INSTITUTO DE HIGIENE E MEDICINA TROPICAL
DESDE 1902

***BIOTROPICAL RESOURCES*, BIOTROP**

THE GHTM IHMT NOVA BIOBANK / BIOLOGICAL RESOURCES CENTRE

REPORT OF ACTIVITIES 2021 - 2024

ACTIVITY PLAN FOR 2025 - 2027

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CONTENT

SUMÁRIO EXECUTIVO

O BIOTROP (Biotropical Resources Biobank) funciona como um biobanco (para amostras humanas) e como um centro de recursos biológicos (para amostras não humanas e coleções microbiológicas).

Após a sua fase de implementação (2016-2020), o BIOTROP desenvolveu um Plano Estratégico para 2021-2023, centrado em quatro áreas-chave: i) qualidade e diversidade das amostras; ii) gestão das amostras; iii) visibilidade; e iv) sustentabilidade. Entre 2021 e 2024, o BIOTROP participou ativamente em projetos de investigação e atividades de divulgação, incluindo publicações científicas, apresentações em conferências e formação avançada. Tornou-se também uma infraestrutura de confiança para investigadores externos depositarem as suas coleções biológicas. Através da participação em redes de colaboração, o BIOTROP beneficiou da otimização e normalização de procedimentos de gestão das suas amostras, ao mesmo tempo que aumentou a sua visibilidade e oportunidades de financiamento.

Para o próximo ciclo estratégico (2025-2027), o BIOTROP pretende consolidar as iniciativas em curso, ao mesmo tempo que implementa novas ações num quadro reestruturado de seis áreas de foco interligadas: i) gestão de coleções biológicas, ii) participação em projetos de investigação, iii) formação avançada, iv) parcerias e redes, v) disseminação e vi) sustentabilidade. As principais prioridades incluem o reforço das infraestruturas e a melhoria dos procedimentos de gestão das coleções biológicas. Adicionalmente, o BIOTROP continuará a fomentar as suas colaborações no âmbito das redes nacionais e a promover a Rede Lusófona de Biobancos e Coleções Biológicas, recentemente lançada.

EXECUTIVE SUMMARY

BIOTROP (Biotropical Resources Biobank) serves as both a Biobank (for human samples) and a Biological Resource Centre (for non-human samples and microbiological collections).

Following its implementation phase (2016–2020), BIOTROP developed a Strategic Plan for 2021–2023, focusing on four key areas: i) sample quality and diversity; ii) sample management; iii) visibility; and iv) sustainability. Between 2021 and 2024, BIOTROP has actively participated in research projects and dissemination activities, including scientific publications, conference presentations, and advanced training. It has also become a trusted infrastructure for external researchers to deposit their biological collections. Through involvement in collaborative networks, BIOTROP has benefited of the optimization and standardization of critical management procedures while has expanded its visibility, dissemination reach, and funding opportunities.

For the next strategic plan (2025–2027), BIOTROP aims to consolidate ongoing initiatives while implementing new actions within a restructured framework of six interrelated focus areas: i) Management of biological collections, ii) Participation in research projects, iii) Advanced training, iv) Partnerships and networking, v) Dissemination and vi) Sustainability. Key priorities include strengthening the infrastructure and enhancing the management procedures of biological collections. Additionally, BIOTROP will continue fostering collaborations within the national networks and promoting the recently launched Lusophone Network of Biobanks and Biological Collections.

LIST OF ABBREVIATIONS AND ACRONYMS

ADMT - Associação para o Desenvolvimento da Medicina Tropical

BIOTROP – Biotropical Resources biobank

CCA - Centro de Custos e Apuramento

CEIHMT – Comissão de Ética do IHMT

CNPq - Conselho Nacional de Desenvolvimento Científico e Tecnológico, Brazil

EDCTP - European and Developing Countries Clinical Trials Partnership

FCG – Fundação Calouste Gulbenkian

FCUL - Faculdade de Ciências da Universidade de Lisboa

GHTM – Global Health and Tropical Medicine (Unit of R&D)

ICEMR - International Centers of Excellence for Malaria Research

IHMT – Instituto de Higiene e Medicina Tropical

iMM - Institute of Molecular Medicine João Lobo Antunes

IPQ – Instituto Português da Qualidade

IT - Information technology office (Gabinete de Informática)

LAC - Laboratório de Análises Clínicas

LIMS - Laboratory Information Management System

MDA - Material Deposit Agreement

MTA - Material Transfer Agreement

NIAID - National Institute of Allergy and Infectious Diseases, USA

NIH – National Institutes of Health, USA

NMS – NOVA Medical School

NOVA – Universidade NOVA de Lisboa

PALOP – Países Africanos de Língua Oficial Portuguesa

PI – Principal Investigator

PT-mBRCN/MIRRI-PT - The Portuguese Network of Microbiological Resources

R&D - Research and Development

RFBB - Rede Fiocruz de Biobancos

SOP - Standard Operating Procedures

VIASEF - In vivo Arthropod Security Facility

INTRODUCTION

BIOTROP is both a Biobank (human samples) and a Biological Resource Centre (non-human samples and microbiological collections); considering that both terms are often used synonymously and biobank has become a “hat-holder” term (1), it will be used in this document with this broader sense.

During BIOTROP’s implementation, a variety of documents such as Forms, Standard Operating Procedures (SOPs), Material Transfer and Deposit Agreements (MTA and MDA) were produced in compliance with the Ethical guidelines both regarding human material and associated data (eg. the Informed consent) and non-human material (eg. Nagoya Protocol). The process was analysed [1] and a Strategic Plan for 2021-2023 was designed [2], centred on four areas of intervention: i) sample quality and diversity; ii) sample management; iii) visibility; and iv) sustainability (Figure 1).

Vision		**Reference structure for collections of biological products associated with Infectious Diseases and Tropical Regions**			
Mission		Maximize the biological resources existing at GHTM, to promote research of excellence on health sciences, particularly of infectious diseases and tropical medicine			
Areas of intervention		**Diversity and quality of sample collections**	**Sample management**	**Visibility**	**Sustainability**
Objectives and Execution plan		**Establish prospective collections**	**Promote the utilization/requisition of samples**	**Improve the BIOTROP sections at IHMT and GHTM websites**	**Establish fees for maintenance and ordering samples**
		Encourage donation of samples within projects	**Implement a Laboratory Information Management System (LIMS)**	**Promote the participation in collaborative networks**	**Start providing services**
		Promote within GHTM activities involving RGs and/or CCIs to establish new collaborations		**Participate in scientific and dissemination activities**	**Participate in projects as team member**
		Develop SOPs for quality assessment			**Establish collaborations with industry**

Figure 1. Summary of strategic plan of BIOTROP for the 2021 – 2023 triennium.

In 2023 and 2024, **there were changes in both the Coordination Team and the Scientific Committee**. The Technical Coordinator, Investigator Ana Tavares, left on 30 September 2023 and in the Scientific Committee, Professor Silvana Belo was replaced by Investigator Sofia Seabra due

[1] (http://ihmtweb.ihmt.unl.pt/Download/BIOTROP/BIOTROP_2016-2020_IMPLEMENTATION_vsf.pdf)
[2] http://ihmtweb.ihmt.unl.pt/Download/BIOTROP/BIOTROP_2021-2023_STRATEGIC_PLAN_vsf.pdf

to retirement. Senior Technician Jorge Ramos started working at BIOTROP in part-time in July 2024 (7 hours a week dedicated to the biobank), taking on the role of Interim Technical Coordinator. Even with the Jorge Ramos' collaboration in the infrastructure, it is urgent to hire a full-time researcher to maximise the BIOTROP's scientific intervention.

For the three-year period 2025 - 2027, the main aim is to continue the ongoing activities and to implement those not yet initiated in these four areas. Yet, bearing in mind the evolution of the infrastructure, the plan has now been restructured into six interrelated areas of action:

i) Management of biological collections,

ii) Participation in research projects,

iii) Advanced training,

iv) Partnerships and networking,

v) Dissemination

vi) Sustainability.

The primary objectives for each of these areas are presented below and a priority list is displayed at the end of the document for quick reference (Annex 1). For each area, objectives are preceded by a summary of the actions that have been taken between 2021 and 2024.

I. MANAGEMENT OF BIOLOGICAL COLLECTIONS

I.1. REPORT 2021 - 2024

Integration of samples within research projects

- Ethical Committee of IHMT (CEIHMT) has approved the project and workflow related to the collaboration with the *Associação para o Desenvolvimento da Medicina Tropical* (ADMT) and the *Laboratório de Análises Clínicas* (LAC) aiming at storing an aliquot of positive samples for any infectious agent, collected during the diagnostics routine, donated after informed and voluntary consent of patients in post-travel consultation, as well as the posters and flyers created to place in the waiting rooms and on the web pages of the IHMT and ADMT/Traveller's Consultation, but these procedures have never been fully implemented due to a lack of commitment on the part of practising doctors and clear institutional directives;
- BIOTROP has collaborated in several project proposals for external funding (e.g. respiratory microbiome, wastewater metavirome, antimicrobial resistance, malaria, vectors of re-emerging diseases). So far, sample collections associated to these projects have not been integrated, either because the projects have not been funded yet, are not finalised or because samples will remain at the partner institutions (see section II);
- BIOTROP has been requested by external researchers as a reliable infrastructure to deposit their biological collections. Two collections of Portuguese flora have been received – a collection of bryophytes from the high-mountains region of Madeira, considered as an endangered species, and specimens of *Corema album* (from the European project Annotating the *Corema album* Genome: A Step Toward Coastal Ecosystem Conservation) – PI Manuela Sim-Sim, *Faculdade de Ciências da Universidade de Lisboa* (FCUL). Also, a researcher from the Polytechnic Institute of Setúbal has contacted BIOTROP to integrate a collection related to hereditary deafness, and the process is about to be initiated.

Sample turnover

In February 2023, a sample request process - blood and serum samples positive for dengue virus, was carried out by a researcher from the Universitat Rovira i Virgili, Tarragona, in order to develop a lateral flow assay to detect dengue fever.

I.2. PLAN 2025 - 2027

Integration of samples within research projects

- To increase the diversity of the biological collections we intend:
  - ➢ To suggest to GHTM's coordination, the obligatory donation of sample aliquots to the biobank within internal exploratory projects financially supported by the GHTM that include collection of new biological material;
  - ➢ To pursue trying to stimulate researchers to voluntary donate aliquots of the collected samples under the scope of projects with external funding;
- In addition to the collections mentioned above (point II.1.), within the project 'The Alqueva reservoir, climate change and migrant birds: a dangerous liaison for emerging snail-borne diseases? (doi:10.54499/2022.01349.PTDC, PI Manuela Calado), a collection of freshwater snails, reservoirs of *Schistosoma*, the agent of cercarial dermatitis, a possible reemergent disease in the Mediterranean (2), is being integrated;
- It would be important for BIOTROP, as a member of The Portuguese Network of Microbiological Resources (PT-mBRCN/MIRRI-PT) network, to strengthen its microbiological collections; this will be a priority in the next years, and it will be achieved as part of a PhD project (see section III.2).

Quality assessment

SOPs to assess the quality of the samples stored in BIOTROP – regularly or when requested, do not exist yet. Its preparation is a priority; we intend to benefit from the exchange of existing procedures in use within biobanco.pt network.

Sample turnover

A sample turnover of less than 15-20% can become critical due to the excess of samples and space limitations, risking the functioning of the structure. This is not a problem yet at BIOTROP but it is important to continue to disseminate information on available collections and the requisition process.

Laboratory Information Management System (LIMS)

- BIOTROP has only two modules from the LabCollector LIMS for BioBanking software (LabCollector LITE Acad and LabCollector Custom Web Interface), which allows the organization of samples and associated data and provide an accessible online catalogue. An upgrade to include other functionalities is desirable and is now foreseen in the GHTM budget for 2025-2029;

- The catalogue that already exists on BIOTROP[3], is going to be restructured to better suit the infrastructure's mission and the integration of new collections [examples of possible new fields: scientific name, strain, availability, preservation method, applications, bibliographic reference, isolation date, restrictions, security level, cultivation conditions - medium, pH, optimum, minimum and maximum temperatures, deposit history - origin, depositor, geographical origin - locality, country, latitude and longitude, elevation, systematic classification - kingdom, phylum, class, order, family, genus, specific restrictive, GENBANK access number, etc];
- The security of the BIOTROP's database/catalogue hosted in the server of the GHTM should be increased, which is also a priority. The IHMT's IT office has already confirmed that the server hosting the biobank data/catalogue no longer complies with the security rules laid down in the required security certificate. The possibility of hosting the database and catalogue in the cloud of the software provider is being considered.

[3] http://biotropical.ihmt.unl.pt/

II. PARTICIPATION IN RESEARCH PROJECTS

BIOTROP has been involved as a team member in research proposals/projects, a practice that will continue in the coming years. The participation of BIOTROP varies depending on the characteristics of the project (examples below):

i) contributing to capacity building in developing regions

- 2023. Data science to guide malaria control and elimination in continental and insular Central Africa, submitted to NIAID ICEMR program, PI Joana Carneiro da Silva, University of Maryland NOT FUNDED
- 2023. *Plasmodium falciparum* demography in Angola, a country with highly heterogenous malaria incidence, submitted to NIH R01 grant program, PI Joana Carneiro da Silva, University of Maryland NOT FUNDED
- 2023. Airway colonization and microbiome in relation to asthma and atopy in children from Cabo Verde (Respira-CV), We'Search program of FCG / La Caixa, PI Isabel Inês Araújo, University of Cabo Verde[4] **ON GOING**
- 2024. Health, environment and vulnerable populations, submitted to CNPq, PI Marly Cardoso, University of São Paulo UNDER EVALUATION
- 2024. AnTimicrobial ResistANce Situation in AFrica from a one health pERspective (TRANSFER), submitted to EDCTP, PI Sara Soto, Fundación Privada Instituto de Salud Global de Barcelona (ISGlobal) NOT FUNDED

ii) providing a backup for the biological collections associated to the project

- 2023. Data science to guide malaria control and elimination in continental and insular Central Africa, submitted to NIAID ICEMR program, PI Joana Carneiro da Silva, University of Maryland NOT FUNDED
- 2023. *Plasmodium falciparum* demography in Angola, a country with highly heterogenous malaria incidence, submitted to NIH R01 grant program, PI Joana Carneiro da Silva, University of Maryland NOT FUNDED

iii) contributing to the development of SOPs for collection and storage of biological material, and integration of the biological collections gathered within the project

- 2021. Identification of biomarkers of the upper respiratory tract microbiome as predictors of susceptibility to respiratory diseases, submitted to FCT, PI Sofia Seabra, IHMT NOVA NOT FUNDED

[4] https://www.facebook.com/IHMT.NOVA/posts/1278541396831771?ref=embed_post / https://ghtm.ihmt.unl.pt/researchers-and-phd-students-from-the-ghtm-ihmt-travelled-to-santiago-island-cape-verde-to-take-part-in-fieldwork-for-the-respira-cv-project/

- 2024. WasteWater-Adapt - Wastewater Genomic Surveillance: A Multi-Pathogen Adaptive Approach for Pandemic Preparedness, submitted to FCT, PI Sofia Seabra, IHMT NOVA UNDER EVALUATION

III. ADVANCED TRAINING

III.1. REPORT 2021 - 2024

Short training programmes

- In 2021 and 2023, short summer training courses were held as part of the Ciência Viva programme, with the participation of five high school students;
- In June 2024, BIOTROP welcomed Dr Edson Cassinela, Assistant Researcher and Scientific Director of the National Centre for Scientific Research, Luanda, Angola, to carry out a six-month voluntary post-doctoral internship on 'Implementation and Management of Biobanks in a Global Health Context'. This internship was part of the FCG's ENVOLVE Ciência PALOP programme (Support the Development of Scientific Careers in Health Sciences in Portuguese-speaking African Countries). Unfortunately, in September 2024, Dr Cassinela had to give up the internship for reasons unrelated to BIOTROP and inherent to the researcher's host institution. Still, during his short stay had the opportunity to participate in the daily routine of the biobank, to contact with the requirements in terms of facilities and software and in the revision of a few SOPs.

III.2. PLAN 2025 - 2027

Short training programmes

- Submission of internship proposals under the ENVOLVE Ciência PALOP or similar programmes;
- Voluntary internships for training, on request.

MSc and PhD projects

- As part of the RESPIRA-CV project, in October 2024, Alexandra Santos, a PhD student in International Health started the 4-year PhD project on 'Epidemiological aspects of bronchial asthma in a cohort of children on the island of Santiago, Cape Verde'. One of the objectives of this project is to establish a biological collection, precursor to a biobank at FCT Uni-CV; to this purpose, Alexandra Santos has been participating in all routine activities of BIOTROP, especially those related with SOPs development or revision and sample management;
- By the end of February 2025, Jorge Ramos will apply to the FCT's Call "Doutor AP": new Scientific Training Program for Public Administration, with the plan “Implementation and Validation of Biological Collections associated with Emerging Diseases and Drug Resistance in a One Health Surveillance Context”. This program will allow employees to obtain a doctorate degree, while aligning their work plans with the research and development strategies of the entities in which they work; the grant will last for a maximum of six years.

This will be an opportunity not only to upgrade human resources but also to strengthen BIOTROP's microbiological collections;

- A class dedicated to biobanks is usually given in the doctoral and master's programmes in Biomedical Sciences at IHMT NOVA, and the proposal of master's thesis topics is a possibility in the future.

IV. PARTNERSHIPS AND NETWORKING

Since its very beginning, BIOTROP integrates the Portuguese Roadmap of Strategic Research Infrastructures as member of two national networks – The National Biobank Network Biobanco.pt[5] and The Portuguese Network of Microbiological Resources (Pt-mBRCN/MIRRI-PT) and launched a Lusophone Network of Biobanks and Biological Collections aiming at sharing expertise and increasing the impact of these facilities in the Lusophone world.

IV.1. REPORT 2021 - 2024

As a result of the participation in collaborative networks, BIOTROP has been involved in several activities that may led not only to the optimisation and standardisation of relevant management procedures and strategies, but also to greater visibility and dissemination (see section V.1.) and funding opportunities (see section VI.1.). Main activities have been:

- Training on the best practices in the management and requalification of biological collections in Oswaldo Cruz Foundation - FIOCRUZ (Fiocruz Biological Collections and COVID19 Biobank) under the ICM NOVA - International Credit Mobility project, Erasmus+ Program. July 2022, Rio de Janeiro, Brazil[6].
- Participation in the inauguration event of the MIRRI-ERIC European headquarters and networking meeting with PT-mBRCN/MIRRI-PT. December 2022, Braga, Portugal[7].
- **Launching of the Lusophone Network of Biobanks and Biological Collections**

In April 2023, BIOTROP organised the scientific meeting on "Biobanks in Lusophone countries" prior to the 6th National Congress of Tropical Medicine (CNMT[8]) which brought together 30 representatives from 15 institutions from Angola, Brazil, Cape Verde, Mozambique, Portugal and the two national networks(3,4) (Summary in Annex 2).

The network needs to be revitalised, but this task has been difficult due to the lack of support in the coordination and the heavy workload associated to the evaluation process for the GHTM R&D Unit during the two previous years. Membership forms (Annex 2) have been filled in by the infrastructures participating in the meeting and a Teams group and a contact list has been set up that has been used to publicise training activities or scientific meetings. Dissemination activities have also been carried out (see section V).

[5] https://biobanco.pt/
[6] https://ghtm.ihmt.unl.pt/mission-to-fiocruz-biological-collections-allowed-networking-acquire-new-tools-and-share-good-practices-and-experiences/
[7] https://ghtm.ihmt.unl.pt/?s=mirri-eric
[8] https://6cnmt.admeus.pt/?page=62

IV.2. PLAN 2025 - 2027

- In February 2024, BIOTROP was invited by the Portuguese Quality Institute (IPQ) to participate in the ad hoc Technical Commission for Standardisation on biobanks of microorganisms; a first meeting occurred in March 2024, but the activity will only be developed in 2025;
- In September 2024, the BIOTROP's coordinator was invited by the Coordination of the Fiocruz Biobank Network (RFBB) to join the workgroup that will translate the International Society for Biological and Environmental Repositories (ISBER) Manual of Good Practices for Repositories(5); the activity has started in November 2024 and will continue in 2025.
- To become an ISBER member through a [Small] Organizational membership (2 sub-accounts, 1 electronic journal subscription - $426 USD/year). ISBER is a global forum that addresses scientific, technical, legal, and ethical issues for biobanks and biorepositories. It fosters collaboration, creates education and training opportunities; provides a forum for the dissemination of state-of-the-art policies, processes, and research findings; and provides an international showcase for innovative technologies, products, and services.
- **Lusophone Network of Biobanks and Biological Collections**

It will now be important to i) try to stimulate a commitment from members and an integrated effort to gather/contribute with resources and expertise to the common interest of the network, leading to its formalisation, and ii) try to stimulate coordinated activities for its development and sustainability.

➢ Organisation of a new meeting in 2025, which could be online or, as suggested by the Fiocruz Biological Collections Coordination, organised as a satellite of the 60th Congress of the Brazilian Society of Tropical Medicine (MEDTROP 2025)[9], ideally in hybrid format. Important issues to be discussed would include:

- To define an organisational structure and governance;
- To create a logo and regulations (network structure, formal written description of the roles, rules, and expected outcomes, goals and responsibilities);
- To build a common agenda for sharing activities, seeking resources and synergies for planning and identifying the challenges and common issues in each infrastructure and thus verifying priorities, as well as identifying opportunities for support;
- To establish discussion forums or focus groups on the topics identified as priorities at the initial meeting:

  - implementation of standardised procedures for protocols, access to and sharing of biological material, pathogens, results, software and its parameterisation, etc;

[9] https://medtrop2025.com.br/

- joint analysis of existing regulations, their adaptation and consensual application;

- procedures to ensure traceability of the same sample between different collections (possible for collections of microorganisms that can be replicated; difficult to implement for material of human origin);

- existence/creation of backup structures for biological collections - space and resources required, possible partners to ensure these backups;

- importance and mechanisms to ensure the sustainability of these structures (turnover of deposited samples, partnerships with industry, etc);

- availability of members to act as consultants at specific stages of the processes, namely i) support for existing or planned structures already in place or planned in the PALOP (procedures, obtaining funding, etc.) and ii) in cases where a structure does not yet exist, support in the strategy to be followed for its implementation;

- training of human resources in the various programmes and courses available in the most developed infrastructures and/or their networks;

- clarification and standardisation of terms (example: biorepository versus biobank).

➢ To look for <u>funding opportunities</u>

- either for the implementation of the network itself; a possible workplan could be:

  - Comparative analysis of existing laws and guidelines (legal and ethical)

  - Comparative analysis of governance systems - Identification of examples of effective governance

  - Training and equalisation of resources for members at different stages of implementation and development

  - Development of common protocols, SOPs, governance systems, etc

  - Development of a common catalogue

  - Website

- or for specific projects involving a few partners within the network;
- or for programmes of staff exchange and mobility.

V. DISSEMINATION

BIOTROP dissemination and promotion activities are announced in the Biobank section of the IHMT website[10] under the *Notícias* tab. Besides these activities, researchers are asked to acknowledge BIOTROP in publications that result from studies that used BIOTROP's collections (as stated at the MTA, FORM #9).

V.1. REPORT 2021 – 2024

Publications and presentations in scientific meetings

- Biobanking African Pediatric Upper Respiratory and Gut Microbiomes. Poster at Congress of Microbiology and Biotechnology 2021 (Microbiotec'21). 23-26 November 2021. Online.[11]
- Presentation at the Panel 6 - Biobanco, pesquisa, internacionalização e medicina de precisão [Biobank, research, internationalisation and medicine], II International Symposium on Human Genetics, Faculty of Medicine, Agostinho Neto University. 14 July 2022. Luanda, Angola.
- Building a Network of Biobanks and Biological Resource Centres Across Portuguese-Speaking Countries: Collaborative Efforts for Global Sustainability. Poster at Congress of Microbiology and Biotechnology 2023 (Microbiotec'23). 7-9 December 2023. Covilhã Portugal.[12]
- Arez AP, Couto I, Belo S 2024. Construindo uma Rede Lusófona de Biobancos e Coleções Biológicas: oportunidades na ciência e contribuição para uma saúde global. *Anais do IHMT*, 23:2, pág. 20-26. doi: 10.25761/anaisihmt.495
- Arez AP, Souto A, da Silva M, do Nascimento CRS, Couto I, Belo S and Lima N 2024. Biobanking for tropical health: leveraging collaborative initiatives in the Lusophone world. *Front. Trop. Dis*, **5**:1438842. doi: 10.3389/fitd.2024.1438842
- Guest editing of a special issue: Importance and Applications of Biological Collections and Biobanking Activities for Tropical Health at *Frontiers in Tropical Diseases, Disease Prevention and Control Policy*

[10] https://www.ihmt.unl.pt/investigacao/biobanco/

[11] https://www.ihmt.unl.pt/wp-content/uploads/2023/01/Poster-no-Congresso-Nacional-MicroBiotec21.-23-26-Novembro-2021.-Online.pdf

[12] https://research.unl.pt/ws/portalfiles/portal/78353697/Poster_Topic_9.pdf

Presentations and lectures

- Começar um biobanco – experiências portuguesas [Starting a biobank - Portuguese experiences]. Round table at the Advanced Course "Biobancos: potenciar a investigação em saúde" [Biobanks: boosting health research]. Institute of Molecular Medicine João Lobo Antunes (iMM). 13-15 September 2023. Lisbon, Portugal.
- Coordination of the Module 5 "Management of biological samples and associated data/Gestão de amostras biológicas e de dados associados" (and Session "Collection and processing of biological samples") in the 1st and 2nd edition of the Advanced course on Clinical Research (16 Oct – 12 Dec 2023; 06 May – 08 Jul 2024). FCG (organised by IHMT NOVA).
- Rede lusófona de Biobancos – Oportunidades na Ciência [Lusophone Network of Biobanks - Opportunities in Science]. Closing conference of the Advanced Training Course in Biobanks. FCG (organised by iMM). 24 January 2024. Lisbon, Portugal.
- Experiência Portuguesa e a Rede de Biobancos da Lusofonia [The Portuguese Experience and the Lusophone Biobank Network]. Presentation at the launching session of Animal Biodiversity Biobank. Eduardo Mondlane University Biotechnology Centre. 15 February 2024. Maputo Mozambique.
- Gestão e Conservação de Coleções Biológicas e Biobancos [Management and preservation of biological collections and biobanks]. University of Cabo Verde. 19 June 2024. Cidade da Praia, Cabo Verde.
- Implementação de Coleções Biológicas e Biobancos [Implementation of Biological Collections and Biobanks]. Multidisciplinary Centre of the Forest Campus of the Federal University of Acre. 2 October 2024. Cruzeiro do Sul, Brazil.
- Round table "Qual o papel das coleções de culturas de biológicas na sociedade e no futuro? / What role do biological culture collections play in society and in the future?" Os recursos biológicos na sociedade: uma conversa com futuro / Biological resources in society: a conversation with the future. University of Coimbra Exploratory Centre of Coimbra, 30 October 2024.[13]

[13] https://ghtm.ihmt.unl.pt/biotrop-at-discussion-on-biological-culture-collections/

V.2. PLAN 2025 - 2027

It will be important to continue publicising the infrastructure and available collections. BIOTROP will continue to participate in **dissemination activities** aimed at both the scientific community (e.g. Microbiotec, other national and international scientific meetings and lectures) and non-specialist audiences (e.g. Encontro Ciência, European Researchers' Night, etc).

The production of updated **promotional material** (posters, leaflets or videos) is also being planned with the collaboration of IHMT NOVA's Communication Office.

Efforts have been made to keep the biobank section of the IHMT NOVA website regularly updated, but the main priority is to create an English-language website; whenever needed NOVA Innovation website is used[14], but the information provided is very limited.

[14] https://novainnovation.unl.pt/biotrop-biotropical-resources-biobank/

VI. SUSTAINABILITY

VI.1. REPORT 2021 – 2024

- At the end of 2022, a proposal for a **business model** (Annex 3) was drawn up; the plan was to finish it together with the institutional services and implement it, integrated with other institutional infrastructures;
- In January 2023, **a *Centro de Custos e Apuramento* (CCA**) was created for BIOTROP, essential for providing services and purchasing goods and services for its own activity;
- **BIOTROP Regulations** and a **Price list of services provided by BIOTROP** for internal and external researchers have been updated and approved by the IHMT NOVA Director in December 2024 and are displayed on the website (Annex 4);
- In July 2024, the proposal "Biobanco.PT@LIS: Innovation at the Service of Health" was submitted for funding in the call "Scientific Infrastructures and Equipment, LISBOA2030-2024-15" by the Lisbon Region node of the National Biobank Network, of which BIOTROP is a member. The management team of Biobanco.PT@LIS consists of Sérgio Dias, Co-Director of Biobanco-iMM and Coordinator of Biobanco. PT@LIS, Helena Canhão, Dean and Full Professor of Medicine at NMS, Ana Paula Arez, Principal Investigator at the GHTM IHMT NOVA and Coordinator of the GHTM - Biotropical Resources Biobank (BIOTROP), and Mireia Castillo-Martin, MD, PhD and Director of the Champalimaud Foundation Biobank (CFB). The net budget allocated to BIOTROP is ~87 000,00€ (of which ~20 600,00€ will be shared with VIASEF, the *In vivo* Arthropod Security Facility of IHMT). UNDER EVALUATION

VI.2. PLAN 2025 - 2027

- Finalisation and implementation of the Business model;
- Implement and publicise BIOTROP services;
- Search for new sources of funding.

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ANNEXES

ANNEX 1

QUICK REFERENCE LIST OF PRIORITIES

1. Database and catalogue restructuring;
2. Integration of pending collections;
3. Ensure the security and reliability of the maintenance of the database and catalogue on GHTM's servers or find an alternative;
4. Promotion of the Lusophone Network of Biobanks and Biological Collections;
5. Create an English-language website;
6. Prepare SOPs to assess the sample quality;
7. Strengthening the microbiological collections;
8. ISBER membership;
9. Implement and publicise BIOTROP services.

ANNEX 2

LUSOPHONE NETWORK OF BIOBANKS AND BIOLOGICAL COLLECTIONS

(Rede Lusófona de Biobancos e Centros de Recursos Biológicos)

Summary of the meeting 'Biobanks in Lusophony', 19 April 2023, 14h00

Os biobancos na Lusofonia

Reunião, 19 de abril 2023, 14h00

RESUMO

Nesta primeira reunião de lançamento de uma Rede Lusófona de Biobancos realizada em formato híbrido no IHMT, estiveram presentes 30 participantes, representantes de 15 instituições de Angola, Brasil, Cabo Verde, Moçambique e Portugal (Programa da sessão e Lista de participantes em anexo)

Sobre os exemplos de biobancos e centros de recursos biológicos (designados doravante pelo termo genérico biobanco) apresentados na reunião, ficou patente a diversidade dos diferentes níveis de desenvolvimento e infraestruturas existentes, com estratégias e programas distintos, assim como fontes de financiamento e políticas de governança.

Como exemplos de infraestruturas fortemente desenvolvidas e consolidadas, salienta-se a rede MIRRI-ERIC (*The Microbial Resource Research Infrastructure-European Research Infrastructure Consortium*)[1] coordenada por Nelson Lima (Universidade Minho), rede que integra 10 países europeus e 1 país observador, dispondo de forte financiamento de agências europeias e concursos internacionais. Para além do elevado acervo de espécies/estirpes microbianas caraterizadas e diversas parcerias em projetos de investigação internacional, a rede disponibiliza formação transnacional, com cursos em gestão de centros de recursos microbiológicos[2], o que é uma oportunidade para o desenvolvimento de biobancos e parcerias no espaço lusófono.

À semelhança do MIRRI, as Coleções Biológicas[3] e o Biobanco COVID19[4] da Fiocruz (Brasil), é outro exemplo de infraestrutura nacional consolidada envolvendo vários parceiros do país, com património de espécimes considerável e infraestruturas específicas, como a referente à de vírus altamente patogénicos, apresentada por Aline Souto, Manuela da Silva e Carlos Nascimento. O seu financiamento é assegurado pelo governo brasileiro, complementado com outras verbas provenientes de projetos de investigação, para os programas e infraestruturas do seu plano estratégico. Como exemplo, o programa PRESERVO, de preservação do edificado, de acervos científicos e culturais, como das coleções entomológicas (com 120 anos), construção de novas

[1] https://www.mirri.org/
[2] https://ismirri21.mirri.org/2023/01/26/now-open-applications-to-the-euromirc-advanced-studies-course/
[3] https://portal.fiocruz.br/colecoes-biologicas
[4] https://biobanco-covid19.fiocruz.br/pt-br

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estruturas para material biológico humano e não humano e *backup* destas coleções, digitalização do acervo, entre outros.

Como exemplo de uma infraestrutura de formação recente e desenvolvimento intermédio, foi apresentado por Ana Paula Arez, o biobanco do GHTM IHMT NOVA[5] (BiOTROP), cuja implementação se iniciou em 2016, tendo como foco principal o acervo de coleções biológicas existentes na instituição. Toda a organização funcional, incluindo integração em redes e programa do país e Universidade NOVA de Lisboa, plano estratégico, constituição de conselho de consultores, comissão científica e infraestrutura física, processos de depósito e requisição de amostras, etc – ficou concluída em 2020. Para além dos recursos biológicos, o plano e programa integram outros aspetos como atividades de disseminação e extensão, prestação de serviços e a dinamização de parcerias no espaço lusófono.

A relevância das questões éticas, legais, institucionais e a sua amplitude legislativa em todos os procedimentos de recolha de material biológico foi abordada pela apresentação de Dinora Lopes, ressalvando que aspetos como direitos individuais, partilha inter-instituições, contextos socioculturais, resultados e armazenamento, devem estar definidos e consignados *a priori*.

A experiência bastante positiva de biobancos parceiros ou em proximidade com instituições médicas, como é o exemplo do biobanco do iMM (Instituto de Medicina Molecular)[6], salientada por Sérgio Dias, não só potencia e facilita a recolha de diverso material biológico e a sua caraterização, como é geradora de difusão e impacto científico a nível global, como no caso da pandemia de COVID-19. Vantagens adicionais de redes de biobancos, incluem a promoção de partilha e de cultura da investigação biomédica, fundamentais para o desenvolvimento científico e sustentabilidade das próprias infraestruturas.

A outro nível de desenvolvimento, em fase "embrionária" mas já com planos estratégicos definidos para a sua implementação, são exemplos as infraestruturas existentes nos PALOP.

Como exemplos de infraestruturas em início de desenvolvimento, Madalena Chimpolo apresentou o plano da Faculdade de Medicina da Universidade Agostinho Neto (Luanda, Angola) iniciado em 2021 para criação inicial de um biorepositório, mais adequado ao contexto do país. O plano atual foca-se na captação de financiamento para implementação da infraestrutura, laboratórios, equipamentos e materiais fundamentais, assim como formação de recursos humanos.

Um biorepositório é também a infraestrutura implementada existente no INIS (Instituto Nacional de Investigação em Saúde, Angola), com coleções de amostras biológicas de diversas patologias

[5] https://www.ihmt.unl.pt/investigacao/biobanco/
[6] https://biobanco-imm.biobanco.pt/

(ex. malária, tuberculose (TB), doenças genéticas e oncológicas), com alguns procedimentos padrão já estabelecidos. Joana Morais salientou, contudo, as dificuldades existentes

(manutenção, regulamentação, outros procedimentos), considerando fundamental a integração em rede de biobancos para o desenvolvimento da estrutura existente.

Opinião também partilhada por Isabel Araújo da Universidade de Cabo Verde, cuja estrutura existente – biorepositório, carece de investimento/financiamento. A constituição formal de biobancos não tem sido alvo de discussão no país, o que considera que seria fundamental para a difusão do conhecimento e tomadas de decisões e políticas públicas de saúde, por exemplo na área da legislação sobre ensaios clínicos.

De Moçambique, Elda Anapakala apresentou o Biobanco do Instituto Nacional de Saúde que conta já com diversas coleções de sangue e produtos derivados, amostras fecais e de exsudado nasofaríngeo cobrindo doenças e infeções por TB, HIV e Sars-Cov-2, estando em curso o estabelecimento de um sistema de registo e mapeamento de amostras e formação de recursos humanos.

Também em Moçambique, Carlos Bento apresentou o Centro de Recursos Biológicos do Museu de História Natural da Universidade Eduardo Mondlane, direcionado para a biodiversidade da flora e fauna naturais, salientando a integração de coleções de amostras recebidas em 2021 de mamíferos terrestres e marinhos.

Mais desenvolvido a nível de infraestrutura e mecanismos de gestão de amostras, o biobanco do CISM (Centro de Investigação em Saúde da Manhiça, Moçambique), apresentado por Gloria Matambisso, foi implementado no âmbito do projeto *GenMoz. Malaria Genomics in Mozambique*.

De Portugal, Maria Assunção da *NOVA Medical School*, e Marta Barreto (Instituto Nacional de Saúde Dr Ricardo Jorge, INSA), que integram tal como o BIOTROP a rede Biobanco.pt (coordenada pelo iMM) apresentaram as infraestruturas existentes nestas instituições, dando os seus contributos e experiências, que poderão ser partilhadas e implementadas numa rede de biobancos da lusofonia.

Conclusões

Tendo sido consensual a aprovação da proposta de criação da rede lusófona de biobancos, destacam-se de seguida os principais pontos e ações a levar a cabo e/ou para discussão conjunta futura:

- Trabalho conjunto para a implementação de procedimentos padronizados (SOPs – protocolos, acesso e partilha de material biológico, agentes patogénicos, resultados, software e sua parametrização, etc);
- Análise conjunta de regulamentos existentes e sua adaptação e aplicação consensuais;
- Procedimentos para a rastreabilidade da mesma amostra entre diferentes coleções (possível para coleções de microrganismos em que é possível replicar a amostra; difícil de implementar para material de origem humana);
- Existência/Criação de estruturas *backup* - espaço e recursos que necessitam, eventuais parceiros para assegurar esses backups;
- A importância e mecanismos de garantia da sustentabilidade destas estruturas (*turnover* das amostras depositadas, parcerias com a indústria farmacêutica e outras);
- Dentro da rede, disponibilidade de membros para participarem como consultores em etapas específicas dos processos
  i. Apoio às estruturas em desenvolvimento já existentes ou planeadas nos PALOP, nas diversas etapas (procedimentos, captação de financiamento, etc);
  ii. Nos casos onde não existe ainda estrutura, apoio na estratégia por onde começar e para onde avançar; se uma estrutura mais generalista ou mais especializada;
- Interesse e disponibilidade para a formação de recursos humanos nos diversos programas e cursos disponíveis nas infraestruturas mais desenvolvidas e respetivas redes[7];
- Biorepositório *vs* Biobanco: necessidade de clarificação e consensualização de conceitos.

[7] Reuniões e Cursos: 15th International Conference on Culture Collections (ICCC15), Braga (Portugal), 12 a 16 junho 2023, formato híbrido (https://www.iccc15.com/)
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Os biobancos na Lusofonia

Reunião, 19 de abril 2023, 14h00

Formato híbrido: IHMT sala Fraga de Azevedo e zoom

Organização: Biotropical Resources (BIOTROP), GHTM IHMT NOVA

ENQUADRAMENTO E OBJETIVO DA REUNIÃO

Presentemente, os Biobancos e os Centros de Recursos Biológicos, são infraestruturas centrais para a investigação biomédica e uma fonte de recursos essenciais para a inovação e translação na Saúde Global, especialmente para o desenvolvimento de novos biomarcadores, terapias e testes de diagnóstico.

Atualmente, a maioria dos biobancos está localizada na América do Norte e na Europa; em África, existem duas importantes redes, o B3Africa project (*Bridging Biobanking and Biomedical Research across Europe and Afric*a, Horizonte 2020) com quatro países africanos (África do Sul, Quénia, Nigéria e Uganda) entre os seus 10 membros, e a ESBB (*European, Middle Eastern & African Society for Biopreservation and Biobanking*), com representações da África do Sul e da Gâmbia.

No mundo lusófono, salientamos as Coleções Biológicas da Fundação Oswaldo Cruz e o recém estabelecido Biobanco Covid-19 da Fiocruz (BC19-Fiocruz). Em Portugal, existem duas redes importantes - MIRRI-PT (*Microbial Resource Research Infrastructure*, coordenada pela Universidade do Minho) e Biobanco.pt (coordenada pelo Instituto de Medicina Molecular, iMM), que integram o Roteiro Nacional de Infraestruturas Estratégicas para a Investigação.

Objetivo:

Partilhar experiência na área do estabelecimento de coleções biológicas e implementação de Biobancos ou Centros de Recursos Biológicos nos países lusófonos, de forma a dinamizar a criação de uma Rede Lusófona de Biobancos que englobe instituições com infraestruturas já existentes e instituições com interesse na sua implementação, contribuindo para aumentar a sua visibilidade e impacto a nível global.

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AGENDA

14h00 – Abertura, Miguel Viveiros, Coordenador do GHTM IHMT NOVA, Vice-Diretor IHMT NOVA

14h10 – 15h30 – Apresentações (15min apresentação + 5min discussão)

1. **Importância de trabalhar em rede**. Nelson Lima, Coordenador da Rede MIRRI, Diretor da Micoteca da Universidade do Minho
2. **Coleções da Fiocruz**. Aline Souto, Coordenadora Executiva da Coleções da Fiocruz Fundação Oswaldo Cruz
3. **Biobancos e Questões Éticas.** Dinora Lopes, Diretora dos Serviços de Apoio à Ciência e Comunidade e Membro da Comissão de Ética do IHMT NOVA
4. **BIOTROP – biobanco do GHTM IHMT NOVA.** Ana Paula Arez, Coordenadora Geral do Biotropical Resources (BIOTROP)

15h30 – 16h - Pausa

16h00 – 17h45 – Apresentações breves das infraestruturas e Discussão

(aproximadamente 5-9min apresentação)

Angola

1. Instituto Nacional de Investigação em Saúde (Joana Morais)
2. Faculdade de Medicina, Universidade Agostinho Neto (Madalena Chimpolo)

Brasil

3. Biobanco Covid-19 da Fiocruz (BC19-Fiocruz) (Manuela da Silva e Carlos do Nascimento)

Cabo Verde

4. Centro de Investigação em Ciências da Vida, Faculdade de Ciências e Tecnologia, Universidade de Cabo Verde (Isabel Inês Araújo)

Moçambique

5. Instituto Nacional de Saúde (Elda Anapakala)
6. Museu História Natural / Centro de Biotecnologia, Universidade Eduardo Mondlane (Carlos Bento)
7. Centro de Investigação em Saúde da Manhiça (CISM) (Gloria Matambisso)

Portugal

8. Instituto de Medicina Molecular / Biobanco.pt (Sérgio Dias)
9. Faculdade de Ciências Médicas (Ana Oliveira / Maria Assunção)
10. Instituto Nacional de Saúde Dr Ricardo Jorge (Marta Barreto)

17h45 – 18h00 – Considerações finais e encerramento

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Reunião Os biobancos na Lusofonia
Lista de participantes

19 de abril, 2023
IHMT, Lisboa

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	biobanco.pt / Instituto de Medicina Molecular (iMM)		Sérgio Dias	sergiodias@medicina.ulisboa.pt
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	Instituto Nacional de Saúde Dr Ricardo Jorge (INSA)		Marta Barreto	marta.barreto@insa.min-saude.pt
			Célia Ventura	celia.ventura@insa.min-saude.pt

Membership form of Lusophone Network of Biobanks and Biological Collections

NOME DA INFRAESTRUTURA	
Instituição	
Localização/Morada	
WEBSITE	
PONTO(S) FOCAL/CONTACTO(S)	
Nome	
Telefone	
e-mail	
DESCRIÇÃO	
Missão	
Estado de implementação	A iniciar _____ Em implementação _____ Implementada _____
Certificação/Acreditação	Não _____ Sim _____ Especifique a ISSO _____
INSTALAÇÕES E RECURSOS	
Condições e Procedimentos de Armazenamento e Processamento (máx 75 palavras)	
LIMS software disponível	
Pessoal dedicado	
DESCRIÇÃO DAS COLEÇÕES	
Amostras humanas (biobanco) _____ Amostras não humanas (centro de recursos biológicos) _____	
Descrição (máx 75 palavras)	
ASPETOS ÉTICOS E LEGAIS (máx 50 palavras)	
SERVIÇOS PRESTADOS (máx 50 palavras)	
PARTICIPAÇÃO EM REDES OU CONSÓRCIOS	
NOTAS ADICIONAIS (máx 25 palavras)	

ANNEX 3

BUSSINESS MODEL FOR BIOTROPICAL RESOURCES (BIOTROP)

The Business Model Canvas **Designed** by APA / **Reviewed** by SC BIOTROP
Designed for ***BIOTROPICAL RESOURCES (BIOTROP)*** **Date** December 2022 / January 2023
GHTM IHMT NOVA

Rationale for the Bussiness Model Design

Biobanking is crucial for biomedical research. Areas such as precision healthcare, drugs or diagnostic methods development and inumerous medical procedures rely on continuous scientific investigation to be constantly improved and very often depend on biospecimens (biological material and data) donated by consenting patients. Biobanks maintain an infrastructure that can collect and store samples in optimal conditions either for a known project or for an as-yet undetermined future project[1].

BIOTROP - Biotropical Resources, is the biobank of GHTM IHMT NOVA, whose main mission is to provide access to high-quality biological resources existing at the institution to promote research of on health sciences, particularly on infectious diseases and tropical medicine.

Following the analysis of the 1st phase of implementation[2], four main areas of intervention have been established for the the 2021 - 2023 triennium[3]: Diversity and quality of the sample collections, Sample management, Visibility and Sustainability.

According to Van der Stijl & Eijdems[4,5], BIOTROP is an academic biobank, a non-profit organization that works in a challenging legal, ethical, and scientific context, while addressing the ethical, scientific and economic demands as well as the societal and research expectations. Sustainability as the ability to remain operational, effective, and competitive throughout its lifetime, as defined by Organization for Economic Co-operation and Development (OECD)[4,5], is crucial and implies a financial component but business planning is still infrequent in the biobanking activity, as few biobanks drafted a business plan to support their operational costs[6].

According to the pan-European Biobanking and Biomolecular Resources Research Infrastructure (BBMRI)[4,5], the business plan that best suits BIOTROP is a Core facility business model, as it acts as centralised core facility that provides handling, storage, and distribution services within a hosting research institution, which provides structural funding. In this context, the biobank needs to to prove its worth to the hosting institute to maintain structural support or actively engage the Directive Board and clarify its added value to the institution[4].

Sustainability and demonstration of value is challenging because biobanks operate on a timescale of 10 to 30 years and there is a considerable lag between a biobank's start and its potential output for benefits. Samples and data collection, and the subsequent scientific research, is a time-consuming process and outcomes start only to accumulate after the first few years. Due to their timescale, biobanks need to get commitment and funding over a long period. Further, usually the funding structure evolves over time; in the initial stages of a biobank infrastructure, single donor infrastructure and project grants are the major sources of funding, while mixed funding resources become essential for the biobank's survival in the latter stage of development[6].

The storage of biospecimens and their use for research purposes is the key function of a biobank. If the specimen utilisation rate is low, the biobank does not serve its basic purpose, and becomes financially and socially unsustainable. BIOTROP is now fully implemented but the utilisation rate is still low, making it difficult to do a cost-benefit a cost-benefit, impact or risk management/mitigation analysis. Nevertheless, In this first version of a business model, we have focused on defining 1) who are our customer segments, 2) our main value propositions, 3) our financial structure and 4) our key resources and processes (business model canvas).

Meanwhile, we are trying to increase the utilisation of specimens through continuous advertising of BIOTROP collections and services, engagement and networking with stakeholders. At same time the selection of samples to be stored is being refined, preferentially integrating prospective, well-characterised research-driven collections instead of a model based on retrospective samples. While all these actions as well those related to regulatory requirements, implementation of standardisation and certification procedures, increase the opportunities to participate in prestigious research programmes and collaborations, they also impose additional operational costs.

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Label:

who? (*customers/users*)
what? (supplies)
how? (infrastructure)
how much? (finances)

1 Customer Segments

For whom are we creating value?
Who are our most important customers?

2 Value Propositions

What value do we deliver to the customer?
Which one of our customer's problems are we helping to solve?
What bundles of products and services are we offering to each Customer Segment?
Which customer needs are we satisfying?

3 Channels

Through which Channels do our Customer Segments want to be reached?
How are we reaching them now?
How are our Channels integrated?
Which ones work best?
Which ones are most cost-efficient?
How are we integrating them with customer routines?

4 Customer Relationships

What type of relationship does each of our Customer Segments expect us to establish and maintain with them?
Which ones have we established?
How are they integrated with the rest of our business model?
How costly are they?

5 Revenue Streams

For what value are our customers really willing to pay?
For what do they currently pay?
How are they currently paying?
How would they prefer to pay?
How much does each Revenue Stream contribute to overall revenues?

6 Key Resources

What Key Resources do our Value Propositions require?
Our Distribution Channels? Customer Relationships?
Revenue Streams?

7 Key Activities

What Key Activities do our Value Propositions require?
Our Distributions channels?
Customer relationships?
Revenue streams?

8 Key Partners

Who are key partners?
Who are key suppliers?
Which Key Resources are we acquiring from partners?
Which Key Activities do partners perform?

9 Cost Structure

What are the most important costs inherent in our business model?
Which Key Resources are most expensive?
Which Key Activities are most expensive?

The Business Model Canvas

Designed for ***BIOTROPICAL RESOURCES (BIOTROP)***

GHTM IHMT NOVA

Designed by **APA** / Reviewed by **SC BIOTROP**

Date **December 2022**

Iteration 1. **January 2023**

8 Key Partners

patients/population
researchers
clinicians/clinical analysis laboratory
similar infrastructures (networks)
ethical boards
institutional governing bodies
industry

7 Key Activities

store, sort and categorise specimens
store and manage associated data
communicate w/ population and researchers
create/update SOPs
update online catalogue
dissemination activities
consultancy

6 Key Resources

storage facilities (freezers, liquid nitrogen
temperature monitoring (data logger)
basic laboratory equipment
molecular biology laboratory equipment
biosafety cabinet
IT infrastructure
office equipment

2 Value Propositions

1. For Population
improved healthcare
trust for fair use of biospecimens
best use of biological products
compliance to ethical and legal guidelines
2. For Academic research
established infrastructure
rapid access to samples
compliance to ethical and legal guidelines
biological sample ensured quality
guarantee of sample origin
standardized procedures
3. For Industry research
established infrastructure
rapid access
compliance to ethical and legal guidelines
guarantee of sample quality
guarantee of sample origin
standardized procedures
single contractual partner

4 Customer Relationships

webpage
social networks
open sessions/dissemination activities
e-mailing
promotional material
annual reports
face-to-face contact

3 Channels

online catalogue
web-based information on request/deposit forms/procedures
e-mail
phone
shipping by regular mail

1 Customer Segments

1. Population
precision medicine
new diagnostic tests
new/improved therapies
new infection control measures
2. Academic research
disease/agent biology
biomarkers
infection transmission dynamics
population genetics - pathogens & vectors
population dynamics - pathogens & vectors
host-pathogen interactions
3. Industry research
biomarkers
diagnostic tests
drug targets
drug development

9 Cost Structure

human resources (salary)	€ 5 000,00 *
capital cost of facilities and equipment	€ 65 000,00
capital cost of IT technology (online catalogue, LIMS)	€ 2 000,00 **
operational cost of storage (electricity, liquid nitrogen)	
operational cost of office and communication (web page, mailing, phone, dissemination activities, promotional material)	
sample handling and data management (laboratory consumables)	

* (gross salary + all legally associated costs)/month
** only 2 modules (full cost of 1 licence around ~€80 000.00)

5 Revenue Streams

projects-associated budget
deposit/distribution fees
contracts w/ industry
shipping

services fees

organization of collections

support for preparation of MTAs, SOPs, questionnaires, informed consents, etc

molecular biology techniques

no payments/income yet
no institutional procedures for internal payments

who? (*customers/users/stakeholders*)
what? (supplies - what do users value?)
how? (infrastructure)
how much? (financial structure)

APA - Ana Paula Arez, Coordinator
SC - Scientific Committe (Ana Tavares, Celso Cunha, Isabel Couto, Luís Távora Tavira, Luís Varandas, Silvana Belo)

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GHTM IHMT NOVA

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APA - Ana Paula Arez, Coordinator
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ANNEX 4

BIOTROPICAL RESOURCES (BIOTROP) REGULATIONS

REGULAMENTO DO BIOTROP

PREÂMBULO

O biobanco / centro de recursos biológicos (CRB) "Biotropical Resources", adiante designado por BIOTROP, é uma infraestrutura de suporte à investigação no âmbito das ciências biomédicas, com especial foco nas doenças infeciosas. O BIOTROP está integrado e é administrativa e financeiramente dependente do centro de investigação *Global Health and Tropical Medicine*, do Instituto de Higiene e Medicina Tropical, Universidade Nova de Lisboa (GHTM IHMT NOVA), localizando-se nas suas instalações, sitas na Rua da Junqueira 100, 1349-008 Lisboa, Portugal.

ARTIGO 1º

MISSÃO E OBJETIVOS

1 - O BIOTROP tem como Missão fortalecer a comunidade científica, contribuindo para a investigação na área das ciências da saúde, em particular das doenças infeciosas e medicina tropical. Procura harmonizar as estratégias base de funcionamento e os procedimentos técnicos com os requisitos legais e éticos vigentes. Além disso, tem o compromisso de assegurar o respeito pelos direitos fundamentais e liberdade dos doentes e dadores em geral, com especial ênfase na proteção da dignidade e identidade, bem como no tratamento adequado e confidencialidade dos seus dados individuais.

2 - O BIOTROP tem como objetivos:

a) Fornecer à comunidade científica o acesso a coleções e dados com qualidade, através de uma estrutura colaborativa;

b) Obter coleções variadas que possam corresponder às necessidades atuais e futuras dos investigadores e indústria;

c) Contribuir para a inovação tecnológica ou desenvolvimento da investigação na área das ciências biomédicas;

d) Fornecer produtos e/ou serviços a instituições públicas ou privadas.

ARTIGO 2º

BOAS PRÁTICAS E BIOSSEGURANÇA

1 - Os procedimentos e boas práticas da atividade do BIOTROP e os procedimentos relacionados com a biossegurança serão baseados em versões atualizadas das diretivas da

Organização para a Cooperação e Desenvolvimento (OCDE[1][2]), Sociedade Internacional para Repositórios Biológicos e Ambientais (ISBER [3]), Manual de Segurança Biológica da Organização Mundial da Saúde (OMS)[4], e outras diretrizes internacionais aplicáveis;

2 - Todas as atividades a desenvolver no BIOTROP decorrerão de acordo com Procedimentos Operacionais Padrão (SOP, *Standard Operating Procedures*);

3 - Os SOP relativos ao funcionamento e à manutenção de equipamentos e da infraestrutura são elaborados pela Coordenação;

4 - Os SOP relativos às amostras depositadas resultantes de projetos de investigação são elaborados pelos seus investigadores em colaboração com a Coordenação;

5 - Os SOP são sujeitos a parecer da Comissão Científica do BIOTROP.

ARTIGO 3º

ORGANIZAÇÃO FUNCIONAL

1 - Integram o BIOTROP:

a) A Coordenação;

b) A Comissão Científica;

c) O Conselho de Consultores.

ARTIGO 4º

COORDENAÇÃO

1 - A Coordenação do BIOTROP é realizada por dois membros da instituição de acolhimento, GHTM IHMT NOVA:

a) O Coordenador Geral, é o investigador responsável pelo supervisionamento e funcionamento da infraestrutura; coordena as atividades do Coordenador Técnico e da Comissão Científica e faz a articulação com a Comissão Científica do GHTM e com todos os órgãos do IHMT NOVA;

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[1] OECD Best Practice Guidelines for Biological Resource Centres. Paris, France: OECD (2007). Disponível em https://www.oecd-ilibrary.org/science-andtechnology/oecd-best-practice-guidelines-for-biological-resource-centres_9789264128767-en

[2] OECD guidelines on human biobanks and genetic research databases. Paris, France: Organisation for Economic Co-operation and Development (2009). Disponível em https://www.oecd.org/sti/biotech/44054609.pdf

[3]. 2023 ISBER Best Practices: Recommendations for Repositories. 5th edition. Vancouver, Canada: ISBER (2023). Disponível em https://www.isber.org/page/BPR.

[4] Laboratory biosafety manual, fourth edition. Geneva: World Health Organization (2020) (Laboratory biosafety manual, fourth edition and associated monographs). Disponível em https://www.who.int/publications/i/item/9789240011311

b) O Coordenador Técnico, é o investigador responsável por assegurar o funcionamento e a manutenção da infraestrutura; substitui o Coordenador Geral em caso de impedimento deste; trabalha em conexão com os elementos da Comissão Científica; é o responsável pela receção, controlo de qualidade, armazenamento e gestão da base de dados das amostras; responsável pelos procedimentos que envolvem a preparação e envio das amostras; e responsável pela manutenção dos equipamentos.

ARTIGO 5º

COMPETÊNCIAS DA COORDENAÇÃO

1 - Compete à Coordenação definir as orientações estratégicas e acompanhar a política geral da infraestrutura, nomeadamente:

a) Definir estratégias de colaboração intrainstitucionais, interinstitucionais nacionais e internacionais;

b) Definir estratégias de divulgação da infraestrutura;

c) Elaborar o plano de atividades;

d) Efetuar e acompanhar a gestão orçamental da infraestrutura;

e) Definir estratégias de angariação de fundos;

f) Elaborar o relatório anual de atividades do BIOTROP em articulação com os órgãos e serviços institucionais competentes;

g) Analisar e propor os processos referentes aos serviços referidos no Artigo11º;

h) Apreciar as alterações propostas ao presente regulamento e propor a sua homologação;

i) Sempre que exista renúncia ou cessação de algum membro da Comissão Científica ou do Conselho de Consultores, proceder à sua substituição por outro elemento da mesma área de competência em articulação com o GHTM IHMT NOVA, nos termos do presente Regulamento, no prazo máximo de trinta (30) dias;

j) Convocar as reuniões da Comissão Científica e Conselho de Consultores e presidir às mesmas;

k) Elaborar Atas das reuniões da Comissão Científica e Conselho de Consultores;

l) Trabalhar em articulação com a Comissão de Ética do IHMT (CEIHMT), sempre que necessário algum parecer relacionado com questões éticas e legais.

ARTIGO 6º

COMISSÃO CIENTÍFICA

1 - A Comissão Científica é constituída por membros do GHTM IHMT NOVA, devendo abarcar competências nas áreas da Microbiologia, Parasitologia, Clínica e Diagnóstico;
2- A Comissão Científica reúne com a Coordenação pelo menos duas vez por ano, ou sempre que necessário.

ARTIGO 7º

COMPETÊNCIAS DA COMISSÃO CIENTÍFICA

1 - À Comissão Científica compete a gestão científica do BIOTROP, nomeadamente:
a) Participar nas reuniões convocadas pela Coordenação;
b) Acompanhar técnica e cientificamente o funcionamento do biobanco;
c) Apoiar a elaboração dos SOP, e na resolução de problemas decorrentes da sua implementação;
d) Analisar os processos referentes aos serviços referidos no Artigo 11º com base em critérios científicos, éticos e operacionais;
e) Propor à Coordenação alterações ao Regulamento, sempre que o considerar necessário;
f) Apreciar o plano de atividades, o orçamento e o relatório anual de atividades do BIOTROP.

ARTIGO 8º

CONSELHO DE CONSULTORES

1 - O Conselho de Consultores é composto por três personalidades externas, propostas pela Coordenação e aprovadas pelo IHMT NOVA, com competências nas áreas dos Centros de Recursos Biológicos (coleções de origem não-humana), Biobancos (coleções de origem humana) e Questões ético-legais.
2 - O Conselho de Consultores reúne com a Coordenação pelo menos uma vez por ano.

ARTIGO 9º

COMPETÊNCIAS DO CONSELHO DE CONSULTORES

1 - Compete ao Conselho de Consultores:
a) Apoiar a Coordenação na definição de estratégias de inovação;
b) Propor à Coordenação, projetos de parcerias estratégicas que contribuam para a consecução da Missão do BIOTROP;

c) Apoiar a Coordenação na mobilização de recursos para o desenvolvimento das atividades de cooperação.

ARTIGO 10º

APOIO TÉCNICO E CIENTÍFICO

1 – O apoio técnico e científico para matérias específicas relacionadas com a elaboração e avaliação dos SOP poderá ser solicitada a todos os elementos doutorados do IHMT NOVA com experiência no tema.

2 - Sempre que o BIOTROP solicite colaboração a um membro Doutorado do IHMT NOVA espera-se que este participe, dentro das suas possibilidades, de forma a assegurar a excelência do funcionamento estrutural do BIOTROP.

ARTIGO 11º

SERVIÇOS DISPONÍVEIS

1 – São serviços do BIOTROP, disponibilizados a investigadores e estudantes do IHMT NOVA ou externos:

a) Fornecimento de amostras biológicas;

b) Organização de coleções;

c) Apoio no estabelecimento de SOP;

d) Apoio na transferência de amostras biológicas entre países;

e) Deteção e identificação de agentes infeciosos através de técnicas moleculares;

f) Aluguer de espaço para depósito de amostras;

g) Prestação de serviços específicos por solicitação e não descritos no presente regulamento.

2 - O custo dos serviços será estipulado em tabela atualizada anualmente ou mediante pedido de orçamento à Coordenação em articulação com os órgãos e serviços do IHMT NOVA competentes na matéria.

ARTIGO 12º

ENTRADA EM VIGOR

Este Regulamento entra em vigor no dia seguinte ao da sua homologação pela Direção do GHTM IHMT NOVA.

PRICE LIST OF SERVICES PROVIDED BY BIOTROP

Price list of services provided by BIOTROP biobank[1]

(Euro, €)

REF	SERVICES (€)	INTERNAL RESEARCHERS GHTM IHMT NOVA	EXTERNAL ** RESEARCHERS/OTHERS
SRE	**Sample Request** (/sample)	1,00	2,00
SHI	**Sample Shipment** (/sample) [2]	-	3,50
DEP	**Safe Deposit**[3]		
DEP.01	Up to 100 samples	100,00	200,00
DEP.02	100 – 500 samples	500,00	1000,00
DEP.03	500-1000 samples	1000,00	2000,00
DEP.04	More than 1000 samples	3000,00	6000,00
OCO	**Organization of Individual Collections** [2]	200,00	300,00
SMS	**Support for Sample Management Software (LIMS) Implementation** (training and configuration assistance)	75,00	100,00
SPR	**Samples Management Products**		
SPR.01	Label printing (/tube)	0,20	0,30
PRE	**Support for Preparation of SOPs, MTAs, Questionnaires, Informed Consent** [2]	50,00	75,00
ELT	**Support for Ethical & Legal Transfer of Biological Samples Between Countries** [2]	75,00	100,00
NEX	**Nucleic Acid Extraction** (/sample)		
NEX.01	w/ Kit DNA	8,00	16,00
NEX.02	w/ Kit RNA	12,00	24,00
NQC	**Nucleic Acid Quantification/Quality Control** (/sample)		
NQC.01	DNA/RNA/Protein by Nanodrop	0,50	1,00
NQC.02	DNA/RNA/Protein by Qubit	0,60	2,00
MDI	**Molecular biology assays** (/sample)[4]		
MDI.01	PCR	50,00	100,00
MDI.02	qRT-PCR	75,00	150,00
	Other services	to be defined on request	

****The IHMT overhead (25%) will be added to all prices**

(1) Revised in 2024; (2) Prices may differ with no prior warning; (3) Prices may differ if cryopreservation tubes and boxes are required; (4) Prices may vary according to the protocol provided by the researcher.