Taylor & Francis
Taylor & Francis Group

Global Public Health

An International Journal for Research, Policy and Practice

ISSN: 1744-1692 (Print) 1744-1706 (Online) Journal homepage: www.tandfonline.com/journals/rgph20

The BERC-Luso project: Legislative, institutional, and educational impact evaluation

Jorge Pedro Barroso Batista, Maria Alexandra Ribeiro, Leonor Soares, Joana Araújo, Helder Mota Filipe & Maria do Céu Patrão Neves

To cite this article: Jorge Pedro Barroso Batista, Maria Alexandra Ribeiro, Leonor Soares, Joana Araújo, Helder Mota Filipe & Maria do Céu Patrão Neves (2025) The BERC-Luso project: Legislative, institutional, and educational impact evaluation, Global Public Health, 20:1, 2499094, DOI: 10.1080/17441692.2025.2499094

To link to this article: https://doi.org/10.1080/17441692.2025.2499094

Published online: 06 May 2025.

GLOBAL PUBLIC HEALTH
2025, VOL. 20, NO. 1, 2499094
https://doi.org/10.1080/17441692.2025.2499094

Routledge
Taylor & Francis Group

CASE REPORT

OPEN ACCESS

The BERC-Luso project: Legislative, institutional, and educational impact evaluation

Jorge Pedro Barroso Batista [a,b], Maria Alexandra Ribeiro [c,d], Leonor Soares [a], Joana Araújo [e], Helder Mota Filipe [a,f] and Maria do Céu Patrão Neves [g]

[a]Portuguese Pharmaceutical Society, Lisbon, Portugal; [b]Instituto de Higiene e Medicina Tropical, Universidade NOVA de Lisboa, Lisbon, Portugal; [c]Portuguese National Ethics Committee for Clinical Research, Lisbon, Portugal; [d]NOVA Medical School, Lisbon, Portugal; [e]Universidade da Maia, Maia, Portugal; [f]Faculty of Pharmacy, University of Lisboa, Lisbon, Portugal; [g]Faculty of Humanities and Social Sciences, University of the Azores, Ponta Delgada, Portugal

ABSTRACT

The Biomedical Ethics and Regulatory Capacity Building for Portuguese-Speaking African Countries Project (BERC-Luso) was a four-year project that aimed to enhance biomedical ethics and regulatory capacities in five Portuguese-Speaking African Countries (PSAC). BERC-Luso was developed considering the PSAC scarce number of clinical trials, exploring an untapped potential. The project's interventions focused on three primary areas: legislative, institutional, and capacity building. The common aim was to create attractive conditions for conducting clinical trials, guaranteeing population protection and benefit of the country. The project evaluated national legislative frameworks and recommended strengthening actions. Through implementing top-down and bottom-up approaches, BERC-Luso involved ministries, political stakeholders, policymakers, and diplomatic channels. These strategies prompted legislative initiatives and reforms. The outcomes evaluation reflected a high level of success rate, with 78.59% of the targets being achieved. The impact level was demonstrated by the engagement with stakeholders, resulting in activities that impacted over 71,149 professionals. The project emphasises the need for more investment in capacity-building, reinforcing best practices' implementation at legislative, institutional and training levels. BERC-Luso fostered collaboration between partner countries, contributing to a supportive environment of African biomedical research.

ARTICLE HISTORY
Received 26 October 2024
Accepted 23 April 2025

KEYWORDS
Biomedical ethics; regulatory capacity building; Portuguese-Speaking African Countries (PSAC); clinical trials; legislative frameworks

Introduction

The Biomedical Ethics and Regulatory Capacity Building for Portuguese-Speaking African Countries Project (BERC-Luso) was a four-year project (2018–2022), financed by the European and Developing Countries Clinical Trials Partnership (EDCTP) that aimed to enhance biomedical ethics and regulatory capacities in Angola, Cabo Verde, Guinea-Bissau, Mozambique, and São Tomé and Príncipe, the Portuguese-speaking African countries (PSAC). This was the first time that all PSACs were convened in a single project with the aim to attract biomedical research and boost capacity in the field. The Project was supported by the World Health Organization

CONTACT Jorge Pedro Barroso Batista jorge.batista@ordemfarmaceuticos.pt Rua da Sociedade Farmacêutica 18, 1169-075 Lisboa, Portugal

(WHO) and the United Nations Educational, Scientific and Cultural Organization (UNESCO) (Patrão Neves & Batista, 2021).

There were three determining factors to draw up this project that shaped its design:

- *Scientific,* in its economic impact. Biomedical research, particularly clinical trials, is a driving force of clinical, scientific, technical, economic, educational and social development, with direct (e.g. access to innovative medicines and cutting-edge technologies) and indirect (e.g. establishment and associated industries and services) gains (Lang & Siribaddana, 2012). However, only 3.84% of clinical trials are carried out in Africa, and only 1.11% of these are in Portuguese-speaking African countries (*Studies on Map – ClinicalTrials.Gov, n.d.*).
- *Social* in the need to benefit and protect the population. African countries can become extremely attractive for conducting clinical trials and other biomedical research due to two main aspects. One, structural, concerns the favourable natural and unique conditions the continent offers: one of the world's largest working-age populations; a genetically diverse population which has mostly not yet been exposed to any types of medicines thus reducing the risk of drug–drug interaction which is essential in clinical research to minimise bias; a significant number of neglected endemic tropical diseases (e.g. Dengue, Malaria, Human African Trypanosomiasis); improvements in infrastructure, and continued investment (Taylor-Robinson et al., 2021; Weigmann, 2015). A second aspect, circumstantial, concerns the lack of a robust regulatory and institutional framework, and the paucity of highly qualified professionals for evaluation, authorisation, and supervision of clinical trials. Clinical trial sponsors seek safe environments to carry out research: comprehensive and clear regulations, efficient institutions and skilled professionals (Hwenda et al., 2022). Provided that there is a lack of the conditions above mentioned, these countries are at a disadvantageous level. However, the rapid development and implementation of regulatory frameworks and training of highly capacitated professionals is a golden opportunity to overcome this and make African countries more attractive for clinical research.
- *Justice* in overcoming a chronic situation of exclusion. Capacity building in Africa that has been promoted for decades by international institutions, such as the WHO and UNESCO, is invariably carried out in English and French, marginalising Portuguese-speaking African countries (Patrão Neves & Batista, 2021).

The Project aimed at reviewing and revising the legislative framework, building capacity at the national level – through training high-level professionals and creating a body of knowledge of ethical revision of biomedical research in Portuguese language –, and implementing good practices at both the National Ethics Committee (NEC) and the National Regulatory Authority (NRA) levels. These solutions sought to be addressed through a detailed plan of action during the time span of the project, with multiplying effects past its deadline, and a high emphasis on sustainability.

BERC-Luso aimed at acting at three priority levels – legislative, institutional, and capacity building –, to create appropriate and attractive conditions for conducting biomedical research and clinical trials, guaranteeing the protection of the population and benefit of the country. These priority domains were selected as they are the cornerstone for biomedical research in a country. Furthermore, the domains were directly linked and intertwined with the Project's 4 Work Packages, and they pose a strategic importance to the implementation of clinical trials in PSAC: legislative actions mould the legal framework of a country, institutional interventions facilitate good practice implementation at NRA and NEC level, and capacity-building activities guarantee and secure highly skilled professionals on the evaluation, authorisation, and supervision of clinical trials.

BERC-Luso planning, strategies and actions

BERC-Luso focused on drafting legislation, setting up institutions, and building capacity through training professionals. It developed into four Work Packages (WP), four lines of intervention

that intersect as they unfold. The project's implementation strategy was a determining factor in its success, developing in two complementary directions: both top-down and bottom-up approaches. This global strategy, detailed below in each WP, has resulted in the strengthening of relationships and trust between stakeholders, intensifying interventions and promoting objectives, contributing to the project's effectiveness.

WP1 On legislation (*De Legis*), worked at the level of political and legislative power. Contact was made with multiple policy and diplomatic stakeholders for early involvement. Each PSAC's Ministry of Health appointed a lawyer to build up an international legal team. PSAC ambassadors in Portugal were engaged, acting as interlocutors between the political and legislative African decision-makers and the Portuguese Project coordination. WP1 progressed *top-down*. Relations were established and strengthened with the political authorities, specifically with the Ministries of Health, which appointed lawyers and trainees for the project, and the Embassies of the PSAC in Lisbon. Ambassadors and Senior Diplomatic Officials were involved through presenting the project, continued collaboration, and sharing its findings and outcomes.

Acting on legislation focused on the current legislation in the PSAC within the field of biomedical research and clinical trials. Through comparative analysis of existing legislation with international good practices, the international legal team identified the missing requirements in each national law. This resulted in concrete proposals to the construction and consolidation of a legislative framework in line with international good clinical practice, so that PSAC can host, collaborate and lead international biomedical research projects (Martinho da Silva, 2019).

WP2 and WP3 On education and training (*De educationis* and *de praxis*), worked at the level of institutions, professionals and capacity building. Each PSAC identified five professionals, from existing bodies working as NRA and NEC, to participate in the project as trainees. WP2 and WP3 progressed *bottom-up*. A capacity-building programme was developed, with participants co-creating a strategic framework with time-bound progress targets for their institutions, and to lobby their countries' legislative and political authorities.

Acting on education consisted of a theoretical-practical educational programme on ethical and legal requirements for biomedical research and clinical trials in line with international best practices. *Acting on training* consisted of a hands-on internship in the Portuguese institutions that carry out the regulatory (NRA) and ethical (NEC) evaluation inherent to the entire scientific project. Educational and training programmes focused on the capacity building of professionals in each PSAC for the regulatory and ethical evaluation of biomedical research projects, specifically those involving human participants in clinical trials, considering international good practices. Throughout the education-training programme, respective national laws were reviewed, and appropriate changes in NRA and NEC were identified, based on the needs of everyday practice in each PSAC.

WP4 On connecting (*De rete*), centred on institutions, professionals and building networks, and enabled the trainees to become national promoters of BERC-Luso's objectives through targeting healthcare professionals, professional associations, research centres, universities, the government, policymakers, and lawmakers. This ensured the project's multiplier effect beyond its official end date. WP4 progressed *bottom-up-top-down*. Professionals and institutions increased direct pressure on politicians and legislators in meetings. Working together with all the institutions and professionals identified as potential stakeholders promoted the necessary legislative and institutional changes to host and be attractive to clinical trials.

Acting on connecting took place internally and externally. Internally, new forms of online connection were introduced as the project unfolded, such as a Facebook group for community building, a public website for communication and dissemination of the project's actions and results, and a co-working website platform for project participants with open access to all materials produced and collected, creating a repository in Portuguese. Externally, synergies were established in each country (such as working groups and focus groups), with each working team contributing as a lobbying group, each trainee into a trainer among their peers and into educators of the population. This was further reinforced by the presence in media, national television and radio, and social media

(*BERC-Luso – Biomedical Ethics and Regulatory Capacity Building Partnership for Portuguese-Speaking African Countries*, 2019).

It was thus possible to create a network that expanded and strengthened as the project progressed.

Evaluating outcomes and impacts

Evaluation is an integral part of the project, both as a formal requirement and because of the advantages of assessing, throughout its course, how well the various stages have been achieved.

The BERC-Luso project evaluation was carried out based on indicators drawn up by the project participants (trainees) and coordinators. At the end of the project (year 4), two sets of indicators were systematised for evaluating results: one related to the level of achievement of the proposed targets; the other related to the level of impact achieved by BERC-Luso on society in general and on its different interlocutors.

Indicators to evaluate the level of achievement

The first set of indicators included developing national roadmaps with actions to lever development at legislative, institutional, and capacity-building areas, which were refined in the course of its development. Countries' target information (available as Appendix) details national indicators. In the second year of the project (WP2), based on an analysis of their specific national situation and development level, each team of trainees set concrete and realistic targets at every level to be achieved, identifying the respective strategies to meet them. A year later, a preliminary joint evaluation of the targets was carried out, followed by fine-tuning. This was essential due to the impact that the COVID-19 pandemic had on the project, requiring the revision of the targets' completion dates, rethinking any other aspect planned but not carried out, or considering new targets to be integrated. Targets were framed having in mind the current and future impact of the COVID-19 pandemic on the project´s development.

Indicators were evaluated based on score points: fully completed = 100%, partially completed = 50%, not completed = 0%. At the end of the project, score points were attributed to each indicator, with the calculation of score mean values.

Three types of indicators were assessed to evaluate the *level of achievement*:

- legislative indicators, including revising and adapting existing legislation in line with international best practice and drafting new legislation.
- institutional indicators, including the restructuring or creation of NRA and NEC.
- capacity-building indicators, including training programmes, internships, and webinars, producing papers and public work presentations.

Overall, there were 57 targets mapped within the 5 PSAC, as follows (Figure 1):

- Angola, 13 indicators (4 legislative, 7 institutional, 2 capacity-building)
- Cabo Verde, 12 indicators (5 legislative, 4 institutional, 3 capacity-building)
- Guinea-Bissau, 5 indicators (2 legislative, 2 institutional, 1 capacity-building)
- Mozambique, 13 indicators (2 legislative, 8 institutional, 3 capacity-building)
- São Tomé and Príncipe, 14 indicators (3 legislative, 8 institutional, 3 capacity-building)

The evaluation of these indicators concluded that the success rate in the achievement through roadmap and indicators' analysis, was 78.59%, a high success rate achieved, as follows:

- 63.16% ($n = 36$) fully completed.
- 36.84% ($n = 21$) partially completed.

No proposal was left completely unfinished.

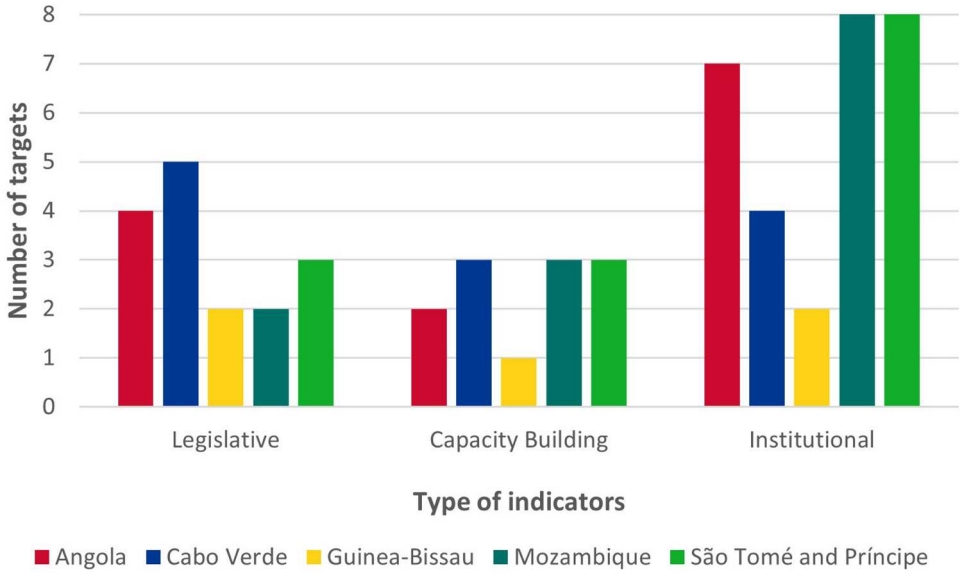

Figure 1. Type of objectives.

Analysis per country (Figure 2) shows varying degrees of success from 60.00% (Guinea-Bissau) to 96.43% (São Tomé and Príncipe). This means that all the countries achieved well over 50% of the set targets, defined as a minimum to be considered as successful.

In general, targets partially achieved refer to those that fell outside the direct scope and responsibility of the project partners during the project time span (e.g. financing mechanisms, political instability/elections), or were still ongoing at the time of the end of the project (e.g. working groups to review national laws, continuous adaptation of *modus operandi* in view of recent training).

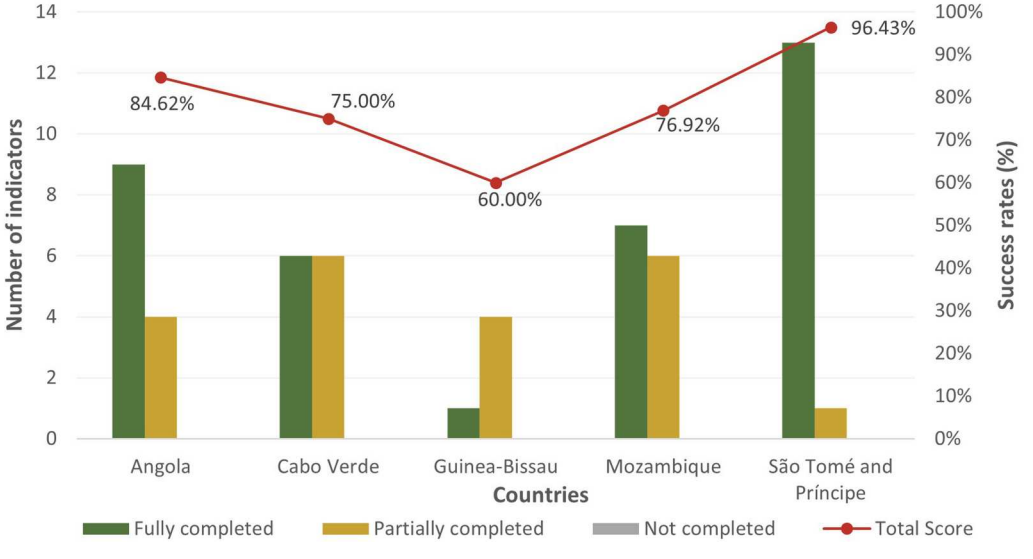

Figure 2. Score for each country.

Indicators to evaluate the level of impact

Concerning the indicators to measure the *level of impact* on society in general and on its different interlocutors, there were four types of actions with descriptive analysis evaluated within the five countries:

- High-level meetings included monthly meetings with partners; audiences with PSAC Ambassadors in Portugal; BERC-Luso coordination meetings with the trainees of all PSAC; meetings between BERC-Luso and other international projects; meetings with political and institutional leaders in all PSAC. There were 127 high-level meetings which impacted at least 265 people.
- Public events included a Symposium in Lisbon; Opening Session of the educational programme in Cabo Verde and the Solemn Session with the participation of the Minister of Health and Social Security of Cabo Verde; participation in the 9th, 10th and 11th EDCTP Forum, and in the African-European Symposium; organisation of one workshop/conference on clinical trials and biomedical research in each of the PSAC; TV broadcast of the project's initiatives and Radio interviews. There were 26 public events that impacted more than 2,240 people, considering mass media and public coverage of some of the actions.
- Publications included 48 BERC-Luso Newsletters, three peer review articles published, seven posters presented in conferences and international meetings. There were 120 publications that impacted more than 68,521 people.
- Trainings included 36 webinars, an educational programme for lawyers, a training on biomedical research and clinical trials in Cabo Verde, and a training programme on ethical/regulatory review of clinical trials in Lisbon. There were 39 training sessions which impacted 123 people and included 172 h of training and education.

Overall, 311 activities were developed, impacting at least 71,149 professionals from different backgrounds (Figure 3). Over 172 hours of training were delivered, and the project registered mass dissemination through television broadcast, radio, and media. The impact assessment shows high engagement with multiple stakeholders, through diverse activities.

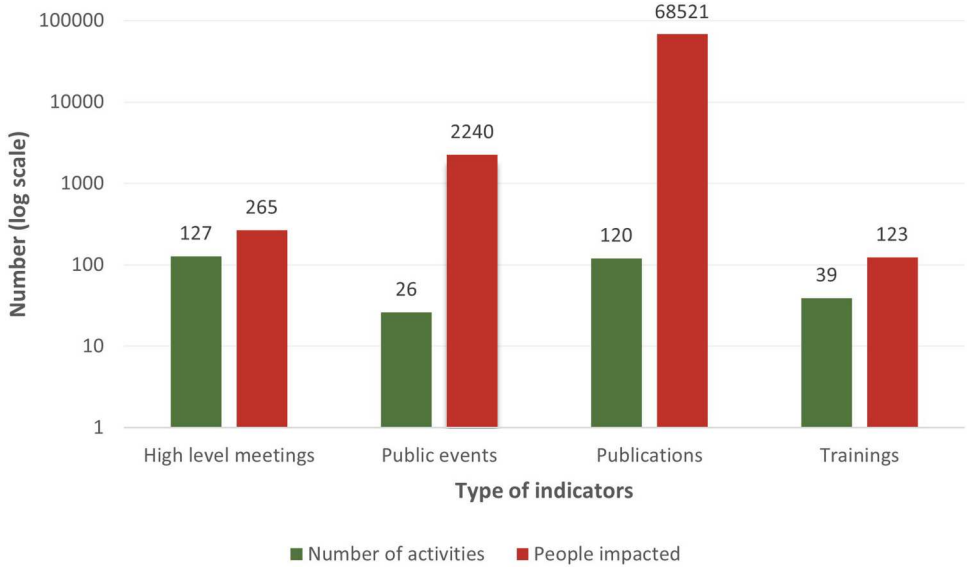

Figure 3. Impact of BERC-Luso activities.

However, the BERC-Luso Project's real impact goes beyond the data presented and is hard to estimate, due to the high level of coverage in television, radio, printed and electronic publications, and public events.

Challenges, barriers and enabling factors of the project

During its four years, BERC-Luso faced challenges that had to be addressed and overcome to make the project a success. Firstly, the direct involvement of the political power at national and international levels. All ministries of health of the PSAC were contacted, visited and involved in the project duration, liaising with the Embassies established in Portugal. The involvement of the diplomatic body was key to arrange high-level meetings and advocate for changes in the regulatory and legislative framework of the PSAC.

The COVID-19 pandemic was addressed as a challenge, as the project stalled for a year. During this period, engagement with partners was maintained through a series of webinars, focusing on the needs of the PSAC. These were keys to maintaining a high level of involvement, sharing best practices and addressing shortcomings.

When examining target completion, it is possible to draw some conclusions in relation to barriers that might have hindered their full attainment. Targets that involved external financing, were part of a larger and more structurally institutional reform, or were subject to high political decision, had only partial accomplishments. Furthermore, targets that pertained to official working groups led by government structures and law drafting initiatives (including its derivative pieces of implementation) registered partial completion. Authors recognise that complex structural institutional transformations and law development might be lengthy and fitted within political cycles, which might be only partially consistent with the rigid timeframe of a capacity-building project.

Enabling factors of the project can be described as multifactorial.

Firstly, biomedical research communities beyond the project partners were involved, such as Academia, Clinical Research Centres and Hospitals, which were used to spread the message and communicate the initiatives. Particularly, it highlights the public conferences with high levels of attendance, and the presence on media, fundamental to showcase the project outcomes.

Secondly, the project partners were high-level representatives of national competent authorities, which proved useful in implementing changes from a top-down approach. Targets that were successfully completed share the fact that they were under the direct responsibility of the representatives of the involved partners and stakeholders, which enacted pressure and action to complete the goals. The networking effect powered by conducting the project in the same language – Portuguese – was also critical to success, as no language barrier existed.

Finally, the last enabling factor of the project was occupying a vacuum previously identified: the lack of training available on the ethical and regulatory revision of clinical trials in Portuguese and for Portuguese-speaking African countries. The possibility of creating a network, developing original materials and establishing privileged connections was the cornerstone for the success of BERC-Luso Project.

The communication channels, powered by the online networks and communities that existed before the COVID-19 pandemic (regular meetings and a Facebook group) were sustained even after the end of the pandemic period, showcasing long-term sustainability of the project. Partners continued organising meetings to discuss topics of common interest, including further training online. The sense of community was continuously fostered, which culminated in the development of a proposal of a second capacity building project, already approved, financed, and operating (*Home | Ct-Luso*, n.d.).

Conclusion

According to the analysis of the indicators, BERC-Luso has achieved a significant level of success, due to its top-down and bottom-up approaches. Despite the significant disruption that the COVID-

19 pandemic caused on the project's course of action, the results are encouraging in all three areas of development (legislative, institutional, capacity building). The project had a high impact on every partner country, with the development of a sense of community and ownership. All activities developed were considered successful, achieving the proposed objectives.

There is a need to further invest in the development of capacity-building of Portuguese-Speaking African Countries and reinforce the implementation of best practices at legislative, institutional and training levels. It remains crucial that the previously established goals for each country are pursued to ensure their successful achievement.

The BERC-Luso project laid the foundations for the Portuguese-Speaking African Countries to continue boosting innovation and investing on the reform of their legislative frameworks and building capacity at the national level, with the ultimate goal to attract clinical research projects at a lusophone-cluster level.

Acknowledgements

The authors would like to acknowledge all BERC-Luso partners.

Author contributions

J. P. B. B. and M. P. N. wrote the manuscript together, with substantial input both in the first draft and in the revision process. M. A. R., L. S., J. A., and H. M. F. read and provided feedback to the manuscript, having been part of the development of the project. All authors read and approved the final manuscript.

Disclosure statement

No potential conflict of interest was reported by the author(s).

Funding

BERC-Luso was funded by the European and Developing Countries Clinical Trials Partnership under the grant agreement CSA2016ERC-1414 and by the Calouste Gulbenkian Foundation.

ORCID

Jorge Pedro Barroso Batista http://orcid.org/0000-0002-1140-5869
Maria Alexandra Ribeiro http://orcid.org/0000-0003-1947-0523
Leonor Soares http://orcid.org/0000-0001-5473-1624
Joana Araújo http://orcid.org/0000-0003-4586-6660
Helder Mota Filipe http://orcid.org/0000-0003-3045-2553
Maria do Céu Patrão Neves http://orcid.org/0000-0001-7246-6182

References

BERC-Luso- Biomedical ethics and regulatory capacity building partnership for Portuguese-speaking African countries. (2019). Retrieved February 9, 2024, from https://berc-luso.com/EN/

Home | ct-luso. (n.d.). Retrieved January 11, 2025, from https://ct-luso.com/?lang=en

Hwenda, L., Sidibe, M., & Makanga, M. (2022). The African medicines agency: The key to unlocking clinical research in Africa. *The Lancet Global Health*, *10*(8), e1088–e1089. https://doi.org/10.1016/S2214-109X(22)00243-1

Lang, T., & Siribaddana, S. (2012). Clinical trials have gone global: Is this a good thing? *PLoS Medicine*, *9*(6), e1001228. https://doi.org/10.1371/journal.pmed.1001228

Martinho da Silva, P. (2019). *BERC-Luso – estudo legislativo comparativo: Práticas internacionais e desafios legislativos.* BERC-Luso. https://berc-luso.com/projectobercluso/files/Estudo%20legislativo%20comparativo_2_pt.pdf

Patrão Neves, M., & Batista, J. P. B. (2021). Biomedical ethics and regulatory capacity building partnership for Portuguese-speaking African countries (BERC-Luso): A pioneering project. *South African Journal of Bioethics and Law*, *14*(3), 79–83. Article 3. https://doi.org/10.7196/SAJBL.2021.v1431.749

Studies on Map—ClinicalTrials.gov. (n.d.). Retrieved February 9, 2024, from https://classic.clinicaltrials.gov/ct2/search/map/click?map.x=886&map.y=666&mapw=1636

Taylor-Robinson, S. D., Spearman, C. W., & Suliman, A. A. A. (2021). Why is there a paucity of clinical trials in Africa? *QJM: An International Journal of Medicine*, *114*(6), 357–358. https://doi.org/10.1093/qjmed/hcab010

Weigmann, K. (2015). The ethics of global clinical trials. *EMBO Reports*, *16*(5), 566–570. https://doi.org/10.15252/embr.201540398

Appendix

Table A1. Countries' target information.

	Type of Indicator		
Country	Legislative	Institutional	Capacity-Building
Angola	Strengthen initiatives to create a full-fledge NEC	Create a digital database to oversee biomedical research projects and clinical trials	Adaptation of a checklist for standardising administrative work for ethical assessments
	Development of a Proposal for Regulation of the National Ethics Committee	Contribute to the full implementation of biomedical research projects and clinical trials in accordance with GCP&GLP	Implement the position of technical managers as part of the structure of the Angolan NEC secretariat team
	Propose requirements for civil liability insurance for clinical trials	Promote advanced scientific validation of research protocols	
	Propose requirements for a financial contract between the promoter and clinical trial centres	Contribute to the technical regulatory evaluation of clinical trial protocols	
		Contribute to compliance with ethical aspects linked to research and therapeutic clinical trials	
		Complete the development of the registry for controlling biomedical research projects and clinical trials carried out in the country	
		Adopt new official communication models between NRA and NEC, and clinical research involved stakeholders	
Cabo Verde	National discussion on the topic through participation in official working groups and outlining strategies for policy development	Promotion of coordination channels between NEC and NRA	Technical and scientific training for NEC/NRA officials
	Promoting the update of the legal framework on scientific research, through supporting law development	Establishment of a System of Quality Management that allows the administrative and technical management of requests for authorisation of clinical trials	National discussion on the topic through event attendance and outlining strategies for policy development
	Promoting the update of the legal framework on scientific research, through supporting rules on the regulation of clinical trials	Promoting further transparency in NRA regulatory procedures	Advanced BERC-Luso training for NEC members
	Advocate for the review of legislative framework for research in health	Incorporate good practice acquired in the training programme to the NEC operations	
	Participate in the review process of the legislative framework		
Guinea-Bissau	Implement a legal and normative instrument for the NEC	Develop an official webpage for the NEC	Create an advanced and robust information management system for clinical trials
	National adoption of a country Law on Biomedical Research	Implement the Health Scientific Studies Registration System	

(*Continued*)

Table A1. Continued.

Country	Type of Indicator		
	Legislative	Institutional	Capacity-Building
Mozambique	Adopt specific regulations on Clinical Trials	Ensure compliance with legislation when carrying out clinical trials, through adherence to the international Registries	Ensure compliance with legislation when carrying out clinical trials, through risk-based inspection and oversight reports
	Propose a ministerial order on the creation of a Commission for evaluation	Ensure compliance with legislation when carrying out clinical trials, through supervising and carrying inspections on GCP	Manage unexpected serious ADRs resulting from RCTs through defining notification pathways
		Improve RCT management system through internal database development	Manage unexpected serious ADRs resulting from RCTs through proposing workflows on notifications
		Improve RCT management system through introduction of codification and changes	
		Reduce RCT approval time	
		Review assessment report template	
		Create evaluation committee	
		Proposal of new committee members	
Sao Tomé and Príncipe	Official approval of the NRA	Implementation of a database and/or a digital support system	Invest in the training and education of professionals to meet new challenges
	Approval of the NRA internal regulations, as well as all proposed legislative diplomas	Recommend the creation of a support structure to focus on the prior validation of clinical trials authorisation request processes	Raise pressure with the competent Ministries for the need to have specialised personnel in different areas of the health sector
	Define the application of a submission fee for all processes, which is legally supported by a directive from the Ministry of Health (initial submission and substantial changes)	Establish partnership protocols with other regional and international counterpart institutions to share experiences	Develop a report model for the Inspections that are carried out and guidelines for carrying them out
		Propose the creation of a National pharmacovigilance system led by the NRA with specific regulations	
		Propose the creation of ADR notification and treatment systems for RCT	
		Propose the creation of a National GCP Inspection Plan with its respective well-defined and comprehensive criteria	
		Allocate the amount collected from the RCT registration for the improvement and logistical maintenance of the work carried out by the NRA	
		Evaluate the possibility of including a financial support item at the level of the Ministry of Health	