United Nations Development Programme

**PROJECT DOCUMENT**

*Montenegro*

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**Project Title**: Strengthening Health System in Montenegro (Phase 2)
**Project Number:** 00103594
**Implementing Partner:** UNDP
**Start Date:** October 17, 2018     **End Date:** December 31, 2024     **PAC Meeting date:** August 3, 2023

| Brief Description |
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| Enhancement of the Health Information System - HIS is of enormous importance for the further development of the entire healthcare system, strategic planning of activities and required resources, and appropriate provision of health services.<br><br>The results of the analysis that was carried out during the project's first phase indicate that the existing information system in the health sector is incomplete, fragmented and insufficiently interoperable to provide satisfactory information for the efficient management of the health system. The analysis also identified weaknesses in the management of the health information system and indicated the necessity to set up an organizational unit at the Ministry of Health to deal with the information system management, IT and analytical activities.<br><br>Development of the strategic documents was also supported during the first phase of the project, including the Integrated Health Information System Development Strategy 2018-2023, which defined a new approach in the development of HIS using microservice web architecture, defined priority projects for the improvement of the IT infrastructure in health sector and offered solutions for integration of all existing health systems.<br><br>The goal of phase 2 is to set up the comprehensive Integrated Health Information System (IHIS) and accordingly implement the activities in order to achieve full improvement of the IT infrastructure in the health sector and facilitate centralized and timely management and use of reliable data for strategic decision-making. System modernization and improvement of IT infrastructure will significantly increase its efficiency and also result in savings related to maintenance and everyday operation and thus facilitate significant investments to improve the quality and standard of health services. |

| Contributing Outcome (UNDAF/CPD, RPD or GPD): <br><br> By 2027, all people, especially vulnerable people, benefit from improved social cohesion, increased realization of human rights and rule of law, and accountable, gender-responsive institutions <br><br> Indicative Output(s) with gender marker[2]: <br><br> Capacities for merit-based and people-centred governance system at national/local level and judiciary strengthened to deliver services in an effective, efficient, inclusive manner. <br> GEN 2 | | |
|---|---|---|
| **Total resources required:** | **USD 3,300,147** | |
| **Total resources allocated:** | **USD** | **3,300,147** |
| | Transferred from phase 1 | $ 91,000 |
| | Government of Montenegro: | $ 3,177,147 |
| | UNDP | $ 32,000 |
| **Unfunded:** | | n/a |

Agreed by (signatures):

| Government | UNDP |
|---|---|
| Dragoslav Scekic <br> Minister of Health of Montenegro | Ekaterina Paniklova <br> Resident Representative a.i. in Montenegro |
| Date: | Date: |

# I. DEVELOPMENT CHALLENGE

Montenegro is investing significant efforts into improving the processes of planning, developing and managing the healthcare and health insurance system so that, within available funds, it can provide efficient, effective, high-quality and accessible healthcare system to all its citizens.

According to the Healthcare Law, health services in Montenegro are provided at three levels: primary, secondary and tertiary. The health centre is an institution that provides primary healthcare, as a basis of the healthcare system. The well-developed network of health centres, along with health stations and field units, ensures full coverage and adequate accessibility of primary health services to the citizens of Montenegro. Secondary and tertiary level of healthcare provide specialised and highly specialised healthcare that cannot be provided at the level of primary healthcare.

The health Information System (IS) is defined as a set of tools and procedures used by healthcare staff to collect, process and transfer health data in order to facilitate tracking, evaluation and control within the health system. The information system has the ability to integrate, collect, process, report and use data needed for operational and strategic decision-making, ensuring thus provision of a better healthcare service and improving public health. In order to achieve the general informatisation of the entire healthcare system, one of the key steps for successful implementation of the overall healthcare system reform is the development of the Integrated Health Information System (IHIS). National health legislation, and the national health strategic framework have recognised IHIS as one of the most important segments required for the functioning of the entire health system.

Although the basic informatisation of the healthcare system started relatively early (in 2000), Montenegro still does not have a fully satisfactory and comprehensive IS. Most of the existing information systems were developed for the needs of individual health organisations, and the exchange of data among these systems for tracking, processing and reporting is not fully possible.

In order to identify a solution that would ensure coordinated and planned development of the healthcare IS, and following the request of the Ministry of Health, the UNDP Office in Montenegro in 2017 and 2018 carried out a detailed analysis of the current state of the Information System.

In short, the conducted analyses concluded that the existing information systems are not sufficiently interoperable. Even when you consider them separately, they do not provide reliable, complete and timely information. After the development and implementation (within this Project) of the new IS of the largest healthcare institution in Montenegro - the Clinical Centre of Montenegro, which accounts for some 65% of all healthcare services provided, in order for IHIS to be comprehensive and to provide complete information, it is necessary to significantly improve the entry and processing of data within the existing information systems and develop an interoperability framework that would connect all parts of the information system and thus provide an uninterrupted flow of information.

Also, the existing information system mainly does not enable the collection of sex-disaggregated data, which results in the impossibility of conducting gender analysis and the provision of services that will adequately recognize the different needs of women and men. Also, IS that does not disaggregate data by sex could therefore generate evidence and data that fails to adequately portray the true nature of the gender relations in the health system, leading to the development of policies that fail to consider gendered drivers of inequality. Also, it is necessary to strengthen the existing capacities of civil servants and medical staff managing the IS, regarding the basic principles of gender equality, in order to collect qualitatively improved sex-disaggregated statistical data. In addition to sex, the IS system should also be able to disaggregate data by other social determinants, such as age, race, ethnicity, disability, socioeconomic status, and geographic location, depending on the context and issues under consideration.

Additionally, it should be noted that, according to the State Auditing Institution's report, the current Information System is not sufficiently secured.

In overall, the introduction of an integrated information system in all healthcare institutions in Montenegro would result in a complete and comprehensive information system that provides reliable data for planning and decision-making, which is one of the Ministry's priority objectives.

## II. STRATEGY

In line with the Integrated Information System and eHealth Development Strategy (2018-2023), one of the priority strategic areas within the healthcare system functioning and organisation at the national level is to develop and improve the Integrated Health Information System (IHIS) and eHealth.

For successful development of new and an upgrade of existing information systems that comprise IHIS, it is among other things necessary to identify the development priorities of available resources, define appropriate organisational structure, provide human resources and thus create the conditions for provision of quality and efficient healthcare and decision-making based on reliable data.

One of the major segments in IHIS development involves the security of the system and data protection, in accordance with the principles of human rights protection, international obligations, and applicable EU standards and recommendations.

In line with the aforementioned, the project's general objective is to use informatisation development of the entire health system to contribute to the improvement of population's health and the better health-related policy making based on empirical data.

In other words, the goal of this project is not only to technically enable electronic data exchange among institutions, but to create conditions for multidisciplinary digital transformation processes and support the overall work process and policy-making in this field This will provide complete support to overall healthcare system reforms and facilitate more efficient and effective management of payments and provision of healthcare services.

Also, the implementation of IHIS will enable a more efficient management of the healthcare system, better quality control of gender-responsive healthcare services as well as better control of expenditures, and more efficient and quality collection and processing of sex-disaggregated data related to the health status of citizens and the functioning of the healthcare system, including:

- Reduction of operating costs, primarily through rationalisation of use of medicines and medical devices,
- Resource management in healthcare, primarily of non-medical - administrative and technical staff, whose share in the total number of employees exceeds 25%,
- Improved level of utilization of beds and human resources and shortening of the hospital treatment duration,
- Shortening of the waiting period for a patient - insured person to receive healthcare service, no matter if it is outpatient or stationary one, etc.

By establishing a comprehensive IHIS, Montenegro would make a significant step towards better planning health programmes, addressing specific needs of women and men, girls and boys and developing measures that would ultimately boost the overall health of the Montenegrin population, as well as improve health and early detection of certain diseases, enable the system to combat and detect the risk factors of certain diseases, protect children and youth, protect women during pregnancy and childbirth, and protect the elderly and other vulnerable groups. It will contribute to strengthening gender responsiveness both of the system and policymaking processes. In other words, introduction of IHIS would contribute to easier and more efficient delivery of quality health services to all patients.

Ultimately, the functional Health Information System would be able to identify the existing shortcomings. This would require changing the existing procedures and rules and ultimately contribute to a reduction of costs. Furthermore, IHIS will enable considerably better planning of both the total resources available for this sector and for the beneficiaries, more precise definition of proper and measurable activities, better monitoring of used supplies at the overall level, but also at the level of individual expenditures, as well as monitoring and evaluation of the effects of providing healthcare, i.e. it will improve the credibility of the Healthcare System.

In accordance with the IHIS strategic development principles, the health system informatisation project should produce a comprehensive IS, which should be able to integrate all existing

fragmented information systems into a functional tool, through development and implementation of a central information system for data exchange and control of business processes, and also offer complete solutions for still underdeveloped information systems, such as is the Pharmaceutical Track and trace information system. In this regard, it is necessary to consider the framework and principles pertaining to current investments and cost/efficiency of integrating/ connecting systems and to design phased introduction of software solutions that will deliver quick results, while taking into account scalability, openness to future system evolution/expansion, and enable innovation and competitiveness and maximize the scope. It is very important to accomplish full interoperability within IHIS as well as with external e-services. Ultimately, IHIS must be based on full electronic data processing and exchange, i.e. the establishment of patient's electronic record (EHR), where accurate information on citizens' - patients' health would be available to the authorised person in a timely manner and in the right place. The citizens' personal, health-related data would be protected and managed in accordance with the regulations on personal data protection. In order to improve the consistency and usability of data within the Electronic Health Records and Documentation, it is necessary to provide adaptability of the structure and content of the clinical data, followed by timely and factual information accuracy.

IHIS should be based on single registers and uniform codebooks that are under the jurisdiction of institutions recognised by law, independent from the physical location, accessible to relevant users as a basis for accurate and complete data exchange in order to create reports.

IHIS would have to be developed a technologically independent setting and in accordance with national guidelines and international standards for ICT in healthcare, enabling adequate data exchange within the IHIS while at the same time enhancing competitiveness in selecting proper software solutions.

In addition, for IHIS to be successful, it is necessary to harmonise the organisational/institutional capacities and identify the unit in charge of IT analytics, management, use, planning and development of IHIS.

Bearing in mind the current situation and modern trends in health systems, the Strategy has identified the micro-web service architecture as the most appropriate, strategic solution for the development of IHIS. The microservice architecture enables full integration of already existing applications in healthcare. Some of these systems already exist, some will require an upgrade and customization and some software applications will be procured and implemented only in the forthcoming period. All systems should have the same overarching architecture, defined and adopted standards for electronic availability and exchange of health information, a strictly unique security architecture, and organizational support.

There are multiple advantages to this approach:

- Standardisation and interoperability,
- System based on innovative applications and technologies,
- Easier transfer of knowledge from different fields of expertise,
- Openness towards innovation and other solutions,
- Possibility of frontal quick reaction,
- Flexible structure, demonopolization and introduction of competitiveness,
- Possibility to use OpenSource technologies and standards.

This connectivity/integration model allows the protection of key data generated at the place of provision of healthcare services, provides consistency and usability of this data based on the application of data exchange standards, enables reusability and potential alignment of existing systems while minimizing "direct connectivity", which results in a significant reduction in overall integration/connectivity costs.

When planning the electronic health record system, i.e. in order to have unobstructed functioning of the IHIS, in accordance with the proposed micro-service architecture, it is necessary to define and implement a set of rules and standards based on which the established organization allows interchangeable electronic health records and sex-disaggregated data and communication among applications and parts of the system. In this way, an effective system will be developed that contains fully integrated principles of gender equality and develops and provides gender-responsive healthcare services.

In line with the strategic commitment of the Ministry of Health, the UNDP Office will within the Project implement a part of the priority activities, set by the goals and objectives of the Information System Development Strategy. The vision set by the existing Strategy will be further enhanced through the National Digital Health Strategy in Montenegro for the period 2024-2029, which is envisaged by the Medium-Term Government Work Plan, and which would further elaborate and open new opportunities for the use and implementation of modern information and communication solutions in the healthcare.

The Ministry of Health will be responsible for project implementation, and it will ensure full coordination and smooth implementation of all Project components, comprehensive institutional support of all related institutions, and provide timely information to the Government about all activities implemented within the project as well as about potential difficulties.

Representatives of the Ministry will be involved in all key aspects of project implementation, such as:

- Participation in decision-making about the pace of implementation of individual project components,

- Verification of tender documents in terms of tender subject, content and functional requirements,

- Identification of needs and definition of requirements for expert support to project implementation,

- Participation in the process of selecting bidders for the implementation of project activities,

- Provision of information to all relevant participants in the process, so that they are actively involved in project implementation, organization and facilitation of discussions among stakeholders,

- Monitoring, reporting, and analysis of the results achieved and the quality of project implementation.


Theory of Change


Without investing efforts to accelerate the reform of the health care system through developing a comprehensive Integrated Health Information System (IHIS), thus enabling the health system to develop its full potential, an opportunity to facilitate centralised and timely management and use of reliable data for strategic decision-making could be missed. Considering so far achievements of the health sector digitalization and current situation analysis and priorities envisaged in the relevant strategic documents, achieving this goal rests on several hypotheses. In this regard the Theory of Change (ToC) key components and presumptions are as follows:


If the normative framework is well aligned with best practices and EU standards and reflects the needs of a modern and user-oriented, gender-responsive healthcare system, then none of the groups will remain excluded from development gains.


If institutional capacities for planning, coordination, development, financing, implementation and monitoring the quality of the IHIS are developed enough to respond to the specific needs of the health sector then IHIS will be sustainable and prepared for all further development and implementation.


If we continue to develop the new and improve the existing information systems in the health institutions in line with the interoperability standards as well as to enhance their capacities, then their full integration will be ensured to provide quality and usable data for strategic decision making.


Finally, if we continue with the system modernization and improvement of IT infrastructure, its efficiency will significantly increase and also result in savings related to maintenance and every day operation and thus facilitate significant investments to improve the quality and standard of health services.

The Theory of Change will be regularly reviewed and updated when needed through the Project Board mechanism.

Action will contribute to the country's UNSDCF Outcome - by 2027, all people, especially vulnerable people, benefit from improved social cohesion, increased realization of human rights and rule of law, and accountable, gender-responsive institutions. UNDP is strongly devoted to continuing to support the ongoing and further digitalization of the health sector institutions, in order to facilitate centralized and timely management and use of reliable data for strategic decision-making toward the improvement of the quality and standard of health services..

Gender mainstreaming in the Project implies including women on an equal footing with men in all the project components. Therefore, the Project will mainstream gender policy and gender equality through all the envisaged activities and invest additional efforts to ensure a gender-balanced approach, where the needs of both men and women for health services are equally addressed.

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## III.    RESULTS AND PARTNERSHIPS

### Expected Results

To enhance the setting up of the comprehensive Integrated Health Information System (IHIS) and accordingly implement the activities in order to achieve full digitalization and improvement of the IT infrastructure in the health sector, project interventions have been organized in the following key components:

### 1.  Creation of institutional and organizational framework to make IHIS sustainable

All health institutions in Montenegro, regardless of whether they are at the primary, secondary or tertiary level of healthcare, as well as the Health Insurance Fund (HIF) and the Public Health Institute, are independent institutions established by the Ministry of Health, i.e. the Government of Montenegro. Thus, from the organizational point of view, all the institutions are on the same organizational level because they report directly to the Ministry of Health. In addition to health institutions established by the state  the health system of Montenegro also includes private health institutions established by private individuals under conditions prescribed by the Ministry of Health.

The informatization of the health system started in the Montenegrin Health Insurance Fund in 2000, and it is continued through the reform of the health system of Montenegro with the projects of IT support which was mostly managed by the HIF, with acceptance of the new IS for Clinical Centre of Montenegro, developed through this project initiative. However, if we analyse the system from today's perspective, the HIF is in charge of the administrative and IT support to the information systems whose business processes do not belong to the HIF only, and whose users report to the hierarchical structure that is not managed by HIF.

From the organizational point of view, this situation can also be questionable and it may lead to the development of several independent IT schemes where IT systems in the health sector would develop further, independently of each other. It could also lead to the situation in which current projects are implemented with difficulties due to the inherent differences and particular needs of the institutions within the healthcare system.

In accordance with the Strategy goals and future plans, it is necessary to define the institutional framework for consolidated and quality IHIS management. One of the key activities of the MH is to draft laws and secondary legislation to institutionalize a body for consolidated and quality IHIS management and establish a unit to be involved in planning, coordination, financing, specification, contracting and monitoring the quality of IHIS.

Also, patients who are the owners of their health data should have the possibility to make their health data collected in the public health information system available to private health institutions,

but also for private institutions to generate health data that will be retrieved by public IS with the aim of that data being comprehensive and under the full control of the patient.

Therefore, the Ministry of Health should:

- Define and adopt the organisational structure and job description for planning, coordination, development, financing, contracting and quality monitoring of IHIS

- Finalise the administrative and professional set up of the unit for planning, coordination, financing, specification, contracting and quality monitoring of IHIS

- Ensure normative alignment of requirements and needs so that all services are normatively supported and regulated

Establishment of a national institutional framework and capacity building for consolidated and quality management, which implies planning, coordination, implementation, financing and monitoring of the IHIS and eHealth quality, including also sex-disaggregated data collection and analysis, is a key element of IHIS sustainability and a prerequisite for all further steps in IHIS development and implementation.

## 2. Definition of EHR (Electronic Health Record) and adoption of data exchange standards

Definition of the EHR and adoption of standards is the responsibility of the Ministry of Health (MH) and the unit in charge for the management of the IHIS.

Activities that are planned to be implemented within this component include:

- Definition and adoption of the Interoperability Framework for Health System in Montenegro

- Adoption and implementation of standards for a consolidated microservice architecture

- Definition and adoption of the EHR framework, including structure, content and standards for the Electronic Health Record, that is filled in at different levels and segments of healthcare, with a possibility to interlink parts of the record when necessary and with defined authorizations

- Definition and adoption of data exchange standards

- Normative alignment of requirements and needs so that all services are normatively supported and regulated

The same as Component 1 of this project, Component 2 should be implemented by the Ministry of Health.

The UNDP's contribution to these processes is reflected in the technical support to the MH and IHIS unit (Component 1) in drafting of the architecture and contents of the Electronic Health Record (EHR), standards for harmonization of software solutions in healthcare, and drafting of the Technical Specifications (API Specifications) to be followed when designing applications, and to participate in the process of adapting the existing information systems to the new architecture and adopted standards (Component 2).

It should be emphasised that successful implementation of components 1 and 2 is a prerequisite for successful implementation of all other project components. Namely, the adoption of standards is a prerequisite for implementation of further informatisation and upgrade of the information system (including the new software platforms), as well as for definition of the interoperability framework for the EHR. Establishment of a management unit for IHIS is a precondition for proper management and use of IHIS, reporting and policymaking based on system data.

### 3. Development and implementation of the Electronic Health Record (EHR)

Based on the situation analysis, planned and approved architecture, and the Strategy for Development of the Integrated Health Information System (IHIS) 2018 - 2023, it is necessary to ensure maximum interoperability of all subsystems, existing and planned ones, which will be carried out through development and implementation of the software platform and central data exchange system where, among other things, will be managed a unique Electronic Health Record (EHR) of all insured person and that will condition all other subsystems to use the common databases and standards for data exchange, which has the following goals:

- To support the creation and management of a gender-responsive centralised electronic health record of all insured person, which will automatically lead to creation of the national health record;

- To enforce the implementation of the microservice web architecture across the IHIS by applying the approved data exchange standards and enabling all existing applications in IHIS to harmonise with the new architecture of the System;

- To ensure the application of approved standards for managing the patients' Electronic Health Record, as well as the exchange of data according to the approved protocols;

- To become the main repository for national health statistics and reporting that will be implemented through a special project of setting up the "data warehouse/Business Intelligence" platform. All available statistics and data must be clearly sex-disaggregated, which will create conditions for the subsequent collection of data and preparation of gender analysis.

- Take over the management of all codebooks/registers needed for the functioning of IHIS while respecting the access rights and the obligation to update them.

The Central Information System needs to be built from a scratch, i.e. from the project design phase to the final installation and implementation of the system and completion of activities to adapt the existing software solutions in the healthcare to the consolidated way of communication and exchange of data with the central EHR system. This is one of the key components for implementation of the IHIS Development Strategy.

Special emphasis is on the collection and exchange of sex-disaggregated data which is currently generated and collected in heterogeneous and everyday situations and settings. This means that the complexities in differences regarding access to healthcare services among different genders need to be reflected in EHR data. For example, women's and men's use of healthcare services in Montenegro differs according to the type of service. In this regard, data exchange standards must be defined in a way that will reduce the level of gender bias and enable the collection, fluid transmission and exchange of all available gender disaggregated data and provision of gender responsive services.

### 4. Development and implementation of the IS at CCM

One of the key project components involves development and establishment of the information system for management and development of the work processes at the Clinical Centre of Montenegro (ISCCM). During the project, it is necessary to establish a consolidated system in which all business processes are interlinked, and which is technically stable and enables integration with other information systems (especially EHR), i.e. the system able to cover all the particular functionalities of CCM, which include:

- ✓ Support to processes related to in-patients:
- ✓ Integration with the EHR central system
- ✓ Integration with information systems managing PHI registers

- ✓ Integration with the information system of the Agency for Medicines and Medical Devices for records and processing of notifications on medicines' side effects
- ✓ Integration with the system for Central appointment of special medical examinations in the Clinical Centre's clinics by chosen doctors within IHIS
- ✓ Support to business processes of the CC's Emergency Centre
- ✓ Integration of the reporting and statistical analysis module
- ✓ Business Information System (BIS)
- ✓ Data Collection and analysis

CCM IS should provide simple (intuitive) functionality and be tailored to efficient use, minimizing the number of steps required to perform a particular procedure, and allowing faster access to quality and sex-disaggregated information. After the IS CCM review and implementation of adjustments suggested by the review, future steps will be related to the implementation of highly specialized software solutions for particular medical specialties, as well as integration into the medical devices system.

## 5. Emergency Medical Assistance Informatisation

Based on the situational analysis, planned and adopted architecture, and the Strategy for further development of the Integrated Health Information System (IHIS) from 2018 to 2023, one of the priority activities of the Action Plan for the implementation of the Strategy is informatization of all units of the Institute of Emergency Medical Assistance. Namely, it is necessary to establish a single system in which all processes are interconnected, which is technically stable and which allows integration with other information systems (especially with the EHR system and the Emergency Block of the Clinical Centre), i.e. a system capable of covering all specific functionalities of Emergency Medical Service, among others, structuring anamnesis in outpatient and dispatching work, electronic records, statistics, protocols, business information system and others.

## 6. Development and Implementation of the Pharmaceutical Track and Trace System

The Law on health care defines the obligation of the state to establish a unique methodology for supplying health institutions with medicines, medical supplies, and a real plan of annual needs for medicines, medical supplies and equipment. It is the state's obligation to carry out activities aimed at improving and preserving health and raising the level of the health condition of citizens and providing the necessary medicines and medical equipment. By introducing the Track and Trace System for monitoring the distribution of drugs from wholesalers to the patient, better monitoring of the dispensing, consumption and distribution of drugs, as well as real-time consumption, will be achieved. After the examining and analysis of the existing successful solutions in this area in other countries, the system will be designed to track the path from the entrance of the drug to the wholesale drugstore through dispensing to pharmacies or health institutions and on to the final patient, and to record every change in the charge of the drug. The introduction of the Track and Trace System implies the acquisition of infrastructure for marking all medicines with QR codes, infrastructure for reading QR codes, as well as software for communication with the infrastructure, analytics and statistics. After the introduction of the system, the state of medicines at the country level will be known in real time (initially with public and after harmonization of regulations both with

private pharmacies), precise consumption per patient, consumption control, records of dispensed medicines and batches.

## 7. Analyses and development of the other prioritized software solutions within the IHIS

In line with the general objective of the Project to use informatization development of the entire health system to contribute to the improvement of the population's health the better health-related policy making based on empirical data, the activities in analyses, improvement and development of the following prioritized software solutions will be launched, subject to the available resources:

- Information System for the Ministry of Health (ISMH) for more efficient maintaining the health institutions register, personnel and equipment, donations, medical waste, administrative procedures, as well as integration with existing and future reporting systems.

- The unique platform for the provision of mHealth services

- Health-statistical information system

- Platform for telemedicine

- Apps on prevention in health, and others.

## 8. Optimisation and upgrade of the hardware and software infrastructure

In order to create the preconditions for the unhindered development and implementation of information systems that constitute IHIS, it is necessary to carry out reconsolidation of the existing and procurement of new hardware and communication components. The right way to do it is to establish (or adapt the existing) modern data centre where a CLOUD platform will be set up to include virtual hosts for IHIS applications and data (EHR, eHealth, BI, ...) with the mandatory Disaster Recovery Centre (or adaptation of the existing) that will host copies of necessary applications and data. A study for the establishment of a modern data centre for IHIS will provide the best and most optimal solution for the utilization of the existing server potentials, the need for procurement of new equipment and the strategic management of the complete hardware platform.

In addition to these new software components for IHIS, it is essential for the project to make a plan for continuous renewal of computer/server equipment used for work on the existing software systems in IHIS, where the depreciation period either has expired or will expire soon.

## 9. Capacity building (including continuous training, BI, analytics)

The overall result of this project component will be improved internal capacities, both at the MH and in other institutions of the health system, to properly use, maintain and further develop IHIS.

In order to carry out comprehensive organisational changes and overall processes in the health sector, and for the purpose of proper use of IHIS, together with development of the new software solutions, additional basic and specialist trainings of employees are necessary. This capacity building should enable better use of IHIS on the one hand, but also continued maintenance and further development of IHIS on the other.

The capacity building component will support the organisational changes in MH in order to ensure continued support to the functioning, maintenance and further development of IHIS.

In this context, it is necessary to organise trainings of civil servants at the MH in the field of management and best practices as regards similar systems, and a comprehensive training

primarily for medical staff from health institutions on the use and all IHIS possibilities. Civil servants and medical staff need to be sensitized to both gender and statistics. They should understand basic principles of gender equality, why gender related health data are important, how gender statistics are produced, and where they can obtain sex-disaggregated data. Users and producers also need to work together to improve gender and health statistics by improving concepts and methodologies in emerging areas, such as disability statistics, data on the ageing population, and mental health.

During the Project implementation, the special emphasis will be on using the existing EU integration process mechanisms, intended to strengthening capacities of the Public Administration, and available without significant additional expenses (i.e. TAIEX, ReSPA, etc).

### *Resources Required to Achieve the Expected Results*

The total project budget is in amount of 3,300,147 USD, including the additional contribution of the MH for 2023 and 2024 in the amount of 1,490,947 USD (1,400,000 EUR), managed by the UNDP through a project management unit dedicated to overall project management and coordination, facilitating all project activities. Therefore, it is needed to:

- Set up a Coordination Unit by the Ministry of Health, with the task to ensure full coordination and smooth implementation of all Project components, comprehensive institutional support of all the relevant institutions, and to provide timely information to the Ministry regarding all activities that are undertaken in the process of project implementation, as well as potential difficulties.
- Hire independent experts and set up UNDP project team that will comprise:
  - o Managerial functions
    - Project Manager
    - Project Coordinator
    - Operational support to the Manager by the UNDP office

  - o Technical functions
    - Independent experts/technical advisers for development of software solutions:
      - Development of tender documents
      - Supervision of implementation and testing of new solutions
      - Analysis of the needs to expand IS
    - Independent experts/technical advisers for development of infrastructure and hardware solutions:
      - Development of tender documents
      - Supervision of implementation and testing
      - Analysis of infrastructure/hardware needs to expand IS
    - Consultants to support the Ministry in development of the Strategic documents in the area of digitalization in health
    - Consultants for a redefinition of the legal framework as support to the Ministry's team of expert (as needed)

All the duties of day-to-day management will be performed by the Project Manager appointed by UNDP, under the supervision of the UNDP management. Primary, but not the only role of the Project Manager is to ensure: administrative, financial and overall management and implementation of the Project.

## Required funds in line with the proposed activity framework

| No. | Key items | Amount in USD |
|-----|-----------|---------------|
| 1 | Consulting services for analyses, studies, development of tender documentation, supervision of the implementation of software solutions, roll out and testing | 138,600 |
| 2 | Expenses of development and implementation of the Electronic Health Record | 363,600 |
| 3 | Costs of development, procurement and implementation of the CCM information system | 1,171,000 |
| 4 | Costs of Emergency Medical Assistance informatization | 117,850 |
| 5 | Costs of development, procurement and implementation of the Pharmaceutical Track and Trace information system | 447,000 |
| 6 | Costs of analyses and development of the other prioritized software solutions (ISMH, telemedicine, mHealth, health-statistics…) | 307,197 |
| 7 | Costs of renewal of hardware and communication infrastructure | 409,200 |
| 8 | Strengthening of internal capacities | 23,400 |
| 9 | Project management costs | 322,300 |
| 10 | **Total project costs (Phase 2)** | **3,300,147** |
| 11 | Savings from Phase 1 | 91,000 |
| 12 | UNDP contribution | 32,000 |
| 13 | **Total required funds for Phase 2** | **3,177,147** |

| No. | Required funds by years | |
|-----|-------------------------|---|
| 1 | 2019 | 1,249,851 |
| 2 | 2020 | 436,349 |
| 3 | 2023 | 1,490,947 |
| | **Total for Phase 2** | **3,177,147** |

## Budget analysis

| | |
|---|---|
| Share of funds allocated for procurement of software components and hardware infrastructure through tender procedures | 85.32% |
| Share of funds allocated for consulting services (including analyses, studies, development of tender documents, criteria for selection of the best bidder, implementation supervision, testing, review and acceptance test for software solutions) | 4.20% |
| Training of staff, strengthening of internal capacities | 0.71% |
| **Total share of funds allocated for implementation of the activities** | **90.23%** |
| UNDP project management costs (Project Manager, Project Coordinator and Project Assistant 30%) and administrative costs, which include: planning, management, monitoring of project implementation, operational execution and monitoring of tender procedures, hiring experts, financial and narrative reporting and evaluation of project performance | 9.77% |

**Total**                                                                          **100.00%**

*Note: Budget items 2-7 represent the estimated procurement values for planned software solutions and hardware infrastructure. During the Project implementation, budget adjustments are possible in accordance with the outcomes of tendering procedures.*

### Partnerships

The leading participants in the process of implementation of the project are the Ministry of Health of Montenegro and institutions under the jurisdiction of the Ministry, i.e. health centres, general and special hospitals, Clinical Centre of Montenegro (CCM), Public Health Institute, Pharmacy Institutions of Montenegro, Institute for Emergency Medical Assistance, Blood Transfusion Institute, Montenegrin Agency for Medicines and Medical Devices, Health Insurance Fund.
In addition to this, the Project will include many other state institutions as needed, for example: Ministry of Interior, in relation to data exchange and interoperability. End users, the professionals working in the health sector, will be fully involved from the beginning of the Project.

### Risks and Assumptions

Successful project implementation requires certain preconditions to be met:
- ✓ Ensure the required funds,
- ✓ Human resources - ensure participation of adequately trained staff on the various levels of the health system,
- ✓ Coordination and leadership - define the mechanisms for the timely exchange of information and inter-sectorial cooperation,
- ✓ Due to the fact that the processes and results depend on each other, the responsibilities and allocation of tasks and activities to be implemented by the Ministry team and the UNDP team should be harmonized and clearly defined.

Implementation of components 1 and 2 by MH, as a precondition for implementation of other activities.

The initially identified risks and possible mitigation measures are presented in the table below:

| Type of risk (contextual programmatic, institutional) | Risk | Likelihood (L, M, H) | Impact on result | Mitigation strategies | Risk treatment owners |
|---|---|---|---|---|---|
| Strategic (Change in Government) | Political instability, restructuring of government, or early elections | Medium | Delay or stop to implementation of activities with Government partners | Regular intensive communication and coordination with the Government partners and health institutions to ensure the continuous planning and development of the IHIS. | UNDP Senior Management, UNDP Project Team |
| Strategic (Donors, partnerships) | RM incomplete. Lack of donor interest | Medium | Setting up of Integrated Health Information System (IHIS) will not be completed until the closure of this Project. If additional resources are not (or not sufficiently) | Efforts are being made, in partnership with Ministry of Health to mobilize resources | MH, UNDP Senior Management, UNDP Project Team |

| Type of risk (contextual programmatic, institutional) | Risk | Likelihood (L, M, H) | Impact on result | Mitigation strategies | Risk treatment owners |
|---|---|---|---|---|---|
| | | | mobilized to continue and expand envisaged activities the impact/change in the society will be limited. | | |
| Organizational (Execution capacity) | Unit for IHIS management in the Ministry of Health do not have capacity to develop, finance and maintenance the IHIS | Medium | Political developments as well as transparent but rather complex and demanding procurement/recruitment procedures in public administration may affect the dynamic of work of the Unit for IHIS | The Project will invest additional efforts to support the Unit in the taking over complete management of IHIS. | MH, UNDP Senior Management, UNDP Project Team |
| Organizational (Execution capacity) | Sustainability of the project's results | Medium | Development of IHIS depends on the financial resources available in the central budget which are dependent on external economic developments and tax collection. Limited budgetary funding may directly impact the development of the IHIS. | The Project will invest additional efforts to support the Ministry of Health to present and advocate for the priorities of the health system in front of the Government, in particular the Ministry of Finance. Additionally, efforts are being made to mobilize resources with other donors, especially the European Union. Project results are expected to surpass the duration of the project. All the implemented systems should continue to operate many years after the project's completion. | MH, UNDP Senior Management, UNDP Project Team |

### Stakeholder Engagement

The leading participants in the process of implementation of the project are the Ministry of Health of Montenegro and institutions under the jurisdiction of the Ministry, i.e. health centres, general and special hospitals, Clinical Centre of Montenegro (CCMN), Public Health Institute, Pharmacy Institutions of Montenegro, Institute for Emergency Medical Assistance, Blood Transfusion Institute, Montenegrin Agency for Medicines and Medical Devices, Health Insurance Fund.

**South-South and Triangular Cooperation (SSC/TrC)**

N/a.

### Digital Solutions

This project is fully related to the digitalization of the health sector in Montenegro. Namely, digital transformation is high on the government's agenda and Montenegro is aiming to rapidly deploy cost-effective, secure, and citizen-centric e-services and coordinate the implementation of ICT policies, with the aim to reach the EU standards set out in the Digital Agenda 2020 and the Digital Single Market Strategy. The existing information system in the health sector is still incomplete, fragmented, and insufficiently interoperable to provide satisfactory information for the efficient management of the health system. Digitization and introduction of new digital technologies in health care enables the existing system to be regulated in a way that better use existing resources and, with adequate reporting and monitoring, enables better management, planning and offers evidence for defining the vision, policies and measures in accordance with the EU standards. Namely, significant improvements and upgrades of the IT system and infrastructure in the health sector will facilitate centralized and timely management, processing and use of reliable data for strategic decision-making.

### Knowledge

The project results are regularly presented to all relevant stakeholders within Steering Committee Meetings held at least once in a year. Besides that, information about the activities are timely presented on official web pages (UNDP website and MoLSW), as well as distributed to the national electronic and print media. Al relevant printed materials (guidebooks and analysis) were distributed to all relevant actors. In line with the above presented good practice, the Project team will continue to promote all project results and lessons learned generated by the project.

Also, for the sake of external knowledge sharing, during the process of selection of international consultants, the preference shall be given to the local and experts from the region, i.e. to the experts that have knowledge in the field of informatization of the Healthcare systems in former Yugoslav countries.

### Sustainability and Scaling Up

The fact that digital transformation in the health sector is high on the government's agenda in the ongoing EU integration process, where the Ministry of Health is the key implementer, and at the same time the main partner in project's implementation, is a clear indicator that sustainability of project's results is a national interest. In terms of the continuation of development of the Integrated Health Information System (IHIS) for improved decision-making and provision of health services, the existing strategic documents, normative framework and strong devotion of the Ministry of Health to continue its provision displays the relevance of the action and sustainability of its results, especially with the implemented systems which should continue to operate many years after the project's completion.

# IV. PROJECT MANAGEMENT

## Cost Efficiency and Effectiveness

Due to its scope and critical deadlines for implementation, this initiative is a complex and very particular project. The project is important also because of the fact that its results (recommendations, e-Architecture, key documents that will later serve as the basis for technical specifications for development of IHIS) would to a large extent define further investments into the development of the health system. Therefore, it could be said that the project impact will significantly exceed the invested resources.

## Project Management

The project will be implemented through the Direct Implementation modality. The project costs are subject to direct project costing of operational services as per the UNDP procedures and in accordance with UNDP CO established practices.

All day-to-day management duties will be conducted by the Project Team appointed by UNDP, under the supervision of the senior management, with the strong engagement of all involved partners and stakeholders. Roles and responsibilities regarding the Project implementation will comply with the new UNDP's Results Management Guide, which defines the minimum requirements to be met so that UNDP can accept responsibility for the use of resources during the implementation of the Program activities.

UNDP Project Team will consist of the Programme Manager, Project Coordinator and a Project Assistant. The Project Team will have the following role:

1) Coordinate technical, administrative and financial activities of the project;
2) Ensure monitoring and control of activities;
3) Financially manage the project (including effecting disbursements);
4) Resolve bottlenecks, and
5) Prepare substantive and financial reports for the Project Board and UNDP.

UNDP Project Team will submit a regular progress report to the Project Board when the latter is being convened. The Programme Manager will ensure the organization of Project Board meetings on regular basis.

The Project Steering Committee (SC) was formed during the implementation of the first project phase. The Steering Committee is co-chaired by the Ministry of Health and UNDP. If all stakeholders agree, the SC may decide to redirect the use of funds, modify existing/introduce new activities and decide to change the project duration, in accordance with the overall project goals.

Other members of the Steering Committee are appointed, if necessary, by the Ministry of Health, and it is a usual practice to have representatives of interested institutions, for example CCM, PHI, HIF, etc. as members of the Committee. SC meetings are called by the Ministry of Health. In accordance with the current practice on similar projects, SC is convened at least once a year for the duration of the project. UNDP submits the final report to the Steering Committee, shortly after the completion of the Project, in accordance with UNDP rules.

# V. RESULTS FRAMEWORK

Intended Outcome as stated in the UNSDCF/Country [or Global/Regional] Programme Results and Resource Framework: By 2027, all people, especially vulnerable people, benefit from improved social cohesion, increased realization of human rights and rule of law, and accountable, gender-responsive institutions.

Outcome indicators as stated in the Country Programme [or Global/Regional] Results and Resources Framework, including baseline and targets:
Number of new public, private and judicial institutions leveraging digital technologies to deliver effective services (national/subnational level)

Applicable Output(s) from the UNDP Strategic Plan:
OUTCOME 3: Resilience built to respond to systemic uncertainty and risk

Project title and Atlas Project Number: Strengthening Health System in Montenegro (phase 2).ID: 00103594

| EXPECTED OUTPUTS | OUTPUT INDICATORS | DATA SOURCE | BASELINE | | TARGETS (by frequency of data collection) | | | | | | | | DATA COLLECTION METHODS & RISKS |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | | Value | Year | Year 2017 | Year 2018 | Year 2019 | Year 2020 | Year 2021 | Year 2022 | Year 2023 | Year 2024 | |
| Functioning of the national health information system improved | Number of system informatisation and data exchange standards introduced | MoH | 0 | 2016 | 0 | 0 | 1 | 2 | 2 | 2 | 2 | 3 | MoH data , Steering Committee Reports |
| | Number of new software solutions developed in the health sector | MoH | 0 | 2016 | 0 | 0 | 0 | 0 | 0 | 0 | 2 | 5 | MoH data , Steering Committee Reports |
| | Number of health institutions leveraging newly implemented digital technologies to deliver effective services | MoH | 0 | 2016 | 0 | 0 | 0 | 0 | 0 | 0 | 2 | 4 | MoH data , Steering Committee Reports |
| | Necessary renewal of targeted hardware and computer infrastructure completed | MoH | 0 | 2016 | 0 | 0 | 0 | 35% | 35% | 45% | 55% | 80% | MoH data , Steering Committee Reports |

# VI. MONITORING AND EVALUATION

**Monitoring Plan**

| Monitoring Activity | Purpose | Frequency | Expected Action | Partners (if joint) | Cost (if any) |
|---|---|---|---|---|---|
| **Track results progress** | Progress data against the results indicators in the RRF will be collected and analysed to assess the progress of the project in achieving the agreed outputs. | Annually | Slower-than-expected progress will be addressed by project management. | UNDP | |
| **Monitor and Manage Risk** | Identify specific risks that may threaten the achievement of intended results. Identify and monitor risk management actions using a risk log. This includes monitoring measures and plans that may have been required as per UNDP's Social and Environmental Standards. Audits will be conducted in accordance with UNDP's audit policy to manage financial risk. | Quarterly | Risks are identified by project management and actions are taken to manage risk. The risk log is actively maintained to keep track of identified risks and actions taken. | UNDP | |
| **Learn** | Knowledge, good practices and lessons will be captured regularly, as well as actively sourced from other projects and partners and integrated back into the project. | At least annually | Relevant lessons are captured by the project team and used to inform management decisions. | UNDP | |
| **Annual Project Quality Assurance** | The quality of the project will be assessed against UNDP's quality standards to identify project strengths and weaknesses and to inform management decision-making to improve the project. | Annually | Areas of strength and weakness will be reviewed by project management and used to inform decisions to improve project performance. | UNDP | |
| **Review and Make Course Corrections** | Internal review of data and evidence from all monitoring actions to inform decision-making. | At least annually | Performance data, risks, lessons, and quality will be discussed by the project board and used to make course corrections. | MoH & UNDP | |
| **Project Report** | A progress report will be presented to the Project Board and key stakeholders, consisting of progress data showing the results achieved against pre-defined annual targets at the output level, the annual project quality rating summary, an updated risk long with mitigation measures, and any evaluation or review reports prepared | Annually, and at the end of the project (final report) | | MoH & UNDP | |

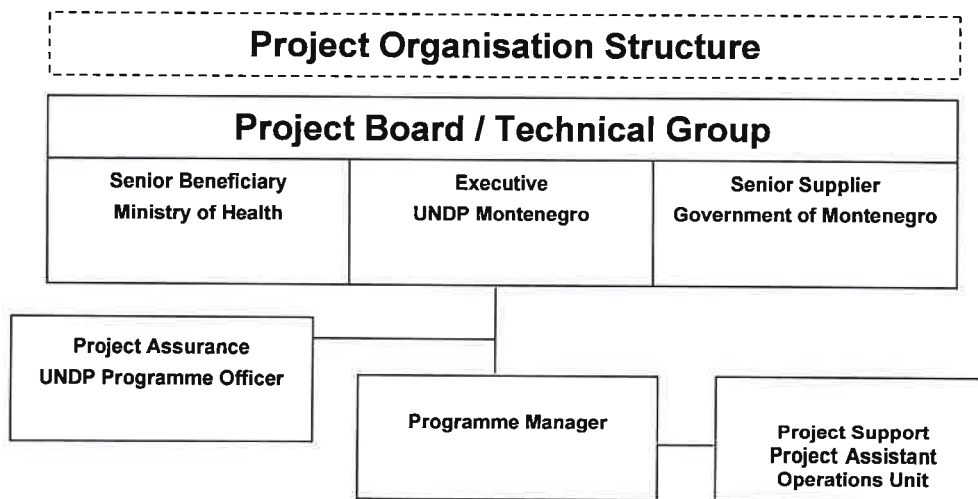| | | | |
|---|---|---|---|
| | over the period. | | MoH & UNDP |
| **Project Review (Project Board)** | The project's governance mechanism (i.e., project board) will hold regular project reviews to assess the performance of the project and review the Multi-Year Work Plan to ensure realistic budgeting over the life of the project. In the project's final year, the Project Board shall hold an end-of-project review to capture lessons learned and discuss opportunities for scaling up and socialize project results and lessons learned with relevant audiences. | At least annually | Any quality concerns or slower-than-expected progress should be discussed by the project board and management actions agreed upon to address the issues identified. |

## VII. MULTI-YEAR WORKPLAN

| EXPECTED OUTPUTS | PLANNED ACTIVITIES | RESPONSIBLE PARTY | Funding Source | Budget Description | Utilized Budget by Year | | | | Planned Budget by Year | | Total Budget (USD) |
|---|---|---|---|---|---|---|---|---|---|---|---|
| | | | | | 2019 | 2020 | 2021 | 2022 | 2023 | 2024 | |
| Strengthening Health System in Montenegro for further improvement of health information system for better delivery of services. | Project Management | UNDP | Gov of MNE | Service contracts individ. (71400) | 10,475 | 10,265 | 6,590 | 5,364 | 57,015 | 65,000 | 154,709 |
| | | | | Salaries GS staff (61200) | 993 | 2,415 | | | 30,000 | 30,000 | 63,408 |
| | | | | Utilities (73100) | 687 | 375 | | | 1,000 | 1,000 | 3,062 |
| | IS development | UNDP | Gov of MNE | Local consultants (71300) | 10,785 | 17,202 | | | 60,613 | 50,000 | 138,600 |
| | | | Gov of MNE | Contr.Companies(72100) | 9,852 | 437,193 | 398,900 | 210,778 | 454,133 | 1,291,425 | 2,802,281 |
| | | | Gov of MNE | Travel (71600) | 6,966 | | | | 20,000 | 10,000 | 36,966 |
| | Evaluation | UNDP | UNDP | Local consultants (71300) | | | | | | 5,000 | 5,000 |
| **Total without GMS** | | | | | 39,758 | 467,450 | 405,490 | 216,142 | 622,761 | 1,452,425 | 3,204,026 |
| 75100 (GMS) | | | Gov of MNE | GMS (75100) | 1,193 | 13,317 | 12,164 | 6,486 | 18,683 | 44,278 | 96,121 |
| **TOTAL** | | | | | **40,951** | **480,767** | **417,654** | **222,628** | **641,444** | **1,496,703** | **3,300,147** |

# VIII. GOVERNANCE AND MANAGEMENT ARRANGEMENTS

The Project Board (Steering Committee) will be responsible for providing general oversight to ensure the achievement of results on the primary project outcomes and making consensus strategic management decisions when guidance is required by the Project Team, including approval of project plans and revisions, as well as evaluation, including meeting the requirements of the Country Programme Document between the Government and UNDP. The Board will meet at least once a year. The main project partner is the Ministry of Health.

The structure of the Project Organisation is depicted below.

## Project Organisation Structure

### Project Board / Technical Group

| Senior Beneficiary | Executive | Senior Supplier |
| --- | --- | --- |
| Ministry of Health | UNDP Montenegro | Government of Montenegro |

**Project Assurance**
UNDP Programme Officer

**Programme Manager**

**Project Support**
Project Assistant
Operations Unit

# IX. LEGAL CONTEXT

*[NOTE: Please choose __one__ of the following options, as applicable. Delete all other options from the document]*

**Option a. Where the country has signed the <u>Standard Basic Assistance Agreement (SBAA)</u>**

This project document shall be the instrument referred to as such in Article 1 of the Standard Basic Assistance Agreement between the Government of (country) and UNDP, signed on (date).   All references in the SBAA to "Executing Agency" shall be deemed to refer to "Implementing Partner."

This project will be implemented by [name of entity] ("Implementing Partner") in accordance with its financial regulations, rules, practices and procedures only to the extent that they do not contravene the principles of the Financial Regulations and Rules of UNDP. Where the financial governance of an Implementing Partner does not provide the required guidance to ensure best value for money, fairness, integrity, transparency, and effective international competition, the financial governance of UNDP shall apply.

# X. RISK MANAGEMENT

*[NOTE: Please choose __one__ of the following options that corresponds to the implementation modality of the Project. Delete all other options.]*

**Option b. UNDP (DIM)**

1. UNDP as the Implementing Partner will comply with the policies, procedures and practices of the United Nations Security Management System (UNSMS.)

2. UNDP as the Implementing Partner will undertake all reasonable efforts to ensure that none of the [project funds][1] [UNDP funds received pursuant to the Project Document][2] are used to provide support to individuals or entities associated with terrorism and that the recipients of any amounts provided by UNDP hereunder do not appear on the list maintained by the Security Council Committee established pursuant to resolution 1267 (1999). The list can be accessed via http://www.un.org/sc/committees/1267/aq_sanctions_list.shtml. This provision must be included in all sub-contracts or sub-agreements entered into under this Project Document.

3. Social and environmental sustainability will be enhanced through application of the UNDP Social and Environmental Standards (http://www.undp.org/ses) and related Accountability Mechanism (http://www.undp.org/secu-srm).

4. UNDP as the Implementing Partner will: (a) conduct project and programme-related activities in a manner consistent with the UNDP Social and Environmental Standards, (b) implement any management or mitigation plan prepared for the project or programme to comply with such standards, and (c) engage in a constructive and timely manner to address any concerns and complaints raised through the Accountability Mechanism. UNDP will seek to ensure that communities and other project stakeholders are informed of and have access to the Accountability Mechanism.

5. In the implementation of the activities under this Project Document, UNDP as the Implementing Partner will handle any sexual exploitation and abuse ("SEA") and sexual harassment ("SH") allegations in accordance with its regulations, rules, policies and procedures.

6. All signatories to the Project Document shall cooperate in good faith with any exercise to evaluate any programme or project-related commitments or compliance with the UNDP Social and Environmental Standards. This includes providing access to project sites, relevant personnel, information, and documentation.

7. UNDP as the Implementing Partner will ensure that the following obligations are binding on each responsible party, subcontractor and sub-recipient:

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[1] To be used where UNDP is the Implementing Partner

[2] To be used where the UN, a UN fund/programme or a specialized agency is the Implementing Partner

a. Consistent with the Article III of the SBAA *[or the Supplemental Provisions to the Project Document]*, the responsibility for the safety and security of each responsible party, subcontractor and sub-recipient and its personnel and property, and of UNDP's property in such responsible party's, subcontractor's and sub-recipient's custody, rests with such responsible party, subcontractor and sub-recipient. To this end, each responsible party, subcontractor and sub-recipient shall:

    i. put in place an appropriate security plan and maintain the security plan, taking into account the security situation in the country where the project is being carried;

    ii. assume all risks and liabilities related to such responsible party's, subcontractor's and sub-recipient's security, and the full implementation of the security plan.

b. UNDP reserves the right to verify whether such a plan is in place, and to suggest modifications to the plan when necessary. Failure to maintain and implement an appropriate security plan as required hereunder shall be deemed a breach of the responsible party's, subcontractor's and sub-recipient's obligations under this Project Document.

c. In the performance of the activities under this Project, UNDP as the Implementing Partner shall ensure, with respect to the activities of any of its responsible parties, sub-recipients and other entities engaged under the Project, either as contractors or subcontractors, their personnel and any individuals performing services for them, that those entities have in place adequate and proper procedures, processes and policies to prevent and/or address SEA and SH.

d. Each responsible party, subcontractor and sub-recipient will take appropriate steps to prevent misuse of funds, fraud or corruption, by its officials, consultants, subcontractors and sub-recipients in implementing the project or programme or using the UNDP funds. It will ensure that its financial management, anti-corruption and anti-fraud policies are in place and enforced for all funding received from or through UNDP.

e. The requirements of the following documents, then in force at the time of signature of the Project Document, apply to each responsible party, subcontractor and sub-recipient: (a) UNDP Policy on Fraud and other Corrupt Practices and (b) UNDP Office of Audit and Investigations Investigation Guidelines. Each responsible party, subcontractor and sub-recipient agrees to the requirements of the above documents, which are an integral part of this Project Document and are available online at www.undp.org.

f. In the event that an investigation is required, UNDP will conduct investigations relating to any aspect of UNDP programmes and projects. Each responsible party, subcontractor and sub-recipient will provide its full cooperation, including making available personnel, relevant documentation, and granting access to its (and its consultants', subcontractors' and sub-recipients') premises, for such purposes at reasonable times and on reasonable conditions as may be required for the purpose of an investigation. Should there be a limitation in meeting this obligation, UNDP shall consult with it to find a solution.

g. Each responsible party, subcontractor and sub-recipient will promptly inform UNDP as the Implementing Partner in case of any incidence of inappropriate use of funds, or credible allegation of fraud or corruption with due confidentiality.

Where it becomes aware that a UNDP project or activity, in whole or in part, is the focus of investigation for alleged fraud/corruption, each responsible party, subcontractor and sub-recipient will inform the UNDP Resident Representative/Head of Office, who will promptly inform UNDP's Office of Audit and Investigations (OAI). It will provide regular updates to the head of UNDP in the country and OAI of the status of, and actions relating to, such investigation.

h. *Choose one of the three following options:*

*Option 3:* UNDP will be entitled to a refund from the responsible party, subcontractor or sub-recipient of any funds provided that have been used inappropriately, including through fraud or corruption, or otherwise paid other than in accordance with the terms and conditions of the Project Document. Such amount may be deducted by UNDP from any payment due to the responsible party, subcontractor or sub-recipient under this or any other agreement.

Where such funds have not been refunded to UNDP, the responsible party, subcontractor or sub-recipient agrees that donors to UNDP (including the Government) whose funding is the source, in whole or in part, of the funds for the activities under this Project Document, may seek recourse to such responsible party, subcontractor or sub-recipient for the recovery of any funds determined by UNDP to have been used inappropriately, including through fraud or corruption, or otherwise paid other than in accordance with the terms and conditions of the Project Document.

*Note:* The term "Project Document" as used in this clause shall be deemed to include any relevant subsidiary agreement further to the Project Document, including those with responsible parties, subcontractors and sub-recipients.

i. Each contract issued by the responsible party, subcontractor or sub-recipient in connection with this Project Document shall include a provision representing that no fees, gratuities, rebates, gifts, commissions or other payments, other than those shown in the proposal, have been given, received, or promised in connection with the selection process or in contract execution, and that the recipient of funds from it shall cooperate with any and all investigations and post-payment audits.

j. Should UNDP refer to the relevant national authorities for appropriate legal action any alleged wrongdoing relating to the project or programme, the Government will ensure that the relevant national authorities shall actively investigate the same and take appropriate legal action against all individuals found to have participated in the wrongdoing, recover and return any recovered funds to UNDP.

k. Each responsible party, subcontractor and sub-recipient shall ensure that all of its obligations set forth under this section entitled "Risk Management" are passed on to its subcontractors and sub-recipients and that all the clauses under this section entitled "Risk Management Standard Clauses" are adequately reflected, *mutatis mutandis,* in all its sub-contracts or sub-agreements entered into further to this Project Document.