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DOCUMENT

Satellite-Enhance Telemedicine and eHealth for sub-Saharan Africa (eHSA) Programme

Study on Regulatory Aspects

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2 BACKGROUND

Regulatory aspects, including the legal, social, ethnical and cultural environments, are essential assets when addressing the possibilities of success and the viability of specific eHealth projects. Even having identified an urgent and clear need for a certain type of service, and even if the solution is the most adequate from a technical point of view, an adverse or weak regulatory environment may appear to be the showstopper for any implementation and operation [RD-5].

2.1 Context and Purpose of this Document

The study on regulatory aspects described in this document will outline and analyse the regulatory situation regarding the implementation and operation of eHealth services in the entire sub-Saharan Africa. This will be a necessary input when planning the phase 2 of the eHSA programme.

2.1.1 Context and Rationale

The eHSA Programme is a key recommendation of the Telemedicine Task Force (TTF)[1], a group which was set up in June 2006 with a view to developing a complete picture of telemedicine opportunities in Sub-Saharan Africa and formulating recommendations for further implementation [RD-1], [RD-2]. Key elements of this effort are strong African ownership, contribution to Millennium Development Goals (MDGs) of the United Nations, and to counteract the workforce shortage in the region. The final goal of the eHSA Programme is to enable the development of a satellite-enhanced eHealth and telemedicine infrastructure for the benefit of the Sub-Saharan African region. This infrastructure shall be capable to deliver a variety of services for education, clinical services, surveillance and management to the Sub-Saharan citizens and health workers. This goal should be reached in full coherence with the strategic priorities of the socio-economic development of the Sub-Saharan African region [RD-3].

[1] The TTF was composed of representatives from: the African Union Commission (AUC), the New Partnership for Africa's Development (NEPAD), the African Development Bank (AfDB), the Communauté Economique et Monétaire de l'Afrique Centrale (CEMAC), the Organisation de Coordination pour la lutte contre les Endémies en Afrique Centrale (OCEAC), the East African Community (EAC), the Economic Community of West African States (ECOWAS), the Secretariat of the African, Caribbean and Pacific Group of States (ACP Sec), the World Health Organization (WHO), the European Commission (EC) and the European Space Agency (ESA).

2.1.2 Purpose of this Document

This Statement of Work (SoW) has been created in the context of the Delegation Agreement between the Luxembourg Agency for Development Cooperation (Lux-Dev) and the European Space Agency (ESA) for the implementation of the first phase of the Satellite-Enhanced Telemedicine and eHealth for Sub-Saharan Africa Programme (eHSA) funded by the EU-Africa Infrastructure Trust Fund (ITF) and the Government of Luxembourg.

2.2 ESA's involvement in eHealth

Over the last decade through several ESA programmes space technologies have been successfully applied to a small number of health-related scenarios. For instance, in the ARTES programme different projects have been initiated to explore and promote the different facets of telemedicine via satellite. The projects aimed at developing hardware, software and content required by the specific telemedicine applications and then using the created system in a pilot utilisation phase with real users under real operational conditions. The new Integrated Application programme is further reinforcing the link with the relevant health communities.

In spite of the potentials offered by space in supporting applications in the field of health ([RD-6]), until today the health sector has seen neither significant utilisation of space technologies nor systematic analyses of needs for space assets. Beside cost considerations, this might mainly be caused by health professionals' limited awareness of space capabilities on one side, and by limited understanding of user needs and regulatory issues by the space actors on the other side. Without a comprehensive understanding of the healthcare domain the chances of a breakthrough in the utilisation of space assets are very limited. In this situation, contributing to paving the way for eHealth and telemedicine service penetrations in developing countries is a significant opportunity for promoting space infrastructure for societal benefit.

2.3 eHealth for Africa

eHealth and telemedicine development has brought hopes to developing countries and their most remote areas. Advanced technologies such as electronic medical records, decision support systems, diagnostic imaging and biosignals, mobile computing, and robot-assisted medical procedures have changed the hospitals and the operating theatres around the Western world. Geographic distance has significantly lost impact on service provision.

However, the global society has not followed the industrial world and its broadband rush. As globalization moves on toward an information society without digital divide, hope and goal are that the gap between developed and developing countries will shrink. The MDGs have set out concrete, measurable objectives to support such development. Sub-Saharan Africa is one of the world's regions which need comprehensive action in order reach these goals [RD-7].

In this respect, it must be noted that there are millions of people in sub-Saharan Africa who live in areas that do not provide the commercial potential for in-vestment in ICT infrastructures in the short to medium term. These people are also likely to live in areas with a lack of health and transport infrastructure, making a trip to the closest hospital a time intensive and expensive journey. The availability of an appropriate ICT infrastructure can allow the sub-Saharan population the access to various services, including eHealth. Just to illustrate this situation, currently just over half of the sub-Saharan African population are covered by the mobile phone network which leaves about 350 million outside of the network coverage. This number will be expected to shrink as mobile networks grow, though this is likely to be at a decreasing rate on an aggregate level as the networks initially reach the most populated and easy-to-access areas first.

Sub-Saharan Africa has significant social and economic development potential but currently faces a number of barriers preventing them to play a more significant role in the global economy. The serious health problems which are evident across the African continent are one of the most critical among such barriers. The MDG already acknowledges the importance of Health explicitly in three out of the eight specific goals: reduction of child mortality; improve maternal health and; combat HIV/AIDS, malaria and other diseases.

The poor health situation is reflected both in high concentrations of communicable diseases and the sparse average health outcomes across the populations, especially amongst disadvantaged groups such as rural dwellers, the poor, women and children. In many places, there are insufficient human and financial resources to apply the required levels of healthcare needed to address these issues. This is often exacerbated in more remote areas where infrastructure have proved insufficient to provide the health-care services required, therefore raising significant barriers to delivery.

Addressing the needs of these areas and populations requires both providers of appropriate medical services and products, and also the means to effectively deliver the requested services to all communities, near and far, that need them.

In this context, ICT offers significant opportunities and the potential for world-wide advancement in health and healthcare. eHealth, i.e. the use of ICT for clinical, educational and administrative purposes within the health sector, both locally and at a distance, is a key enabler for supporting health systems and delivery of healthcare ([RD-4]).

As precursor activity and in response to the actions described in [RD-2], a demonstration project funded by European Commission and delegated to ESA[2] is currently running in order to demonstrate the feasibility of satellite technology to extend the reach of eHealth and to contribute to regional efforts to overcome health workforce shortages.

[2] More information in: http://iap.esa.int/news/SAHEL_News_21022011

2.4 The eHSA Programme

The Satellite-Enhanced Telemedicine and eHealth for Sub-Saharan Africa (eHSA) Programme is a six years programme with an overall budget of 36 MEuro. This programme comprises four horizontal studies and four thematic areas. Figure 1 shows the overall programme structure.

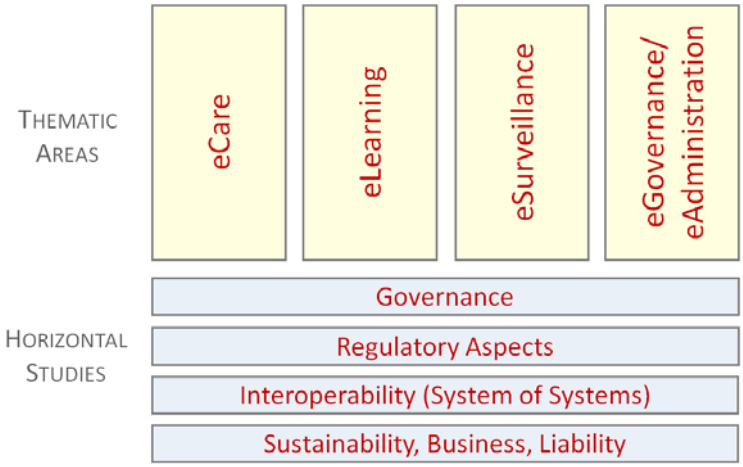

Figure 1: Overall Structure of the eHSA Programme

The programme has been designed to meet the challenges and to exploit the opportunities described in the previous section. The programme focuses on activities towards implementation of sustainable services on a scalable infrastructure. Prior to service implementation projects in thematic areas, four horizontal studies will be conducted. A rough indication of the possible timeline is shown in Figure 2.

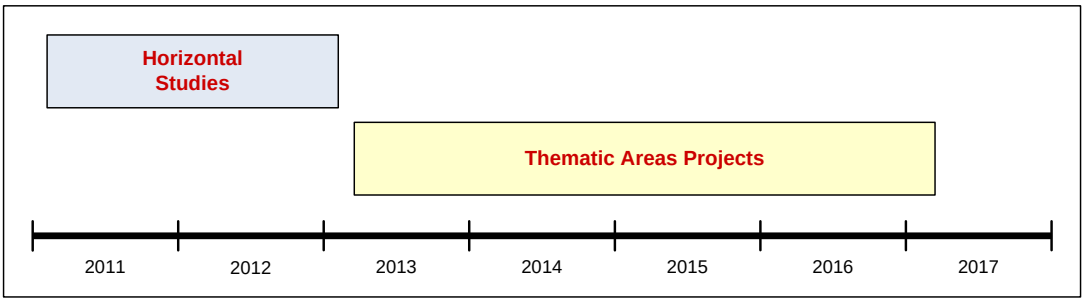

Figure 2: eHSA Programme Timeline

The four horizontal studies are cross-thematic and considered a mandatory precondition of success for the eHSA Programme. They address key issues critical to the implementation of any eHealth and telemedicine service. They will provide the backbone of the programme and emphasize sustainability of infrastructure and services as the major goal, involving the three other aspects as critical success factors. The infrastructure will also be open for services beyond eHealth and in this way contribute to the knowledge economy of the region.

Each horizontal study is expected to be conducted with a budget of 1 MEuro. The subjects to be investigated are: governance, regulatory aspects (which are specifically covered by this SoW), interoperability, and sustainability.

As coordination is of crucial importance in order to grant the necessary inputs to the different studies, the SoW corresponding to each of the four studies defines specific elements facilitating this coordination that will be enabled via ESA.

3 GENERAL ASPECTS OF THE REGULATORY STUDY

3.1 Introduction

Regulatory aspects are one of the major barriers for the deployment of new eHealth services. A proper legal environment supporting aspects such as liability in connection with standards of care and medical malpractice, responsibility for security, guaranteeing confidentiality for sensible health information as well as availability of funding are important to mitigate risks when implementing or operating eHealth services.

But the existence of this legal environment is not enough. Social, ethical, cultural, gender and even environmental aspects are also of uttermost importance: even if the legal environment is favourable, societies have to be prepared to accept not only the introduction of new eHealth services, but also the impact that they will have on their lives. Any eHealth initiative must not destabilise the social, political or medical equilibrium under no circumstance ([RD-8], [RD-9]).

This eHSA study on regulatory aspects will have to address the complex regulatory environment existing in the entire sub-Saharan Africa, understanding what conditions are met to implement which services.

In conformance with [RD-2] the horizontal eHSA Programme Study on Regulatory Aspects shall:

1. Deeply analyse and assess the existing regulations (legal, social, ethical, cultural, etc.) and related authorities relevant to the implementation of eHealth services.
2. Identify regulatory aspects that are or might become critical for the programme.
3. Advice on regulatory complements in case of a lack of specific rules.
4. Evaluate the effective law enforcement capabilities and public / private sector accountability in the region.

3.2 General Requirements

The study must meet general requirements:

- The study shall pave the way to the identification of promising cases of eHealth services and their environment to be considered in phase 2 of the eHSA programme.
- The work of the study must exploit recent relevant work conducted earlier by other programmes and initiatives ([RD-10], [RD-11]) as well as local partnerships to gain a deep understanding of the regulatory situation.
- All efforts in the study must be undertaken in full coherence with the health and eHealth political agendas of the sub-Saharan African countries, Regional Economic Communities (RECs), and the African Union relevant policies ([RD-4], [RD-12], [RD-13], [RD-14]).
- State-of-the-art modelling methods and tools have to be used, such as UML[3], BPML[4] or others. All models and designs of any kind created during the study (structures, processes, etc.) have to be delivered (in addition to the technical reports) in the source format of the modelling tools.

The study must be carried out in full awareness of its outstanding importance which is considered very critical to the entire eHSA Programme.

3.3 General Benefits

In order to achieve its objectives, it is important that this study provides an overview on the regulatory framework needed to provide eHealth services. This basis is essential to provide a comprehensive review on the sub-Saharan regulatory situation affecting eHealth, and to suggest specific actions towards the implementation of a complete regulatory framework supporting eHealth.

In addition to this, the analysis of the regulatory situation in sub-Saharan Africa will help to identify the most promising scenarios for the implementation of the fertilisation projects framed in the second phase of the eHSA programme.

Regulatory aspects in sub-Saharan Africa an essential not only to the eHSA programme objectives, but also to any initiative attempting to create sustainable eHealth services in the entire region.

4 WORK DESCRIPTION

The main scope of the eHSA Regulatory Aspects Study is to analyse the overall processes which constitute the implementation and operation of the different classes of eHealth services in full compliance with existing and expected (if not yet existing) laws, rules,

[3] UML: Unified Modelling Language
[4] BPML: Business Process Modelling Language

regulations and common practices (regulatory environment) in the entire sub-Saharan Africa. To achieve this goal, the following objectives have been defined:

1. Propose a reference regulatory model for the provision of eHealth services in their overall dimension investigating the necessary aspects regulatory environments shall cover. Refine the model with the analysis of a number of worldwide reference regulatory environments.

2. Identify those of the sub-Saharan African countries where the provision of eHealth services could be implemented and welcomed in full compliance with the existing regulatory framework[5]. In the same ambit, identify social behaviours (such as ethnic, religious, tradition and relevant common practices) having impact on the provision of these eHealth services not constituting a significant barrier. This identification shall be done through a comparative analysis based on duly identified best practice examples covering different classes of eHealth services (nominally eLearning, eCare, eSurveillance, eAdministration/eGovernance);

3. On the basis of the reference regulatory model identified at point 1., describe in full details and perform a critical review of all the processes to be followed in sub-Saharan countries in order to implement and operate the above mentioned classes of eHealth services, in conformance with the existing regulatory environments;

4. Advice on suitable roadmaps for sub-Saharan countries where a complete provision of these eHealth services cannot yet be fully supported by the existing rules and regulations. These roadmaps shall describe how to enhance the existing regulatory framework in order to create a fertile environment for the establishment of eHealth services.

The scope of the activities of this study shall be performed following an approach covering two major steps, defined in the following subsections 4.2 and 4.3 on the basis of the general requirements presented in section 3.2.

The contractor shall undertake a programme of work lasting no more than 12 months for the execution of the activity.

The overall study logic is divided in two steps as illustrated in Figure 3.

[5] All rules covering the active (i.e. technicians, practitioners, etc.) and passive (patients) roles related to these activities

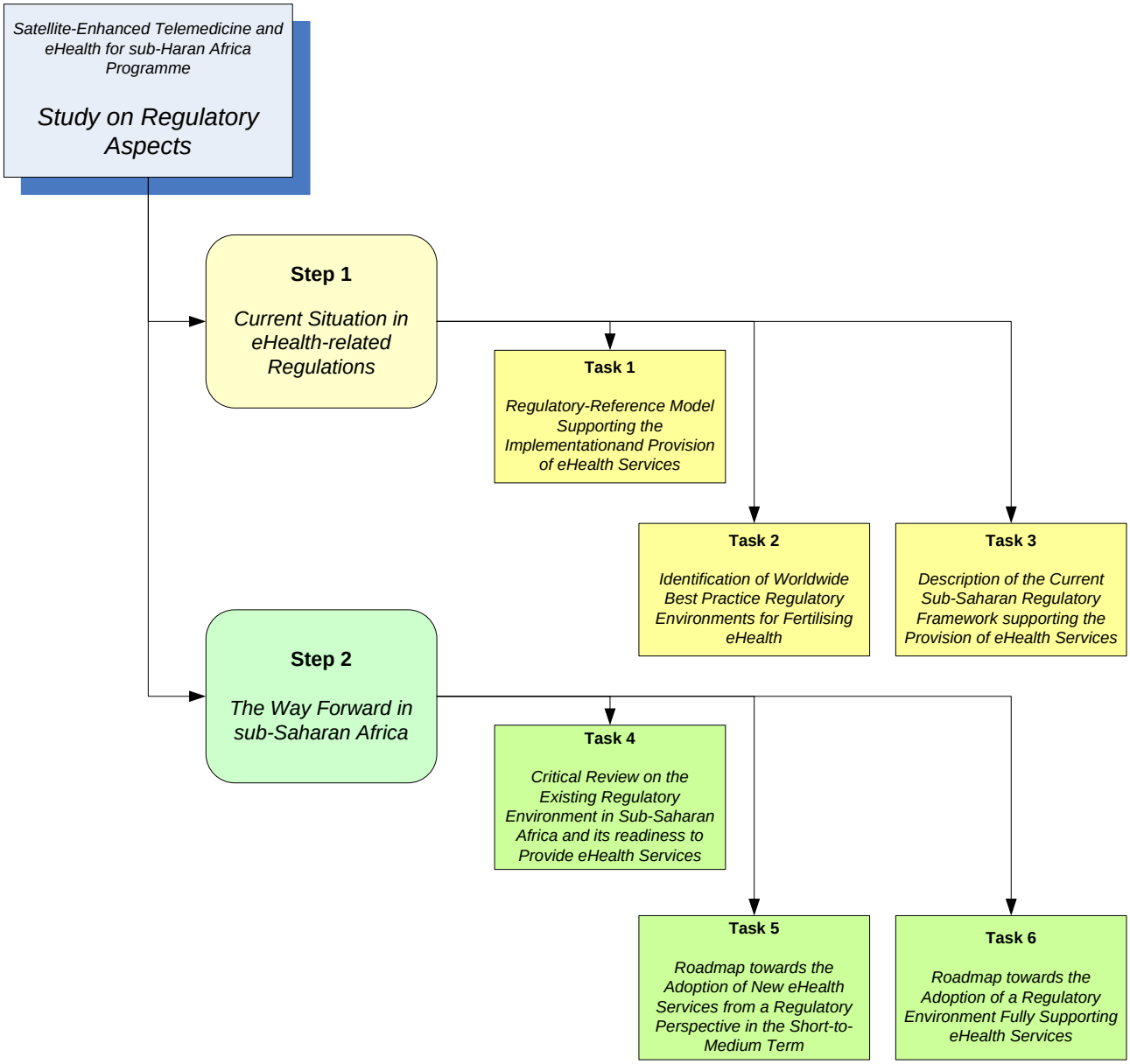

Figure 3: Regulatory Aspects Study Logic

4.1 Terms and Conventions

The present Statement of Work (SoW) contains a list of reference terms in Section 6.2. In addition to that, the following conventions will be adopted:

For convenience, *regulatory environment* or simply *regulations* will be understood as the legal aspects (laws, rules), regulations (administrative regulations) and social behaviours (such as ethnic, religious, tradition and relevant common practices and others) that might have an impact in the provision of eHealth services.

The *entire eHealth dimension* shall be understood not only as the adoption / provision of specific services but also all the non-Health related aspects that might have an impact in the provision of these services. Amongst others, these non-Health related aspects include commitments and rights of active (i.e., technicians, practitioners, etc.) and passive (i.e., patients, etc.) stakeholders, forms of service provision, labour markets, procurement processes, taxation, telecommunication service provision, data privacy protection, public / private sector accountability, effective law enforcement capabilities, cultural aspects, funding mechanisms, etc.

4.2 Step 1: Current Situation Concerning eHealth-related Regulations

Mission:

Describe the global and sub-Saharan situation regarding evidence and best practices in regulatory environments affecting eHealth services.

Objectives:

- Propose a regulatory model covering the whole eHealth dimension that could be used later as a basis for the analysis of the situation in sub-Saharan Africa.
- Identify the worldwide most fertile environments for supporting and consolidating eHealth services while analysing the critical success factors and key challenges of these environments.
- Describe in full detail the current regulatory situation in sub-Saharan Africa regarding the provision of eHealth services.

Rationale:

A reference model is required to describe the current regulatory situation concerning eHealth services in sub-Saharan Africa. This model will be the basis to analyse later the readiness of these regulatory environments concerning eHealth. The identification of successful regulatory environments worldwide can help to build such reference (See [RD-15], [RD-16], [RD-17], [RD-18], [RD-19], [RD-20], [RD-21]).

Approach:

Based on existing accepted categories of services that could be realistically expected to be provided in the sub-Saharan Africa (namely eLearning, eCare, eSurveillance, eAdministration/eGovernance), a reference regulatory model identifying the elements subject to be regulated in these services shall be proposed. This reference model shall address basic and suitable aspects concerning the entire eHealth dimension.

To prove up to a reasonable extent the completeness of this reference model, it is expected to compare and complement it using at least 4 – 5 examples of countries worldwide, continentally representative, whose regulatory environments are considered as a reference. The choice of these example shall be justified in terms of completeness, proven fertility to provide eHealth services, its compliance with social elements and possibly further criteria to be defined and justified by the bidder.

In parallel to this, the full regulatory environment situation concerning the provision of eHealth services in sub-Saharan Africa shall be described at all levels of competence and authority (local, district, national and regional), always in the terms of the reference model already proposed. This will be a basic input to analyse later the regulatory situation in sub-Saharan Africa.

The exact scope of the work will be described later in Tasks 1 to 3 (sections 5.1.1, 5.1.2 and 5.1.3).

Expected Outputs:

- Reference regulatory model supporting the implementation and provision of eHealth services.
- Justified examples representing at least 4 – 5 countries worldwide and continentally representative regarding eHealth regulatory situation, together with a detailed description of their regulatory environment situation concerning the implementation and provision of eHealth services.
- A detailed description of the current regulatory environment situation in the entire sub-Saharan Africa concerning the implementation and provision of eHealth Services.

4.3 Step 2: The Way Forward in Sub-Saharan Africa

Mission:

Provide a plan for implementation and provision of eHealth services in sub-Saharan Africa from a regulatory perspective, taking into account the relevant social elements.

Objectives:

- Perform a comparative analysis between the current regulatory environment situation in sub-Saharan countries and both the regulatory model already identified and the regulatory situation in the countries identified worldwide as reference.
- Provide a ranking of the sub-Saharan countries by regulation-related readiness for implementation and operation of the different types of eHealth services. This ranking shall indicate for each of the sub-Saharan countries which types of eHealth services could be implemented and adopted in full compliance with the current

status of their relevant regulatory environment. This shall include as well social behaviours affecting their provision (ethnic, religious, traditional and other common practices). Describe exhaustively all regulation-compliant processes needed to provide eHealth services at all levels of competence and authority in the entire sub-Saharan Africa.

- Suggest a roadmap for those countries where a complete provision of eHealth services can currently not be fully supported. The roadmap shall include concrete indications on how to enhance the current relevant regulatory framework (particularly, but not exclusively, the accountability of public / private sector and their capability to enforce regulations) further to fertilise such services.

Rationale:

It is necessary to understand from the current regulatory environment existing in sub-Saharan Africa the opportunities offered, the set constraints as well as what is currently missing for the implementation and operation of eHealth services in sub-Saharan Africa. In the same line, the way to overcome barriers within the existing regulatory environments in sub-Saharan African countries shall be investigated.

Approach:

Based on the findings from Step 1 (Section 4.2), the existing sub-Saharan Africa regulatory environment providing eHealth services (including all associated dimensions) shall be compared with the identified references (regulatory model as well as regulatory environment in reference countries worldwide). This analysis shall provide a justified ranking of the sub-Saharan countries indicating, in order of priority, in which of them the referred eHealth services could be implemented and welcomed in full compliance with the current status of the relevant regulatory framework.

Based on the results of the ranking, a description in form of a justified roadmap shall be done, reflecting all necessary regulatory-compliant processes supporting their adoption and later operation. The roadmap shall look forward into a realistic short-to-medium term implementation of eHealth services in those sub-Saharan countries with a higher degree of readiness from a regulatory perspective. This roadmap shall cover all levels (local, district, national and regional where possible) and shall indicate all relevant authorities involved. The roadmap shall target only those services that can currently be supported from a regulatory perspective.

The case that regulatory situation concerning the adoption of eHealth services in some of the sub-Saharan countries may not be ready or may be only partially ready shall be considered as well (i.e., some eHealth services can be implemented, some others not). In this case, a second roadmap shall be suggested targeting a full regulatory support of eHealth services at sub-Saharan scale. This roadmap shall include concrete indications on how to fertilise such services at all levels and reflecting the role of the required authorities.

The exact scope of the work will be described later in Tasks 4 to 6 (sections 5.2.1, 5.2.2 and 5.2.3).

Expected Outputs:

- A well-justified ranking of the sub-Saharan countries describing their readiness to accept eHealth services from a regulatory perspective and social environment.
- A roadmap describing critically and in full detail the regulatory-compliant processes required and the accountability of the public / private sector to adopt eHealth services in the short-to-medium term in the whole sub-Saharan Africa.
- A second roadmap suggesting realistic solutions on how to enhance the current relevant regulatory framework targeting a full support to eHealth in sub-Saharan Africa.

5 RELEVANT TASKS

5.1 Step 1: Step 1: Current Situation Concerning eHealth-related Regulations

Step 1 of the study is dedicated to propose a regulatory reference model together with the investigation of reference regulatory environments supporting eHealth services worldwide as well as in sub-Saharan Africa.

5.1.1 Task 1: Regulatory-Reference Model Supporting the Implementation and Provision of eHealth Services

The contractor shall:

- Provide an analysis on the regulatory aspects and processes required to build eHealth services. These services shall belong to each of the categories of services considered within the eHSA programme or a further refinement if needed (namely, eLearning, eCare, eSurveillance, eAdministration / eGovernance).
- Build a reference regulatory model indicating those regulatory aspects to be considered when implementing and operating eHealth services belonging to the categories already mentioned.
- Illustrate the contents of this reference model with a sample of services to each identified category whose implementation can be realistically expected in sub-Saharan Africa.

Requirements:

1. Regulatory aspects and processes under identification shall engulf the entire eHealth dimension.
2. The refinement of the eHSA categories of services (eLearning, eSurveillance, eCare and eAdministration / eGovernance, 6.2Appendix B, [RD-6]), if necessary shall provide regulatory-homogeneous sub-categories.
3. The regulatory reference model shall take into account as minimum:
    a. On the general level: rules governing security, respect for human rights and protection of the citizen/patient, including: the protection of personal nominative data; regulations on the legal status of electronic documents and signatures; instruments relating to the implementation of directives and international standards, particularly in the field of security and data confidentiality, etc.
    b. On the technical level: liberalisation status of the telecommunication sector and relevant effects concerning the provision of eHealth services; independent arbitration and regulation systems for telecommunications; respect for international norms, standards and related regulations, etc.
    c. On the medical level: codes of ethics for health professionals; rules for the protection of health professionals in the exercise of their duties (radiological protection, contamination, etc.); rules governing the status of medical profession and medical records, responsibility and rights of physicians/practitioners to provide medical services without physical presence, cross—border services, etc.
    d. Other relevant aspects proposed by the bidder to be discussed and agreed with ESA.

    The regulatory reference model shall address not only the minimum necessary to provide eHealth services, but also to make considerations on the accountability of public / private sector and other aspects that can facilitate the adoption of such services.
4. A sample of types of services belonging to each of these refined categories shall be proposed to be analysed later during the study.
5. The sample shall include types of services that can be realistically expected to be implemented in the sub-Saharan Africa.
6. The refined categories as well as the sample shall be discussed and agreed with ESA.
7. Apart from the associated documentation, the contractor shall reflect all findings using an electronic modelling tool (refer to section 3.2) to allow continuous improvement and sustainability of the work to be carried out).

Outcomes:

- An extensive and justified set of aspects / processes associated to the whole eHealth service implementation and provision dimension where laws and regulations play a role (contribution to TN-1).
- A reference regulatory model addressing suitable regulatory aspects to be considered for the implementation and operation of eHealth services (contribution to TN-1)
- A justified list of categories of services including examples per category and their translation to the identified reference regulatory model (contribution to TN-1).
- An instantiation of the reference regulatory model identified using an electronic modelling tool (contribution to ED-1).
- A translation of the regulatory needs of the different services identified into the same electronic modelling tool (contribution to ED-1)

5.1.2 Task 2: Identification of Worldwide Best Practice Regulatory Environments for Fertilising eHealRoadmap toth

Based on the outcomes of Task 1 (section 5.1.1), the contractor shall:

- Identify worldwide reference regulatory environments concerning the provision of the types of eHealth services already considered in Task 1 (section 5.1.1).
- Provide an in-depth analysis of these regulatory environments, focusing especially on critical success factors and the adopted solutions.
- Refine the reference regulatory model identified in Task 1 (section 5.1.1) with the findings where necessary.

Requirements

1. Identify at least 4-5 countries whose regulatory environment supporting eHealth services can be considered as a reference. Countries shall be identified worldwide and shall be representative examples of successful adoption of eHealth services and to have successful regulatory environments supporting them. The selection shall be agreed with ESA.
2. The regulatory environments of these countries shall be put in the context of the regulatory model defined during Task 1.
3. The regulatory environments shall target the categories of eHealth services obtained during Task 1 (section 5.1.1).
4. The selection of the countries has to be described and justified in terms of:

a. Completeness of the relevant regulatory framework including the entire eHealth dimension.

b. Proven fertility of the regulatory framework concerning the implementation and operation of eHealth services. Fertility shall be addressed in terms of degrees of eHealth service adoption and coverage under this regulation.

c. Challenges these countries faced / are facing concerning the support of the entire eHealth dimension

The contractor shall justify assumptions and rationale for the proposed approach.

5. The analysis shall address the strengths, weaknesses, opportunities and threats on the implementation and operation of eHealth services vs. the regulatory environment of the selected countries.
6. The analysis shall address the role of regulatory-relevant stakeholders (i.e. authorities, etc.) and other eHealth-related stakeholders (i.e. technicians, practitioners, patients, etc.)
7. The analysis shall cover as well possible funding sources and their connection to the regulatory environment (e.g., social security, governmental funds, etc.) as well as additional relevant actors in the decision making process (e.g. national health programmes, international cooperation frameworks, political agendas)
8. The overview shall address not only the existing regulatory environment, but also possible regulatory initiatives under discussion.
9. Apart from the associated documentation, the contractor shall reflect all findings using an electronic modelling tool (refer to section 3.2).

Outcomes:

- A justified list of countries whose regulatory environment supporting the full dimension of eHealth regarding service provision (Task 1, section 5.1.1) that can be considered a reference (contribution to TN-2).
- An in-depth analysis of the regulatory environment supporting eHealth services (Task 1, section 5.1.1) in the countries of the list (contribution to TN-2).
- A translation of the regulatory situation in these countries in terms of the reference model defined during Task 1 (section 5.1.1) using the same electronic tools (contribution to ED-1).
- A refinement of the Reference Regulatory Model defined during Task 1 (section 5.1.1) where necessary (contribution to TN-1 and ED-1)
- An instantiation of Task 2 identification and analysis results using an electronic modelling tool (ED-1).

5.1.3 Task 3: Description of the Current Sub-Saharan Regulatory Framework Supporting the Provision of eHealth Services

Based on the outcomes of Task 1 (section 5.1.1), the contractor shall describe in full detail the current regulatory situation in sub-Saharan Africa related to eHealth services.

Requirements:

1. The contractor shall compile and describe the regulatory situation in the whole sub-Saharan Africa[6] at all levels (local, district, national and regional) supporting the considered eHealth services.
2. The description shall cover, for each category of service identified during Task 1 (section 5.1.1):
    a. Existing relevant regulatory framework, including the entire eHealth associated dimensions.
    b. eHealth service regulatory coverage per country under existing rules and regulations.
    c. Social aspects such as ethnicity, religion, traditions and other common practices, together with an evaluation of their impact on the provision of eHealth services.
    d. The role of regulatory-related stakeholders (authorities, etc.) as well as other active / passive players.
    e. Funding sources and their connection to the regulatory environment (e.g., social security, governmental funds, national and international programmes, etc.)
    f. Cross-border relations and cooperation between different countries.
3. The analysis shall address not only the existing regulatory environment, but also possible regulatory initiatives under discussion.
4. The contractor shall justify his own level of confidence on the performed analysis.
5. Apart from the associated documentation, the contractor shall reflect all findings using an electronic modelling tool (refer to section 3.2).

Outcomes:

- A fully detailed description of the regulatory environment supporting eHealth services (Task 1, section 5.1.1) in the whole of the sub-Saharan Africa (TN-3).

[6] South Sudan will be an independent country starting from 09/07/2011, becoming the 48th sub-Saharan country.

- An instantiation of Task 3 identification and analysis results using an electronic modelling tool (ED-2).

ESA's approval is required to proceed with the tasks associated to step 2 of the study.

5.2 Step 2: The Way Forward in Sub-Saharan Africa

5.2.1 Task 4: Critical Review on the Existing Regulatory Environment in Sub-Saharan Africa and its Readiness to Provide eHealth Services

Using as starting point the findings done during Step 1 (5.1), the contractor shall compare and critically review the currently existing sub-Saharan regulatory environment (Task 3 (section 5.1.3)) with the identified references (reference regulatory model (Task 1, section 5.1.1)) and the worldwide examples of reference regulatory environments (Task 2, section 5.1.2)). This analysis shall reveal the most promising countries where eHealth services can be implemented from a regulatory perspective.

Requirements:

1. The whole sub-Saharan Africa shall be analysed.
2. The review shall be done at different levels (local, district, country and regional) where applicable.
3. The review shall be done in terms of the regulatory model defined in Task 1 (section 5.1.1).
4. The review shall address the categories of services identified in Task 1 (section 5.1.1).
5. The review shall address the strengths, weaknesses, opportunities and threats on the implementation and operation of eHealth services in the sub-Saharan Africa in comparison with the reference regulatory model (Task 1, section 5.1.1) and the reference regulatory environments identified (Task 2, section 5.1.2).
6. The methodology to be used for the ranking shall be fully described and justified.
7. The ranking out of the comparative analysis shall address in a justified way:
    a. The readiness of each country to adopt eHealth services from a regulatory perspective.
    b. The regulatory constraints to be faced, the expected degree of risk in the implementation / operation of eHealth services and their criticality.

c. The current regulatory initiatives under discussion, either on the political agenda, or in the process of being approved, including the accountability of relevant stakeholders to enforce these initiatives.

d. Funding sources and their connection to the regulatory environment.

e. Other aspects proposed by the bidder to be discussed and agreed with ESA

The analysis on the regulatory environment shall include the overall eHealth dimension.

8. The contractor shall provide a justified level of confidence for each entry in the provided ranking and for the ranking as a whole.

Outcomes:

- A justified ranking of the sub-Saharan countries illustrating the readiness of these countries to adopt new eHealth services (Task 1, section 5.1.1) from a regulatory perspective (TN-4).

5.2.2 Task 5: Roadmap towards the Adoption of New eHealth Services from a Regulatory Perspective in the Short-to-Medium Term

Starting from the results of the ranking performed in Task 4 (section 5.2.1), and the regulatory model identified during Task 1 (section 5.1.1) the contractor shall illustrate the regulatory requirements needed to adopt new eHealth services in those countries ready to do so. This illustration shall be done by means of a roadmap showing all necessary steps from a legal / social perspective.

Requirements:

1. The roadmap shall focus only on those countries ready to adopt totally or partially eHealth services (Task 1, section 5.1.1), according to the results of Task 4 (section 5.2.1).
2. The roadmap shall describe all kinds of authorisations, licenses, requirements, constraints, commitment and qualifications requested by the applicable regulatory environment. Specific time scales required to obtain them shall be included where applicable.
3. The roadmap shall address consultations with relevant recognised authorities. The approach to and the involvement of these authorities shall be described and justified.
4. The roadmap shall consider the accountability of the public / private sector and their capability to enforce of regulations.

5. The contractor shall investigate simple short-term strategies to overcome regulatory constraints identified during (section 5.2.1) where possible. The aim is to facilitate as much as possible the implementation / operation of new eHealth services. These strategies shall always be compliant with the existing legal and socio-cultural environment.
6. The roadmap shall deal as well with the social environment and the funding sources.
7. The contractor shall justify the applied approach and the degree of confidence achieved with it.
8. The roadmap shall include a tentative frame reference for these actions to take place, assuming a "business as usual" scenario.
9. The roadmap shall be illustrated with examples belonging to each of the categories of services identified during Task 1 (section 5.1.1). These examples should not be necessarily existing or under implementation. The examples to be used shall be discussed and agreed with ESA.
10. The examples shall be used to identify, locate and categorise risks associated to the adoption and operation of eHealth services from a regulatory perspective (taking into account the entire eHealth dimension). The contractor shall provide and justify figures regarding risk severity and risk probability, together with mitigation actions / strategies.

Outcomes:

- Roadmap towards the adoption of eHealth services from a regulatory perspective in the short-to-medium term in sub-Saharan Africa (TN-5).
- An instantiation of Task 5 identification and analysis results using an electronic modelling tool (ED-3).

5.2.3 Task 6: Roadmap towards the Adoption of a Regulatory Environment Fully Supporting eHealth Services

For those countries not ready from a regulatory and social perspective, as shown during the analysis done in Task 4 (section 5.2.1), to adopt eHealth services, the contractor shall provide a roadmap with concrete indications on how to enhance the current relevant regulatory framework further to fertilise the adoption of such services.

Requirements:

1. Starting from the results of Task 4 (section 5.2.1) and Task 5 (section 5.2.2) identify for each sub-Saharan country the missing regulatory environment as well as the accountability of the public / private systems and enforced regulations not allowing

a full support of the examples of services (Task 1, section 5.1.1) in line with the reference regulatory model identified during Task 1 (section 5.1.1),

2. Describe how this missing regulatory environment is covered in the worldwide reference regulatory environments identified during Task 2 (5.1.2).
3. Justify the possibilities of the solutions adopted within these worldwide reference regulatory environments to be realistically implemented in the different sub-Saharan African countries.
4. For those aspects that cannot be covered with the reference, propose and justify a set of realistic indications on how to adopt a fully eHealth supportive regulatory environment.
5. Any justification shall be done in terms of:
    a. Relevant stakeholders at different levels (local, district, country, region).
    b. Readiness from the legal / social environments to adopt such initiatives.
    c. Availability of funding to support these initiatives (national / international).
    d. Frame references required for such changes.
    e. Other relevant aspects proposed by the bidder, to be discussed and agreed with ESA.
6. Provide a fully justified roadmap compiling all the discussed indications for the enhancement of the regulatory environment in sub-Saharan Africa facing the adoption of new eHealth services.
7. The contractor shall indicate his / her level of confidence on the provided roadmap solutions.
8. Apart from the associated documentation, the contractor shall reflect all findings using an electronic modelling tool (refer to section 3.2).

Outcomes:

- Roadmap towards the full regulatory support of eHealth (Task 1, section 5.1.1) in sub-Saharan Africa (TN-6).
- An instantiation of Task 6 identification and analysis results using an electronic modelling tool (ED-3).

6 REQUIREMENTS FOR MANAGEMENT, REPORTING, MEETINGS AND DELIVERABLES

Applicable Management, Reporting, Meetings and Deliverables are included in the Contract.

The list of deliverables is reproduced here for convenience.

Reference	*Title*	*Type*
TN-1.	eHealth Services Reference Regulatory Model	Document
ED-1	eHealth Services Reference Regulatory Model in Electronic Format(*)	Document / Software
TN-2.	Description of the Regulatory Situation Concerning eHealth in Various Reference Countries.	Document
TN-3.	Description of the Regulatory Situation Concerning eHealth in Sub-Saharan Africa	Document
ED-2	Regulatory Situation in Sub-Saharan Africa in Terms of the Reference Regulatory Model(*)	Document / Software
TN-4.	Sub-Saharan Conutries Ranking Concerning their Readiness to Adopt eHealth Services	Document
TN-5.	Roadmap towards the Adoption of eHealth Services from a Regulatory Perspective in the Short-to-Medium Term in sub-Saharan Africa.	Document
TN-6.	Roadmap towards the Full Legal and Regulatory Support of eHealth in sub-Saharan Africa	Document
ED-3	Roadmaps in Electronic Format(*)	Software

(*) Electronic format is referred to design files elaborated using electronic modelling tools. The contractor shall deliver all software licenses acquired for doing this job.

Table 1: Deliverable List

Title	*Type*
Final Report	Document
Executive Summary	Document
Monthly Progress Reports	Document
Minutes of Meetings (kick-off, progress, review, final presentation)	Document
Project Web Page (PWP)	Document

Table 2: Reporting deliverable list

ACRONYMS AND TERMS

6.1 Acronyms

ACP Sec	Secretariat of the African, Caribbean and Pacific Group of States
AfDB	African Development Bank
AIL	Action Item List
AU	African Union
AUC	African Union Commission
CEMAC	Communauté Economique et Monétaire de l'Afrique Centrale
COMESA	Common Market for Eastern and Southern Africa
DOI	Digital Opportunity Index
eHSA	eHealth for Sub-Saharan Africa
EAC	East African Community
EC	European Commission
ECOWAS	Economic Community of West African States
ESA	European Space Agency
EU	European Union
ICT	Information and Communication Technology
ITF	EU-Africa Infrastructure Trust Fund
ITU	International Telecommunication Union
LLU	Local Loop Unbundling
Lux-Dev	Luxembourg Agency for Development Cooperation
MDGs	Millennium Development Goals
NEPAD	New Partnership for Africa's Development
OCEAC	Organisation de Coordination pour la lutte contre les Endémies en Afrique Centrale
PR	Public Relations / Relationships
RD	Reference Document
REC	Regional Economic Community
SADC	Southern African Development Community
SSA	Sub-Saharan Africa

TN	Technical Note
TTF	Telemedicine Task Force
UN	United Nations
WHO	World Health Organisation

6.2 Glossary of Terms

Common Practice: An accepted usual or customary action or proceeding

eHealth: The cost-effective and secure use of information and communications technologies in support of health and health-related fields, including health-care services, health surveillance, health literature, and health education, knowledge and research.

Health & Safety: Health and Safety is a discipline, enshrined in primary legislation, concerned with preserving and protecting human and facility resources in the workplace. All employers are subject to the law and can be inspected.

Health Information System (HIS): A health information system includes the people, processes and technologies to collect, communicate, manage, analyze and present information for decision making. It represents sources of population based data like census, vital events registration, surveys, as well as facility based data like individual health records, health service records, and resource management records. An HIS may be referred to as a health management information system or HMIS and is also likely to be comprised of any number of subsystems.

Health System: According to WHO health systems consist of all organizations, people and actions whose primary intent is to promote, restore or maintain health . This includes efforts to influence determinants of health as well as more direct health-improving activities. A health system is therefore more than the pyramid of publicly owned facilities that deliver personal health services. Based on the functions defined in WHR 2000, the building blocks of health systems are: infrastructure; medical technologies; health workforce; health financing; information systems and stewardship (leadership and governance).

Information and Communications Technology (ICT): Includes the computers, software, data-capture devices, wireless communication devices, and local and wide area networks that move information, and the people that are required to design, implement and support these systems.

Law: The principles and regulations established by a government or other authority and applicable to a people, whether by legislation or by custom enforced by judicial decision.

Legal environment: It is the environment that is effected and controlled by the country's constitution and that consists of laws, rules and regulations and their interpretations.

Medical purposes: Medical purposes include preventive medicine, medical diagnosis, medical research, the provision of care and treatment and the management of healthcare services.

Regulatory framework: A system of regulations and the means to enforce them, usually established by a government to regulate a specific activity.

Regulators or Regulatory Authorities / Agencies / Bodies: A body that has a statutory role to ensure compliance with regulation. Their role is usually described within the relevant primary legislation or associated regulations. They may issues licenses, approvals and usually will have an Inspection.

Rules and Regulations: Any system relating to one subject; as, the medical code, a system of rules for the regulation of the professional conduct of physicians; the naval code, a system of rules for making communications at sea means of signals.

APPENDIX A - SUB-SAHARAN AFRICA

In the scope of the present study, sub-Saharan Africa is defined as the geographical space covering the following 47 countries:

1. Angola	17. Gabon	33. Niger
2. Benin	18. Gambia	34. Nigeria
3. Botswana	19. Ghana	35. Rwanda
4. Burkina Faso	20. Guinea	36. Sao Tome and Principe
5. Burundi	21. Guinea-Bissau	37. Senegal
6. Cameroon	22. Ivory Coast	38. Seychelles
7. Cape Verde	23. Kenya	39. Sierra Leone
8. Central African Republic	24. Leshoto	40. Somalia
9. Chad	25. Liberia	41. Sudan (*)
10. Comoros	26. Madagascar	42. Swaziland
11. Congo	27. Malawi	43. Tanzania
12. Democratic Republic of Congo	28. Mali	44. Togo
13. Djibouti	29. Mauritania	45. Uganda
14. Equatorial Guinea	31. Mauritius	46. Zambia
15. Eritrea	31. Mozambique	47. Zimbabwe
16. Ethiopia	32. Namibia	
(*) From 09/07/2011 Sudan will be split in two countries: Sudan and South Sudan		

Table 3: List of sub-Saharan African Countries

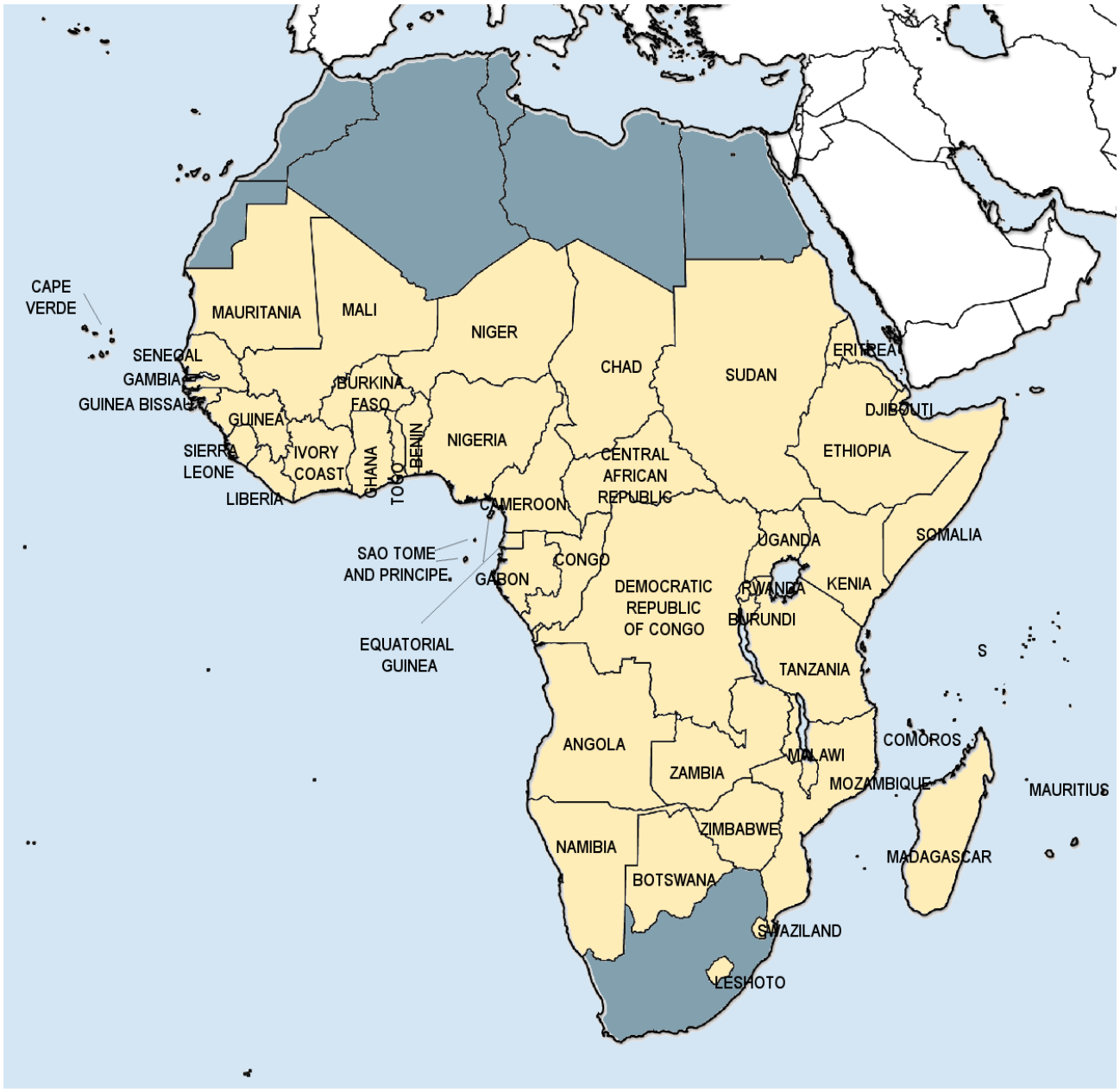

Figure 4: Sub-Saharan Africa (yellow). Source: ESA.

APPENDIX B - EHEALTH SERVICE CLASSIFICATION, CHARACTERISTICS AND EXAMPLES

Based on the four eHealth application areas considered in the eHSA programme, i.e., eCare, eLearning, eSurveillance and eGovernance/eAdministration, the following examples are given as typical representatives of eHealth service classes with largely varying conditions and requirements regarding governance, regulation, interoperability, and sustainability ([RD-6]).

eCare

Basic requirements for services:

- Sensitive contractual relationship between patient and health service provider.
- Storage and transmissions of protectec health information.
- (Typically) Strict regulations ragarding, e.g., data privacy and security, health professionals licensing, etc.
- High to highest demand for service availability (up to 24/7) and service quality.
- For emergency and remote actor applications, real-time QoS connectivity.
- (eHSA specific) Strong African ownership of service.
- (eHSA specific) Seamless incursion of remote populations via satellite communications.

Typical examples of services:

- Electronically supported self-help.
- Self-management of a chronic disease with telemedicine support.
- Telediagnosis in various specialties (e.g. radiology, dermatology, cardiology, pathology).
- Remote professional consultation and sharing of data amongst professionals, especially the provision of remote second opinions.
- Access to specialized care.
- Electronic prescription of medicines.
- Interventions assisted by an expert via telepresence (typically by videoconferencing).
- Interventions performed via actor (robot) over distance by a remote expert (e.g. telesurgery).

- Telemonitoring of vital parameters and health-related actions, especially in patients at risk.
- Telemedicine for emergency , trauma, and catastrophes.
- Access to and maintenance of electronic health records.
- Specific prevention programmes enhanced and monitored through ICT (with registration of participant).

eLearning

Basic requirements for services

- Quality of content must be assured (evidence, didactic).
- Content must be adapted to the local needs (language, culture).
- Interaction between learner and eLearning application must be intuitive.
- Specific security requirements for Internet-based exams.
- (eHSA-specific) Sufficient portion of content from African content providers.
- (eHSA-specific) eLearning services must be suitable for remote training of health workers in isolated areas via satellite communication, e.g. compliant with educational regulations.

Typical examples of services

- Certified training programs for healthcare professionals.
- Remote patient learning for preventative care and disease management.
- Remote access to high-quality health information including current literature.
- Scientific databases used by healthcare professionals for CME (continuous medical education) and research.

eSurveillance

Basic requirements for services

- Requires effective and efficient health data collection.
- Data must be anonymized and aggregated, including its geographic origin.

- Remote sensing data can be incorporated in the analysis, fusing them with health data collected by health workers and patients.
- Quality assurance on the anonymised data, regarding e.g. correctness and sufficient completeness, is mandatory.
- State-of-the-art data analysis and visualization in Geographic Information Systems (GIS).
- Early Warning Systems (EWS) detecting critical situations and triggering alarms, based on collected and data and/or earth observation data (depending on the underlying model).
- (eHSA-specific) Balanced ownership of service from global (e.g. Earth observation data acquisition) to local level (disease and health staff data acquisition and reporting).
- (eHSA-specific) eSurveillance services (e.g. GIS, EWS) must also serve remote areas via satellite connectivity.

Typical examples of services

- Public health and disease reporting.
- Electronic health statistics analysis.
- Real-time epidemiological analysis.
- Early warning systems (EWS) based on collected health & remote sensing data.
- Management of consequences to health of natural and man-made disasters.
- Geographic information systems (GIS) for presentation/visualization of data and analysis results, of different types serving different purposes, such as crisis management, general forecasts of environmental conditions for the public, or resource planning and political decision making.

eAdministration / eGovernance

Basic requirements for services

- Sensitive contractual and regulatory relationships between health service providers, health insurers, public authorities, and patients.
- Storage and transmission of protected health and financial information.
- Typically, strict regulations, e.g. regarding data transmission intervals and data formats, as well as data privacy and security (access control).
- Moderate demand for service availability.

- High demand for service reliability and accountability.
- (eHSA-specific) Preferably total African ownership of services.
- (eHSA-specific) eGovernance/ eAdministration services must support the inclusion of remote areas with scattered populations (high potential of improvement) via satellite communication.

Typical examples of services

- Billing and administrative data management to support the healthcare process.
- Aggregation and reporting of administrative data including quality indicators and clinical outcomes.
- Health information management systems to support informed decision making through access to comprehensive information.
- Services with clear impact and manageable complexity supporting advocacy for eHealth technology.