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Building Biomedical Ethics / Regulatory Capacity in Portuguese Speaking African Countries (BERC-Luso): an international comparative legislative study

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Background

BERC-Luso is a project for Ethics and Regulatory Capacity Building that is being developed in 4 African countries – Angola, Guinea Bissau, Mozambique and Cape Verde –, engaging National Ethics Committees (NECs) and National Regulatory Authorities (NRAs) (total of 6 institutions), partnering with 4 Portuguese institutions (experts in ethical review and regulatory supervision), with the collaboration of WHO and UNESCO. The project spans for 3 years (October 2018 - September 2021).

Purpose

BERC-Luso unfolds in four different stages, each one aiming at a specific goal in converging dynamics:

1. Legislative (1st year) – revision of Portuguese Speaking African Partner Countries' (PSAPC) legislation on NECs and NRAs, and proposal of review recommendations. The goal is to promote adequate legislation internationally recognized (good clinical practices).

2. Educational (2nd year) – organization of an intensive and comprehensive ethical and legal Education Program. The goal is to promote capacity building.

3. Training (2nd year) – organization of internships in Portugal to apply what was learned before. The goal is to develop knowledgeable and skilled experts.

4. Networking (1st-3rd years) – building powerful digital tools to connect partner institutions, creating a digital repository of documents, and different tools for ethical and regulatory evaluation.

These actions converge to provide internationally recognized legislation and validated expertise for the development of biomedical research for the benefit of the population.

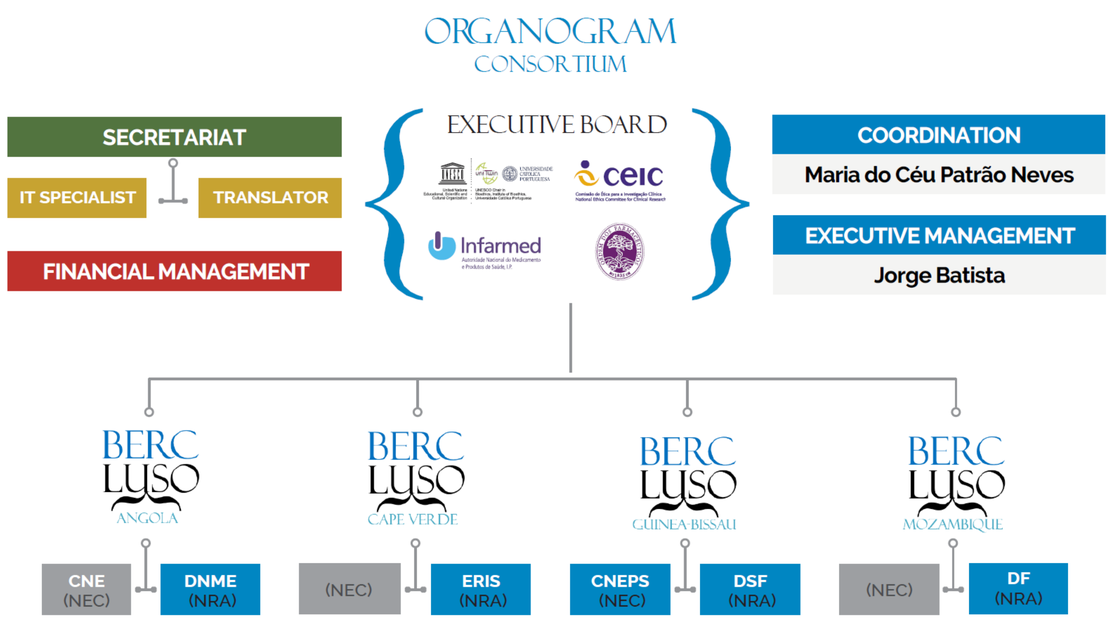

Image 1 – Consortium and Management structures

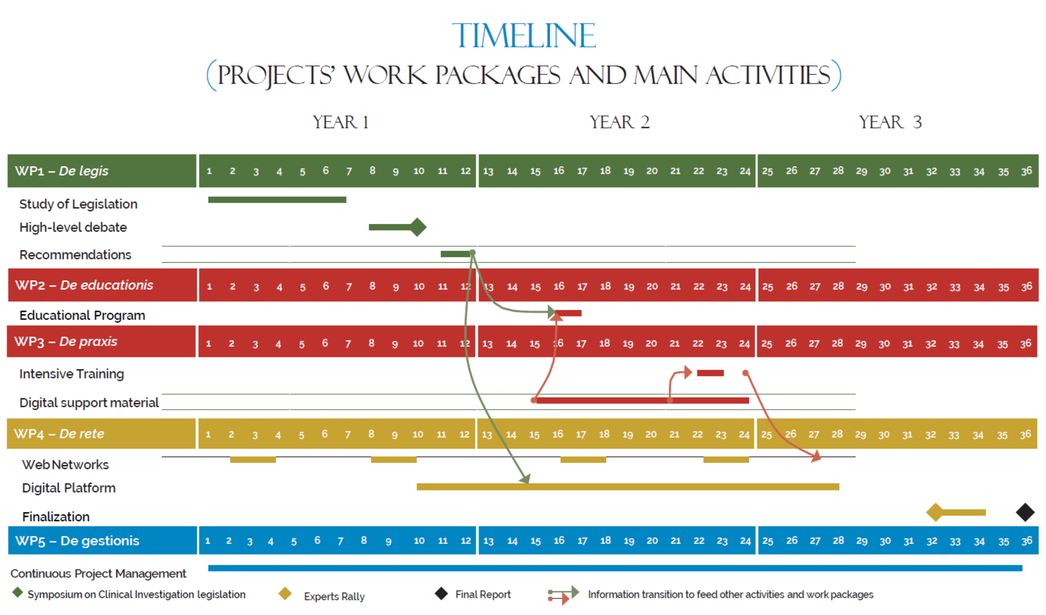

Image 2 – Timeline of Project's work packages and main activities

Methods

To fulfil the first goal at the legislative level, a legal team, composed of lawyers of the Portuguese Speaking African Partners Countries and coordinated by a Portuguese Lawyer, was constituted. A survey among the African partners was circulated, to gather information on the *status quo* of the legislation on biomedical research. National legislations were compared with international ethical/legal requirements of good practices, and recommendations for revision were drawn. The political power was involved along the process through regular contact with the Embassies accredited in Portugal, who reviewed the recommendations. A 3-day Workshop for the lawyer team was held in June, followed by a Symposium for public debate of the legislative study and gathering suggestions and comments for the final recommendations. The Ambassadors of the African partner countries were also involved in this event.

Results

Mostly of the African Partner Countries – Angola, Cape Verde, Guinea-Bissau and Mozambique – have some legislation on biomedical research, although not often regulated. Most NECs/NRAs are not regulated, and their procedures aren't clear or public. There is a strong political will to implement changes, at legislative/institutional levels. The relevant findings are depicted in the following tables:

Countries	Legislation	Name of the law	Concrete provision	Clinical trials in medicinal products	Other research
Angola	Law no. 21-B/1992, of 28 August	Basic law of the National Health System	Article 16 (Research), no. 1, 2	Article 21 (Clinical Trials of medicinal products)	-
	Presidential Decree no.180/2010, of 18 August	Basic Law of the National Pharmaceutical Policy	Article 16 (Medicines sample), no. 2	-	-
Cape Verde	Law no. 41/IV/2004, of 5 April	Basic law of the National Health System	Article 22 (Research)	Yes	Yes
	Implementing Decree no. 23/2014, of 10 June	Approves the Statutes of the National Institute of Public Health (INSP)	Article 5 no. 1 "The INSP'S attributions in health research are: h) To develop clinical research in collaboration with the units providing assistance services."	Yes	Yes
	Resolution no. 5/2008, of 18 February	Approves the National Health Policy (2007)	VIII.8 Strategies for health research	Yes	Yes
Guinea-Bissau	Still in project	National Regulatory Authority of Medicines and Health Products (ARFAME, I.P.)	Article 4, no.2, c) and d)	Yes	-
Mozambique	Law no. 12/2017, of 8 September	Law on medicines, vaccines and other biological products for human use	Article 39 to 44 (Clinical trials – unregulated)	Yes	-
	Resolution no. 4/2017, of 26 May	Organic Statutes of the Ministry of Health	Article 10, no. 1 f)	-	-

Table 1 – Existing legislation and applicable guidelines.

Countries	Legislation/soft law	Name of the law	Concrete provision	Clinical trials in medicinal products	Other research	Mandatory
Angola	-	-	-	-	-	-
Cape Verde	Resolution no. 5/2008, of 18 February	National Ethics Commission in Health Research	VIII.8, no. 5	-	-	-
	Decree Law no. 26/2007, of 30 July	National Ethics Committee in Health Research	All	All health research	All health research	Yes
	Implementing decree no. 43/2014, of 10 June	National Institute of Public Health, as the national coordinating agency for health research in the country	Article 5, no.1 a)	Yes	Yes	-
Guinea-Bissau	-	-	-	-	-	-
Mozambique	Law no. 12/2017, of 8 September	Law on medicines, vaccines and other biological products for human use	Article 39, no.1 and 2: Authorization given by the National Regulatory Medicines Authority, with the opinion of the National Bioethics Commission for Health Article 42 and 43: Inspection of Clinical Trials facilities to comply with Good Clinical Practices (Article 42, no.1). In the event of inconformity may temporarily interrupt or definitively cancel the Clinical Trials (Article 42, no. 2). Submission of partial and final reports, and submission of adverse drug reactions to the National Competent Authority for Health (Article 43)	Yes	-	-
	Internal document	National Bioethics Committee on Health	-	Yes	Yes	Yes (Only in clinical trials)

Table 2 – Independent validation and inspection.

Countries	Primacy of the human being / dignity	Scientific approval	Ethical approval	Informed consent	Consent of people who can't consent	Data confidentiality	Conflict of interest	Risk/benefit assessment	Safety and supervision
Angola	✓	✓	-	-	-	-	-	-	-
Cape Verde	✓	-	✓	✓	-	-		-	✓
Guinea-Bissau	-	-	-	-	-	-	-	-	-
Mozambique	-	-	✓	✓	-	✓	✓	✓	-

Table 3 – Check-list, comparing the different partner countries on the essential points covered in the existing legislation or in internal regulation.

Countries	Willingness	Project description	Results dissemination	Adverse reactions
Cape Verde	✓	-	-	-
Mozambique	✓	✓	✓	✓ Mandatory communication to the National Competent Authority for Health (Article 43, Law no. 12/2017, of 8 September)

Table 4 – Other relevant legislation related to clinical trials and biomedical research.

Conclusions

The legislative study together with the political involvement are leading to a more robust legislative framework. The revision of the already existing legislation in the scope of Clinical trials, and the comparison with the international guidelines, proved to be an effective tool for assessing the countries' needs in terms of further development of the legislative framework.

Reference

To perform the legislative study, the public-accessible legislation was consulted, as well as ready-to-approve legislation in the area of human research, biomedical research, bioethics and ethics.

Contact details

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