



Developing the potential of Thalassia testudinum in the health sector in Cuba in accordance with the Nagoya Protocol and Biodiversity Conservation

Part I: Project Information

GEF ID

11037

Project Type

MSP

Type of Trust Fund

GET

CBIT/NGI

CBIT **No**

NGI **No**

Project Title

Developing the potential of Thalassia testudinum in the health sector in Cuba in accordance with the Nagoya Protocol and Biodiversity Conservation

Countries

Cuba

Agency(ies)

UNDP

Other Executing Partner(s)

Environment Agency (AMA)

Executing Partner Type

Government

GEF Focal Area

Biodiversity

Taxonomy

Focal Areas, Biodiversity, Protected Areas and Landscapes, Coastal and Marine Protected Areas, Species, Plant Genetic Resources, Biomes, Sea Grasses, Supplementary Protocol to the CBD, Access to Genetic Resources Benefit Sharing, Influencing models, Strengthen institutional capacity and decision-making, Stakeholders, Local Communities, Beneficiaries, Communications, Education, Awareness Raising, Civil Society, Academia, Gender Equality, Gender Mainstreaming, Sex-disaggregated indicators, Gender results areas, Access and control over natural resources, Capacity Development, Participation and leadership, Knowledge Generation and Exchange, Capacity, Knowledge and Research, Innovation, Knowledge Exchange, Knowledge Generation, Learning

Sector

Rio Markers

Climate Change Mitigation

Climate Change Mitigation 1

Climate Change Adaptation

Climate Change Adaptation 1

Submission Date

5/18/2022

Expected Implementation Start

12/1/2022

Expected Completion Date

11/30/2026

Duration

48In Months

Agency Fee(\$)

86,521.00

A. FOCAL/NON-FOCAL AREA ELEMENTS

Objectives/Programs	Focal Area Outcomes	Trust Fund	GEF Amount(\$)	Co-Fin Amount(\$)
BD-3-9	Further development of biodiversity policy and institutional frameworks through the Implementation of the Nagoya Protocol on Access and benefit sharing	GET	910,745.00	1,204,340.00
Total Project Cost(\$)			910,745.00	1,204,340.00

B. Project description summary

Project Objective

Promote the equitable distribution of benefits and conservation of the genetic resources of biodiversity by strengthening the regulatory authority and evaluating a product for the therapeutic management of cancer obtained from *Thalassia testudinum* angiosperm

Project Component	Financing Type	Expected Outcomes	Expected Outputs	Trust Fund	GEF Project Financing(\$)	Confirmed Co-Financing(\$)
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Project Component	Financing Type	Expected Outcomes	Expected Outputs	Trust Fund	GEF Project Financing(\$)	Confirmed Co-Financing(\$)
1. Strengthening the legal framework and capacities for the implementation of the Nagoya Protocol on Access to Genetic Resources and Benefit Sharing	Technical Assistance	<p>1.1. Strengthened political, legal and institutional framework regarding access to genetic resources and benefit sharing measured by:</p> <p>- 1 proposal for a legal standard on access to genetic resources and benefit-sharing and 1 methodological tool to support the implementation of the legal standard presented for approval by the competent authority.</p> <p>- 255 participants in capacity building programs for ABS aimed at authorities, NGOs / civil society and other key partners (female/male)</p>	<p>1.1.1. Procedures, methodologies, and model clauses are proposed to complete the legislation that implements the Nagoya Protocol.</p> <p>1.1.2. Strengthened capacities of the regulatory authority to control access to genetic resources.</p> <p>1.1.3 Tools for training, protection, information management and scope of intellectual property rights.</p> <p>1.1.4 Dialogue platform to exchange of information on ABS and knowledge associated with biodiversity conservation.</p>	GET	93,000.00	37,160.00

Project Component	Financing Type	Expected Outcomes	Expected Outputs	Trust Fund	GEF Project Financing(\$)	Confirmed Co-Financing(\$)
2. Strengthening institutional and individual capacities for the research and development of a pharmaceutical product from a marine angiosperm	Technical Assistance	<p>2.1 Increased institutional capacities for bio-product development measured by:</p> <p>-200 staff and students trained on the non-clinical evaluation of products derived from marine biodiversity in controlled environment.</p> <p>- Request for permit to start clinical trials of a new product for human use from marine angiosperm submitted to the National Authority.</p>	<p>2.1.1. Updated ICIMAR technical and operational capacities enable obtaining permission from the National Regulatory Unit to conduct non-clinical studies on the product.</p> <p>2.1.2. Strengthened human resources in the non-clinical evaluation of products derived from marine biodiversity under a controlled environment.</p> <p>2.1.3. Phytochemical characterization of natural extracts, identification of metabolites, and evaluation of anti-tumor effects and margin of safety of the active ingredient derived from T. testudinum.</p> <p>2.1.4. Documentation to obtain authorization for clinical studies under biodiversity conservation principles is completed.</p>	GET	269,903.00	570,100.00

Project Component	Financing Type	Expected Outcomes	Expected Outputs	Trust Fund	GEF Project Financing(\$)	Confirmed Co-Financing(\$)
3. Conservation of marine biodiversity and habitat of angiosperm used for pharmaceutical bioproduct development	Technical Assistance	<p>3.1 Conservation and sustainable use of genetic resources associated with seagrass in 3 target sites measured by:</p> <p>- 118 hectares under improved management for conservation and sustainable use.</p> <p>-513 hectares under improved practices.</p> <p>-170 g/m2 of leaf biomass maintained in Rincon Guanabo by project end.</p> <p>-XX of g/m2 of leaf biomass maintained in Camagüey by project end.</p> <p>-XX of g/m2 of leaf biomass maintained in Santiago de Cuba by project end</p> <p>- XX tons of carbon stock in three intervention sites by project end.</p>	<p>3.1.1 Evaluation of environmental quality of seagrass ecosystem at intervention sites.</p> <p>3.1.2 Management protocols and recommendations for the conservation and sustainable use of seagrass.</p> <p>3.1.3 Population analysis of <i>Thalassia testudinum</i> angiosperm.</p> <p>3.1.4. Approved best practice/procedural tools for the management and sustainable use of <i>Thalassia testudinum</i>.</p> <p>3.2.1 Training program on supply and value chains management associated to the</p>	GET	458,500.00	521,550.00

Project Component	Financing Type	Expected Outcomes	Expected Outputs	Trust Fund	GEF Project Financing(\$)	Confirmed Co-Financing(\$)
4. Monitoring and knowledge management	Technical Assistance	<p>4.1 Increase awareness amongst Cuban society about the importance and legality of the conservation and sustainable use of genetic resources measured by:</p> <p>-Full implementation of the awareness campaign on ABS and BD in Cuba</p>	<p>4.1.1 Awareness campaign aimed at different stakeholders and users of genetic resources to promote a change in behavior, highlights responsible harvesting and treatment procedures and practices.</p> <p>4.1.2 M&E Plan, SESP, and GAP implemented.</p> <p>4.1.3 Publication and dissemination of the results and lessons learned.</p>	GET	59,800.00	40,000.00

Sub Total (\$)	881,203.00	1,168,810.00
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Project Management Cost (PMC)

GET	29,542.00	35,530.00
Sub Total(\$)	29,542.00	35,530.00
Total Project Cost(\$)	910,745.00	1,204,340.00

Please provide justification

C. Sources of Co-financing for the Project by name and by type

Sources of Co-financing	Name of Co-financier	Type of Co-financing	Investment Mobilized	Amount(\$)
Recipient Country Government	Office for Environmental Regulation, ORSA, Ministry for Science, Technology and Environment	Grant	Recurrent expenditures	6,274.00
Recipient Country Government	Office for Environmental Regulation, ORSA, Ministry for Science, Technology and Environment	In-kind	Recurrent expenditures	30,888.00
Recipient Country Government	Environmental Agency AMA (Sectorial Program of Biodiversity), Ministry for Science, Technology and Environment	Grant	Recurrent expenditures	292,587.00
Recipient Country Government	Environmental Agency AMA (Sectorial Program of Biodiversity), Ministry for Science, Technology and Environment	In-kind	Recurrent expenditures	90,800.00
Recipient Country Government	Institute of Marine Science, AMA, CITMA	Grant	Investment mobilized	35,525.00
Recipient Country Government	Financial Fund for Science and Innovation (FONCI) and National Environment Fund (FNMA)	Grant	Recurrent expenditures	625,000.00
Recipient Country Government	Havana Provincial Delegation, CITMA	Grant	Investment mobilized	45,000.00
Recipient Country Government	Habana University, Ministry of Higher Education (MES)	In-kind	Recurrent expenditures	29,931.00
Other	Pharmaceutical Laboratories ?Oriente?, Higher Business Development Organization (OSDE) BioCubafarma	Grant	Recurrent expenditures	1,335.00

Sources of Co-financing	Name of Co-financier	Type of Co-financing	Investment Mobilized	Amount(\$)
Other	Pharmaceutical Laboratories ?Oriente?, Higher Business Development Organization (OSDE) BioCubafarma	In-kind	Recurrent expenditures	7,000.00
GEF Agency	UNDP	In-kind	Recurrent expenditures	40,000.00
Total Co-Financing(\$)				1,204,340.00

Describe how any "Investment Mobilized" was identified

a Investments will be directed to cover the cost of conducting the remodeling of the ICIMAR's Experimental Unit. b Investments will be directed to cover the cost of conducting the Guababo beach restauration.

D. Trust Fund Resources Requested by Agency(ies), Country(ies), Focal Area and the Programming of Funds

Agency	Trust Fund	Country	Focal Area	Programming of Funds	Amount(\$)	Fee(\$)	Total(\$)
UNDP	GET	Cuba	Biodiversity	BD STAR Allocation	910,745	86,521	997,266.00
Total Grant Resources(\$)					910,745.00	86,521.00	997,266.00

E. Non Grant Instrument

NON-GRANT INSTRUMENT at CEO Endorsement

Includes Non grant instruments? **No**

Includes reflow to GEF? **No**

F. Project Preparation Grant (PPG)

PPG Required **false**

PPG Amount (\$)

PPG Agency Fee (\$)

Agenc y	Trust Fund	Country	Foca l Area	Programmin g of Funds	Amount(\$)	Fee(\$)	Total(\$)
Total Project Costs(\$)					0.00	0.00	0.00

Core Indicators

Indicator 2 Marine protected areas created or under improved management for conservation and sustainable use

Ha (Expected at PIF)	Ha (Expected at CEO Endorsement)	Ha (Achieved at MTR)	Ha (Achieved at TE)
0.00	118.00	0.00	0.00

Indicator 2.1 Marine Protected Areas Newly created

Total Ha (Expected at PIF)	Total Ha (Expected at CEO Endorsement)	Total Ha (Achieved at MTR)	Total Ha (Achieved at TE)
0.00	0.00	0.00	0.00

Name of the Protected Area	WDP A ID	IUCN Category	Total Ha (Expected at PIF)	Total Ha (Expected at CEO Endorsement)	Total Ha (Achieved at MTR)	Total Ha (Achieved at TE)
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Indicator 2.2 Marine Protected Areas Under improved management effectiveness

Total Ha (Expected at PIF)	Total Ha (Expected at CEO Endorsement)	Total Ha (Achieved at MTR)	Total Ha (Achieved at TE)
0.00	118.00	0.00	0.00

Name of the Protected Area	WDP A ID	IUCN Category	Total Ha (Expected at PIF)	Total Ha (Expected at CEO Endorsement)	Total Ha (Achieved at MTR)	Total Ha (Achieved at TE)	METT score (Baseline at CEO Endorsement)	METT score (Achieved at MTR)	METT score (Achieved at TE)
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Name of the Protected Area	WDP ID	IUCN Category	Total Ha (Expected at PIF)	Total Ha (Expected at CEO Endorsement)	Total Ha (Achieved at MTR)	Total Ha (Achieved at TE)	METT score (Baseline at CEO Endorsement)	METT score (Achieved at MTR)	METT score (Achieved at TE)
Akula National Park Paiaje National Protected Region de Guanabo	125689	Selectected Landscape/Seascape		118.00			49.00		

Indicator 4 Area of landscapes under improved practices (hectares; excluding protected areas)

Ha (Expected at PIF)	Ha (Expected at CEO Endorsement)	Ha (Achieved at MTR)	Ha (Achieved at TE)
0.00	513.00	0.00	0.00

Indicator 4.1 Area of landscapes under improved management to benefit biodiversity (hectares, qualitative assessment, non-certified)

Ha (Expected at PIF)	Ha (Expected at CEO Endorsement)	Ha (Achieved at MTR)	Ha (Achieved at TE)
	513.00		

Indicator 4.2 Area of landscapes that meets national or international third party certification that incorporates biodiversity considerations (hectares)

Ha (Expected at PIF)	Ha (Expected at CEO Endorsement)	Ha (Achieved at MTR)	Ha (Achieved at TE)

Type/Name of Third Party Certification

Indicator 4.3 Area of landscapes under sustainable land management in production systems

Ha (Expected at PIF)	Ha (Expected at CEO Endorsement)	Ha (Achieved at MTR)	Ha (Achieved at TE)
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Indicator 4.4 Area of High Conservation Value Forest (HCVF) loss avoided

Ha (Expected at PIF)	Ha (Expected at CEO Endorsement)	Ha (Achieved at MTR)	Ha (Achieved at TE)
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Documents (Please upload document(s) that justifies the HCVF)

Title	Submitted
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Indicator 11 Number of direct beneficiaries disaggregated by gender as co-benefit of GEF investment

	Number (Expected at PIF)	Number (Expected at CEO Endorsement)	Number (Achieved at MTR)	Number (Achieved at TE)
Female		344		
Male		131		
Total	0	475	0	0

Provide additional explanation on targets, other methodologies used, and other focal area specifics (i.e., Aichi targets in BD) including justification where core indicator targets are not provided

Part II. Project Justification

1a. Project Description

1) the global environmental and/or adaptation problems, root causes and barriers that need to be addressed (systems description);

1. Cuba is among the 5 most important biodiversity hotspots on the planet. It has more than 11,700 species of invertebrates and 655 species of terrestrial and freshwater vertebrates. 96% of mollusks, 75% of arachnids and 95.2% of amphibians and 83.2% of reptiles are endemic. It holds third place in the world in plant endemism with respect to its territorial extension with more than 3,000 exclusives[1]; of the 5,367 taxa of flora studied, 47% are under some degree of threat. Among vertebrates, there are 52 critically endangered, 42 endangered and 63 vulnerable species, while among invertebrates, mollusks constitute the most threatened group with 31 critically endangered and 34 vulnerable species. In addition to having 26 endemic bird species, due to its geographical location, Cuba is the most important island region in the Caribbean for Nearctic and Neotropical migratory birds, several of which are threatened at the continental level[2]. In an effort to conserve Cuba's biodiversity, 211 protected areas have been declared, 77 of national significance, and 119 with legal approval by the Executive Committee of the Council of Ministers[3].

2. In addition to the conservation efforts made by the protected areas system, the sustainable use of biodiversity is a crucial opportunity for Cuba. Access and benefit-sharing (ABS) is a recognized and relevant topic in the commercial use of biological diversity (BD) and the perspectives of biotechnology and industries developed in Cuba, particularly with regards to the health sector. The Cuban State provides health care to its citizens through the National Health System (NHS), a unique, free and accessible health care system. The NHS has evolved with the needs of the country, with advancements in the control of non-communicable, communicable and immuno-preventable diseases, as well as the permanent search for independence with regards to technology, production of medicines and biotechnological products. The country's adoption of a co-development model between the NHS and the biotechnological and pharmaceutical industry, based on the health needs of the Cuban population, is distinguished worldwide. The government has established research and development institutes to facilitate the production of their respective products, research-production centers or full-cycle institutions.

3. BioCubaFarma, a Cuban state-owned business organization that integrates the country's biotechnology and pharmaceutical sectors, was created as part of the business reorganization process within the Cuban economic model. It focuses on the introduction of new drugs, technologies and the manufacture of 525 of the 849 medicines that make up the Basic Table of Medicines of the Cuban Ministry of Public Health, which has been decisive for the operation of several public health programs and the socioeconomic life of the country. It represents a strategic industry with high standards for its products and services and a solid international position. It has more than 21,600 workers, hundreds of high-level professional specialists involved in research-production and 62 production facilities. There are 16 productions, 3 marketing and 2 service companies with branches in all the provinces of Cuba, which are responsible for national distribution throughout the island. BioCubaFarma integrates an effective cycle for research, development and distribution. In addition, BioCubaFarma's approach has facilitated technology transfer to other countries. As such, BioCubaFarma is an important source of income for the country through the commercialization of part of its products and technologies in different countries, representing approximately 0.4% of GDP/ US\$ 84 693 M (2019).

4. The loss of biodiversity is recognized in the National Environmental Strategy as one of the main environmental problems that must be addressed. This is associated, among other things, with the modifications and loss of habitats that have taken place on the island and with the vulnerability of an island country, which receives the impacts of climate change and various anthropogenic processes.

5. Furthermore, to date, little progress has been made in terms of providing legal protection and recognition of the biological heritage that sustains Cuba's biopharmaceutical industry. Actions have focused on copyrights and patents granted to institutions for products derived from biological resources, particularly from terrestrial biodiversity, and on patents related to traditional knowledge or practices that foster the production or synthesis of such products and the communities that contribute such knowledge. However, Cuba's regulatory framework is inadequate for enabling research, negotiations and investment in genetic resources. The current framework needs to be strengthened to regulate the use and protection of genetic resources under conditions of equity among the parties, and to promote and guarantee the conservation and sustainable use of biological diversity. The country needs to establish a legal framework to protect natural resources and the knowledge derived from them, which is directly related to their economic value, associated with the food, agriculture and biopharmaceuticals industries.

6. There is a growing trend towards the use and exploitation of genetic resources, practices and associated traditional knowledge, as well as the understanding of the goods and services that BD provides, both on land and sea. In Cuba, an important segment of the population depends on traditional medicine and largely on therapies derived from nature to cure their ailments, which has been taken advantage of by the biopharmaceutical industry worldwide. Indeed, a considerable number of prescription drugs in both developed and developing countries come from natural sources, so the benefits from such developments could be enormous. In the case of marine biodiversity, for example, it has been estimated that a compound derived from a marine sponge to treat herpes is worth US\$ 50-100 million per year. Estimates of the value of anti-tumor agents derived from marine organisms amount to US\$ 1 billion per year^[4].

7. Seagrasses, in particular, are highly valued for the goods and services they provide, such as climate regulation, erosion control, nutrient cycling, habitat, food production, raw materials, genetic resources, recreation, and cultural services. Seagrasses are estimated to cover about 50 % of the Cuban shelf equivalent to 26,563 km² (2,656,300 ha). The most part of this area has *Thalassia testudinum*, a late-successional competitively-dominant species and the dominant seagrass in the Caribbean, South Atlantic and Gulf of Mexico. *T. testudinum* is highly resilient to natural phenomena such as hurricanes, but is very susceptible to anthropogenic impacts that provoke the reduction of light availability (eutrophication, erosion, dredges) as is common near coastal zones along the Cuban shelf. Unfortunately, *Thalassia testudinum* is often subject to clearcutting by hotels along the coast. Hotels 'clean and improve' the coastal area to create conditions for the enjoyment of tourists. Recent studies suggest *T. testudinum* could possess viable anti-tumor agents, of particular interest in the treatment of colon cancer. While there is potential for medicinal/pharmaceutical use of *T. testudinum*, the lack of a proper legal and institutional framework and sustainable harvesting/management protocols could threaten this genetic resource.

8. It is crucial that the development cycle of medical treatments in Cuba be based on a legal, regulatory and institutional framework in accordance with the Nagoya Protocol to ensure access to genetic resources and associated knowledge, as well as the fair and equitable sharing of the benefits derived from the utilization of genetic resources, taking into account all rights over those resources, and through the appropriate transfer of relevant technologies, thereby contributing to the conservation of biological diversity and the sustainable use of its components.

9. The Cuban State has devoted considerable resources and efforts to create the basis for knowledge on resources derived from nature and to develop scientific knowledge. This has favored the characterization of ecosystems throughout the island and has encouraged the development of biotechnology on the basis of the conservation and sustainable use of biological diversity. An articulated effort has been made to develop the means to commercialize genetic resources for the well-being of the people, but the distribution of benefits has not fulfilled society's expectations. There is a new economic scenario in Cuba comprised of new possibilities for industrial and local development, such as small-scale production. Under certain conditions, these opportunities for local small-scale production offer an important means to develop equitable access to genetic resources and sharing of benefits derived from them.

10. Despite the years of work and the country's interest in this matter, there are still barriers that prevent the sustainable use of biodiversity from becoming a significant alternative for income generation with an impact on the welfare of the people and the community. These barriers include:

11. Barrier 1. Absence of specific procedures, methodologies and other guidance for the adequate implementation of the existing legislation on access to genetic resources and the equitable distribution of the benefits derived from their use. Consequently, the degree of implementation of the norm is remarkably low. In particular is the outdated Citma Resolution No. 111/1996, which is the main applicable norm in the matter of ABS, dated October 14, 1996. This Norm is ineffective and inefficient in relation to the implementation of the Nagoya Protocol as it lacks fundamental elements of the international regime due to its age, in relation to technological advances. In particular, it is ineffective with regards to access in emergency situations, prior informed consent, and the information exchange mechanism, just to mention a few.

12. In addition, although current legislation establishes that once access to genetic resources has been granted, as part of the mutually agreed conditions, the parties must agree on the benefit-sharing measures that will be applied, in practical terms there is no experience in the country in the application of these measures resulting in a limited application of this regulation. The project constitutes an opportunity to design and test possible measures - monetary and non-monetary - that could be applied in the context of Cuban society.

13. Key elements that define the context of Cuban society are:

? Socialist state ownership of natural resources (therefore there is no private ownership of wildlife and plants).

? A society with high social inclusion, in particular in terms of public health, priority care programs for certain diseases and / sectors of society (infants, adolescents, pregnant women, older adults, patients with HIV, etc.); and subsidized medicines to guarantee access.

14. Barrier 2. Weak research & development processes to obtain products from biodiversity. There is national interest and human resources for the development of products from the country's biodiversity, but access is limited to the material resources and infrastructure necessary to carry out all stages of the process of research-development-innovation of bioproducts. Only one institution (Center for Natural Products/National Center for Scientific Research) in the country has managed to register two medicines for human use from a genetic resource of Cuba's biodiversity, in this case, from land. To date, the country's capacity to carry out bioprospecting and obtain products from marine sources is low and greater support is needed to market these resources for the well-being of local communities throughout the country.

15. Cuba is currently unable to pursue robust research and development activities for pharmaceutical products derived from natural marine sources due to the lack of materials such as reagents, expendable material, updated equipment and infrastructure. These are basic necessities for experimental models that combine in vitro and the use of experimental animals, as is the case of the tumor models required for the evaluation of the antitumor activity of a new therapeutic candidate. These tests require that the cells be kept in culture and then implanted in laboratory animals, in order to develop the tumor. For the success of these studies, the laboratory for the cultivation of tumor cells and the Bioterium (an installation for the maintenance and care of animals) must coincide in the same institution. There are only two research centers in the country that can undertake this type of tests in compliance with 'Good Laboratory Practice' criteria: the Center for Molecular Immunology (CIM) and the Institute of Genetic Engineering and Biotechnology (CIGB), both from the Higher Organization of Business Management of BioCubaFarma. These institutes focus their research on the development of drugs by obtaining monoclonal, recombinant proteins, therapeutic vaccines, among other products from genetic engineering, immunology and biotechnological fermentation.

16. ICIMAR has relied on both institutions for the development of some of the research, but it has only been possible in a time-constrained and limited way, since the available infrastructure, equipment and materials do not allow them to expand their research beyond the current focus. Other constraints are found with regards to the materials required to carry out phytochemical characterization of natural extracts, particularly marine extracts, the identification of metabolites and compounds

responsible for their activity, activity-guided chemical characterization studies. Currently, Cuba does not have enough cutting-edge analytical technology to carry out these studies, nor adequate training for marine areas, equipment and chemical reagents. Similarly, there are gaps in the area of genetic studies for the characterization of marine species, particularly marine plants.

17. Barrier 3. Limited capacity to establish and manage a sustainable value chain that benefit local communities. For the successful commercialization of genetic resources in Cuba, it is necessary to increase the capacities and knowledge about both the most promising species, their role within the ecosystem, as well as their conservation and productive management. In the case of marine angiosperms, there is no documented traditional knowledge in Cuba for their use in any form. Research on these organisms as a source of bioactive substances is relatively recent. Furthermore, there is little knowledge by the Cuban population and decision makers about the importance of this ecosystem as a provider of numerous goods and services to humans and marine biodiversity in general. It is also not known whether the leaves of the species that arrive at the shores are bioactive, or whether the available resource allows for their ecological and economically sustainable use. For this reason, studies are needed to locate the best collection areas, determine the times of year to carry out these collections, reproduce the biological material with the best characteristics, have a management and conservation plan for the species and have trained and equipped personnel to carry out sustainable collection of biological material. It is essential to have a method of sustainable use for the conservation of this ecosystem and involve all value chain stakeholders, including local communities.

18. Barrier 4. There is little knowledge on the part of the Cuban population and decision makers about the importance of this ecosystem as a provider of numerous goods and services to humans and marine biodiversity in general. While there is worldwide evidence of the benefits of using natural products in the treatment of many ailments, terrestrial organisms have been the most widely used, while marine organisms are less recognized despite being a source of enormous prospects. Marine organisms are subject to unique environmental conditions (high pressure, high concentration of salts, predation), which favors the synthesis of molecules. These conditions may lead to the discovery of new structures and compounds with beneficial sui generis effects for the development of life on the planet. Therefore, the diversity of marine species today constitutes a resource of unlimited potential, which can be used in a beneficial way, through biotechnology, to develop new products for agriculture and the pharmaceutical industry, among other uses. However, to date, knowledge of marine biodiversity is incomplete and fragmented. This situation is a critical barrier to its sustainable use.

19. Furthermore, the presence of important volumes of *Thalassia testudinum* in areas used for tourist activities often leads to complaints from hotels and tourists because it inconveniences their recreational activities. Currently, there is an abundance of this plant in locations that compete with the need for clean beaches for the development of tourism in the country. This is noticeable, for example, in the tourist poles such as the north of Camagüey (Santa Lucía Beach). This situation is counterproductive to the conservation of the large *Thalassia* grasslands; measures are needed in these areas to reduce anthropogenic pressures on the sea grasses. Among these, the development of harvesting protocols under criteria of sustainability of the genetic resource would contribute to regulate its extraction in bathing areas with high tourist activity.

2) the baseline scenario and any associated baseline projects,

20. Cuba signed the Convention on Biological Diversity (CBD) at the opening for signature and ratified it in March 1994, with the Ministry of Science, Technology and Environment as its Focal Point. In 1997, the National Environmental Strategy was elaborated and provided the basis for the National Biological Diversity Strategy and Action Plan, which have been updated continuously. At present, these actions have resulted in the National Program for Biological Diversity (PNDB) 2016-2020, which has 20 goals and constitutes the main platform of action for the implementation of the strategic objectives defined in the national environmental policy to confront the loss of biological diversity. The GEF project is directly aligned with several of these goals/targets: Target No. 15, which aims to "Ensure adequate access to genetic resources and benefit sharing in accordance with the Nagoya Protocol", has four actions aimed at full implementation of the Protocol in the country. Target 4 aims to restore coastal and aquaculture ecosystems through sustainable management; Target 10 aims to help

reduce the multiple anthropogenic pressures on coral reefs, seagrasses, mangroves and beaches vulnerable to climate change; and Target 17 aims to make progress in developing human resources to support the implementation of the PNDB.

21. Thanks largely to the progress made in implementing the CBD and to national actions that have been developed in favor of the conservation and sustainable use of genetic resources, the country has recognized and studied the wealth, abundance and uniqueness of its biological diversity at different levels. It has monographs on Cuban marine and terrestrial flora and fauna, and a characterization of its ecosystems. There is a recognized development of biotechnology and this information is available to all communities in the country.

22. However, an analysis of the current reality identifies the need to deepen and continue working on the understanding that it is not only a matter of protecting plants and animals or forests and reefs, but also of continuing to build a country that is highly committed to natural resources, capable of using it on a sustainable basis and fulfilling the third objective of the CBD by achieving a fair and equitable distribution of the benefits derived from them. Cuba must become capable of sustainably exploiting its genetic resources in order to increase the well-being and health of all its people. For example, despite the efforts made by the Health System, high rates of morbidity/mortality are reported annually in the country for certain diseases that urgently need to be solved and programs for their prevention and control established at the national level. These programs could be supported if the country had the mechanisms to implement an adequate distribution of benefits based on evidence of the biopharmaceutical potential of Cuba's biological biodiversity, both terrestrial and marine.

23. In order to achieve the above, Cuba signed the Nagoya Protocol (NP) in November 2015 and has ratified the need to increase, at different levels, the knowledge of the mechanisms and legal actions required to improve access to the equitable distribution of the benefits derived from the use of genetic resources. Cuba's incorporation as a State party to the Nagoya Protocol has been a high-profile political decision, demonstrating the island's commitment to the conservation and sustainable use of biodiversity. Crucial to this is the aforementioned National Program for Biological Diversity (2016-2020), which establishes the country's programmatic platform against indiscriminate use and appropriation by third parties to guarantee the fair and equitable distribution of resources to all citizens, and thus provides a solid baseline for the proposed project, considering the following:

24. There is a rich biological diversity of terrestrial and marine organisms in the extensive Cuban coastline and marine platform (more than 109,886.19 km².) The potential of these resources has been studied. However, they are still under-exploited. Thus, there is ample opportunity to test the effectiveness of the legal framework that this initiative seeks to establish. It is important to mention that about 25.51% of the national marine surface is under some category of protected area. In addition, there is a system of permits to access the areas of intervention, all of which favors applying the NP's goals.

25. The Cuban Biotechnology Industry has the capacity to obtain new medicines, from natural sources, through genetic engineering and biotechnology techniques. This capacity is a strength. In addition, Cuba has professionals and qualified labor that can assimilate and develop new technologies in research centers and the targeted communities. The project, without question, will raise the scientific capacity and the quality of the proposed outputs and results.

26. The approved Strategic Plan for the Development of Science, Technology and Innovation at the national level has among its objectives: promote the conservation and rational use of natural resources such as soil, water, beaches, atmosphere, forests and biodiversity. In this regard, CITMA approved the implementation of a National Program for the Sustainable Use of the components of biological biodiversity in Cuba. One of the objectives of this program is to generate new knowledge to increase the conservation and rational use of biological biodiversity, with emphasis on the ecosystem level, as well as the inter-relations between its entities and abiotic components, including the use and management of genetic resources in the area of ABS.

27. The project is also associated with the National Program for the Sustainable Use of the Components of Biodiversity that began its execution in January 2019 and whose objectives are to develop chemo-pharmaceutical studies, non-clinical efficacy and safety of the extract obtained from *T.*

testudinum under solid scientific criteria and to lay the foundations for obtaining a new product with application in human health as a nutraceutical and biomedical. This is the result of two projects previously conducted within the program that aimed to study and characterize the marine biodiversity of the island platform of Cuba, and provide data on the bioactive potential of the species in question, but is also in synergy with other projects being implemented in ICIMAR and in collaboration with participating institutions. In addition, there are two national programs directed and organized by the Ministry of Public Health that aim to study determinants of health, risk and disease prevention in vulnerable groups in the country, as well as to develop new phytomedicines and supplements from natural sources, with which this project also makes synergy.

28. The components of the proposed project contribute to the achievement of the objectives of the NPSUCB. First, all components aim directly or indirectly to improve the sustainable use of biological biodiversity in the Cuban marine platform. Second, the project will strengthen the management of such resources to benefit the Cuban society by providing an alternative solution to a health problem on a national and supra-national scale. Third, the project components will contribute to achieving a more balanced and diverse income at the local level, i.e., balancing income from tourism activities and the additional income from biodiversity use and equitable ABS.

29. The project's development stems from a constant interaction between local communities, the Cuban civil society, and public agencies. It began with identifying the areas where the *Thalassia* meadows grow throughout the archipelago and the planning of its sustainable management. Consequently, the project will strengthen the above-indicated interaction to ensure a successful implementation and long-lasting results.

30. Given that the health-care system in Cuba provides community-wide and primary health care coverage for all citizens across the country, the project's benefits are expected to have a positive impact on the quality of life of patients at the community level in all regions of the country.

31. The project is framed within the different objectives defined in the national policies on science and technology. These objectives are included in the guidelines 131, 132, 136, 156, 221 and 222 of the Economic and Social Policy approved at the Seventh Congress of the Party and with the strategic trans-sectorial axis of the Program for Economic and Social Development of Cuba until 2030. The objectives are related to natural resources, environment and the development of the biotechnology industry, for example:

? Support and develop comprehensive research to protect, conserve and rehabilitate the environment and adapt environmental policy to the new projections of the economic and social context.

? Prioritize studies aimed at confronting climate change and, in general, the sustainability of the country's development.

? Emphasize the conservation and rational use of natural resources such as soils, water, beaches, the atmosphere, forests and biodiversity, and in particular the protection of marine genetic resources, as well as the promotion of environmental education throughout all communities in the country.

? Sustain and develop the results achieved in the field of biotechnology, medical-pharmaceutical production, the software industry and the process of computerizing society, basic sciences, natural sciences, scientific and technological services with high added value.

? Consolidate the pharmaceutical and biotechnology industry to develop its maximum export capacity, and introduce new products into the domestic market to substitute imports in priority areas.

? Develop the dietary supplements and natural medicine industry, from domestic inputs, for domestic consumption and export.

32. The project is aligned with the recently approved State Plan to Combat Climate Change (Tarea Vida). Task No. 6 of this plan aims to: Stop the deterioration, rehabilitate and conserve the coral reefs throughout the archipelago, with priority given to the crests that border the island platform and protect urbanized beaches for tourist use. Cuban sea grasses are one of the priority ecosystems to be conserved as part of Tarea Vida. Therefore, in order to take advantage of the sea grasses without losing

the goods and services they provide, it is essential to develop methods that prevent the deterioration of the ecosystem.

33. Finally, this project contributes to the implementation of the Sustainable Development Goals (SDGs) in Cuba, as follows:

? SDG 3 ?Ensure healthy lives and promote well-being for all at all ages? / (goal 3.b: Support the research and development of vaccines and medicines for the communicable and non-communicable diseases that primarily affect developing countries, provide access to affordable essential medicines and vaccines, in accordance with the Doha Declaration on the TRIPS Agreement and Public Health, which affirms the right of developing countries to use to the full the provisions in the Agreement on Trade-Related Aspects of Intellectual Property Rights regarding flexibilities to protect public health, and, in particular, provide access to medicines for all);

? SDG 4 ?Ensure inclusive and equitable quality education and promote lifelong learning opportunities for all? / (goal 4.3: By 2030, ensure equal access for all women and men to affordable and quality technical, vocational and tertiary education, including university);

? SDG 5: ?Achieve gender equality and empower all women and girls? / (goal 5.5: Ensure women?s full and effective participation and equal opportunities for leadership at all levels of decision-making in political, economic and public life);

? SDG 8 ?Promote sustained, inclusive and sustainable economic growth, full and productive employment and decent work for all? / goal 8.5: By 2030, achieve full and productive employment and decent work for all women and men, including for young people and persons with disabilities, and equal pay for work of equal value);

? SDG 14 ?Conserve and sustainably use the oceans, seas and marine resources for sustainable development? / (goal 14.2: By 2020, sustainably manage and protect marine and coastal ecosystems to avoid significant adverse impacts, including by strengthening their resilience, and take action for their restoration in order to achieve healthy and productive oceans);

? SGD 15 ?Protect, restore and promote sustainable use of terrestrial ecosystems, sustainably manage forests, combat desertification, and halt and reverse land degradation and halt biodiversity loss? / (goal 15.6: Protect access to genetic resources and fair sharing of the benefits. UN definition: Promote fair and equitable sharing of the benefits arising from the utilization of genetic resources and promote appropriate access to such resources, as internationally agreed); and

? SGD 17 ?Strengthen the means of implementation and revitalize the global partnership for sustainable development? / (goal 17.17: Encourage and promote effective public, public-private and civil society partnerships, building on the experience and resourcing strategies of partnerships? Data, monitoring and accountability).

3) the proposed alternative scenario with a description of outcomes and components of the project;

34. This project aims to complete the legal framework needed for the effective implementation of the provisions of the Nagoya Protocol, as well as the development of programmatic and strategic instruments to establish priority actions. The project will take into account the national projections to 2030 and the implementation of policies related to genetic resources in the current context. The project will develop a guideline (standards) for the harvest and collection of the species, taking advantage of the beneficial properties identified in the marine plant angiosperma *T. testudinum*. It will make it possible to lay the groundwork for obtaining a new candidate drug with potential application in anti-tumor therapy and related diseases, based on the sustainable use of a marine diversity resource. It will also promote the recognition of the ecosystemic benefits of the species at a local level. The project will promote the future commercialization of a derivative of the genetic resource on the basis of an equitable sharing of its benefits, i.e. the implementation of the protocol in the country.

35. The Office of Environmental Regulation and Security, proposed as the National Authority for the Nagoya Protocol, and the Environmental Directorate of CITMA, have personnel trained to

complete and implement a legal framework for access to genetic resources and benefit sharing. Likewise, these agencies can develop the programmatic and policy instruments that will support the existing legal framework. In this regard, a legal norm has been drafted to regulate the essential aspects of biodiversity and access to genetic resources; the norm is in an advanced stage of approval. The existing human resources of the scientific and productive institutions that will participate in the project, in particular ICIMAR, CIM-UH, IMRE-UH and "Oriente" Pharmaceutical Laboratories, are sufficient to complete the studies (i.e., produce the proof of concept) and subsequently start the clinical research phase under quality and sustainability criteria. However, in order to achieve these goals, financial and technological resources are needed. Finally, the project will generate new procedures that contribute to increasing the conservation and rational use of marine diversity, with emphasis on taxonomic groups of vital importance, according to the guidelines contained in the national goals for the conservation of biological diversity.

36. There is a market and social opportunity for the commercialization of the product derived from *T. testudinum*, and therefore, the project can develop a national model for generating economic benefits resulting from the conservation and use of products of its biodiversity. Further, taking into account the ongoing economic and structural transformation in Cuba that favors the adoption of policies in relation to genetic resources, it is the appropriate moment to initiate actions to strengthen the implementation of the Nagoya Protocol.

37. The project's four components aim at developing and strengthening the existing capacities to safeguarding the accumulated information on genetic resources of the Cuban marine platform, and making it available. The intervention will increase awareness on genetic resources and ABS in the institutions and local communities involved in the project. The project will allow them to have better access to information and strengthen their capacity to analyse different alternatives for the sustainable use of biological diversity, specifically of the Cuban marine platform, thus favoring the fair and equitable access to the benefits.

38. Component 1 aims to complete and implement the legal framework in accordance with the Nagoya Protocol and the ongoing introduction of a new economic model in the country, particularly in areas related to the use of natural resources and the distribution of wealth and benefits. In addition, this Component ensures, together with Component 3 (described below), an adequate level of information-sharing regarding the purpose and benefits derived from the project. This approach will demonstrate transparency and promote the participation of stakeholders from the government sector and local communities.

39. Component 2 aims at strengthening the national capacity to conclude the research-development phase of the pharmaceutical product from *Thalassia testudinum*. This component will update ICIMAR's Experimental Unit facilities and equipment to conduct pharmaco-toxicology using Good Laboratory Practice Standards (GLPS) and train researchers to ensure the adoption of GLPS. Thus, the project investment will enable ICIMAR's capacity to evaluate compounds obtained from natural sources with potential application in human therapeutics. The project will also help generate the pending technical data required to obtain permission to begin clinical evaluation of products from *Thalassia testudinum*.

40. Component 3 contributes to gathering and analyzing essential information on **seagrass conservation with an emphasis on** the behaviour of the *Thalassia testudinum*'s habitat and the characterization of the species in **the intervention** sites. At the same time, it will contribute to strengthening the local communities' capacity to manage and harvest genetic resources from marine biodiversity using environmentally sustainable practices. Equally important, this component will set the foundations to establish the *T. testudinum* supply and value chains.

41. Finally, Component 4 will raise awareness in Cuban society about the importance of the conservation and sustainable use of genetic resources on a legal basis in order to foster an enabling environment to implement the Nagoya Protocol.

42. The Theory of Change (ToC, Figure 1) describes the strategy to deliver GEBs through four impact pathways:

? framework for Nagoya Protocol implementation pathway;

- ? research and development of a pharmaceutical product pathway;
- ? conservation marine biodiversity pathway; and
- ? monitoring and evaluation (M&E) and knowledge management (KM).

43. A central aspect to achieving the project objective will be to directly collaborate with key public, local communities and business sector stakeholders, including women; this aspect of the project is linked to the M&E and KM pathway through the implementation of a Stakeholder Engagement Plan and a Gender Action Plan, although stakeholder participation and gender mainstreaming is embedded throughout all the impact pathways. The identified four barriers described above, the causal pathways, and their key underlying assumptions are as follows.

44. Barriers:

Barrier 1. Absence of specific procedures, methodologies and other guidance for the adequate implementation of the existing legislation on access to genetic resources and the equitable distribution of benefits derived from their use.

Barrier 2. Weak research & development processes to obtain products from biodiversity.

Barrier 3. Limited capacity to establish and manage a sustainable value chain that benefits local communities.

Barrier 4. There is little knowledge on the part of the Cuban population and decision-makers about the importance of this ecosystem as a provider of numerous goods and services to humans and marine biodiversity in general.

45. Causal Pathway

Causal Pathway 1: Enhanced legal framework and capacities for the implementation of the Nagoya Protocol on Access to Genetic Resources and Benefit Sharing.

- Key assumptions: 1a) there is political will to promote the required changes.

Causal Pathway 2: Improved institutional and individual capacities for the research and development of a pharmaceutical product from a marine angiosperm.

- Key assumptions 2a): key stakeholder, including national government, local communities and the pharmaceutical industry are actively involved.

Causal Pathway 3: Conservation of marine biodiversity and habitat of angiosperm used for pharmaceutical product development.

- Key assumptions: 3a) availability of the technical and financial resources to develop and assimilate the planned conservation actions.

Causal Pathway 4: Improved information sharing mechanisms and monitoring tools.

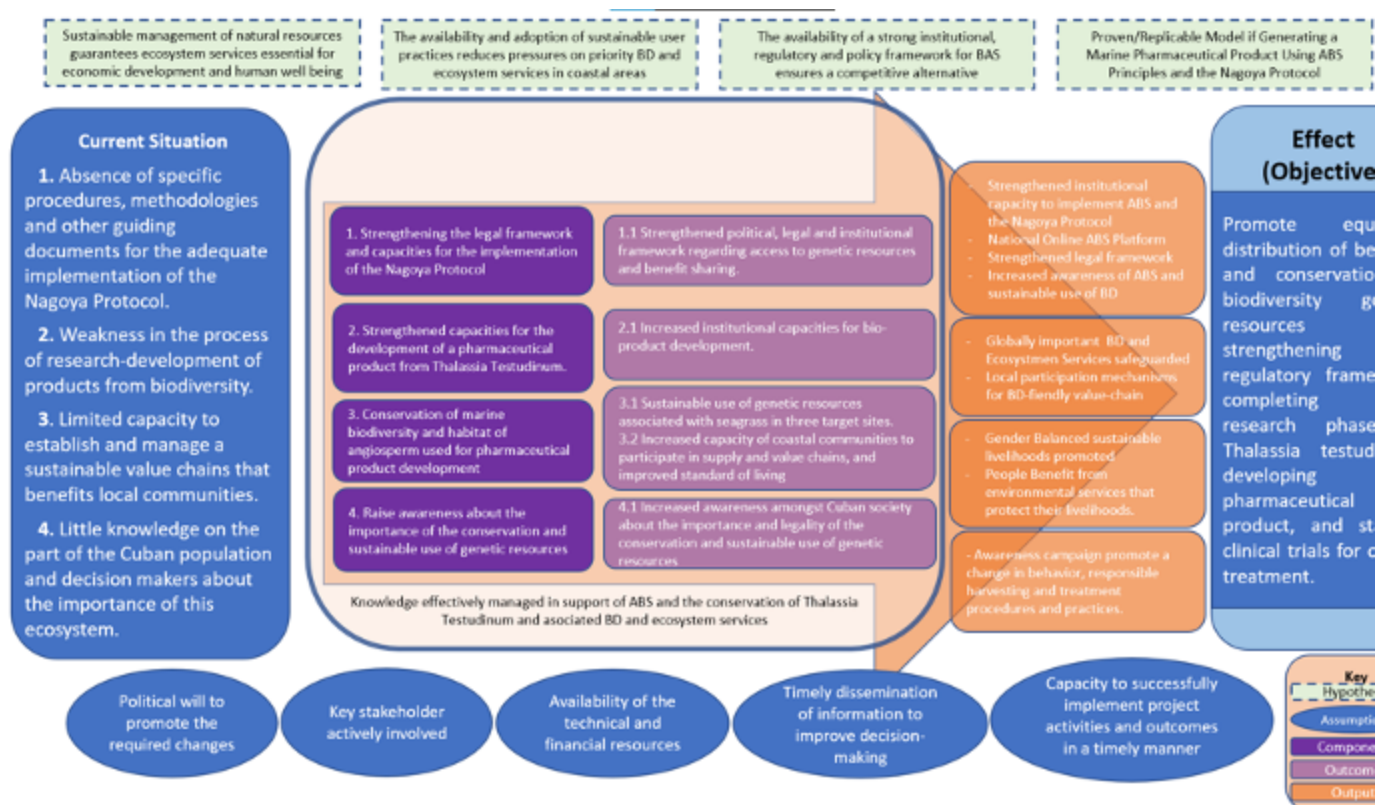
- Key assumption: 4a) there is broad and timely dissemination of information to improve decision-making and replication.

- Key assumption: 4b) institutions at the national and local levels have the capacity to successfully implement project activities and outcomes to deliver GEBs in a timely manner.

46. It is also assumed that climate variability will be within ranges that do not significantly affect the outcomes of the project and the COVID-19 pandemic will recede. The identified pathways are based on the analysis of barriers. The supporting outputs and outcomes for each pathway, and the assumptions that they are built upon, will address the problems and barriers described above, allowing sustainable management of marine ecosystem, the adoption of sustainable practice to reduce pressure on priority marine ecosystem, the availability of strong regulatory framework to support the implementation of the implementation of the Nagoya Protocol and the development of a pharmaceutical natural product from marine biodiversity bases on Nagoya principles. The project's ToC considers the active participation of public, business, and civil society stakeholders, as well as actions to contribute to gender equality and the empowerment of women in the local communities.

47. The ToC will serve multiple objectives, such as:
- ? Support adaptive management during implementation, e.g., the adaptation of the project's results framework (including indicators and targets), organizational structure and/or project management unit, gender and stakeholder participation approach, timelines and work plans, and priorities as a result of changes in context and needs including evolving and/or new social and environmental risks, or other risks;
 - ? Engage all stakeholders and develop ownership;
 - ? Communicate the rationality of the Project's goals, outcomes, outputs, and activities to relevant internal and external audiences; and
 - ? Ensure that adequate data is collected to enable sound monitoring and evaluation throughout the life span of the Project and beyond.
48. The ToC is a dynamic framework that will be continually managed and appraised during project implementation. This strategy will deliver GEBs as well as social and economic benefits at the local level. The interrelated components described above are the means to achieve the GEB.
49. The GEBs to be delivered are:
- ? 631 hectares Total Area under improved management, corresponding to:
 - i. 118 hectares of marine protected areas under improved management for conservation and sustainable use (GEF Core Indicator 2);
 - ii. 513 hectares of marine habitat under improved practices (excluding protected areas) (GEF Core Indicator 5);
 - ? Selected species under conservation and sustainable use;
 - ? 475 (344 women + 131 men) direct beneficiaries as co-benefit of GEF investment (GEF Core Indicator 11).
50. The project is aligned with the GEF7 Biodiversity (BD) Focal Area Objective 3: Further develop biodiversity policy and institutional framework, Focal Area Investments: Implementing the Nagoya Protocol on Access and Benefit Sharing.

FIGURE 1. THEORY OF CHANGE, ABS IN CUBA



Expected Results:

51. GEF investment will increase national and regional capacity to design and implement a regulatory framework in accordance with the Nagoya Protocol on Access and Benefit-Sharing of Genetic Resources. The project will lead to the completion and implementation of the legal basis that will regulate access to genetic resources in a more effective manner, as well as benefit sharing from its use, an issue that is currently not sufficiently regulated in the country. It will make available to the national authority officials, material for training in ABS, and will allow the evaluation and report on the project's products, so that the construction of the regulatory framework is informed. This will be achieved through four components that complement each other, and that promote access and benefit sharing of genetic resources as a competitive alternative for the country.

52. The project will strengthen institutional and local capacity for the sustainable use and development of a natural product with potential application in cancer treatment. The project will improve preclinical evaluation conditions to ensure the introduction of the product, currently under development at ICIMAR, to the clinical research phase. The preclinical and clinical tests of the new product will meet national and international quality standards and could be subsequently registered for human use. The project will strengthen the supply and value chains, i.e., promoting a sustainable and efficient supply and market for medicines or nutraceuticals obtained from natural marine sources. In parallel, the project will improve the management and monitoring capacity of the *T. testudinum* species under sustainability and biodiversity conservation criteria. It will lay the groundwork for the future commercialization of a standardized quality product. The engagement of local communities is critical for developing the project and its sustainability. Through training directed to these ends, communities will be involved in harvesting, monitoring, and conservation of the seagrass (seibadales).

53. The above-indicated results will be achieved through the following Components:

Component 1. Strengthening the legal framework and capacities for the implementation of the Nagoya Protocol on Access to Genetic Resources and Benefit Sharing.

54. This component seeks to strengthen the existing political and legal framework and the regulatory authority on ABS, through the design of procedures and other norms that complement the

legislation. Consequently, the project aims to increase access and participation of Cuban civil society and local communities in the benefits derived from the management of the genetic resources. The expected results from this component are multiple, as they permeate every aspect of ABS in Cuba. Ultimately, this component will provide the strengthened capacities and regulatory framework necessary for Cuba to develop a standardized final product to be introduced in clinical evaluation; generate production capacity at an institutional and local level in sustainable management of marine ecosystems throughout the island; improve the plant material produced and increase the capacity to supply the leaves of the species; substantially increase the conservation of the species; validate the implementation of the provisions of the Nagoya Protocol; provide documents on access to the genetic resource, benefit sharing; and increase the capacity of institutions to manage procedures, permits and knowledge on access to the genetic resource.

Outcome 1.1. Strengthened political, legal and institutional framework regarding access to genetic resources and benefit sharing.

Output 1.1.1. Procedures, methodologies, and model clauses proposed to complete the legislation that implements the Nagoya Protocol.

55. The project will increase national and regional capacity in the design and implementation of ABS procedures and guidelines, taking into account that there is also a Biodiversity Program that includes an ABS goal. The activities financed will lead to the completion and implementation of a legal basis that will regulate access to genetic resources in a more effective manner, as well as benefit sharing, which is currently not sufficiently regulated in the country. This will be complemented by a compilation and analysis of international experiences on ABS contractual procedures to determine what would work better in the context of Cuba. Based on these analyses, the project will elaborate proposals for procedures, methodologies and model clauses to bolster the ABS legislation (Norm) currently under elaboration.

56. The project will also support the development of methodological guidelines to identify monetary and non-monetary benefits derived from genetic material. These will first be used for the *Thalassia* supply chain in the Cuban context. In this sense, the project will take into account not only the pharmaceutical (antitumoral) uses of *Thalassia testudinum* but also the other potential uses (nutraceutical, cosmetic, and agriculture) of this species.

57. The results from the other project components will also be documented and used to ensure that the construction of the Norm is informed by practical experiences. In particular, the project will support the elaboration and validation of proposed procedures for the use of marine angiosperm based on the experiences generated with regards to obtaining a bioproduct from *Thalassia testudinum* in Component 3.

Output 1.1.2. Strengthened capacities of the regulatory authority to control access to genetic resources.

58. Despite the investments and resources available in the baseline scenario, the regulatory authority does not have sufficient capacity to advance ABS and generate impacts that are competitive with other land uses, such as tourism, which currently offer better sources of income for local coastal communities. GEF resources will help to break down commercial and legal barriers, and provide development possibilities to a level that would otherwise not be competitive. This will be achieved in synergy with the other project components.

59. The project will provide material to the national authority officials for training in ABS. The project will organize workshops and facilitate exchanges with national and international experts to develop complementary materials on ABS and associated knowledge, including those related to protecting and managing information and intellectual property rights. The purchasing of equipment (such as a laminar flux cabinet, CO₂ incubator, centrifuge, plate reader, microscopes, and freezers) will complement training and strengthen the authorities (CITMA, MES). For example, ICIMAR will need the laminar flux cabinet, CO₂ incubator, centrifuge, and the inverter microscope to establish checkpoints related to the starting of the cell culture laboratory. The project alternative will strengthen CITMA institutions and local communities in the targeted intervention areas. With project support, stakeholders will improve knowledge of marine genetic resources and management, including

generating benefits and compensations for local communities. Harvesting the marine resources, applying conservation strategies, and accessing benefits derived from each of the project's interventions throughout implementation will involve local communities.

Output 1.1.3 Tools for training, protection, information management and scope of intellectual property rights.

60. The project will design high-leverage training tools such as a combined on-line and in-person training course aimed at building capacity in the different aspects of ABS covered by the project, especially contract negotiation, information management and scope of intellectual property rights. The course will target at least 255 participants from ORSA and related institutions located in the eastern, central and western regions of the country. This approach is critical to manage the COVID-19 pandemic situation. As a result of this training, it is expected that communities and stakeholders will have sufficient knowledge to participate in benefit sharing and progress in the case of study activities in Component 3. Ultimately, this increased capacity will facilitate and accelerate the negotiation of ABS agreements. Existing agreements and contracts will be reviewed in accordance with the Nagoya Protocol, identifying corrective measures for full compliance with its provisions and validating the research-development process of the *T. testudinum* product.

Output 1.1.4 Dialogue platform to exchange of information on ABS and knowledge associated with biodiversity conservation.

61. The project will develop a dialogue platform for the exchange of information on ABS and knowledge associated with biodiversity conservation. Central to this is the design and construction of National ABS Platform online ? the ABSCH ? to house Cuba's official information on ABS as well as to disseminate the results of the project. The ABSCH will be consolidated and linked/integrated with the CBD's ABS Clearing House Mechanism (CHM). Furthermore, the project will conduct a seminar/workshop on the results of the project and the implementation of the Nagoya Protocol to exchange experiences and evaluate its impact on local communities and Cuban civil society. This project will facilitate the coordination between ORSA and AMA/IGT to ensure that the Infogeo platform of the National Environmental Information System (NEIS) includes Cuba's official information on ABS after project implementation.

Component 2. Strengthening institutional and individual capacities for the research and development of a pharmaceutical product from a marine angiosperm.

62. Component 2 seeks the development of a new product for human use from the marine angiosperm *T. testudinum*. This requires tests that guarantee its efficacy and safety. Therefore, studies related to the standardization and characterization of the product in question must be conducted. Non-clinical efficacy and safety trials play a defining role and must be carried out in harmony with the standards established at national and international level. To achieve this, GEF resources will be used to increase the existing human capacities of the institutions involved in the development of the product, as well as the introduction of new methodologies and Standard Operating Procedures (SOPs) for the conduct of studies in compliance with quality standards.

63. The Institute of Marine Sciences (ICIMAR) has most of the technical infrastructure needed to support the project. However, this component aims to improve ICIMAR's technical and operational capacities to evaluate compounds obtained from natural sources with potential application in human therapeutics. Specifically, the infrastructure of ICIMAR's Experimental Unit to conduct pharmacotoxicology research needs upgrading to meet Good Laboratory Practice Standards.

64. ICIMAR has experimental evidence about the anti-tumor potential of *T. testudinum* extract, but this is insufficient to request the Cuban Regulatory Unit to introduce it in the clinical research phase, a condition required to obtain a Health Registration as an alternative medicine or nutritional supplement to conventional anti-tumor therapy. Component 2 will support the remaining 35% of the scientific-technical studies identified as necessary to fulfil the clinical information requirement as per national regulation. These includes key elements as following: characterization of the species in different collection sites, data on metabolism of the organism, combination analysis with conventional antitumoral drugs, data on chronic toxicity, technological development of the active pharmaceutical

ingredient, and definition of the pharmaceutical form. Completing the above-listed data is indispensable to register a natural product.

65. The project's investment will trigger the establishment of the *T. testudinum* supply and value chains. This investment is critical to ensure sustainable sourcing, marketing and revenue generation. Besides, medicines or nutraceuticals, the project will include potential bioproducts such as cosmetics and agricultural input (fertilizer) obtained from marine sources. The project will also support the preparation of the documents required by the Cuban Regulatory Agency (CECMED) for authorization to begin the clinical research phase.

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Outcome 2.1 Increased institutional capacities for bio-product development.

Output 2.1.1. Updated ICIMAR technical and operational capacities enable obtaining permission from the National Regulatory Unit to conduct non-clinical studies on the product.

66. With project support, ICIMAR seeks to conclude a research and development process that has been initiated but is pending completion to register a natural product with beneficial properties obtained from the marine angiosperm *T. testudinum*. The project will support the design and identification of technical standards to carry out the remodeling of the facilities of the Biotherium and laboratories involved in ICIMAR. It will facilitate the strengthening of the technical and operational capacities, and the necessary inputs for the execution of the work protocols related to the non-clinical studies. Finally, it will enable the installation of updated equipment and establishment of technical conditions to carry out the investigations under a controlled environment. These action will lead to the improvement of preclinical evaluation conditions for the introduction of the product in the clinical research phase. If feasible, the product will meet national and international quality standards to be registered as a new product for human use.

Output 2.1.2. Strengthened human resources in the non-clinical evaluation of products derived from marine biodiversity under a controlled environment.

67. Cuba has deployed considerable resources and efforts to creating the basis for knowledge and experience in resources derived from nature and to developing scientific knowledge. There is national interest and human resources for developing products from natural and autochthon biodiversity, but there is limited access to didactic resources and infrastructure to carry out all stages of the process of research-development-innovation of bioproducts and improve human resources specialization. The research-development stage includes the scientific-technical studies (65% completed, 35% will be supported by the project's activities) and the pharmaceutical product development from *Thalassia testudinum*, which will be supported by BIOCUBAFARMA / Laboratorios Oriente (national co-financing).

68. The project will strengthen and train approximately 200 personnel, technicians and students from ICIMAR, CIM-UH, Havana University and BIOCUBAFARMA in the non-clinical evaluation of products derived from marine biodiversity in controlled environment. The availability of professionals and qualified labor will facilitate the uptaking of new technologies by the project's targeted agencies and communities, and will raise the quality of the outputs and results. The project also will promote the participation in scientific exchanges, workshops, seminars and courses to strengthen stakeholder's and contribute to increasing the scientific knowledge to conduct of non-clinical studies for the evaluation of bio-products.

Output 2.1.3. Phytochemical characterization of natural extracts, identification of metabolites, and evaluation of anti-tumor effects and margin of safety of the active ingredient derived from T. testudinum.

69. The project will address constraints found in the baseline with regards to the materials required to carry out the phytochemical characterization of natural extracts, particularly marine extracts, the identification of metabolites and compounds responsible for their activity, and activity-guided chemical characterization studies. The project will facilitate the acquisition of the necessary inputs for the execution of the experimental protocols. This project will enable the collection of specimens in the three intervention areas for studies on chemical-physical, microbiological

characterization, genetic variability, efficacy, and safety. Finally, the project will support the standardization of the process to obtain the bio-product under solid scientific criteria and it will make it possible to lay the groundwork for obtaining a new candidate drug with potential application in anti-tumor therapy and related diseases. *Thalassia testudinum* possesses antitumor activity, which indicates that there is potential for medicinal/pharmaceutical use of this species. To date, 65% of these studies have been concluded. The project will support the development of the remaining 35% of the studies to complete all the information and data requirements, as per national regulation.

Output 2.1.4. Documentation to obtain authorization for clinical studies under biodiversity conservation principles is completed.

70. This output will support the preparation of the documentation to be submitted for the application to the Cuban Regulatory Agency for authorization to begin the clinical research phase. In this sense, project should be into account the Regulation 21/2008 of the Regulatory Authority for Medicines, Equipment and Medical Devices of the Republic of Cuba (CECMED). These national regulations establish the "Requirements for the authorization of clinical trials". These requirements include both Administrative Information, Ecological - Chemical - Pharmaceutical - Information. As indicated above, *T. testudinum*'s research and development phase has a substantial advance, estimated by the MINSAP at 65%. Thus, the project intervention is critical to complete the clinical trial application file.

Component 3. Conservation of marine biodiversity and habitat of angiosperm used for bioproduct development.

71. Given the strategic importance of coastal/marine ecosystems, this component is essential to ensure the conservation and sustainable use of seagrasses, its habitat, and associated biodiversity. The project will identify best practices and optimal levels of harvesting and pruning to ensure that *T. testudinum* and its associated biodiversity continue providing ecosystems services. In addition, these sustainable harvesting techniques will contribute to increase the standard of living of the inhabitants of coastal communities by engaging them in sustainable supply and value chains.

Outcome 3.1 Conservation and sustainable use of genetic resources associated with seagrass in three target sites.

Output 3.1.1. Evaluation of environmental quality of seagrass ecosystem at intervention sites.

72. The ecosystem services of seagrass beds include sustaining diverse faunal communities, supporting fisheries, providing coastal protection through stabilization of sediments, cycling of nutrients, and carbon sequestration. The project will use the Ecological Evaluation Index (EEI) to assess the ecological status of the seagrass ecosystem, before and after the intervention. Variables addressed by this index include changes in seawater and sediments quality including salinity levels, nutrients, and heavy metals. Seagrasses are also an important food source and habitat for wildlife, supporting a diverse community of organisms including fish, octopuses, sea turtles, shrimp, blue crabs, oysters, sponges, sea urchins, anemones, clams, and squids. The project will assess the biodiversity associated to seagrasses in all collection sites. Seagrass ecosystems are also effective carbon sinks. Scientists have estimated that seagrass sequestration of carbon is 35 times more efficient than in the rainforest. The project will estimate the organic carbon sequestered in the sediments and seagrass biomass and the impact of harvesting practices on carbon sequestration in the three pilot sites of the project. The EX-Ante Carbon-balance Tool (EX-ACT) has a seagrass and mangrove module that could be used for this exercise.

Output 3.1.2. Management protocols and recommendations for the conservation and sustainable use of seagrass.

73. Based on the scientific information collected in previous outputs, the project will propose management protocols and recommendations for the conservation and sustainable use of seagrasses. This information will improve the management plan of the protected area (PNP Rincón de Guanabo), where one of the intervention areas is found. Recommendations for the conservation of seagrasses at non-protected areas will be provided to the environmental authorities of the provinces Camagüey and

Santiago de Cuba. This activity will contribute to maintain the valuable ecosystem services provided by seagrasses.

Output 3.1.3. Population analysis of *Thalassia testudinum* angiosperm.

74. The project's areas of intervention cover approximately 137 hectares, which is a relatively small area but with great potential for replication due to the extensive presence of *T. testudinum* in Cuba. The project will assess the variability of bioactive metabolites during project implementation which will provide information on the potential impacts of climate change and anthropogenic factors. It will also determine the availability of leaf biomass in the selected meadows. This output will also focus on assessing the effect of successive pruning of leaves with different intensities on the vitality of the plant (density, biomass, protein content, carbohydrates, and photosynthetic pigments). In parallel, the project will support an assessment of the genetic variability of *T. testudinum* meadows and its possible impact on the resilience and bioactive properties of the product. The project will propose a methodology to ensure the conservation and sustainable use of *T. testudinum*. This output will identify areas with healthy *T. testudinum* meadows and assess their bioactive potential for the production of secondary metabolites which are required for the research process and potential development of a product. In addition, through this output, the project will assess levels of pollution from land-based sources and potential conflicts with productive sectors (fishing and tourism) that might impact the conservation of seagrass beds and their associated biodiversity. Based on the findings of previous outputs, the project will conduct a population analysis model and feasibility study to evaluate the impact of harvesting practices on *T. testudinum*.

Output 3.1.4. Approved best practice/procedural tools for the management and sustainable use of *Thalassia testudinum*.

75. The project will work with the competent authority in obtaining approval of a best practice/procedural tool for the sustainable harvest (and use) of the leaf biomass of *T. testudinum* by the local communities. To confirm the validity of proposed operational procedures, the project will carry out evaluations of the health of the seagrasses, analysis of the quality of the seawater and sediments, as well as existing information of the targeted areas. These actions will allow the harmonization and integration of the objectives of biodiversity conservation and sustainable use along the lines of the policies, regulations and strategies, and will inform decision-making processes at different levels.

Outcome 3.2 Increased capacity of coastal communities to generate a value chain and improved standard of living.

Output 3.2.1. Training program on supply and value chain management associated to the seagrass ecosystem with emphasis on sustainable use of *Thalassia testudinum*.

76. This output aims to increase the capacity of local communities to establish sustainable supply and value chains and improve the standard of living of the inhabitants of coastal communities. To this end, the project will build local capacity to develop products from natural and autochthon biodiversity. The project will also strengthen the capacity of the institutions involved in the management, monitoring, and conservation of marine species. It is envisioned that supply and value chain experts with skills to work at a multi-stakeholder level will lead the achievement of this output. For example, at the supply chain level, the experts will work with local producers (communities) and input suppliers, assess the collection and pre-processing, and develop a road map for working at the value chain level in the future, once the product is approved. This output will be supported by output 1.1.3.

Output 3.2.2 Certification program for workers involved in the sustainable management and collection of samples in the intervention sites.

77. The Project will develop a certification program and training on the sustainable management and collection of samples of *T. testudinum* targeting workers (women and men) from local communities. Approximately 20 workers will be certified by the regulatory authority (ORSA and CECMED). The certification is key to obtaining consistent and standardized samples for research that meet

phytopharmaceutical requirements. Certification is also critical to support the establishment of sustainable supply and value chains and, therefore, improve the standard of living of the inhabitants of coastal communities. Local communities and individuals will participate in the project through the stakeholder engagement process. Women, in particular, will be trained and engaged in processing the *Thalassia*. Ultimately, the activities implemented and promoted by the project will have a positive social and environmental effect and generate cumulative impacts with other existing activities in the area.

Component 4: Monitoring and knowledge management

78. This component will raise awareness in Cuban society about the importance of the conservation and sustainable use of genetic resources within a legal framework that can expedite the Nagoya Protocol's implementation.

Outcome 4.1 Increased awareness amongst Cuban society about the importance and legality of the conservation and sustainable use of genetic resources

Output 4.1.1 Awareness campaign aimed at different stakeholders and users of genetic resources to promote a change in behavior, highlights responsible harvesting and treatment procedures and practices.

79. The Project will support the development and implementation of an awareness campaign. During inception, the project will define how communication activities can directly contribute to the project's objectives. This includes identifying the most effective strategy and messages to influence behavior change. A survey will be conducted at the project start with key stakeholders and project beneficiaries to determine their level of awareness about ABS, Intellectual Property management, and BD conservation. Based on the results of this survey, the Project will develop a campaign to increase awareness amongst key stakeholders and project beneficiaries. The campaign will promote behavior change, responsible harvesting, and sound treatment procedures and practices.

Output 4.1.2 M&E Plan, SESP and GAP implemented.

80. In accordance with GEF, UNDP and national policies, a series of social and environmental management plans have been developed based on analyses conducted during the Project's preparation. As such, the project will ensure the implementation and monitoring of these plans, and pursue adaptive management strategies, where appropriate.

Output 4.1.3 Publication and dissemination of the results and lessons learned.

81. The project will support increased knowledge of marine biodiversity found on the island platform. In particular, the project will provide new evidence on the biodiversity associated to *T. testudinum*, to support biodiversity conservation practices and models for this important ecosystem along the coasts of Cuba and other Caribbean islands. The project will redefine/update scientific knowledge on seagrass beds through publications of scientific findings, best management practices, and technical reports. Under this output the project will also publish methodological guidelines to identify monetary and non-monetary benefits derived from genetic material. Socialization will be carried out through publications and participation in scientific trainings, exchanges, workshops, courses, seminars, and events. Participation in these events will contribute to strengthen capacity building of scientists and local stakeholders. The project will also support participation of project staff in workshops, seminars and national and international events to facilitate the socialization and dissemination of outcomes and lessons learned.

4) alignment with GEF focal area and/or impact program strategies;

82. The proposed project is fully aligned with the GEF7 Biodiversity Focal Area Objective 3: Further develop biodiversity policy and institutional frameworks? specifically with regards to strengthening biodiversity policy and institutional frameworks to implement the Nagoya Protocol on Access and Benefit Sharing. The successful implementation of ABS at the national level has the potential to make considerable contributions to biodiversity conservation and sustainable use. In

particular, the GEF will support the following core activities to comply with the provisions of the Nagoya Protocol:

? Development (or revision) of national measures to implement and enforce the Protocol (e.g. the legislative, administrative or policy measures on access and benefit-sharing); and

? Building capacity among stakeholders, especially institutional capacity-building to carry out research and development to add value to their own genetic resources and traditional knowledge associated with genetic resources. The GEF will also support the participation in the ABS Clearing-House Mechanism.

5) incremental/additional cost reasoning and expected contributions from the baseline, the GEFTF, LDCF, SCCF, and co-financing;

83. The GEF increment will facilitate the development of new capacities in Cuba with regards to ABS, building upon a solid baseline of BD conservation, national healthcare and scientific know-how. With clear regulations and a successful case of development of a product obtained from a genetic resource in its preclinical research stage, it is expected that this project will encourage greater investment in bioprospecting and derive future benefits for other communities and ecosystems in the country. Second, the project is built on a previous investment and an advanced social and economic process, to make a minimum investment that leads to the financial, social, institutional and environmental sustainability of the sustained and rational use of a genetic resource, upon the successful completion of the preclinical stage of product development.

Scenario without GEF increment:

84. Without GEF resources, the current Budget assigned by the State to the Ministry of Science, Technology and Environment (CITMA) is insufficient and a longer period of time would be required for the full implementation of the Nagoya Protocol and compliance with the commitments assumed by the State under this international instrument. From a legislative and programmatic point of view, the adequate implementation of the Nagoya Protocol requires an inclusive and extensive process with various actors from the early stages of any ABS-related initiative. In more advanced stages, the participation of diverse public sectors must be guaranteed to ensure the effective validation of new initiatives and, in turn, their socialization amongst a more general public. Without GEF support, there is a risk that the proposals for ABS-related initiatives would not only be delayed, but would not be developed in participatory settings.

85. With regards to the completion of the product, whose development is planned as a validation of the administrative framework, ICIMAR, in collaboration with the CIM-UH and the IMRE-UH, would continue with the product development process at the scale that its current resources allow. The inability to cover all the costs of the tests and permits required to obtain the permit to start clinical studies would result in the institution concentrating on finding space for its use within the cosmetic market ? this might cover the costs of toxicological and basic stability tests necessary for cosmetic use, but not sufficient for the pharmaceutical market. While CITMA (via the National Program for the Use and Conservation of the components of Biodiversity in Cuba, led by the Ministry's Environment Agency) would provide the resources for the execution of the minimum preclinical tests required, the product would only be studied at the extract scale, in this scenario, but its characterization would not be completed and all the chemical components responsible for its beneficial effect would not be identified, the accumulation and leaf mass studies could not be carried out in their entirety. The conservation studies would be delayed, as well as the participation of the community in the management of their areas.

86. Similarly, CITMA would continue working to define procedures for access to genetic resources and for the distribution of benefits to communities, but would be limited to developing all the necessary guidelines to define the distribution of monetary and non-monetary benefits. However, despite the potential of the product to be introduced in the market for natural cosmetic products, the fact that cancer is the leading cause of morbidity / mortality, the high prevalence and incidence rates of the disease in the country implores the need to establish new guidelines in its therapy and control. The

baseline scenario represents a slow advance in the commercialization of derivatives of genetic resources that have the potential to substantially increase the quality of life of the Cuban people. Despite the efforts of the State in the search for solutions in this, cancer continues to be a serious health problems across the country.

Scenario with GEF increment:

87. Although the Cuban State has the full authority to regulate the use of biological resources and its policy considers that the benefits derived from access to genetic resources reach all the country's communities, it does not have the capacity to stimulate research, development and commercialization of all products derived from them. Therefore, GEF resources will play a decisive role in capacity building related to ABS and implementation of the Nagoya Protocol.

88. The GEF increment will help to overcome commercial and legal barriers related to the conservation and sustainable use of *Thalassia*, and give momentum to a process that would not otherwise be competitive. It will achieve this through three components that complement each other and contribute to favoring access to genetic resources and the distribution of benefits as a competitive alternative for the Cuban coastline, and in general for the country. In the case of Component 1: GEF intervention in the elaboration of an administrative and programmatic framework, based on the effective implementation of the Nagoya Protocol; it is decisive in order to complete a legislation that incorporates the commitments derived from this instrument, and that responds to the complex context imposed by the economic, social and structural transformations occurring in Cuba. A more complete and fully contextualized legislation through policy documents that guide it in compliance with defined routes in terms of priorities and time limits, is only achieved through participatory processes. Attracting the different sectors of society towards implementing the legislation through the project interventions will trigger ownership, and informed decision-making and, consequently, enhance impact. This will only be achieved through adequate financing and the provision of appropriate spaces and scenarios to draw those institutions, NGOs and representatives of other sectors towards this goal. Furthermore, GEF resources would permit a more agile and fluid dissemination of the objective of promoting legislation and policy documents, involving the media, through effective messages that reach the entire society.

89. The GEF increment will support the strengthening of the framework and capacities necessary to develop a product with antitumor properties obtained from the marine angiosperm *T. testudinum*. The initiative seeks to terminate non-clinical investigations so that they meet standards to arrive at a product that has its complete documentation to present to the Cuban Regulatory Unit to request permission for clinical studies and its subsequent introduction into social practice. The project will strengthen a value chain that will include sustainable, efficient and environmentally friendly supply, and the obtaining of a product that, in addition to contributing to solving serious health problems, may favor the development in the country of a market for products obtained from natural sources. The strengthened capacity to manage natural resources and conserve Cuban marine biodiversity, based on sustainability criteria, is fundamental to set up the supply and value chain foundations.

6) global environmental benefits (GEFTF) and/or adaptation benefits (LDCF/SCCF);

90. The project will deliver GEBs related to the conservation of biodiversity and genetic resources. This will be achieved with the equal participation of men and women, ensuring that both groups benefit equally from the project and that the concerns and experiences of the women involved are an integral part of the design, implementation, and M&E of the project. The GEBs to be delivered are as follows:

- ? Fair and equitable sharing of the benefits arising from the utilization of genetic resources (to local communities, resource managers, and PA officials)
- ? Improved conservation of native marine biodiversity (118 hectares within PAs and 513 hectares outside)
- ? Improved conservation of coastal ecosystems from which leaves are collected (631 hectares)
- ? Increased awareness of the existence, use, and option values of biological resources among key audiences (475 direct beneficiaries)

- ? Contribution to the generation and potential replication of ABS best practices (agreements)
- ? Contribution to national development strategies and economic growth.

91. The project will contribute to implementing the Nagoya Protocol on ABS entry point under Objective 3 of the GEF Focal Area on Biodiversity. This project will develop an adequately supportive environment for the implementation of the NP, in terms of policy, legal, and planning instruments. To accomplish this, it will focus on the capacity building contemplated under GEFTF support to BD-3-9: including institutional capacity-building to carry out R&D to add value to genetic resources and capacities amongst stakeholders to negotiate between providers and users of genetic resources.

92. The project will contribute to implementation of Aichi Target 16: By 2015, the Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization is in force and operational, consistent with national legislation, by contributing to the sustainable availability of biological crop protection agents. The project will also contribute to Sustainable Development Goal 9: Build resilient infrastructure, promote inclusive and sustainable industrialization and foster innovation, and Goal 15: Protect, restore and promote sustainable use of terrestrial ecosystems, sustainably manage forests, combat desertification, and halt and reverse land degradation and halt biodiversity loss, to which Cuba is committed; specifically the promotion of fair and equitable sharing of the benefits arising from the utilization of genetic resources and promotion of appropriate access to such resources as internationally agreed.

93. The project is in line with Aichi target 10, which aims to reduce the multiple anthropogenic pressures on ecosystems. The project would promote the sustainable use of *T. testudinum*, while maintaining its integrity, by demonstrating the sustainable management of *T. testudinum* and the harvesting of its leaves. The project envisages actions that would allow the sustainable regulation of the extraction of the resource and ensures the conservation of the species and its ecosystem services, thereby contributing to the achievement of the CBD's goals in Cuba.

94. Finally, the project would strengthen Cuba's human resource capacity in the knowledge and use of new technologies (bioinformatics, metabolomics, proteomics and genomics, among others) as part of the technological development of bioproducts, i.e. bioproducts obtained from the marine environment that are virtually unknown. To date, this work has been encouraged and developed in the country, but its scope and future success depends on having the financial and technological resources required for this task.

95. Finally, this project contributes to the implementation of the Sustainable Development Goals (SDGs) in Cuba, as follows:

- SDG 3 ?Ensure healthy lives and promote well-being for all at all ages? / (goal 3.b: Support the research and development of vaccines and medicines for the communicable and non-communicable diseases that primarily affect developing countries, provide access to affordable essential medicines and vaccines, in accordance with the Doha Declaration on the TRIPS Agreement and Public Health, which affirms the right of developing countries to use to the full the provisions in the Agreement on Trade-Related Aspects of Intellectual Property Rights regarding flexibilities to protect public health, and, in particular, provide access to medicines for all);

- SDG 4 ?Ensure inclusive and equitable quality education and promote lifelong learning opportunities for all? / (goal 4.3: By 2030, ensure equal access for all women and men to affordable and quality technical, vocational and tertiary education, including university);

- SDG 5: ?Achieve gender equality and empower all women and girls? / (goal 5.5: Ensure women's full and effective participation and equal opportunities for leadership at all levels of decision-making in political, economic and public life);

- SDG 8 ?Promote sustained, inclusive and sustainable economic growth, full and productive employment and decent work for all? / goal 8.5: By 2030, achieve full and productive employment and decent work for all women and men, including for young people and persons with disabilities, and equal pay for work of equal value);

- SDG 14 ?Conserve and sustainably use the oceans, seas and marine resources for sustainable development? / (goal 14.2: By 2020, sustainably manage and protect marine and coastal ecosystems to avoid significant adverse impacts, including by strengthening their resilience, and take action for their restoration in order to achieve healthy and productive oceans);
- SGD 15 ?Protect, restore and promote sustainable use of terrestrial ecosystems, sustainably manage forests, combat desertification, and halt and reverse land degradation and halt biodiversity loss? / (goal 15.6: Protect access to genetic resources and fair sharing of the benefits. UN definition: Promote fair and equitable sharing of the benefits arising from the utilization of genetic resources and promote appropriate access to such resources, as internationally agreed); and
- SGD 17 ?Strengthen the means of implementation and revitalize the global partnership for sustainable development? / (goal 17.17: Encourage and promote effective public, public-private and civil society partnerships, building on the experience and resourcing strategies of partnerships? Data, monitoring and accountability).

7) innovativeness, sustainability and potential for scaling up. ?

96. This Project will promote the sustainable use on ABS principles of Cuba's marine diversity, specifically of the marine angiosperma *Thalassia testudinum* as a source of potentially useful chemical entities such as phytopharmaceuticals and nutritional additives, all with full participation of local communities. The proposal will also help in the search for innovative alternatives to meet the challenges of current therapeutics and health standards of the population. Under this approach, the project finds a niche at the interface between its health benefits and Cuba's natural and cultural diversity. As part of the innovation-development process, local communities will be involved, so this approach is novel and has not been attempted before for marine biodiversity. Innovation is privileged through cooperative prospecting between local communities, industry and researchers involved in the project and will be developed under components 2 and 3.

97. As part of the project's activities, the foundations to establishing the *Thalassia testudinum* supply and value chains will be established. In this sense, the project's approach will ensure a fair distribution of benefits across the supply and value chains stakeholders. Another innovative aspect is the collaboration with and co-financing from the Cuban pharmaceutical industry (OSDE Biocubafarma / Laboratorio Oriente). At the same time, the project will facilitate the development of corporate social and environmental responsibility.

98. This project will multiply its benefits through the Cuban program for sustainable local development, which is a source of innovation, making it possible to scale up the beneficial and sustainable use of Cuba's marine biodiversity resources and achieve national coverage. Cuba has a defined, robust and functional legal system that is beginning to be articulated with the environmental projection of state policy. In this way, the continuity and sustainability of the results derived from the project is secured. Besides, the introduction of ABS will provide legal support to the interrelations, processes and transactions that will allow the national industry, the academic sector and the local communities to share more widely and equitably the benefits derived from Cuban biodiversity. Therefore, it is expected that discoveries related to biodiversity will accelerate and expand sustainably, after the project is concluded.

99. Scientific: It will allow the expansion of knowledge on marine biodiversity based on chemical diversity and bioactivity of organisms that inhabit the island platform, particularly in this case new evidence will be provided about sea grasses, the angiosperma *T. testudinum* the most abundant on the coasts of Cuba and the most abundant located in the Caribbean Sea, its habitat, population dynamics, potential uses, chemical diversity, management and conservation.

100. Technological: The project will enable the development of future environmental management pilot studies. The implementation and development of new methodologies and technologies under a control environment aimed at obtaining bioproducts from marine organisms. The process of research-development of new candidates for nature-based drugs for the Cuban biotechnology industry is strengthened, particularly using the sea as a source, and the benefits derived

from this are guaranteed to reach the local communities. New methods of management, collection and harvesting of the species will be implemented, allowing synergy with other proposals.

101. Social: It will allow the harmonization and integration of the objectives of conservation and sustainable use of biodiversity with the policies, regulations and strategies of the country and with the decision-making processes at different levels according to social development. It will promote the development of a new drug candidate to be used in anti-tumor therapy in combination with the drugs of conventional use for the management and treatment of cancer, the second cause of death in Cuba.

102. COVID-19 context: According to the most recent WHO reports, older patients and those with significant comorbidity conditions are at substantially higher risk of dying from COVID-19 than the rest of the population. This has led to the identification that patients diagnosed with cancer are among the most vulnerable populations and are more likely to contract Covid 19. These observations correspond to the higher percentage of lethality observed in cancer patients in different affected countries compared to those who do not suffer from the disease. These observations correspond to the higher percentage of mortality observed in cancer patients in different affected countries compared to those without the disease. These people face great uncertainty in the era of COVID-19, the pandemic has fundamentally changed the balance between risks and benefits in cancer treatment (WHO, 2020).

103. In Cuba, the latest MINSAP report placed cancer as the leading cause of morbidity/mortality in the Cuban population in 2019 (Anuario Estadístico, MINSAP 2019).

104. Environment: It will be a space to increase environmental education at the level of the communities adjacent to the areas of intervention on the perspectives of rational use of genetic resources. It will allow for the first time in the country the possibility of using the benefits of a resource from marine biodiversity in line with national policies and guidelines that take into account the protection of taxonomic groups, the ecosystem and the environment in general. It will result in the first case study that considers the use of a marine resource in an environmentally-friendly manner.

[1] González H. 2002. Biodiversidad de Cuba. Ediciones Polimita S. A, Guatemala. 320 pp

[2] González H. 2002. La migración de las aves. En: Aves de Cuba (H. González ed.) UPCPrint, Finland pp: 16- 19.

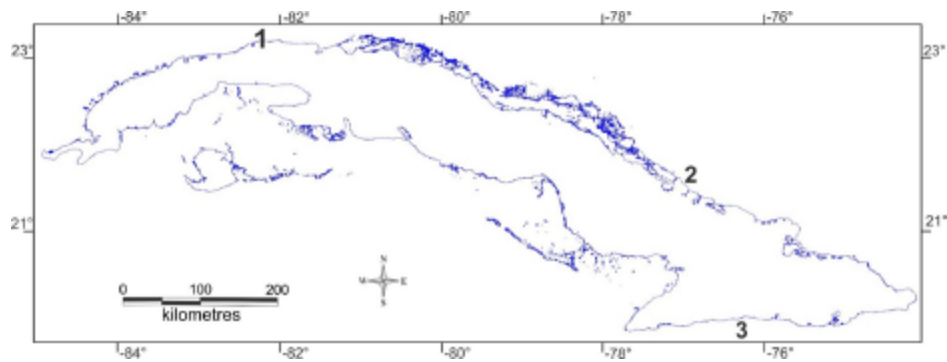
[3] Estrategia Ambiental Nacional 2016- 2020. Ministerio de Ciencia Tecnología y Medio Ambiente

[4] Clear rules needed to govern deep sea bioprospecting: UNU Vast genetic treasure on sea beds Peer-Reviewed Publication, UNITED NATIONS UNIVERSITY
http://www.ias.unu.edu/binaries2/DeepSeabed_FINAL.pdf

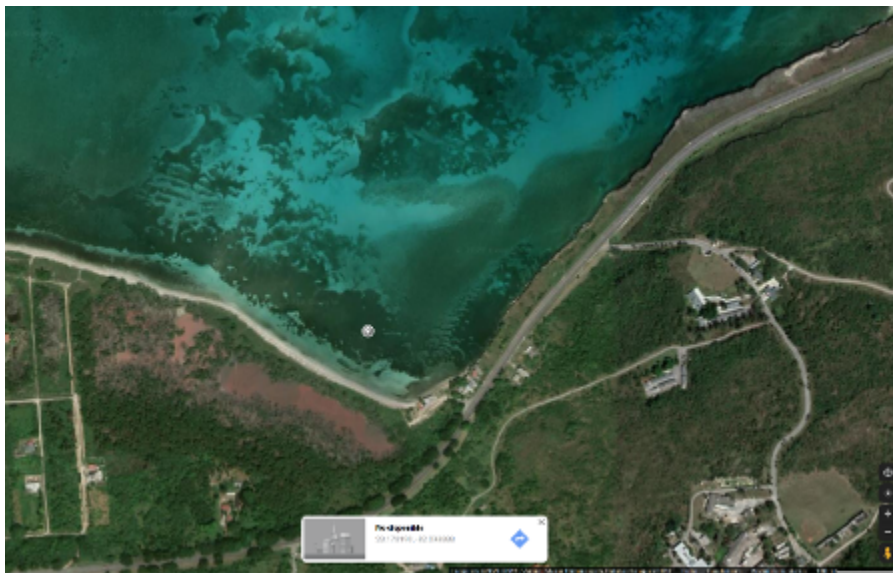
1b. Project Map and Coordinates

Please provide geo-referenced information and map where the project interventions will take place.

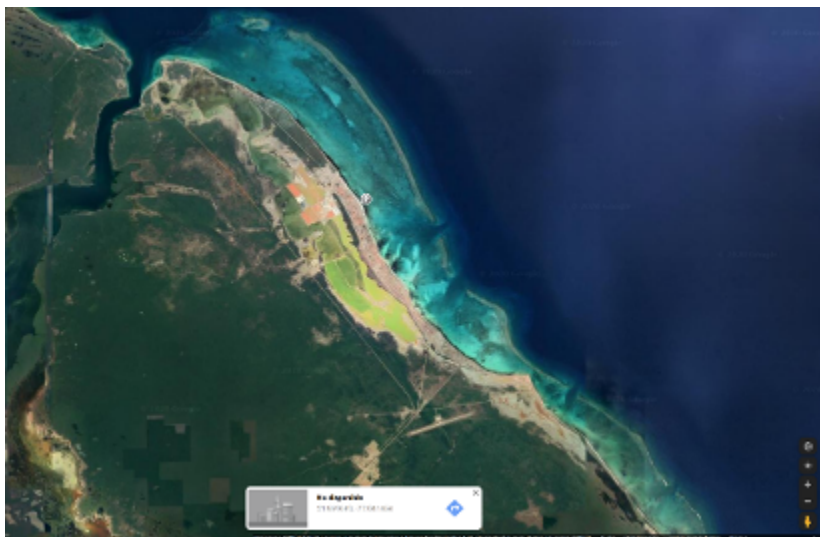
Location of the 3 areas of intervention of the project:



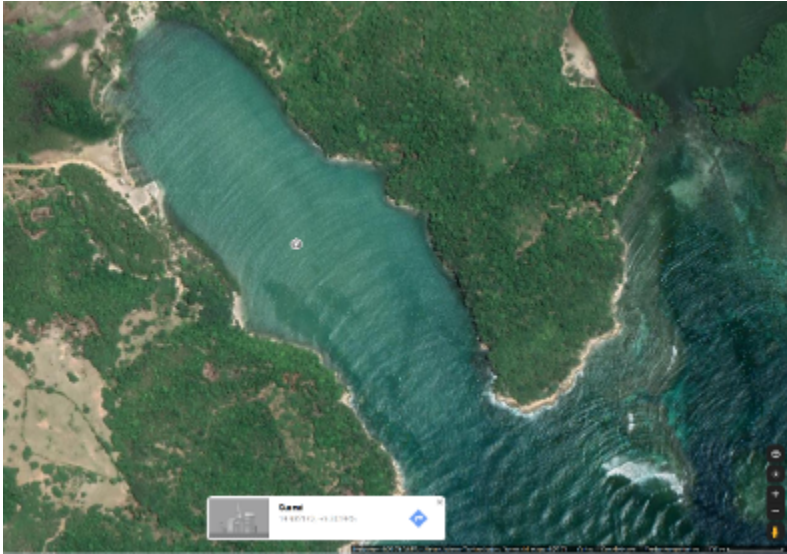
1. Rincón de Guanabo, Playas del Este, Havana; Coordinates: 23° 10' 26", -82° 05' 50"; Intervention area: 14 ha



2. Santa Lucía Beach, Camagüey; Coordinates: 21° 33' 26", -77° 02' 07"; Intervention area: 100 ha



3. Larga Bay, Guam?, Santiago de Cuba: Coordinates: 19° 58' 58", -76° 18' 07"; Intervention area: 23 ha.



1c. Child Project?

If this is a child project under a program, describe how the components contribute to the overall program impact.

N/A

2. Stakeholders

Please provide the Stakeholder Engagement Plan or equivalent assessment.

105. The successful implementation of the project will largely depend on effective communication and coordination with the multiple project stakeholders and the implementation of mechanisms to ensure their participation in project's activities. The key national and sub-national stakeholders include AMA, DMA, ICIMAR CITMA, ORSA, CIM-UH, BIOCUBAFARMA, BIOECO, University of La Habana, among others. At the local level, the most relevant stakeholders are the Protected Area "Rincón de Guanabo", Diving Club Guanabo Community, and NGOs, among others.

106. The stakeholder consultations and engagement that began during the design phase will be continued throughout project implementation. To achieve this, the project will make use of several mechanisms, including: a) Project Inception Workshop: the project will be presented to both direct and indirect stakeholders and beneficiaries; b) Project Board: comprised of representatives of the government agencies, local institutions and representatives of direct project beneficiaries; it will be responsible for approving the work plans, participating in the recruitment processes, and providing overall strategic guidance to the project; c) Project Management Unit (PMU): responsible for the implementation of the Stakeholder Engagement Plan, Gender Action Plan (GAP), Environmental and Social Management Plans (ESMPs), grievance redress mechanisms, and M&E; d) Communication and Information Management: ICIMAR will be responsible for maintaining fluid communication with the stakeholders through traditional means and new informational technologies. This communication will be duly recorded on a monthly basis in scorecards that indicate the type of communication, the reason, and the responsible parties; e) Governance role for project target groups: project target groups will be represented on the Project Board; f) GAP: will secure the involvement of both genders, including women; the GAP on a periodic basis; g) Grievance Mechanism: the project will establish a project-level Grievance Redress Mechanism (GRM) for addressing complaints or grievances that might arise

during the implementation of the project; the grievance mechanism will be published so that all stakeholders are aware of its existence, documenting any potential grievances and ensuring they are addressed in a timely manner; h) Opportunities to increase the participation of stakeholders at the local level: by facilitating knowledge, awareness-raising, and dissemination of information about the importance of the sustainable use of the *Thalassia Testudinum*; and i) M&E: this will include meetings and interviews with direct beneficiaries, and meetings with special groups such as women to verify gender ?based indicators.

107. The project was prepared in collaboration with relevant stakeholders from the Cuban government and civil society, and will benefit of their permanent participation during implementation. The key stakehoklders are shown in the following Table:

Stakeholders	Role in Project Implementation
Ministry for Science, Technology and Environment (CITMA)	CITMA is a key Project partner together with ICIMAR and its Environmental Agency (AMA). In addition, its Environment Directorate (DMA) in coordination with ORSA, also CITMA, are important actors in Component 1 of the project.
Department of Environment (DMA), CITMA	The DMA is in charge of the preparation and proposal of the environmental policy and the control of its compliance in the country. Since the very creation of the Agency, this direction has lead the development of the environmental legislation program and the dissemination of existing regulations. It is currently in charge of the coordination and control of the State Plan for Confronting Climate Change at the national level. In this project, it will participate in Component 1 aimed at strengthening the legal framework and the necessary capacities for the implementation of the Nagoya Protocol on Access to Genetic Resources and Benefit Sharing in the country.
Environment Agency (AMA), CITMA	AMA coordinates the State Plan for Confronting Climate Change at the sectoral level. It will contribute with knowledge and tools to consolidate the integrating vision of the project from its components. It will facilitate the coordination of actions with other OSD, OACE and binding national and international projects. As part of its functions, it would also supervise the effective progress of the National Project Implementation Office. It also participates through its key research institutions, such as ICIMAR, BIOECO and CIMAC.
Institute of Marine Sciences (ICIMAR), AMA, CITMA	<p>ICIMAR is the Project Implementing Partner. ICIMAR's mission is to carry out research aimed at developing the scientific bases for the knowledge, management, conservation, sustainable use and rehabilitation of natural resources and processes in the marine and coastal zone, as well as the commercialization of oceanographic, biological and of biomedical and industrial applications for the solution to social, environmental and economic problems. Its vision and the lines of research and services are firmly aligned with the main interventions proposed in the Project.</p> <p>It will act as the main executing entity and national coordinator of the different components and activities proposed in technical and administrative terms. In addition, it will be in charge of directing and conducting the non-clinical research-development process of the extract obtained from <i>T. testudinum</i> within an ethical framework that guarantees the fair and equitable distribution of the benefits derived from the results of the project (Component 2), which will be carried out with the participation of IMRE-UH and Oriente Pharmaceutical Laboratories BioCubaFarma.</p>

Stakeholders	Role in Project Implementation
Office for Environmental Regulation and Environmental Safety (ORSA), CITMA	ORSA is the entity that has the mission of regulating and controlling in the national territory compliance with the regulations in force in matters of environmental protection. Ensure compliance with the international commitments contracted by the Cuban State in the field of environmental protection assigned to it. In the project, ORSA is responsible for directing and conducting the strengthening of the legal framework and capacities for the implementation of the Nagoya Protocol on Access to Genetic Resources and Benefit Sharing (Component 1), which it will develop in coordination with the DMA of CITMA and ICIMAR.
Marine Research Center of the University of Havana (CIM-UH), MES	<p>The CIM-UH's mission is to contribute to the conservation of the environment and sustainable development, through the integration of scientific research and continuous training of professionals in Marine Biology, Aquaculture and Coastal Management, with a multidisciplinary approach and excellence.</p> <p>In the project, it participates in Component 3, designed for the development of studies on the conservation of marine biodiversity and the habitat of the angiosperm <i>T. testudinum</i> used for the development of the pharmaceutical product. To this end, ICIMAR, the Rincón de Guanabo Natural Landscape, CIMAC and BIOECO will collaborate in the development of the component.</p>
Institute of Materials Science and Technology, University of Havana (IMRE-UH), MES	The IMRE is a higher education institution that will participate in Component 2, in the development and conduction of non-clinical studies aimed at obtaining the bioproduct from <i>T. Testudinum</i> , this entity will also participate In the design and execution of different studies framed in said component, it will be responsible for carrying out the bio-computer studies and the bio-statistical analyzes that support the efficacy and safety of the bio-product.
Higher Business Development Organization (OSDE) BioCubaFarma	OSDE will be involved in the technological development of the pharmaceutical formulation that will be obtained in Component 2, through its entity Laboratorios Farmacéuticos "Oriente".
Pharmaceutical Laboratories "Oriente", OSDE BioCubaFarma	Laboratorios "Oriente" is a productive entity that belongs to the BioCubaFarma Superior Business Development Organization that will participate in Component 2, it is in charge of obtaining the pharmaceutical formulation of the bioproduct.

Stakeholders	Role in Project Implementation
Protected Area ?Rinc?n de Guanabo? Natural Landscape, Havana del Este Municipality Museum, Ministry for Culture.	This is one of the intervention and data collection sites of component 3. It will participate in the studies of foliar biomass of <i>T. testudinum</i> , its incidence in the bioactivity and resilience to the pruning of leaves and the studies directed to the development of the most suitable method for the use of angiosperm.
Center for Biodiversity and Eastern Ecosystems (BIOECO), AMA, CITMA	BIOECO is an institution of the AMA of CITMA. In the project, it will participate in studies of foliar biomass and the effects of genetic variability of <i>T. testudinum</i> meadows, its impact on bioactivity and resilience to leaf pruning and studies aimed at developing the most appropriate method for the use of angiosperm.
Camag?ey Environmental Research Center, CIMAC, AMA, CITMA	In the project, it will participate in studies of foliar biomass and the effects of genetic variability of <i>T. testudinum</i> meadows, its impact on bioactivity and resilience to leaf pruning and studies aimed at developing the most appropriate method for the use of angiosperm.
Diving Club (TCP - Self- employed modality) Guanabo Community.	Direct beneficiaries
Community Initiative and Exchange Center (CIERIC), Non- governmental organization (NGO).	Accompanies the project stakeholders, gives visibility and support to the project results.
Centro F?lix Varela (CFV)	Accompanies the project stakeholders, gives visibility and support to the project results.

Stakeholders	Role in Project Implementation
Cuban Society of Pharmacology (SCF), ONG.	Accompanies the project stakeholders, gives visibility and support to the project results.
Local Government of the municipality of Habana del Este	The local community Rinc?n de Guanabo will be involved in the project through the participation of the residents who carry out the Self-Employment activity called "Collector seller of natural resources", in accordance with the provisions of Decree-Law No. 356/2018 "On the Exercise of Self-Employment". During the process of formulation and implementation of the Project, the Local Government of the Popular Power of Guanabo, of the municipality of Habana del Este, will be involved, including the Popular Councils that are framed in this area of intervention.
Territorial Delegations of CITMA	CITMA is the key body for the execution of the activities related to the project, fundamentally those related to those that will be developed in the intervention areas and with the implementation of the Nagoya Protocol, through the coordination of control, supervision and the analysis of the results.
General Customs of the Republic	This is a control body that guarantees the security and protection of society and the national economy at the border, as well as tax collection and foreign trade statistics. It is a key actor for the purposes of Project Result 1 in relation to the definition of checkpoints for the control of the transboundary movement of genetic resources.

In addition, provide a summary on how stakeholders will be consulted in project execution, the means and timing of engagement, how information will be disseminated, and an explanation of any resource requirements throughout the project/program cycle to ensure proper and meaningful stakeholder engagement.

Select what role civil society will play in the project:

Consulted only; Yes

Member of Advisory Body; Contractor;

Co-financier;

Member of project steering committee or equivalent decision-making body;

Executor or co-executor;

Other (Please explain)

3. Gender Equality and Women's Empowerment

Provide the gender analysis or equivalent socio-economic assesment.

108. Cancer is the leading cause of death in Cuba, both in men and women. Data from the last National Population Census showed that more women than men live on the island by sex category and that women play a decisive role in the family, the nucleus of Cuban society, as well as occupying a more significant percentage of the country's productive force every year. However, their capacities and quality of life are significantly affected by the onslaught of this disease, which is increasing annually in all provinces of the country. According to the latest epidemiological reports of the Ministry of Public Health (Annual Report, 2019), lung, breast and colon tumours are the most common cause of morbidity and mortality among Cuban women, followed by gynaecological causes. This disease, which has long been associated with old age, has begun to appear significantly earlier in the country in the last five years. Breast, cervical and colon cancer are among the priority programmes for prevention and early diagnosis at the population level. However, despite significant resources allocated to cancer control and prevention in Cuba, at present it is one of the top ten diseases for which there is no solution in the country. It is therefore a priority for the Cuban State to find new therapeutic alternatives for controlling the disease, and particularly the tumours with the highest frequency of occurrence and mortality rate. The increased survival observed in cancer patients as a result of the new therapeutic approaches will make it possible in the future to approach cancer as a chronic non-communicable disease that causes patients pain and compromises their quality of life, with a serious impact on the rate of incapacity for work in productive ages for women. Pain affects 48% of patients in the early stages of the disease and between 64-75% of those in advanced stages, so its alleviation as part of the management of the disease, considered a human right in accordance with the Montreal Declaration and the development of Palliative Care, is also a priority in Cuba as part of the control and management of the disease.

109. The decisive participation of women within the country's Science, Technology and Innovation (STI) system is reflected in this project, in the institutions and actors involved in it. To cite an example, in the Institute of Marine Sciences (ICIMAR), which is the guiding center of the project's activities, the presence of women predominates, representing 52% of all workers. Among the women, 31 are researchers and 32 are specialists or technicians directly linked to Science and Technology activities. Of the total number of researchers with scientific degrees from ICIMAR, 55% of doctors are women and 60% of science teachers. The institute has a total of 6 women administrative cadres, 66% and 10 reserves of which 70% are women. Likewise, in the conception, coordination and execution of project tasks from ICIMAR, the presence of women predominates. This panorama is representative of the human potential of the rest of the centers and of the intervention sites involved.

110. In February 2020, a Gender Analysis was carried out within the framework of the preparatory phase for the formulation of this initiative, which made it possible to identify which could be the main actions to be carried out within the framework of the project to cross-examine the gender issue. As a result of the analysis carried out, it was possible to identify that it is important in the framework of the project to address the issue, which is conceived to be carried out through transformative actions in the productive activities of collection and processing of *Thalassia testudinum* in the community of Rinc?n de Guanabo. The participation of women in the tasks of the project that will be carried out in the intervention sites and in the participating scientific institutions during its development will be encouraged. In addition, their working conditions will be improved and the professional and technical capacities of women will be increased, so that they will also be indirect beneficiaries of the development of the project. Likewise, priority will be given to the participation of women in activities related to research, training, updating and support for the implementation of the political and regulatory framework of the Nagoya protocol. The gender gaps identified were the following:

- The greater female workload, associated with the still widespread consideration in society that women are the most responsible for the education and care of the offspring, is also a gap in the scientific sector and identified within the framework of the project.
- Some prejudices persist that limit the participation of women in tasks of greater physical effort (collections of marine species, execution of some industrial processes).

111. A Gender Action Plan was developed based on this analysis and is included in Annex 11 of the ProDoc.

Does the project expect to include any gender-responsive measures to address gender gaps or promote gender equality and women empowerment?

Yes

Closing gender gaps in access to and control over natural resources; Yes

Improving women's participation and decision making Yes

Generating socio-economic benefits or services or women Yes

Will the project's results framework or logical framework include gender-sensitive indicators?

Yes

4. Private sector engagement

Elaborate on private sector engagement in the project, if any

112. For the Cuban context, the "private sector entities" is represented by Socialist State Enterprises. During the formulation and implementation of the project, pharmaceutical companies that develop drugs from active principles of natural products will be involved, in order to jointly analyze the possible benefit distribution measures that could be more convenient in the country. At the same time, environmental and financial sustainability strategies will be jointly analyzed to maintain the availability of the drug in the market, once it has been approved as part of the authorized drugs / nutritional supplements in the country.

113. Furthermore, Self-Employed Workers authorized to carry out the activity "Collector seller of natural resources" are considered a non-state sector in Cuba. These actors will be involved in the collection process through sustainable use in local communities. The training of these actors determines if the use of *Thalassia testudinum* is carried out without affecting the ecosystem services provided by seagrasses, at the same time as meeting the quality standards necessary for the natural product to meet the requirements demanded by the pharmaceutical industry

5. Risks to Achieving Project Objectives

Elaborate on indicated risks, including climate change, potential social and environmental risks that might prevent the project objectives from being achieved, and, if possible, the proposed measures that address these risks at the time of project implementation.(table format acceptable):

The project identified the following risks: organizational, institutional, cofinancing, climate change-related, and potential social and environmental risks that might prevent achieving the project objectives. The following table includes the risks and the proposed measures that address these risks at the time of project implementation:

#	Description	Risk Category	Impact & Probability	Risk Treatment / Management Measures	Risk Owner
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1	<p>Delays in Project implementation start.</p> <p>Signing the National Terms of Reference is a prerequisite for signing the Project Document (ProDoc) between the Government of Cuba and the UNDP.</p>	Organizational	<p>Causes for the delay in Project implementation .</p> <p>L = 2</p> <p>I = 4</p> <p>Moderate risk</p>	<p>The National Terms of Reference have been discussed with Project key stakeholders during the drafting phase of the ProDoc. The Terms of Reference are expected to be signed well in advance, so as to ensure the signing of the ProDoc once it has been approved by GEF.</p>	PMU ^[1] / ICIMAR/AMA
2	<p>Delay in Project implementation due to delays in the procurement processes (import processes).</p> <p>Due to insufficient supply in the domestic market and the Cuban financial context, the execution of any international project requires a procurement process for importing goods, equipment and technologies according to the technical specifications defined. This implies the possibility of delays in Project deadlines since the import process affects the financial execution of the Project, as well as the implementation of the pilot interventions.</p>	Organizational	<p>Limits the procurement of equipment and disposable material required for non-clinical research related to the pharmaceutical product to be obtained. It would cause delays in the schedule of nonclinical tests, which would in turn imply delays in submitting the documents for product approval, which represents the main component of product, representing the main outcome of component 2 of the Project.</p> <p>L = 4</p> <p>I = 5</p> <p>High risk</p>	<p>During the project formulation phase a Procurement Plan was defined for each of the project execution years (See Annex XX). National regulations on additional requirements of the import process were also defined.</p> <p>Timely Identification of bottlenecks associated with import processes.</p> <p>Closely monitor the importation process, jointly with MINCEX, AMA, ICIMAR and the importing company.</p> <p>Opportunities arising from the emerging domestic non-state market have been identified in order to procure certain goods required by the Project such as cages for laboratory animals, lighting systems for vivarium, and equipment for evaluating animal behavior.</p>	PMU / ICIMAR/AMA

3	<p>Institutional changes at national and local levels.</p> <p>Institutional changes at national and local levels in the context of the process of updating the economic and social model in Cuba generate changes in Project key stakeholders and their respective responsibilities.</p>	Regulatory	<p>It would imply the need to adjust the roles and functions of key stakeholders involved in the Project, in case there is any change in their subordination and field of competence. Likewise, it could imply the need to include new stakeholders in the implementation of the Project.</p> <p>P = 3</p> <p>I = 3</p> <p>Moderate risk</p>	Systematic monitoring of institutional status and timely adjustment in Project coordination and implementation roles.	PMU / ICIMAR/AMA
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4	<p>Delays in outsourcing national services for construction repairs in ICIMAR facilities, to be carried out with domestic cofinancing.</p> <p>Construction repairs required to refurbish ICIMAR facilities in order to build the required capacities for obtaining the product, must be approved under the investment plan, which can be a long and complicated process. Besides, once the relevant approvals have been obtained, shortage of building resources may delay or even prevent the construction work foreseen or affect its quality. Shortage of resources is due to the economic situation of our country, plus the fact that priority is given to persons who have lost their homes due to natural disasters as well as works that carry a big economic impact, such as hotel and industrial infrastructures.</p>	Organizational	<p>Failure to carry out the refurbishment of ICIMAR facilities will affect the implementation of tests necessary for the 100% information required to submit the ?Request for authorization of clinical trials? for the new pharmaceutical product.</p> <p>P = 4</p> <p>I = 3</p> <p>Moderate risk</p>	<p>A recruitment plan has been developed and approved with the relevant financial support commitment, feasibility study and consultation with the construction companies, as well as for the procurement of construction materials on time.</p>	PMU / ICIMAR/AMA
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5	<p>Limited availability of committed domestic cofinancing or material resources in the domestic market.</p> <p>Lack of adequate public financial allocations for the procurement of the proposed activities in the project.</p> <p>The Project has domestic committed cofinancing. However, the epidemiological or climate emergencies (such as pandemics or tropical hurricanes) could limit the availability of these funds due to the need to allocate available resources to address said emergencies.</p> <p>In addition, given the economic situation of the country, there could be insufficient availability of material resources in the country (laboratory animals, fuel, construction materials) that may limit the implementation of activities under the Project, as is the case of the tests foreseen in it (laboratory research), the study of the Thalassia Testudinum in its natural habitat and the refurbishment of ICIMAR's laboratory.</p>	Financial/ Organizationa 1	<p>Failure to carry out the tests/studies on laboratory animals and the refurbishment required in ICIMAR facilities, as well as delays in the studies on the Thalassia Testudinum species, would affect the development of the tests required for the 100% information necessary for the Request for authorization of clinical trials? for the new pharmaceutical product.</p> <p>P = 3</p> <p>I = 3</p> <p>Moderate risk</p>	<p>A plan has been developed and approved for the design and approval of a study protocol, which includes a contract for the procurement of animals with the supplying center, in order to reduce the risk of non-availability of such animals.</p> <p>A recruitment plan has been developed and approved with the relevant financial support commitment, feasibility study and consultation with the construction companies, as well as for the procurement of construction materials on time.</p> <p>In case limited availability of fuel will not enable the Project to support transportation for the activities related to the study of the Thalassia in its natural habitat, the problem will be addressed with the resources of their own by key stakeholders.</p>	PMU / ICIMAR/AMA
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6	<p>Low connectivity to access ABS information mechanisms.</p> <p>Though in recent years, connectivity in our country has experienced a significant improvement, connection speed is still not sufficient to easily access big international databases. This is mainly due to lack of state-of-the-art technology and the restrictions imposed by the US Government regarding access to servers based in its country. Our country is currently involved in developing an IT policy to which this Project will contribute since building up the technological infrastructure of entities involved, in particular the AN, and easier access to the ABSCH databases through a national portal, are among the objectives of the Project. Hence, the probability</p>	Operational	<p>Any connectivity problem will have an impact on the results of all Project components, since they all depend on access to information available in databases in international websites</p> <p>P = 3</p> <p>I = 2</p> <p>Low risk</p>	<p>A connectivity plan has been designed as scheduled.</p> <p>Communication capacity through mobile phones and Internet (mobile data) of key stakeholders will be supported with Project funds. This is particularly important for a working scenario under the tele-computer modality.</p>	PMU / ICIMAR/AMA
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7	<p>Failure to obtain authorization to collect species in the areas proposed for the implementation of the Project.</p> <p>The Environmental Regulatory Authority is also part of the Project and is highly involved in the Project decision-making process. Besides, there is wide experience in the process for obtaining this kind of prior authorization for the collection of species in one of the areas. Most importantly, however, is the fact that the Project foresees the sustainable and environmentally safe use of the species, thus there is little probability of the authorization being denied.</p>	Organizational	<p>The existing environmental legislation in our country states that intervention in any natural area must be submitted to an evaluation and approval process by the environmental regulatory authority, specifically regarding the collection of species from biodiversity. In the worst case scenario, i.e. if collection of the species in the intervention areas under the Project is denied, Project outcomes related to the product to be obtained will be at risk.</p> <p>P = 1</p> <p>I = 3</p> <p>Low risk</p>	Permits and licenses required for the collection of biological material have been requested as scheduled.	PMU / ICIMAR/AMA
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8	<p>Lack of perception about the opportunities provided by the Project could imply the involvement of local key stakeholders.</p> <p>Raising awareness about the objective, scope and benefits of the Project is essential to involve local stakeholders, as well as for appropriate understanding of the opportunities provided by this initiative for sustainable use of the species and for generating new jobs at the local level.</p> <p>This is essential for fishing communities with a sense of ownership regarding local biodiversity, mainly fishermen and other persons whose livelihood is directly linked to the use of biodiversity and may think that the Project will hinder their access to these resources if they are not properly informed about the objectives and scope of the Project.</p>	Strategic (public opinion and media)	<p>The involvement of the local community is essential to achieve the objectives of the Project. The community is taken into consideration not only as the beneficiary of the Project outcomes but also as the main actors in harnessing the <i>Thalassia Testudinum</i> to obtain a pharmaceutical product.</p> <p>P = 1</p> <p>I = 3</p> <p>Low risk</p>	<p>Designing communication products to socialize the objectives, scope and outcomes of the Project, where appropriate, at the community level and through the media.</p> <p>Follow-up of commitments made during the prior consultation process with the communities</p> <p>Introduction of Project objectives in community Councils and the development and implementation of involvement strategies to increase the community's understanding of their role and the potential benefits of the provided by the Project.</p>	PMU / ICIMAR/AMA
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9	<p>Climate change impact causing modifications in the expected production pattern of secondary metabolites, higher degree of organic pollutants in the environment, and impact of hurricanes and other natural hazards.</p> <p>The probability of this hazard depends to a great extent on the duration of the Project. Being a 4-year Project, the direct impact of climate change due to modification of environmental parameters such as salinity, temperature, and other, should not be significant. Also, climate change could affect the bioactive metabolites in this species. Though the probability of the impact of a high intensity hurricane in 4 years is high, the fact that the Project has three intervention areas consequently reduces the probability of running out of raw material for the product. In addition, the fact that the use of this marine resource is sustainable makes populations more resilient to the impact of these natural hazards.</p>	Environmental 1	<p>As a marine organism, there are many environmental parameters that can affect the production of these metabolites, which are essential for the development of the product. Storms and hurricanes could also affect salt meadows, which will in turn affect the production of biomass and metabolites.</p> <p>P = 3</p> <p>I = 3</p> <p>Moderate risk</p>	<p>Hazard, vulnerability and risk protocols regarding the extinction of this species in the marine ecosystem due to climate change impacts in Cuba have been designed and are in place.</p> <p>Output 3.1.3 includes an activity on assessing the variability of bioactive metabolites during project implementation which will provide information on the potential impacts of climate change and anthropogenic factors.</p>	PMU/ICIMAR/AM A
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10	<p>Participation in project activities could pose a potential risk of exposure to COVID-19.</p> <p>This is considered a low risk due to strong national policies to protect worker health and safety and a national strategy to guide the reopening of the tourism sector post-pandemic. Cuba is preparing to gradually restart its tourist services, for which it has designed and implements rigorous sanitary and hygienic protocols. This allows the gradual recovery of the tourism sector, contributing to the economic recovery of the country, without compromising national health security. The design of the project interventions will take into account the specific measures necessary to mitigate any potential risk of exposure during implementation.</p>	Health	<p>P = 3</p> <p>I = 3</p> <p>Moderate risk</p>	<p>In accordance with current health restrictions associated with the COVID-19 pandemic, project implementation will employ videoconferencing equipment for virtual meetings and workshops, when necessary; adjust the workplan so that some activities in the field or related to consultations take place later, as necessary; and/or provide personal protective equipment (PPE) to prevent exposure among project stakeholders and participants. During the PPG, Budget will be included for IT support and PPE.</p>	PMU/ICIMAR/AM A
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11	<p>The results of the research-development phase do not demonstrate the anticancer properties of the Thalassia testudinum.</p> <p>Thalassia testudinum's anticancer properties has been demonstrate based on 65% of the scientific-technical studies developed. However, a risk that the remaining 35% of the scientific-technical studies suggest the opposite is identified.</p>	Strategic	<p>P = 3</p> <p>I = 3</p> <p>Moderate risk</p>	<p>If the Project cannot demonstrate the hypothesis that the product obtained from T. Testudinum can be used as an antitumor/anticancer drug, the project will adjust it engagement protocol. This adjustment will be done considering other potential alternatives to use this bioproduct (pharmaceutical, cosmetic and agriculture). The project does not include the commercialization process, its scope is limited to support the activities leading to the presentation of the request for the Clinical Trial authorization.</p>	PMU/ICIMAR/AM A
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12	<p>There is a risk that insufficient/ineffective engagement and consultation with certain stakeholders will limit their participation in the project activities and/or in decisions that might affect them.</p> <p>Project outputs 1.1.1, 1.1.2, 1.1.3, and 1.1.4 will establish the regulatory framework, strengthened capacity and tools needed for the application of an ABS mechanism to the harvesting and exploitation of <i>T. testudinum</i>. Insufficient/ineffective consultation and engagement with local communities and other stakeholders could lead to their interests/rights not being fully represented in the project and/or these stakeholders not achieving their full potential benefits.</p> <p>This risk relates to the application of Prior Informed Consent (PIC) under the Nagoya Protocol.</p>	Social	<p>I = 3</p> <p>L = 2</p> <p>Moderate risk</p>	<p>Stakeholder engagement was conducted as part of the project formulation (Stakeholder Engagement Plan SEP ? Annex 9 of ProDoc). Going forward, stakeholder engagement will need to be conducted according to the <i>Bonn Guidelines on Access to Genetic Resources and Fair and Equitable Sharing of the Benefits Arising out of their Utilization</i> to ensure no stakeholder group is excluded from the ABS mechanism. The ESMF (Annex 10 of PRODOC) includes a set of guidelines for stakeholder engagement during implementation.</p> <p>There are no records of a traditional use of this marine species in Cuba, whose ownership belongs to the state. However, the applicability an exact nature of PIC and mutually agreed terms (MAT) for this project needs to be established as part of the stakeholder engagement process in the early stages of project implementation. The ESMF (Annex 10 of ProDoc) includes the basic principles of PIC as established in the Bonn Guidelines.</p> <p>In addition, the project will support assessments and develop methodological proposals to define monetary and non-monetary benefits derived from genetic</p>	PMU/ICIMAR/AM A
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13	<p>Women's limited participation and benefit sharing due to prevailing cultural and social norms that prevent women from fully participating in the project.</p> <p>Despite of the significant role of women in social and economic development in Cuba, some prevailing gender stereotypes in the targeted communities and in the Cuban society at large may hinder women's participation in the project's activities: form harvesting to processing of <i>T. testudinum</i>. For instance, some prejudices persist that limit the participation of women in activities involving physical effort (e.g., harvesting of marine species, execution of some industrial processes, etc.).</p>	Social	<p>I = 3</p> <p>L = 3</p> <p>Moderate risk</p>	<p>Gender-responsive ABS schemes are essential to enable effective participation of both women and men in the design, negotiation, distribution and use of benefits.</p> <p>The Gender Analysis and Action Plan (GAAP) ? Annex 11 of the ProDoc ? includes a number of actions to encourage women's participation: mainstreaming gender considerations, training and awareness actions and working conditions.</p>	PMU/ICIMAR/AM A
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14	<p>Damage to <i>Thalassia testudinum</i> habitat and associated ecosystem services provided by marine seagrasses meadows.</p> <p>Inappropriate harvest practices could lead to damage of the seagrass meadow ecosystem and the provision of ecosystem services, including its capacity to regulate wave impacts in case of extreme meteorological events or coastal floods due to the sea level rise, as well as its role as refuge of marine species of environmental and/or commercial interest.</p>	<p>Environmenta 1</p>	<p>I = 4 L= 2</p> <p>Moderate risk</p>	<p>A better understanding of the environment of <i>T. testudinum</i> is required to identify risks to biodiversity and ecosystem services. The ESMF (Annex 10 of PRODOC) includes ?Biodiversity Risks Assessment? guidelines and the outline of a Biodiversity Action Plan.</p>	<p>PMU/ICIMAR/AM A</p>
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15	<p>Potential adverse impacts to environmentally sensitive areas.</p> <p>The harvesting of <i>Thalassia Testudinum</i> for testing its potential medical benefits will take place in the Rincon de Guanabo Protected Area. This area is classified under the management category "Protected Natural Landscape". Although harvesting will not take place in the core conservation areas of this protected area, without sustainable practices, the seagrass can be affected, and consequently, reduce the flow of ecosystem services.</p>	Environmental	<p>I = 4</p> <p>L = 2</p> <p>Moderate risk</p>	<p>The ESMF includes the outlines of a Biodiversity Action Plan (to mitigate potential biodiversity risks). This tool will be developed and updated throughout the Project to avoid any impacts to the protected landscape of Rincon de Guanabo.</p> <p>In addition, the project will ensure full compliance with the provision on environmental quality and sustainability contained in the Decree-Law 201 (National System of Protected Areas).</p>	PMU/ICIMAR/AM A
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16	<p>Induced overexploitation of <i>Thalassia testudinum</i>. Although there are no records of a traditional use of <i>Thalassia Testudinum</i> in Cuba, there is a potential risk for the expansion of the use of the species by other local communities, once they become familiar with the pharmaceutical product. This awareness could lead to the spontaneous and inappropriate search, harvesting and consumption of the species by part of the population and harm the composition and health of marine seagrasses meadows.</p>	<p>Environmental 1</p>	<p>I = 4 L=2</p> <p>Moderate risk</p>	<p>Component 4 of the Project involves raising awareness of stakeholders and users of genetic resources to promote a change in behavior, highlight responsible harvesting and treatment procedures and practices.</p> <p>As part of the Stakeholder Engagement Plan - SEP (Annex 9), promote communication and awareness with local communities and more broadly at the national level with communication products and campaigns to raise awareness on ABS practices and benefits.</p>	<p>PMU/ICIMAR/AM A</p>
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17	<p>Climate risks impacting the production and harvesting of <i>Thalassia testudinum</i>.</p> <p>The coastal infrastructure (ports, docks, etc.) in the intervention areas and the marine seagrasses meadows themselves could be affected by tropical cyclones, hurricanes and other extreme events (severe winds, storm surges). These events could impact the production and harvesting of <i>T. testudinum</i>.</p>	Environmental	<p>I = 4</p> <p>L = 2</p> <p>Moderate risk</p>	<p>Because the pilot nature of the Project (with a 4-year duration), long-term changes in climate variables are not likely to become apparent during the lifespan of the Project. However, prior to the selection of the intervention areas, a Climate Risk Assessment will be conducted according to the guidelines includes in the ESMF (Annex 10 of PRODOC). This assessment will allow the Project to select areas of marine seagrasses production where the probability to be damaged by extreme events is lower.</p> <p>Institutions/stakeholders engaged in the Project will include in the Civil Defense System Action Plan in order to coordinate any actions require to prevent and manage climate risks.</p>	PMU/ICIMAR/AM A
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18	<p>Occupational risks associated to the harvesting and processing of <i>Thalassia testudinum</i> including laboratory tasks. A number of occupational risks have been identified in some of the steps involved in the harvesting and processing of <i>T. testudinum</i>: divers involved in harvesting (output 3.1.3), use of cutting tools in the mill facility, and exposure to hazardous chemicals at the laboratory facilities.</p>	Environmental 1	<p>I = 4 L = 2</p> <p>Moderate risk</p>	<p>The Project will develop Labor Management Procedures (outline included in the ESMF ? Annex 10 of PRODOC) including an Occupational Health and Safety Plan with provisions for the prevention and management of these risks. This plan also includes the training of workers and personnel involved in the harvesting and processing of <i>T. testudinum</i>.</p> <p>To manage any potential occupational risk, the project will also upgrade ICIMAR Research Unit facilities, including occupational hazard control mechanisms.</p>	PMU/ICIMAR/AM A
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19	<p>Inadequate disposal of non-hazardous solid waste generated as a by-product of processing <i>Thalassia Testudinum</i>. The Project will generate non-hazardous waste as part of the processing of seagrass (Component 2). If this waste is not disposed adequately, there could be pollution risks.</p>	<p>Environmental 1</p>	<p>I = 4 L= 2</p> <p>Moderate risk</p>	<p>The Project will develop a Pollution Prevention and Waste Management Plan (outline included in the ESMF ? Annex 10 of PRODOC) to ensure adequate disposal of waste. This plan will be part of the Standardized Working Procedure for the processing of <i>T. testudinum</i>.</p> <p>The Waste Management Plan is part of ICIMAR?s risk prevention plan developed considering the evaluation and characterization of <i>Thalassia Testudinum</i> waste. One of the waste management options to be explored is the use of dried solid waste in controlled-released manures and fertilizers for agriculture.</p>	<p>PMU/ICIMAR/AM A</p>
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20	<p>Accidental release of hazardous effluents (ethanol).</p> <p>As part of the extraction process (Component 2) of the pharmaceutical formula a flammable chemical reagent (graded ethanol 50%) will be used. If turned into waste, it would be considered a ?hazardous waste? and, accordingly, it will require specific management measures in accordance with the national legislation.</p>	Environmental 1	<p>I = 4 L= 2</p> <p>Moderate risk</p>	<p>The Project will need to develop a Pollution Prevention and Waste Management Plan (outline included in the ESMF ? Annex 10 of PRODOC) to ensure adequate provisions are implemented to avoid the release of ethanol. This plan will be part of the Standardized Working Procedure for the processing of <i>T. testudinum</i>. This procedure will be refined and validated throughout the implementation of the Project.</p>	PMU/ICIMAR/AM A
21	<p>Energy use and water consumption.</p> <p>The <i>Thalassia testudinum</i> washing process during the harvest requires water and energy for the grinding process. If not implemented well or appropriately, the project could overuse those resources</p> <p>Given the pilot nature of the activity, it will not imply the consumption of considerable quantities of water and energy.</p>	Environmental 1	<p>I = 2 L= 2</p> <p>Low</p>	<p>Measures aren?t needed in this case because the current risk is low. As part of the Project implementation, water and energy consumption, per kilo of collected material, will be calculated. This action is key to systematize information to define appropriate levels of water and energy consumption for this activity.</p>	PMU/ICIMAR/AM A

22	<p>Exposure to Covid-19. International consultants will not travel to Cuba during the first year of implementation. The project does not involve work in indoor crowded places. The risk of exposure to Covid-19 infection is therefore considered low.</p>	Environmental	<p>I = 2 L = 2 Low</p>	<p>Measures aren't needed in this case because the risk is low. However, this risk category will be updated according to the national regulations from the Health Authority to combat Covid-19.</p>	PMU/ICIMAR/AM A
23	<p>Impacts on marine-based livelihoods.</p> <p>Harvesting of <i>T. testudinum</i> may conflict with other uses of these marine areas in the target coastal areas, particularly shellfish harvesting and tourism. If new regulations and procedures (outputs 1.1.1, 1.1.2, 1.1.3, and 1.1.4) restrict access to intervention areas, there might be an impact on the livelihoods (economic displacement) of individuals (mainly to self-employed workers) engaged in marine-based activities. Restrictions of access are expected to be temporary (only for the duration of harvesting; output 3.1.3).</p>	Social	<p>I = 3 L = 2 Moderate risk</p>	<p>More information is needed in order to identify the current uses of the target marine areas and the socio-economic structure of the coastal communities. A Livelihoods Risk Assessment will be conducted at the intervention areas. Based on the results of this assessment, a Livelihoods Action Plan might be required for SES compliance. The ESMF (Annex 10 of ProDoc) includes the outlines for both Livelihoods Risk Assessment and Livelihoods Action Plan.</p>	PMU/ICIMAR/AM A

24	<p>Limited capacity of the duty-bearers to meet their obligations in the Project.</p> <p>The national stakeholders involved in the project (BioCubaFarma, ICIMAR, CIM-UH, University of Havana) are established institutions with relevant experience for the project's objectives. However, the strengthening of capacities foreseen by the project (specialized laboratory equipment, training of personnel in the application of laboratory practices and training of the local peoples on environmentally sustainable production practices) is decisive to ensure the achievement of the project's objectives regarding the sustainable development of the pharmaceutical product. Also, it is critical to strengthen capacity at the community level to ensure the appropriation of environmentally sustainable production practices.</p>	Social	<p>I = 4</p> <p>L= 2</p> <p>Moderate risk</p>	<p>The ProDoc includes activities and budget to support:</p> <ul style="list-style-type: none"> - Strengthening research capacities, through the acquisition of laboratory equipment and training of personnel in the application of laboratory practices. The increased capacity will enable the completion the relevant data on the properties of the <i>Thalassia testudinum</i>. This data is required to submit, to the Cuban Regulatory Agency, the application for authorization to begin the clinical research phase. - Strengthening the capacity of local people to harvest <i>Thalassia testudinum</i>. To this end, the project will support the acquisition of diving equipment (necessary for monitoring seagrasses and for its harvesting) and training of local personnel, to ensure the use of sustainable practices. 	PMU/ICIMAR/AM A
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^[1] Project Management Unit

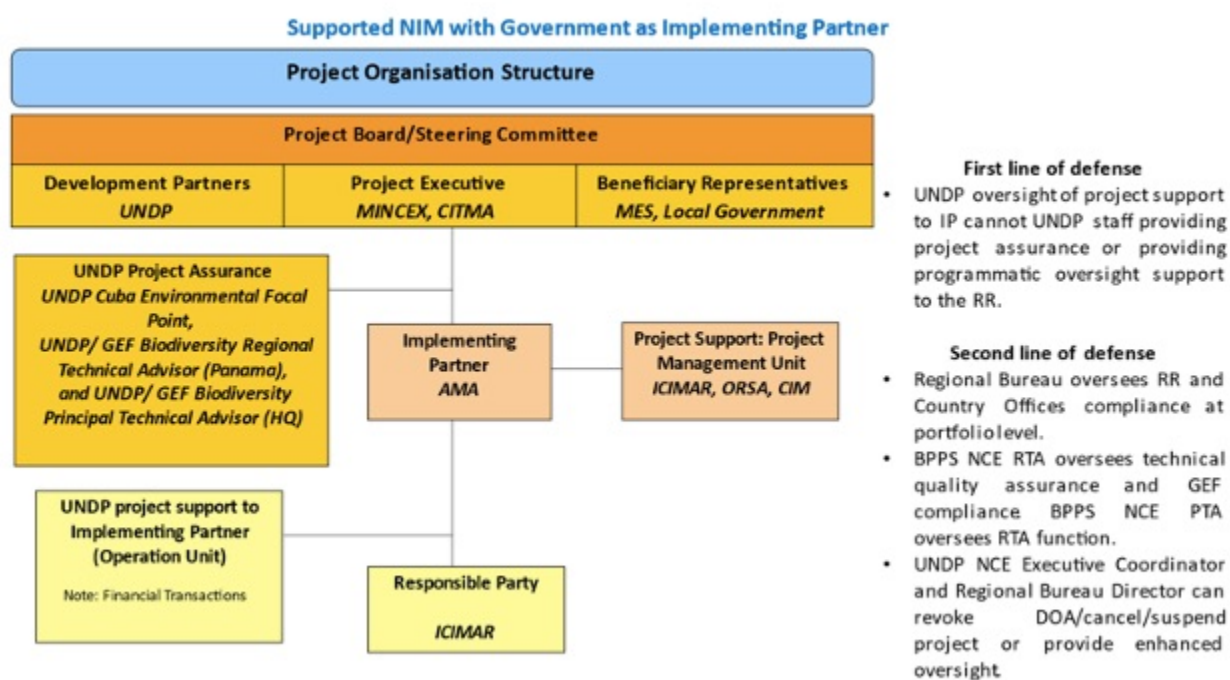
6. Institutional Arrangement and Coordination

Describe the institutional arrangement for project implementation. Elaborate on the planned coordination with other relevant GEF-financed projects and other initiatives.

114. The Implementing Partner for this project is the Environmental Agency (AMA).
115. The Implementing Partner is the entity to which the UNDP Administrator has entrusted the implementation of UNDP assistance specified in this signed project document along with the assumption of full responsibility and accountability for the effective use of UNDP resources and the delivery of outputs, as set forth in this document.
116. The Implementing Partner is responsible for executing this project. Specific tasks include:
- Project planning, coordination, management, monitoring, evaluation and reporting. This includes providing all required information and data necessary for timely, comprehensive and evidence-based project reporting, including results and financial data, as necessary. The Implementing Partner will strive to ensure project-level M&E is undertaken by national institutes and is aligned with national systems so that the data used and generated by the project supports national systems.
 - Overseeing the management of project risks as included in this project document and new risks that may emerge during project implementation.
 - Procurement of goods and services, including human resources.
 - Financial management, including overseeing financial expenditures against project budgets.
 - Approving and signing the multiyear workplan.
 - Approving and signing the combined delivery report at the end of the year; and,
 - Signing the financial report or the funding authorization and certificate of expenditures
117. Responsible Parties: Responsible party for this project is the Institute of Marine Sciences (ICIMAR).
118. Project stakeholders and target groups: The Ministry of Science, Technology and Environment (CITMA) and its Territorial Delegations at the provincial levels are a key stakeholder in the project and will be involved in several activities implemented by the project at the national and the local level. In addition, Stakeholders and target groups of the project will be incorporated through the Technical Groups and Coordination Team at the provinces level (Camaguey and Santiago de Cuba) regarding the monitoring of the seagrasses habitats. In the Habana del Este municipality will be developed regarding both the seagrasses monitoring and its harvesting under sustainable practices through the active participation of the local peoples. See Annex 8: Stakeholder Engagement Plan for details.
119. UNDP: UNDP is accountable to the GEF for the implementation of this project. This includes overseeing project execution undertaken by the Implementing Partner to ensure that the project is being carried out in accordance with UNDP and GEF policies and procedures and the standards and provisions outlined in the Delegation of Authority (DOA) letter for this project. The UNDP GEF Executive Coordinator, in consultation with UNDP Bureaus and the Implementing Partner, retains the right to revoke the project DOA, suspend or cancel this GEF project. UNDP is responsible for the Project Assurance function in the project governance structure and presents to the Project Board and attends Project Board meetings as a non-voting member.

120. A firewall will be maintained between the delivery of project oversight and quality assurance performed by UNDP and charged to the GEF Fee and any support to project execution performed by UNDP (as requested by and agreed to by both the Implementing Partner and GEF) and may be charged to the GEF project management costs (only if approved by GEF). The segregation of functions and firewall provisions for UNDP in this case is described in the next section.

Project organisation structure:



7. Consistency with National Priorities

Describe the consistency of the project with national strategies and plans or reports and assessments under relevant conventions from below:

NAPAs, NAPs, ASGM NAPs, MIAs, NBSAPs, NCs, TNAs, NCSAs, NIPs, PRSPs, NPFE, BURs, INDCs, etc.

- National Biodiversity Strategies and Action Plan (NBSAP) under UNCBD
- National Communications (NC) under UNFCCC
- National Capacity Self-Assessment (NCSA) under UNCBD, UNFCCC, UNCCD
- Others

121. Cuba signed the Convention on Biological Diversity (CBD) at the opening for signature and ratified it in March 1994, with the Ministry of Science, Technology and Environment as its Focal Point. In 1997, the National Environmental Strategy was elaborated and provided the basis for the National Biological Diversity Strategy and Action Plan, which have been updated continuously. At present, these actions have resulted in the National Program for Biological Diversity (PNDB) 2016-2020, which has 20 goals and constitutes the main platform of action for the implementation of the strategic objectives defined in the national environmental policy to confront the loss of biological diversity. The GEF project is directly

aligned with several of these goals/targets: Target No. 15, which aims to "Ensure adequate access to genetic resources and benefit sharing in accordance with the Nagoya Protocol", has four actions aimed at full implementation of the Protocol in the country. Target 4 aims to restore coastal and aquaculture ecosystems through sustainable management; Target 10 aims to help reduce the multiple anthropogenic pressures on coral reefs, seagrasses, mangroves and beaches vulnerable to climate change; and Target 17 aims to make progress in developing human resources to support the implementation of the PNDB.

122. Cuba signed the Nagoya Protocol in November 2015 and has ratified the need to increase, at different levels, the knowledge of the mechanisms and legal actions required to implement in the country the access to the equitable distribution of the benefits derived from the use of genetic resources. Cuba's incorporation as a State party to the Nagoya Protocol has been a high-profile political decision, demonstrating the island's commitment to the conservation and sustainable use of biodiversity. Crucial to this is the aforementioned National Program for Biological Diversity (2016-2020), which establishes the country's programmatic platform against indiscriminate use and appropriation by third parties to guarantee the fair and equitable distribution of resources to all citizens, and thus provides a solid baseline for the proposed project.

123. Cuba also has the national-level Strategic Plan for the Development of Science, Technology and Innovation. The key objectives of this plan include: To emphasize the conservation and rational use of natural resources such as soils, water, beaches, atmosphere, forests and biodiversity. In this context, the implementation of a National Program for the Sustainable Use of the Components of Biological Biodiversity (NPSUCBB) in Cuba was approved by CITMA. This program's objectives include the generation of new knowledge to allow increasing the conservation and rational use of biological biodiversity with an emphasis on the ecosystem level, as well as the inter-relationships between its entities and abiotic components, particularly with respect to the use and management of genetic resources in ABS matters.

124. Task No. 6 of the State Plan for Confronting Climate Change (Tarea Vida) aims to stop the deterioration and facilitate the rehabilitation and conservation of coral reefs throughout the archipelago, with priority on the ridges that border the insular platform and protect urbanized beaches for tourist use. The achievement of these goals depends on the ecosystem services that seagrasses provide to the health of the reef, hence the importance of their proper management and conservation.

125. The project contributes to the achievement of the objectives of the National Sustainable Use Program in three fundamental directions. All the components contribute directly or indirectly to the sustainable use of biological biodiversity, especially of the Cuban marine platform, with the aim of ensuring that the management of these resources benefits the entire population in the search for solutions to a health problem of national and international scope. At the same time, through the application of the precepts of the Nagoya protocol, the Project components contribute to achieving a sustainable balance between local needs for development and achieving a more equitable participation in the benefits that are derived from the initiatives created.

126. The project Components contribute to the development of capacities or the strengthening of those already existing in terms of the safeguarding and availability of the accumulated information regarding the genetic resources of the Cuban marine platform. They aim to increase the cultural preparation of the human resources of the institutions and local communities involved in the proposal, the conduct of the project will allow them to have the information generated for the development of their own capacities and for the search for other local alternatives in function of the sustainable use of biological diversity, specifically of the Cuban marine platform, thus favoring fair and equitable access to benefits.

127. Component 1 proposes to complete and implement the legal framework in accordance with the Nagoya Protocol and the current environment marked by the transformations imposed by the establishment of a new economic model in the country, particularly those related to the use of natural resources and the distribution of wealth and benefits. In addition, this Component guarantees, together with Component 3, the level of dissemination of the purposes and benefits derived from the project to guarantee transparency and promote the participation of actors from the government sector and local communities in the use of biological diversity. Cuba under the principles of profit sharing, promoted by the implementation of the Nagoya protocol.

128. Given that the healthcare system in Cuba serves the entire community, the benefits that will emanate from the results of the project will undoubtedly have an impact on the quality of life of patients at the community level in all regions of the country.

129. The project is framed within different objectives defined in the national science and technology policies, among which the following stand out, included in guidelines 131, 132, 136, 156, 221 and 222 of the Economic and Social Policy approved in the VII Congress of the Party and with the strategic cross-sectoral axis of the Economic and Social Development Program of Cuba until 2030, related to natural resources and the environment and the development of the biotechnology industry.

130. The project will support and develop comprehensive research to protect, conserve and rehabilitate the environment and adapt the environmental policy to the new national economic, social, and environmental projections. The project will prioritize studies aimed at confronting climate change and, in general, the sustainability of the country's development. The project will emphasize the conservation and rational use of natural resources such as soils, water, beaches, the atmosphere, forests, and biodiversity. The project addresses the protection of marine genetic resources and promotes environmental education in local communities. More specifically, the project will contribute to:

- Sustain and develop the results achieved in biotechnology, medical-pharmaceutical production, the software industry, expanding technology use at the societal level, and providing high value-added scientific and technological services.
- Consolidate the pharmaceutical and biotechnology industry as one of the activities with the greatest export capacity in the economy, and incorporate new products into the national market to substitute imports in areas of priority attention by the State based on social welfare.
- Develop the industry of dietary supplements and natural medicines, from national supplies, for national consumption and export.

8. Knowledge Management

Elaborate the "Knowledge Management Approach" for the project, including a budget, key deliverables and a timeline, and explain how it will contribute to the project's overall impact.

131. Knowledge management is a cross-cutting component in the project's design, promoting learning and continuous improvement, generating documents for upscaling of lessons learned and experiences and visibility strategies for capacity development. The results of the project will be disseminated within and beyond the project intervention areas through a number of networks, forums and conferences specialized in the subject for the exchange of information. Additionally, the project will participate, as relevant and appropriate, in networks sponsored by UNDP, organized by expert personnel working on projects that share common characteristics. The project will identify and participate, as appropriate, in scientific networks that could benefit from the lessons learned in the implementation of the project. The project will identify, analyze and share lessons learned that may be of benefit in the design and implementation of similar projects in the future. UNDP should provide a format and support the project team in the categorization, documentation and reporting of lessons learned.

9. Monitoring and Evaluation

Describe the budgeted M and E plan

132. Project-level monitoring and evaluation will be undertaken in compliance with UNDP requirements as outlined in the UNDP POPP (including guidance on GEF project revisions) and UNDP Evaluation Policy. The UNDP Country Office is responsible for ensuring full compliance with all UNDP project M&E requirements including project monitoring, UNDP quality assurance requirements, quarterly risk management, and evaluation requirements.

133. Additional mandatory GEF-specific M&E requirements will be undertaken in accordance with the GEF Monitoring Policy and the GEF Evaluation Policy and other relevant GEF policies . The M&E plan and budget included below will guide the GEF-specific M&E activities to be undertaken by this project.

134. In addition to these mandatory UNDP and GEF M&E requirements, other M&E activities deemed necessary to support project-level adaptive management will be agreed during the Project Inception Workshop and will be detailed in the Inception Report.

Minimum project monitoring and reporting requirements as required by the GEF:

135. Inception Workshop and Report: A project inception workshop will be held within 60 days of project CEO endorsement, with the aim to:

- Familiarize key stakeholders with the detailed project strategy and discuss any changes that may have taken place in the overall context since the project idea was initially conceptualized that may influence its strategy and implementation.
- Discuss the roles and responsibilities of the project team, including reporting lines, stakeholder engagement strategies and conflict resolution mechanisms.
- Review the results framework and monitoring plan.
- Discuss reporting, monitoring and evaluation roles and responsibilities and finalize the M&E budget; identify national/regional institutes to be involved in project-level M&E; discuss the role of the GEF OFP and other stakeholders in project-level M&E.
- Update and review responsibilities for monitoring project strategies, including the risk log; SESP report, Social and Environmental Management Framework (where relevant) and other safeguard requirements; project grievance mechanisms; gender strategy; knowledge management strategy, and other relevant management strategies.
- Review financial reporting procedures and budget monitoring and other mandatory requirements and agree on the arrangements for the annual audit.
- Plan and schedule Project Board meetings and finalize the first-year annual work plan. Finalize the TOR of the Project Board.
- Formally launch the Project.

136. GEF Project Implementation Report (PIR): The annual GEF PIR covering the reporting period July (previous year) to June (current year) will be completed for each year of project implementation. UNDP will undertake quality assurance of the PIR before submission to the GEF. The PIR submitted to the GEF will be shared with the Project Board. UNDP will conduct a quality review of the PIR, and this quality review and feedback will be used to inform the preparation of the subsequent annual PIR.

137. GEF Core Indicators: The GEF Core indicators included in Annex 14 will be used to monitor global environmental benefits and will be updated for reporting to the GEF prior to MTR and TE. Note that the project team is responsible for updating the indicator status. The project will share the updated monitoring data with MTR/TE consultants before evaluation missions so that there is indispensable data available for subsequent ground-truthing. The methodologies to be used in data collection have been defined by the GEF and are available on the GEF website.

138. Independent Mid-term Review (MTR): The terms of reference, the review process and the final MTR report will follow the standard UNDP templates and UNDP guidance for GEF-financed projects available on the UNDP Evaluation Resource Center (ERC).

139. The evaluation will be 'independent, impartial and rigorous'. The evaluators that UNDP will hire to undertake the assignment will be independent from organizations that were involved in designing, executing or advising on the project to be evaluated. Equally, the evaluators should not be in a position where there may be the possibility of future contracts regarding the project under review.

140. The GEF Operational Focal Point and other stakeholders will be actively involved and consulted during the evaluation process. Additional quality assurance support is available from the BPPS/NCE-VF Directorate.

141. The final MTR report and MTR TOR will be publicly available in English and will be posted on the UNDP ERC by December 2024. A management response to MTR recommendations will be posted in the ERC within six weeks of the MTR report's completion.

142. Terminal Evaluation (TE): An independent terminal evaluation (TE) will take place upon completion of all major project outputs and activities. The terms of reference, the evaluation process and the final TE report will follow the standard templates and guidance for GEF-financed projects available on the UNDP Evaluation Resource Center. TE should be completed 3 months before the estimated operational closure date, set from the signature of the ProDoc and according to the duration of the project. Provisions should be taken to complete the TE in due time to avoid delay in project closure. Therefore, TE must start no later than 6 months to the expected date of completion of the TE (or 9 months prior to the estimated operational closure date).

143. The evaluation will be "independent, impartial and rigorous". The evaluators that UNDP will hire to undertake the assignment will be independent from organizations that were involved in designing, executing or advising on the project to be evaluated. Equally, the evaluators should not be in a position where there may be the possibility of future contracts regarding the project being evaluated.

144. The GEF Operational Focal Point and other stakeholders will be actively involved and consulted during the terminal evaluation process. Additional quality assurance support is available from the BPPS/NCE-VF Directorate.

145. The final TE report and TE TOR will be publicly available in English and posted on the UNDP ERC by August 2026. A management response to the TE recommendations will be posted to the ERC within six weeks of the TE report's completion

146. Final Report. The project's terminal GEF PIR along with the terminal evaluation (TE) report and corresponding management response will serve as the final project report package. The final project report package shall be discussed with the Project Board during an end-of-project review meeting to discuss lesson learned and opportunities for scaling up.

Agreement on intellectual property rights and use of logo on the project's deliverables and disclosure of information: To accord proper acknowledgement to the GEF for providing grant funding, the GEF logo will appear together with the UNDP logo on all promotional materials, other written materials like publications developed by the project, and project hardware. Any citation on publications regarding projects funded by the GEF will also accord proper acknowledgement to the GEF. Information will be disclosed in accordance with relevant policies notably the UNDP Disclosure Policy and the GEF policy on public involvement.

147. **Monitoring Plan**: The project results, corresponding indicators and mid-term and end-of-project targets in the project results framework will be monitored by the Project Management Unit annually, and will be reported in the GEF PIR every year, and will be evaluated periodically during project implementation. If baseline data for some of the results indicators is not yet available, it will be collected during the first year of project implementation. Project risks, as outlined in the risk register, will be monitored quarterly

Monitoring and Evaluation Plan and Budget:		
GEF M&E requirements	Indicative costs (US\$)	Time frame

Monitoring and Evaluation Plan and Budget:		
GEF M&E requirements	Indicative costs (US\$)	Time frame
Inception Workshop and Report	3,400	Inception Workshop within 2 months of the First Disbursement
M&E of GEF core indicators and project results framework	3,000	Annually and at mid-point and closure.
GEF Project Implementation Report (PIR)	None	Annually typically between June-August
Monitoring of environmental and social risks, and corresponding management plans, as relevant (i.e. stakeholder engagement plan, gender action plan)	10,000	On-going.
Supervision missions	None	Annually
Learning missions	None	-
<i>Independent Mid-term Review (MTR)</i>	11,000	<i>December 2024</i>
Independent Terminal Evaluation (TE)	11,000	<i>August 2026</i>
TOTAL indicative COST	38,400	

	Objective and Outcome Indicators	End of Project Target	Description of indicators and targets	Data source/ Collection Methods	Frequency	Responsible Party	Means of Verification
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Project Objective: Promote the equitable distribution of benefits and conservation of genetic resources of biodiversity through the strengthening of the regulatory framework and the evaluation of a product for the therapeutic management of cancer obtained from angiosperm <i>Thalassia testudinum</i> .	1. Mandatory Indicator 1: # direct project beneficiaries disaggregated by gender (female/male)	(475) (344/131)	<i>Comp 1: 255 participants in capacity building programs for ABS aimed at authorities, NGOs / civil society and other key partners (female/male)</i> <i>Comp 2: 200 personnel trained</i> <i>Comp. 3: 20 workers trained and certified in the sustainable use of Thalassia by ORSA and CECMED</i>	Data must be disaggregated by gender -Evaluation survey -Focus groups- -Registration of participants in all events carried out by the project or for the purposes established by the Project.	Quarterly	Project Team	Information extracted or calculated based on information from third parties will be reviewed together with the Project Partners, as relevant to their competence
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	<u>2. Mandatory GEF Core Indicator 2 :</u> <i>Marine protected areas created or under improved management for conservation and sustainable use (Hectares)</i>	118	- Area under sustainable harvest management and measures to conserve biodiversity	Calculation based on surface of harvest areas.	Quarterly	Project Team	Information extracted or calculated based on information from third parties will be reviewed together with the Project Partners, as relevant to their competence
	<u>3. Mandatory GEF Core Indicator 5:</u> <i>Area of marine habitat under improved practices (excluding protected areas) (Hectares)</i>	513	- Area under sustainable harvest management and measures to conserve biodiversity	Calculation based on surface of harvest areas.	Quarterly	Project Team	Information extracted or calculated based on information from third parties will be reviewed together with the Project Partners, as relevant to their competence
Component 1	<i>Strengthening the legal framework and capacities for the implementation of the Nagoya Protocol on Access to Genetic Resources and Benefit Sharing</i>						

Outcome 1.1 Strengthened political, legal and institutional framework regarding access to genetic resources and benefit sharing	Indicator 4: # national-level methodological instruments for ABS (Proposal for a legal standard on access to genetic resources and benefit sharing and a methodological tool to support the implementation of the legal standard).	2	Proposal for a legal standard on access to genetic resources and benefit-sharing and 1 methodological tool to support the implementation of the legal standard presented for approval by the competent authority	- Reports of workshops / technical meetings in support of the elaboration of the instruments - Proposal of legal norms and procedures that regulate the ABS issue	Annual	Project Team	Scorecard Results
Component 2	Strengthened capacities for the development of a pharmaceutical product from a marine angiosperm.						

Outcome 2.1 Increased institutional capacities for bio-product development	<i>Indicator 5:</i> <i>Number of staff and students trained on the non-clinical evaluation of products derived from marine biodiversity in controlled environment</i>	200	# personnel who participate in Project trainings	-Data must be disaggregated by gender -Registration of participants in all events carried out by the project or for the purposes established by the Project.	Quarterly	Project Team	The information verified with the institution involved in project
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	Indicator 6: <i>Request for permit to start clinical trials of a new product for human use from marine angiosperm</i>	100%	Information necessary to compose the application file (32 tests performed)	<ul style="list-style-type: none">- Accredited test certificate- Application file for a clinical trial permit prepared	Quarterly	Project Team	The information verified with the institution involved in project
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Componente 3	3. Conservation of marine biodiversity and habitat of angiosperm used for bioproduct development						
Outcome 3.1 Conservation and sustainable use of genetic resources associated with seagrass in 3 target sites.	Indicator 7: Leaf Biomass of <i>T. testudinum</i>	Maintain baseline values	Data generated by the application of the Protected Areas monitoring protocol and the feasibility study at the 3 sites	Feasibility study that allows establishing the harvest plan without affecting the meadow and associated fauna	Semiannual	Project team	The information verified with the scientific institutions involved in project

	Indicator 8: <i>Carbon stock</i> <i>(tons of carbon biomass)</i>	This value will be estimated during first year of the project implementation	Data generated by the application of the seagrass monitoring at the 3 sites	Study on environmental quality of seagrass ecosystem at intervention sites	Baseline, Mid-term Review and Terminal Evaluation	Project team	The information verified with the scientific institutions involved in project
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Outcome 3.2 <i>Increased capacity of coastal communities to generate a value chain and improved standard of living.</i>	Indicator 9: # workers certified on sustainable management of T. testudinum	20	# workers certified	-Data must be disaggregated by gender -Registration of participants in all events carried out by the project or for the purposes established by the Project aims to support certifications on sustainable management of T. testudinum -Project report on workers certified	Biannual	Project team	Methodology reconciled with the institution involved in the project and presented to CITMA for consideration for replication across the country
Project component 4	Monitoring and knowledge management						

Outcome 4.1 <i>Increase awareness amongst Cuban society about the importance and legality of the conservation and sustainable use of genetic resources</i>	Indicator 10: <i>% implementation of the awareness campaign on ABS and BD conservation in Cuba</i>	100%	The level of knowledge and awareness of the population at the pilot sites regarding ABS, Intellectual Property management, and BD conservation will be assessed through surveys at the beginning and end of the project.	A survey will be conducted, as well as interviews with key actors.	At the beginning and end of the Project.	Project Team	Through surveys and interviews.
	Indicator 11: <i>% implementation of the strategy for disseminating knowledge generated, including procedures on Good Laboratory Practice Standards</i>	100%	The percentage of implementation of the communication and knowledge management strategy to be developed during Y1 of the Project will be evaluated.	The main components and lines of action of the communication and knowledge management strategy should be identified in order to define the stages of progress of its implementation for monitoring.	Annual	Project Team	Evaluation based on the implementation of the main components and lines of action.

Supporting Documents

Upload available ESS supporting documents.

Title	Module	Submitted
PIMS 6311 SESP	CEO Endorsement ESS	
PIMS 6311 ESMF	CEO Endorsement ESS	

ANNEX A: PROJECT RESULTS FRAMEWORK (either copy and paste here the framework from the Agency document, or provide reference to the page in the project document where the framework could be found).

Objective/Component	Objective and Outcome Indicators (no more than a total of 20 indicators)	Baseline <i>Must be determined during PPG phase</i>	Mid-term Target <i>Expected level of progress before MTR process starts</i>	End of Project Target <i>Expected level when terminal evaluation undertaken</i>
Project Objective: Promote equitable distribution of benefits and conservation of biodiversity genetic resources by strengthening the regulatory framework, completing the research phase of <i>Thalassia testudinum</i> , developing a pharmaceutical product, and starting clinical trials for cancer treatment.	1. Mandatory Indicator 11: # direct project beneficiaries disaggregated by gender <i>(female/male)</i>	0 (0/0)	213 (140/73)	475 (344/131)
	2. Mandatory GEF Core Indicator 2: <i>Marine protected areas created or under improved management for conservation and sustainable use (Hectares)</i>	0	60	118
	3. Mandatory GEF Core Indicator 4: <i>Area of marine habitat under improved practices (excluding protected areas) (Hectares)</i>	0	200	513
Component 1	<i>Strengthening the legal framework and capacities for the implementation of the Nagoya Protocol on Access to Genetic Resources and Benefit Sharing</i>			

Objective/Component	Objective and Outcome Indicators (no more than a total of 20 indicators)	Baseline <i>Must be determined during PPG phase</i>	Mid-term Target <i>Expected level of progress before MTR process starts</i>	End of Project Target <i>Expected level when terminal evaluation undertaken</i>
Outcome 1.1 <i>Strengthened political, legal and institutional framework regarding access to genetic resources and benefit sharing</i>	Indicator 4: # national-level methodological instruments for ABS (Proposal for a legal standard on access to genetic resources and benefit sharing and a methodological tool to support the implementation of the legal standard).	0	2 Drafts	- 1 proposal for a legal standard on access to genetic resources and benefit-sharing and 1 methodological tool to support the implementation of the legal standard presented for approval by the competent authority.
Outputs to achieve Outcome 1.1	<p><i>1.1.1. Procedures, methodologies, and model clauses proposed to complete the legislation that implements the Nagoya Protocol.</i></p> <p><i>1.1.2. Strengthened capacities of the regulatory authority to control access to genetic resources.</i></p> <p><i>1.1.3 Tools for training, protection, information management and scope of intellectual property rights.</i></p> <p><i>1.1.4 Dialogue platform to exchange information on ABS and knowledge associated with biodiversity conservation.</i></p>			
Component 2	<i>Strengthening institutional and individual capacities for the research and development a pharmaceutical product from a marine angiosperm.</i>			
Outcome 2.1 Increased institutional capacities for bio-product development	Indicator 5: <i>Number of staff and students trained on the non-clinical evaluation of products derived from marine biodiversity in controlled environment</i>	0	100	200

Objective/Component	Objective and Outcome Indicators (no more than a total of 20 indicators)	Baseline <i>Must be determined during PPG phase</i>	Mid-term Target <i>Expected level of progress before MTR process starts</i>	End of Project Target <i>Expected level when terminal evaluation undertaken</i>
	Indicator 6: <i>Request for permit to start clinical trials of a new product for human use from marine angiosperm</i>	0	75% of application file for permit has been completed	Request for permit submitted to National Authority
Outputs to achieve Outcome 2.1	<p>2.1.1. Updated ICIMAR technical and operational capacities enable obtaining permission from the National Regulatory Unit to conduct non-clinical studies on the product.</p> <p>2.1.2. Strengthened human resources in the non-clinical evaluation of products derived from marine biodiversity under a controlled environment.</p> <p>2.1.3. Phytochemical characterization of natural extracts, identification of metabolites, and evaluation of anti-tumor effects and margin of safety of the active ingredient derived from <i>T. testudinum</i>.</p> <p>2.1.4. Documentation to obtain authorization for clinical studies under biodiversity conservation principles is completed.</p>			
Componente 3	3. Conservation of marine biodiversity and habitat of angiosperm used for pharmaceutical product development			
Outcome 3.1 Conservation and sustainable use of genetic resources associated with seagrass in 3 target sites.	Indicator 7: Leaf Biomass of <i>T. testudinum</i>	<p>170 g/m² in Rincon Guanabo</p> <p>TBD in Camaguey</p> <p>TBD in Santiago de Cuba</p> <p>The two previous values (i.e., TBD) will be estimated during the first year of project implementation</p>	Maintain baseline values	Maintain baseline values

Objective/Component	Objective and Outcome Indicators (no more than a total of 20 indicators)	Baseline <i>Must be determined during PPG phase</i>	Mid-term Target <i>Expected level of progress before MTR process starts</i>	End of Project Target <i>Expected level when terminal evaluation undertaken</i>
	Indicator 8: Carbon stock (tons of carbon biomass)	This value will be estimated during first year of the project implementation	This value will be estimated during first year of the project implementation	This value will be estimated during first year of the project implementation
Outputs to achieve Outcome 3.1	<p>3.1.1 Evaluation of environmental quality of seagrass ecosystem at intervention sites.</p> <p>3.1.2 Management protocols and recommendations for the conservation and sustainable use of seagrass.</p> <p>3.1.3 Population analysis of <i>Thalassia testudinum</i> angiosperm.</p> <p>3.1.4. Approved best practice/procedural tools for the management and the sustainable use of <i>Thalassia testudinum</i>.</p>			
Outcome 3.2 Increased capacity of coastal communities to generate a value chain and improved standard of living.	Indicator 9: # workers certified on sustainable management of <i>T. testudinum</i>	0	10	20
Outputs to achieve Outcome 3.2	<p>3.2.1: Training program on supply and value chain management associated to the seagrass ecosystem with emphasis on sustainable use of <i>Thalassia.testudinum</i>.</p> <p>3.2.2 Certification program for workersinvolved in the sustainable management and collection of samples in the intervention sites.</p>			
Project component 4	Monitoring and knowledge management			
Outcome 4.1 Increase awareness amongst Cuban society about the importance and legality of the conservation and sustainable use of genetic resources	Indicator 10: % implementation of the awareness campaign on ABS and BD conservation in Cuba	0	20%	100%

Objective/Component	Objective and Outcome Indicators (no more than a total of 20 indicators)	Baseline <i>Must be determined during PPG phase</i>	Mid-term Target <i>Expected level of progress before MTR process starts</i>	End of Project Target <i>Expected level when terminal evaluation undertaken</i>
	Indicator II: % implementation of the strategy for disseminating knowledge generated, including procedures on Good Laboratory Practice Standards	0	20%	100%
Outputs to achieve Outcome 4.1	4.1.1 Awareness campaign aimed at different stakeholders and users of genetic resources to promote a change in behavior, highlights responsible harvesting and treatment procedures and practices. 4.1.2 Project's M&E Plan, SESP and GAP implemented. 4.1.3 Publication and dissemination of the results and lessons learned.			
This project will contribute to the following Sustainable Development Goal (s): 3, 4, 5, 8, 14, 15 y 17				
This project will contribute to the following country outcome (UNDAF/CPD, RPD, GPD): Institutions, production and service sectors, territorial governments and communities improve the protection and rational use of natural resources and ecosystems, resilience to climate change, and comprehensive disaster risk reduction management				

ANNEX B: RESPONSES TO PROJECT REVIEWS (from GEF Secretariat and GEF Agencies, and Responses to Comments from Council at work program inclusion and the Convention Secretariat and STAP at PIF).

Comment	Agency Response	Reference
GEFSec Review 25th May 2022		

<p>8. Core Indicators. Are the targeted core indicators in Table E calculated using the methodology in the prescribed guidelines? (GEF/C.54/Infxxx)</p> <p>Secretariat comment at CEO Endorsement Request 5/25/2022</p> <p>Yes. During implementation it would be good to track carbon benefits and if there are broader seascape level impacts as the values are quite low.</p>	<p>Thank you for your comment. A new indicator was included in the Results Framework to track carbon sequestered in the seagrass biomass and sediments during project implementation in the three pilot sites of the project.</p> <p> </p> <p> </p> <p> </p>	<p>Please, see output 3.1.1, ProDoc, paragraph 75, page 19, and CEO ER, paragraph 72, page 21.</p> <p> </p> <p> </p>
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3. Project Description. Is there an elaboration on the proposed alternative scenario as described in PIF/PFD sound and adequate? Is there more clarity on the expected outcomes and components of the project and a description on the project is aiming to achieve them?

Secretariat comment at CEO Endorsement Request

5/25/2022

No, please address the following:

- Case study, general research and/or targeted program? - The writing of the components of this project are a bit confusing as there are often references to "marine angiosperms" as though the work being done will be broadly applicable to a general group (e.g. 3.1.4). However, there is only ever reference to working with one species. Please be clear the writing and consider how, while the project may be highly targeted, it can inform and have larger impacts.

- Sea grass ecosystem research and characterization - In a phone call with GEF Sec, project proponents discussed how the work of this project would result in increased knowledge and understanding of the ecosystem and other species. This is not clear from the text as written. Including the description of this work would help strengthen the case for this project.

- 1.1.4 - Who will be responsible for maintaining and updating this after the project? Will there be coordination with other projects on this?

- Output 2.1.1 and 2.1.2 - These activities are broadly not eligible for GEF support. We would like to see the GEF supporting less equipment and more capacity building. It would also be good to consider how capacity building could be done virtually or through other means that do not require expensive travel.

- Output 3.2.3 - This is quite broad. Given that this species is widely distributed in the Caribbean Sea, and this is not part of TK, what is the ownership of these materials?

- Output 3 - It is unclear how this project will really tie back to conservation or sustainable management of seagrasses more broadly. The project mentions a number of threats to seagrasses, but it is unclear how

Case study, general research and/or targeted program?

Outputs were reorganized under component 3 to clarify the project's contribution (general research) to the conservation of biodiversity in seagrass ecosystems. The revised outputs identify appropriate management measures for biodiversity conservation in seagrass ecosystems (see output 3.1.1). At the same time, project targets the species *T. testudinum* as a biological resource that contains the genetic resource which will be accessed for the development of a pharmaceutical product.

The outputs were adjusted as follows:

- Under output 3.1.1 the project will carry out activities related to the evaluation of the environmental quality of the seagrass ecosystem at the three intervention sites including an Ecological Evaluation Index, a biodiversity assessment, and an estimation on organic carbon sequestered in the sediments and seagrass biomass. The EX-Ante Carbon-balance Tool (EX-ACT) has a seagrass and mangrove module that could be used for this exercise.

- Under output 3.1.2 the project aims to generate data to improve a seagrass management plan within the protected area PNP Rinc?n de Guanabo and in non-protected areas.

- Under output 3.1.3 the project will carry out a population analysis of the *T. testudinum* angiosperm.

Seagrass ecosystem research and characterization:

As described above Outputs under Component 3 were adjusted to increase the knowledge and understanding of the seagrass ecosystem and to facilitate its conservation and management in accordance with best practices.

In this context, activities related to studies on biodiversity conservation were included in the ProDoc (studies on environmental quality of seagrass ecosystem and populations analysis) (See outputs 3.1.1 and 3.1.3).

Please, see ProDoc, section V Results and Partnerships, Component 3, paragraphs 75-81 pages 19-21, and CEO ER, section Expected Results, Component 3, paragraphs 72-77, pages 20-22.

Please, also see ProDoc, section X Total Budget and Workplan, Budget Notes 9 and 15, pages 51-52.

13. Risk. Has the project elaborated on indicated risks, including climate change, potential social and environmental risks that might prevent the project objectives from being achieved? Were there proposed measures that address these risks at the time of project implementation?

Secretariat comment at CEO Endorsement Request

5/25/2022

No, please provide more consideration of the potential changes should the phytochemicals fail to produce anticancer benefits, causes negative impacts that mean it can not be used as a medicine, or otherwise doesn't result in the proposed product. This could be a place to emphasize the other benefits and capacities built by the project.

Thank you. Under Output 3.1.3 the project will assess the variability of bioactive metabolites during project implementation which will provide information on the potential impacts of climate change and anthropogenic factors. Also, this point has been included in the UNDP Risk Register.

In addition, it is important to consider the following points:

- A study on seasonality and variability can reveal the moment when *T. testudinum* produces the highest amount and concentration of active compounds. It cannot be ruled out that climate change could cause changes in the pattern of metabolites in the species which may have an impact on antitumor activity. In this case, the project would analyze concentrations of Thalasiolin B, which has antitumor properties. Studies have shown that the greatest efficacy is observed around 40% of Thalasiolin B in the extract, but even at 15%, the extract shows activity.

- Other compounds (apigenin, luteolin, chrysoeriol, benzoic acid) also show antitumor activity. This could allow the antitumor capacity to be maintained despite changes in the concentration patterns, given the possibility that this action does not fall on a single compound.

- The metabolites of natural phenolics are stable compounds, present in numerous plant species that have adapted to evolutionary changes. *T. testudinum* produces metabolites in response to stress and changes in the marine environment in which it lives, therefore, it is considered that the plant could continue to produce them regardless of impacts associated with climate change.

- On the other hand, for the aforementioned compounds and others, also identified in the extract, antioxidant and anti-inflammatory activity has been demonstrated, which would allow other potential uses for

Please see output 3.1.3, ProDoc, paragraph 77, page 20 and CEO ER, paragraph 74, page 21. Also see ProDoc, Annex 6 ?UNDP Risk Register?. Risk 9.

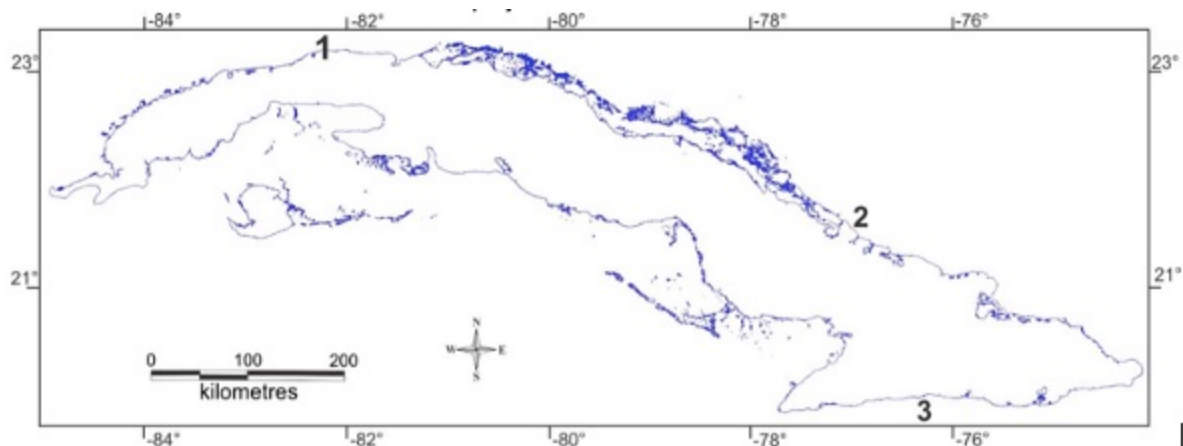
<p>16. Knowledge management. Is the proposed Knowledge Management Approach? for the project adequately elaborated with a timeline and a set of deliverables?</p> <p>Secretariat comment at CEO Endorsement Request</p> <p>5/25/2022</p> <p>Yes, however, this is rather weak. It would be good to consider how knowledge learned about the process from this project could be collected and shared.</p>	<p>Thank you. Please note that a new output (4.1.3) was included under Outcome 4.1. This output aims to strengthen knowledge management for this project.</p> <p>The project will support increased knowledge of marine biodiversity found on the island platform. In particular, the project will provide new evidence on the biodiversity associated with <i>T. testudinum</i>, to support biodiversity conservation practices and models for this important ecosystem along the coasts of Cuba and other Caribbean islands. The project will redefine/update scientific knowledge on seagrass beds through publications of scientific findings, best management practices, and technical reports. Under this output the project will also publish methodological guidelines to identify monetary and non-monetary benefits derived from genetic material.</p> <p>Socialization will be carried out through publications and participation in scientific training, exchanges, workshops, courses, seminars, and events. Participation in these events will contribute to strengthening capacity building of scientists and local stakeholders. The project will also support the participation of project staff in workshops, seminars, and national and international events to facilitate the socialization and dissemination of outcomes and lessons learned.</p>	<p>Please see output 4.1.3, ProDoc, paragraph 84, page 21 and CEO ER, Table B ?Project Description Summary?, page 3-4 and sections Expected Results, paragraph 81, page 22.</p>
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ANNEX C: Status of Utilization of Project Preparation Grant (PPG).
(Provide detailed funding amount of the PPG activities financing status in the table below:

ANNEX D: Project Map(s) and Coordinates

Please attach the geographical location of the project area, if possible.

Location of the 3 areas of intervention of the project:



1. Rincón de Guanabo, Playas del Este, Havana; Coordinates: 23° 10' 26", -82° 05' 50"; Intervention area: 14 ha



2. Santa Lucía Beach, Camagüey; Coordinates: 21° 33' 26", -77° 02' 07"; Intervention area: 100 ha



3. Larga Bay, Guamá, Santiago de Cuba; Coordinates: 19° 58' 58", -76° 18' 07"; Intervention area: 23 ha.



ANNEX E: Project Budget Table

Please attach a project budget table.

Expenditure Category	Detailed Description	Component (USDeq.)							Total (US Deq.)	Responsible Entity
		Component 1	Component 2	Component 3		Component 4	Sub-Total	M & E	PMC	(Executing Entity receiving funds from the GEF Agency)[1]
				Sub-component 3.1	Sub-component 3.2					

Equipment	<p>Equipment located in CIM-UH, PNP Rincon de Guanabo, BIOECO y CIMAC (\$30,100): 3 Stereo microscopes (\$5,800); 3 Biological microscopes (\$10,600) for studying the biodiversity associated to sea grass meadows; Corers for taking samples of biomass and meiofauna, 6 light sensors and temperature (\$3,200); Data loggers for physical variables (salinity, temperature, irradiancy) in meadows; 5 Diving equipment (\$10,500) to support the sampling at the Rinc?n de Guanabo, Camag?ey and Santiago de Cuba, as well as the monitoring of Component results.</p> <p>Equipment located in ICIMAR for the ecosystem environmental quality studies (\$130,000): Standard incubator of CO2, inverted optical microscope, vertical Laminar Flow Cabinet; centrifuges, freezer (-80 oC), nitrogen thermo, peristaltic pump, CO and CO2 cylinders, vacuum pump, filtration equipment, thermostatic bath, absorbance/fluoresce nce microplate reader, splits, technical balances, extraction hood. Office and laboratory furniture (chairs, tables, cabinets) (\$34,400) located in CIM-UH and ICIMAR to strengthen the</p>										
ment			194 500				19 4 50 0			194 500	Environ mental Agency (AMA)

Equip ment	Laboratory equipment for cell cultivation laboratory and Bioterio, both located at ICIMAR) to support the certification of non-clinical testing: transiluminator attached to computer, DNA Electrophoresis chamber, electrophoresis power, UV Lamp, image gel capturator, lab miscellaneous, ventilator racks, conventional cages for rodents and accessories, temperature and humidity equipment, surgical sets, pletysmometer, hot plate analgesimeter. Total cost: \$78,003		78 003				78 003		78 003	Environ mental Agency (AMA)
Equip ment	Audiovisual equipment, communication costs and internet service for specialists (CIM-UH, ICIMAR, PNP Rincon de Guanabo, BIOECO, CIMAC) involved with the activities in Component 3 and to support the access to updated scientific information: - Cell phones (4) = \$2,400 -Digital camera waterproof (7) = \$2,100 -Digital camera GO Pro (3) = \$1,250 -Communication costs (\$40*4years*7persons) = \$1,120 -Internet service = \$1,130			8 000			8 000		8 000	Environ mental Agency (AMA)

Equip ment	Cell phones and internet service for specialists in ORSA in charge of the monitoring and coordination of the activities in Component 1: -Cell phones (1) = \$600 -Internet service = \$1,400	2 000					2 000			2 000	Environ mental Agency (AMA)
Equip ment	Cell phones, communication costs and internet service for specialists (ICIMAR, IMRE, and Laboratorios Oriente) involved with the activities in Component 2: -Cell phones (3) = \$1,800 -Communication costs (\$10*12months*4years*10persons) = \$4,800 -Internet service = \$1,900		8 500				8 500			8 500	Environ mental Agency (AMA)
Equip ment	Cells phones, communication costs and internet service to support the activities of the Project Management Unit: -Cell phones (2) = \$1,200 -Communication costs (\$10*month*4years*4persons) = \$1,920 -Internet service = \$3,380						-		6 500	6 500	Environ mental Agency (AMA)
Equip ment	ICT equipment and accessories for Project Management Unit. 2 Laptops (\$2,800); 1 Projector (\$1,000); accessories (\$242).						-		4 042	4 042	Environ mental Agency (AMA)

Equip ment	ICT equipment and accessories for specialists in CIM-UH, Rincon de Guanabo, CIMAC y BIOECO involved with the activities in Component 3. -3 Laptops (\$3,300); 3 PC (\$3,000); 3 monitors (\$1,200); 3 back-ups (\$300); 3 printers (\$1,000); accessories -external hard drives 1 TB and 2TB, USB flash- (\$1,200).			10 000			10 00 0			10 000	Environ mental Agency (AMA)
Equip ment	ICT equipment and accessories for specialists in ICIMAR, IMRE, and Laboratorios Oriente to support the storage, processing and analysis of data collected during the testings and studies, as well as the preparation of the documentation required to conform the clinical test file. -4 Laptops (\$4,400); 3 PC (\$3,000); 5 monitors (\$2,000); 5 back-ups (\$500); 3 printers (\$900); accessories -external hard drives 1 TB and 2TB, USB flash- (\$1,200)		12 000				12 00 0			12 000	Environ mental Agency (AMA)

Equip ment	ICT equipment and accessories to strengthen the capacities of the regulatory entity (ORSA) and other entities involved in the design of norms, regulations and other legal documents: -3 Laptops (\$3,300); 4 PC (\$3,600); 4 monitors (\$1,200); 4 Back-ups (\$400), 2 printers (\$500); accessories (\$1,000)	10 000					10 00 0			10 000	Environ mental Agency (AMA)
Vehicle	One vehicle (microbus) (\$45,000) located in ICIMAR to support the mobility of specialists in charge of carry on the activities programmed under this Component.			45 000			45 00 0			45 000	Environ mental Agency (AMA)
Sub- contrac t to executi ng partner	Execution support services provided by UNDP, as per signed LoA between Government and UNDP-Cuba and as agreed with GEF. Total Cost: \$6,000; \$1,500 per 4 years, during years 1 to 4.						-		6 00 0	6 000	Environ mental Agency (AMA)
Contra ctual service s- Compa ny	Construction project (Biological Unit at ICIMAR) to ensure the compliance with the biological safety requirements. Total cost: \$45,000 (Year 2).		45 000				45 00 0			45 000	Environ mental Agency (AMA)
Contra ctual service s- Compa ny	Contractual services to design the Web site ABS CH in Cuba. Total cost \$3,000 Contractual services to design graphical outputs (promotional material) Total cost \$3,000	6 000					6 00 0			6 000	Environ mental Agency (AMA)

Internat ional Consult ants	Year 2. International evaluator to conduct the Mid Term Evaluation of the Project. Total cost \$11,000 Year 4. International evaluator to conduct the Terminal Evaluation of the Project. Total cost \$11,000						-	22 00 0		22 000	Environ mental Agency (AMA)
Local Consult ants	National consultants to elaborate the social and environmental safeguards plans as well as risks management plan associated with the project implementation						-	10 00 0		10 000	Environ mental Agency (AMA)
Trainin g, Works hops, Meetin gs	Contractual services to support the inception workshop, annual workshops, monitoring of gender and environmental safeguards and Total cost \$ 6,400						-	6 40 0		6 400	Environ mental Agency (AMA)

[illegible]

Trainin g, Works hops, Meetin gs	<p>International experts on non-clinical evaluation of bioproducts with application in human health, specifically in the development of natural anti-tumoral, safe and effective.</p> <p>Training and advising of Cuban specialists on new knowledge, design and production of studies protocols, data analysis and results reports as well as, supplies acquisition and setting-up for the development of non-clinical testing in the Biological Unit located at ICIMAR</p> <p>Preparation and conduction the following activities:</p> <ul style="list-style-type: none"> - Training on the introduction of new technologies (omics) in non-clinic products development, from natural resources under a controlled environment. Total cost \$5,960 (1 expert, 10 days) - Training on models of cancer in vivo and in vitro. Total cost \$5,960 (1 expert, 10 days) - Workshop on strategies of chemio sensibilization in the research and development of anti-tumoral therapies. Rol of natural products. Total cost \$4,620 (1 expert, 7 days) - Workshop on experimental models for the risk study and the security of pharmaceutical products with natural origin. Total cost \$5,960 (1 expert, 10 days) 		22 500				22 500		22 500	Environ mental Agency (AMA)
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Trainings, Workshops, Meetings	<p>International travels of Cuban specialists to receive theoretical and practical trainings and to conduct experiments related to Thalassia Testudinum genetic, in order to contribute to the implementation of the most effective method for the use of this angiosperm and to the study of its genetic variability and impacts on resilience and bioactivity.</p> <p>Year 2 (\$32,000) -Travel for Training in France, Belgium and Spain. Total cost \$32,000</p> <p>Year 3 (\$14,900) Travel for Training in Latin America. Total cost \$14,900</p> <p>Year 4 (\$7,000) Travel for Training in Latin America. Total cost \$7,000</p> <p>Transfer and accommodation of Cuban specialists, in charge of carry on the field work in the project areas: harvest, gender, training of actors in the community and other activities programmed to accomplish the Component 3 goals. Total cost: \$16,900</p> <p>Year 1: \$1,200, 10 pax Year 2 and 3: \$9,900, 12 pax/5 days/year Year 4: \$5,800, 5 pax/5 days</p>			70800		70800			70800	Environmental Agency (AMA)
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Trainin g, Works hops, Meetin gs	Lessons learned workshops Total cost \$ 4,400					4 400	4 40 0			4 400	Environ mental Agency (AMA)
Trainin g, Works hops, Meetin gs	Regional and National Workshops and meetings, with the participation of local and national authorities, to complete, disseminate and validate the ABS legislation	35 000					35 00 0			35 000	Environ mental Agency (AMA)

Travel	<p>International travel of Cuban specialists to exchange experiences and lessons learned on regulatory and legal framework in ABS:</p> <p>Year 2</p> <ul style="list-style-type: none"> - Exchange of experiences in El Salvador. Total cost \$5,000 (3pax, 6 days. ATKT \$1,500; DSA \$3,355; travel insurance \$45 and visa \$100) - Exchange of experiences in Peru. Total cost \$5,000 (3pax, 6 days. ATKT \$1,500; DSA \$3,355; travel insurance \$45 and visa \$100) - 4 specialists to participate in the Central Region Meeting, 2 days, to socialize the ABS legislation and to complete the required documentation for it (\$4,500) <p>Year 3</p> <ul style="list-style-type: none"> - Exchange of experiences in Mexico. Total cost \$5,000 (3pax, 6 days. ATKT \$1,500; DSA \$3,355; travel insurance \$45 and visa \$100) <p>Year 4</p> <ul style="list-style-type: none"> - Exchange of experiences in Argentina. Total cost \$5,000 (3pax, 6 days. ATKT \$1,500; DSA \$3,355; travel insurance \$45 and visa \$100) - 4 specialists to participate in the Western Region Meeting, 2 days, to socialize the ABS legislation and to complete the required documentation for it. (\$5,500) 	30 000					30 00 0			30 000	Environ mental Agency (AMA)
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	Travel allowance (ATKT, DSA and terminals) for international experts on non-clinical evaluation of bioproducts with application in human health, specifically in the development of natural anti-tumoral, safe and effective to train and advisor Cuban specialists on new knowledge, design and production of studies protocols, data analysis and results reports as well as, supplies acquisition and setting-up for the development of non-clinical testing in the Biological Unit located at ICIMAR. Total cost: \$13,900										
Travel	International travels of Cuban specialists to world-renowned institutions to exchange theoretical and practical experiences, transfer of technologies, update knowledge and upgrade skills in non-clinical evaluation of new products with potential application in cancer therapy, under the compliance of good laboratory practices, as well as in the preparation of the required documentation to be submitted the results to the Cuban regulatory entity. Total cost: \$50,000	93 900					93 900 0			93 900	Environ mental Agency (AMA)
	Transfer and accommodation in the project areas of Cuban specialists, in charge of coordination meetings and the exchange of experiences and										

Office Supplies	Office supplies (paper, pens, files, toners, etc.) to support the activities of the Component 1	10 000					10 000			10 000	Environmental Agency (AMA)
Office Supplies	Office supplies (paper, pens, files, toners, etc.) to support the activities of the Project Management Unit.						-		4 000	4 000	Environmental Agency (AMA)
Other Operating Costs	1 External audit during year 3.						-		5 000	5 000	Environmental Agency (AMA)
Other Operating Costs	<p>Printing of brochures and promotional material, as well as technical documents generated (methodologies, procedures and regulations). (Year 1, \$2,000; Year 3, \$3,000) Total cost \$5,000</p> <p>- Publishing fees of specialized magazines.</p> <p>Publication of the results of the pharmaceutical formulation, in order to give visibility to the use of the bio product obtained in a sustainable way. (\$2,000/year) Total cost \$8,000</p> <p>Printing of brochures and other promotional materials to support education and to promote the sustainable use of Thalassia Testudinum and gender experiences in the project activities (\$1,000/year) Total cost \$4,000</p>					17 000	17 000			17 000	Environmental Agency (AMA)

Other Operating Costs	Chemical reagents for the analysis of chemical composition and genetic variability of <i>Thalassia testudinum</i> , as well as the water quality. Total cost: \$60,000 Laboratory supplies (cover glass, slides, Petri dishes, vials, plastic syringes, and microscopes spare parts) to support the studies of the biodiversity associated to sea grasses. Total cost \$28,000			88 000			88 000			88 000	Environmental Agency (AMA)
Other Operating Costs	Laboratory supplies and reagents for the development of the non-clinical testing (analytical chemistry, pharmacology and toxicology) for the pharmaceutical formulation: -Laboratory supplies (Cell cultivation supplies, trays, test tubes 15 and 50 ml, vials, boots, masks, gloves, lab coats, absorbent paper, material or cleaning and disinfection and other laboratory means of protection) -Chemical and biological reagents (Solvents, laboratory standards, cells, bacterial strains, enzymes, plasmid DNA, diagnosis kits for biomarkers detection)		10 000				10 000			10 000	Environmental Agency (AMA)
Other Operating Costs	Maintenance of transportation equipment, fuel, lubricants and spare parts			12 000			12 000			12 000	Environmental Agency (AMA)

Other Operating Costs	Maintenance of transportation equipment, fuel, lubricants and spare parts.						-		4 000	4 000	Environmental Agency (AMA)
Grand Total		93 000	269 903	428 300	30 200	21 400	84 280 3	38 400	29 542	910 745	

ANNEX F: (For NGI only) Termsheet

Instructions. Please submit an finalized termsheet in this section. The NGI Program Call for Proposals provided a template in Annex A of the Call for Proposals that can be used by the Agency. Agencies can use their own termsheets but must add sections on Currency Risk, Co-financing Ratio and Financial Additionality as defined in the template provided in Annex A of the Call for proposals. Termsheets submitted at CEO endorsement stage should include final terms and conditions of the financing.

ANNEX G: (For NGI only) Reflows

Instructions. Please submit a reflows table as provided in Annex B of the NGI Program Call for Proposals and the Trustee excel sheet for reflows (as provided by the Secretariat or the Trustee) in the Document Section of the CEO endorsement. The Agencies is required to quantify any expected financial return/gains/interests earned on non-grant instruments that will be transferred to the GEF Trust Fund as noted in the Guidelines on the Project and Program Cycle Policy. Partner Agencies will be required to comply with the reflows procedures established in their respective Financial Procedures Agreement with the GEF Trustee. Agencies are welcomed to provide assumptions that explain expected financial reflow schedules.

ANNEX H: (For NGI only) Agency Capacity to generate reflows

Instructions. The GEF Agency submitting the CEO endorsement request is required to respond to any questions raised as part of the PIF review process that required clarifications on the Agency Capacity to manage reflows. This Annex seeks to demonstrate Agencies? capacity and eligibility to administer NGI resources as established in the Guidelines on the Project and Program Cycle Policy, GEF/C.52/Inf.06/Rev.01, June 9, 2017 (Annex 5).