e.g., COVID-19)	Ethics in emergency contexts
Data analysis using various software: Stata, R, and others	Health technologies	The perspective is to understand how to interpret the data obtained	Data analysis
Challenges of public health in the context of the PSAC	Public health	Provide more details on public health vulnerabilities in the context of the PSAC	Public health in the PSAC
Ethics in public health research, ethics of scientific authorship, ethics of research in the digital environment	Public health; Ethics committees	Data collection on social networks and online environments, authorship order and co-responsibility, traceability and anonymisation of online data	Digital environments in ethics
Module 4 session – Research methods in health	Research methodologies	Module 6: Session 4 - Clinical trials with medicines	Clinical trials

Topic (original)	Topic (categorised)	Subtopic (original)	Subtopic (categorised)
Approach to qualitative studies	Research methodologies	Case analysis	Clinical trials
Role of the ethics committee in the evaluation and approval of research protocols	Ethics Committees	How to develop an ethically accepted research protocol	Research protocol
I believe there could have been more focus on how to conduct an ethical evaluation of a clinical trial, as without this, research cannot proceed. The other topics, although very interesting, did not adequately address these aspects.	Ethics Committees	In general, I find the questions very repetitive!	N/A
(1) Neglected tropical diseases and (2) global food safety.	Epidemiology	Neglected tropical diseases and global food safety (processed products)	Neglected tropical diseases; Food safety
In the area of procurement and management of consumable supplies.	Regulatory Affairs	Legislation from different countries, legal and illegal trade;	Ethical and legal framework
Bioethical aspects and research involving human subjects	Ethics Committees	Exploring ethical dilemmas and challenges in science and medicine;	N/A
Ethical and legal aspects of artificial intelligence use in scientific research development	AI applied to biomedicine	Discussing the legal, moral, and ethical aspects of using artificial intelligence in science;	AI applied to health research
Artificial intelligence applied to the pharmaceutical sector	AI applied to biomedicine	The role of artificial intelligence in accelerating drug discovery and development, optimising pharmaceutical production and manufacturing, and strengthening regulation and safety in the pharmaceutical sector.	AI applied to health research

Topic (original)	Topic (categorised)	Subtopic (original)	Subtopic (categorised)
Although the training includes participants from various countries, a topic that could be addressed in a future webinar is specific legislation and national contexts (comparative). It would be very useful to have: A comparative analysis of the main laws and ethics regulations in research across the different participants' countries (e.g., Cape Verde, Portugal, Brazil, Angola, Mozambique). A discussion on how international guidelines are adapted and implemented locally. Case studies or ethical challenges specific to each national context.	Clinical/biomedical research; Regulatory Affairs	For ethics in qualitative and/or social research, I would like an approach oriented toward methodological and practical dilemmas. The suggested subtopics include: - Specific challenges of informed consent in methodologies such as in-depth interviews, focus groups, or participant observation; - Strategies to ensure confidentiality and anonymity in rich and contextual data, especially in sensitive studies; Ethical issues in the researcher–participant relationship, such as dual roles and limits of intervention. - The impact of research on the studied communities and the importance of ethically and sensitively returning results.	Research methodologies; GDPR; GCP; Science communication

Caption: AI – Artificial intelligence; GCP – Good Clinical Practice; GDPR – General Data Protection Regulation; PSAC – Portuguese-speaking African Countries