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| **Abstract:** | This document contains the policy framework design for the standardization of ITU-WHO AI-for-health assessment platform to serve as a global digital public good. |

**CONTENTS**

|  **Page** |
| --- |
| [1 Project scope 3](#_Toc138780268)[2 Motivation 3](#_Toc138780269)[3 Project goal 3](#_Toc138780270)[4 Specific objectives 3](#_Toc138780271)[5 Prospective stakeholders 4](#_Toc138780272)[6 Project background 4](#_Toc138780273)[7 Project need and relevance 6](#_Toc138780274)[8 AI regulatory sandboxes: Country-level adoption barriers and challenges 7](#_Toc138780275)[9 ITU-WHO AI4H Assessment Platform: Potential capabilities as a digital public good 8](#_Toc138780276)[10 Methodological approach 8](#_Toc138780277)[11 Policy framework design 8](#_Toc138780278)[12 Project Schedule 9](#_Toc138780279)[References 10](#_Toc138780280) |

# Project scope

This project aims at the policy framework design for the standardization of ITU-WHO AI-for-health assessment platform to serve as a global digital public good.

The ITU-WHO AI-for-health assessment platform aims to build reasonable assurance mechanisms to maintain and/or improve the performance; safety and effectiveness of AI based products/tools for health applications. One of the core objectives behind the development of ITU-WHO AI-for-health assessment platform is to make it capable of multinational deployment as a global digital public good. To serve the purpose of digital public good, the assessment platform is developed using open source software and policies. The platform also needs to be adapted to different country settings to address their specific health system challenges, needs and priorities with the support of harmonized platform standardization policy framework.

The proposed policy framework by ITU-WHO is intended to be served as a policy tool for the ministries of information technology / ministries of health / regulators of member states with the aim of providing systematic guidance on the standardized procedure and steps needed to adopt and/or adapt the ITU-WHO AI-for-health assessment platform to the country specific requirements.

# Motivation

* At the global level, there is growing consensus that the national governments should provide regulatory sandboxes, conduct ex-ante technology assessments and ex-post regulatory evaluations of AI based products in the wake of sseveral AI regulations and policies getting enacted. (E.g. the EU AI Act is set to take effect in 2023).
* Globally, there are many efforts currently pursued in the development of regulatory sandbox models (NDHB, FDA-Software Pre-Cert, UK’s NHS, ITU-WHO-AI4H Project)
* TheITU-WHOAI4H assessment platform, as a UN computing infrastructure, at the global level, is envisaged to connect large number of clinics, doctors and AI/ML domain experts and user groups in the benchmarking, ex-ante technology assessment and ex-post regulatory evaluation of AI4H products.

# Project goal

* To design a policy framework can guide and support governments and regulators with evidence based policy recommendations for the standardization of ITU-WHO AI-for-health assessment platform to serve as a global digital public good. That means the ITU-WHO AI4H assessment platform serves as a public good, when a country is able to procure the platform and customize it to country specific requirements

# Specific objectives

* To design an analytical framework to generate evidence and explain the causation of policy effects or implications across technological, economic, organizational, political and socio-cultural dimensions for the standardization of AI-for-health assessment platform as a global digital public good.
	+ What are the drivers (economic, social and ecological value and benefits) and barriers (customization, deployment, operational and maintenance cost) for adopting ITU-WHO AI4H assessment platform into a country specific health system?
* To evaluate how the policy design analytical framework can guide preparation of guidelines to standardize regulatory sandboxes to conduct ex-ante constructive technology assessments and ex-post regulation evaluations (regulatory testing, conformance, and prospective certification)of AI4H products
	+ How the ITU-WHO AI4H assessment platform-as-a-service serve as a policy tool for the verification and validation of regulatory requirements of a AI4H solutions ( i.e. act as a AI4H regulatory sandbox)
	+ Evaluate how the proposed policy recommendations helps improve the efficiency of the existing regulatory compliance process in terms of traceability and testability of AI4h product life cycle requirements specifications.
* How can ITU-WHO AI4H assessment platform be deployed as an innovative health service delivery mechanism? That means the ITU-WHO AI4H assessment platform can for instance, be deployed as Platform-as-a-Service business model in a country’s health system to serve as AI regulatory sandbox.
	+ Why is the ITU-WHO AI4H assessment platform considered a useful / best fit solution for AI4H regulatory audit for certain countries (say Norway /Germany/U.K) to be integrated into their health system (e.g. national health system) and in which cases the platform is not useful for other countries (say for Portugal/Spain) ? Which characteristics of the ITU-WHO AI4H assessment platform make it more useful for certain countries compared to other countries?
	+ How to adapt the ITU-WHO AI4H assessment platform to country specific health system requirements?
	+ What are the technological and infrastructural capabilities required for country specific health systems for platform adoption?
* Evaluate how the proposed policy guides formation of innovative business models involving multi-stakeholder engagement and institutional mechanisms towards democratizing an integrated AI-for-health technology platform to be used as a global digital public good.
	+ How the ITU-WHO AI4H assessment platform-as-a-service (digital public good) can serve as a policy tool to support business process innovation for start-ups, SMEs in the AI4H market

# Prospective stakeholders

* government agencies,
* & non-governmental organizations,
* UN agencies,
* startup incubators & accelerators,
* small and medium enterprises,
* entrepreneurs ,
* funders,
* investors, etc.

# Project background

In the last 5 years there has been significant progress in global digital health governance with the emergence of new standardization policies around the AI based technologies. Global guidance on AI technology standardization policies can help inform country-level digital health governance in better managing their digital health systems with increased transparency and accountability. In order to offer controlled autonomy to the AI industry, technical standards must be established while legislative bills are being discussed. **Technical standardization** has the capacity for **regulatory and policy diffusion** (Cantero Gamito, M. (2021).An agile interaction between the “industries and service providers” and the regulatory agency is supported by the standardization of the research process (de Almeida et al., 2021). **Standards governing AI/ ML testing, compliance management and certification** are important processes from a **regulatory assessment** point of view.

The **current structure for the international standardization of AI** is composed of the work of different Standards Development Organizations (SDOs) as well as industry consortia, forums and even individual companies. Relevant SDOs working on AI standardization are the International Standards Organization (ISO), the International Electro-technical Commission (IEC), the Institute of Electrical and Electronics Engineers (IEEE), the International Telecommunications Union (ITU), the Internet Engineering Task Force (IETF), the European Committee for Electro-technical Standardization (CENELEC) or the European Telecommunications Standards Institute (ETSI), etc.( Cantero Gamito, M. 2021).

There are **challenges at the global level for the standardization of AI product assessment methodologies and platforms**. It is desirable to have cross-sector regulation but it will be a difficult task to produce rules that are specific enough to provide clarity for industry. Also initiatives to regulate AI grow in parallel to the practices of multinational companies and their business models. With public opinion divided about AI, its governance is certainly a challenge for public regulators, who, often, do not have the capacity to regulate highly technical fields (Cantero Gamito, M. 2021).It calls for global diplomacy on international collaboration on research and innovation to meet the shared R&D challenges and update guidance on AI ethics and safety in the public sector (Kazim, E. et. al., 2021).

**A harmonized and standards based AI regulatory assessment framework or regulatory sandbox** can make it tangible and feasible to synchronize all the stakeholders’ efforts , thus culminating in the creation of a reference model of AI governance in which maturity levels could be established and be monitored by international bodies in a collaborative way(de Almeida et al., 2021).In the case of the envisaged AI-for-health assessment platform as a global public good, advanced technologies developed for the business economy may not be directly transferable to social economy applications. Hence to facilitate the translation of digital platforms and advanced technologies between the business economy and the social economy, interoperability, standards - open standards - and forward-looking safeguards are critical (Gagliardi Dimitri et al., 2020).

For **policy support**, **regulatory sandboxes** can help to **generate evidence of regulatory compliance of AI-for-health products**. At the global level, there is growing consensus that the national governments should provide **regulatory sandboxes, conduct ex-ante constructive technology assessments and ex-post regulationevaluationsof AI basedproducts**(Gagliardi Dimitri et al., 2020). From the European Union side, one of the recommendations of (Floridi et al., 2018) is to develop an EU oversight agency responsible for the protection of public welfare through the scientific evaluation and supervision of AI products, software, systems or services similar to the European Medicines Agency. Major SDOs provide not only the necessary expertise and institutional capacity for international cooperation but also the critical infrastructure for standards diffusion (Büthe&Mattli, 2011). To this extent, with the help of regulatory sandboxes regulatory bodies, social economy organizations and technology developers may learn and improve on the ways and modes technology may developed and deployed for the common good. Sandboxes are tools, where regulators tryout new regulations in collaboration with the interested party of the social economy. This regulatory tool proved to be adequate to test out regulatory and societal consequences of innovative business models before they had been implemented in society (Gagliardi Dimitri et al., 2020). The regulatory agency could make an “algorithm impact assessment questionnaire” available to the industries and government institutions in order to offer a simulation tool through which they could know, in advance, their level of compliance. It would also fit as a preparation stage for a certification submission(de Almeida et al., 2021).The national government can play a facilitator’s role in creating open technology layers like anonymisers and annotation tools, which can bring down the cost and effort required for innovators in developing and deploying solutions

For the adoption and deployment of **regulatory sandboxes made as global public goods**, regulators in respective countries will need to quickly adapt its vigilance mechanisms as a first goal (as compared to comprehensive clinical evaluations) and ensure safe deployment in the particular country setting (AbhinavVerma et. al, 2020). Regulators need to define holistic certification and benchmarking guidelines keeping in view of the global public goods (AbhinavVerma et. al, 2020). In an enabling role, the regulator also must take a forward-looking approach in building the foundational layers of the ecosystem through collaborations with other governmental, private sector and civil society players. (AbhinavVerma et. al, 2020).

Globally, there are many efforts currently pursued in the **development of regulatory sandbox models**. The NDHB is a prime example of how an enterprise architectural approach with focus on base principles, standard-setting and open source technology layers can achieve the goal of kick starting sustainable and scalable innovations on the top-most application layers. (AbhinavVerma et. al, 2020). In the Software Pre-Cert Program, FDA uses a TPLC approach to the regulation of software products especially the AI based SaMD, to assess the culture of quality and organizational excellence of a particular company and has reasonable assurance of the high quality of their software development, testing, and performance monitoring of their products (US FDA, 2019). Most recently, UK’s NHSx has called for a joint regulatory sandbox for AI in healthcare bringing together all the sandbox initiatives by different regulators and giving innovators a single, end-to-end safe space to develop and test their AI systems (Downey et al., 2020). Another proof of concept of the regulatory sandbox model is the open source AI-for-Health Assessment Platform currently being implemented by the ITU-WHO Focus Group on AI-for-Health (FG-AI4H), see Thomas Wiegand et al. (2020) and Oala et al. (2021). The assessment software platform is developed following a micro services architecture and is planned to be deployed as a full scale Software-as-a-Service (S-a-a-S).Theassessment platform would be hosted and maintained by an UN infrastructure facility at ITU. Potential user groups of the assessment platform include health AI stakeholders such as manufacturers, notified regulatory bodies and health AI standardization bodies.

Facilitating a standardized protocol for creating (writing) datasets to and accessing datasets from (querying, loading, constructing) storage by distributed clients will be a core component of this project. The WHO/ITU Global Initiative on Artificial Intelligence for Health will take a key role in aggregating expertise from national (for example ml commons, Nightingale Science, Big picture and others) and international (for example openml, Lacuna Fund, QuarepLimi, Active loop Deep lake, Lance, Parquet and others) projects to harmonize a coherent data management protocol.

# Project need and relevance

Regulation plays a significant role in ensuring patient and user safety in the commercialization and market acceptance of AI based products/tools for health applications (ITU-T, 2023). AI based health products are highly regulated and one of the major challenges that developers and manufacturers face is the timely conformance with complex and lengthy government regulatory review of these advanced technology products in the market.

Streamlined and systematic regulatory compliance processes conducted over a standardized AI-for-health (AI4H) assessment platform helps to address the product conformity assessment issues, expedite the regulatory approval process and thereby reduce the time-to-market for these products/tools (ITU-T, 2023). An AI4H assessment platform is a software platform that incorporates accountable and responsible processes for the estimation and optimization of regulatory compliance requirements and thus supports the standardized benchmarking, testing, conformance and pre-certification / certification of AI based products/tools for health applications. The software platform is targeted to be used as a universal tool, usable at scale across country borders and thereby combining the needs and expertise globally.

Standards compliance and enforcement becomes one of the important requirements for strengthening regulation and needs to be supported by formal policies. Therefore standardization of AI4H assessment platform at the global level requires a collaborative approach, joint principles and universal solutions. Standardization calls for an open and balanced consensus process that brings together interested and responsible stakeholders including government, manufacturers, researchers, policy makers, interest groups, and medical/healthcare practioners. Consensus standards help ensure user safety and interoperability across global AI/ ML deployment platforms and thus minimize the timelines for AI product technology commercialization. Harmonized standards are used by regulators as important tools that support the supervision and management of AI products. This also promotes alignment and conformance with relevant AI related standards and best practices including ISO, MDR, IEC, IEEE, IMDRF, FDA, XAVIER, AAMI, etc. The open source project on the development of AI-for-Health Assessment Platform carried out by the ITU-WHO Focus Group on AI-for-Health (FG-AI4H), see Thomas Wiegand et al. (2020) and Oala et al. (2021) is a global initiative in this direction.

This thesis project aims to propose the policy framework for the standardization of ITU-WHO AI-for-health assessment platform to serve as a global digital public good. The standardization of ITU-WHO AI4H assessment platform is intended to ensure the integrity of the standards development process in establishing the ITU-WHO AI4H assessment platform to serve as a global digital public good. Global public good in this context refers to the digital health tool that is capable of multinational deployment. That means the ITU-WHO AI4H assessment platform serves as a global public good, when a country is able to procure the platform and customize it to country specific requirements. The digital public good is developed using open source software and can be adapted to different countries and contexts to address their specific health system challenges, needs and priorities. Being open source, in general there is no cost involved in accessing the code for global good but when they are deployed as part of a particular country context (e.g. integration to national health system); there can be adaptation costs associated with aligning the tool to the target country specific policies and settings. The standardization policy thus helps to create a level playing field for both the public and private institutional mechanisms in the development of ITU-WHO AI4H assessment platform to serve as a digital public good. The research problem scope has strong relevance in achieving the goals and targets of the UN SDG 3 (Good health and well being) in terms of policy support for the standardization of accessible and affordable Global Health Information Systems and Services to support Universal Health Coverage.

We envision a process by which an independent body, for example, appointed by the government or ministries of health, adopts the proposed ITU/WHO standardization policy framework that can support the technical and structural integration of AI4H platform into the existing country level health systems and application frameworks. The provisioning of such a global public good augments the country level health systems with capability to identify the gaps in conformity assessment as well perform regulatory testing, conformance, and prospective certification of AI based products/tools in health.

# AI regulatory sandboxes: Country-level adoption barriers and challenges

* Lack of reliable regulatory complaince of global AI4H products with the existing national/regulatory guidelines of the target country is an cost intensive /expensive process
* Lack of standardized evaluation frameworks to perform technology assessment, cost–benefit analysis, cost–effectiveness analysis, risk-benefit analysis, etc of AI4h implementation outcomes
* Country specific digital technology platform architectures not fully compliant with interoperability standards to support technical and structural integration of AI4H technologies into existing national level systems and application frameworks and to assess (*call for FHIR compliance*)
* Country specific technology infrastructure systems do not fully support an integrated data collection mechanism to serve big data based AI4H training (e.g. multi-modal data collection) (*call for federated learning*)
* Lack of prototyping facilities and technology certification & transfer mechanisms for nation-wide scaling and deployment of AI4H technologies(*call for regulatory sandboxes*)
* Lack of adequate capacity building measures on the responsible use AI based technologies for public services in general (*call for platform education and training*)

# ITU-WHO AI4H Assessment Platform: Potential capabilities as a digital public good

* Service Oriented Architecture
* Software-as-a-service (SaaS) / Platform-as-a-service (PaaS) based deployment architecture
* Open Code and Open Standards based architecture
* Data lifecycle management support( data storage and data federation protocols)
* Federated learning and data catalogue service
* Integrated regulatory sandbox
* Reference library for AI4H technical standards, good practice guidelines
* Integrated support for AI4H Model development (design-develop-deploy-optimize processes)

# Methodological approach

For the proposed policy framework design, a qualitative analysis approach will be employed to generate insights evidence linking all the stages in the policy lifecycle. Due diligence regarding data collection and data analysis will be followed in adherence with the ethical compliance processes prescribed by UNU-MERIT.

The methodology shall cover the following broad methods:

1. Literature survey /document review and critical analysis
2. Qualitative data collection , processing and analysis
3. Data analysis results interpretation / mapping to policy formulation

# Policy framework design

The design of the proposed policy framework shall focus on creating a set of policies through a structured and systematic procedure of requirements analysis and modelling for all the 4 major stages of the policy lifecycle namely i) formulation ii) agenda setting , iii) implementation and iv) evaluation .

Policy design shall broadly cover the following aspects:

* Define the policy setting (political and institutional context)
* Perform stakeholder analysis, mapping by analyzing the actor type, role, interest, power ,institutional structures and resources
* Evaluate factors that foster stakeholder dialogue towards setting a common agenda , building consensus and maximizing the chance for policy legitimization
* Define the analytical framework to characterize policy dimensions and measures
* Policy dimensions shall include the following :
	+ Data and technology governance
	+ Standards Development
	+ Infrastructure
	+ Interoperability
	+ Quality assurance
	+ Digital skills competency building
	+ Risks, Fairness and Bias
	+ Business models
	+ Institutional Framework
	+ Partner and stakeholder collaboration
	+ Regulation
	+ Technology transfer and Licensing
	+ Liability
	+ Cost and benefits
	+ Social Implications
	+ Other dimensions as deemed fit
* Define policy monitoring indicators and evaluation criteria and metrics
* Evaluate mechanism for time bound implementation of policy
* Evaluate enablers / factors for successful policy acceptance
* Evaluate mechanisms to establish multi-stakeholder coordination and multi-stakeholder governance of global public good

# Project Schedule

The tentative project schedule in terms of activities, deliverables and time line is shown in Table-1.

**Table-1: Project schedule**

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| --- | --- | --- | --- |
| **No.** | **Activity / Task** | **Deliverable** | **Timeline****(Tentative)****(Year-2023)** |
| 1 | Standardization literature survey and Requirements analysis | * Critical review report with gap / need analysis
 | March 15 – June 30 |
| 2 | Qualitative data collection on stakeholder views and recommendations , processing and analysis | * Stakeholder analysis report
 | June 5–July 30 |
| 3 | Data analysis results interpretation / mapping to policy formulation | * Data quality assurance report
* Analytical codebook
 | July 15 – August 10 |
| 4 | Policy framework design | * Analytical framework design document with evaluation criteria, processes and metrics
 | July 20– August 30 |

# References

1. AbhinavVerma, Krisstina Rao, VivekEluri and Yukti Sharma (2021, July), Regulating AI in Public Health: Systems Challenges and Perspectives, Observer Research Foundation (ORF) Occasional Paper. Available at : <https://www.orfonline.org/wp-content/uploads/2020/07/ORF_OccasionalPaper_261_AI-PublicHealth_FinalForUpload.pdf>
2. Büthe, Tim, & Walter Mattli (2011) The New Global Rulers: The Privatization of Regulation in the World Economy. The New Global Rulers: The Privatization of Regulation in the World Economy Princeton University Press.
3. CanteroGamito, M. (2021). From Private Regulation to Power Politics: The Rise of China in AI Private Governance Through Standardisation. ERN: Regulation (IO) (Topic).
4. de Almeida, P.G.R., dos Santos, C.D. & Farias, J.S. Artificial Intelligence Regulation: a framework for governance. Ethics InfTechnol 23, 505–525 (2021). <https://doi.org/10.1007/s10676-021-09593-z>
5. Downey, Andrea. “Regulatory Sandbox for AI Needed to Test and Build Systems, NHSX Says.” digitalhealth.net, February 12, 2020.
6. ETSI. (2021). Types of standards. Retrieved from ETSI: https://www.etsi.org/standards/types-of-standards?jjj=1620577184012
7. European Commission. (2021, April 21). Impact Assessment of the Regulation on Artificial intelligence. Retrieved from European Commission: https://digital-strategy.ec.europa.eu/en/library/impact-assessment-regulation-artificial-intelligence
8. Floridi, L., Cowls, J., Beltrametti, M., Chatila, R., Chazerand, P., Dignum, V., Lütge, C., Madelin, R., Pagallo, U., Rossi, F., Schafer, B., Valcke, P., Vayena, Ef. (2018). AI4People—An ethical framework for a good AI society: Opportunities, risks, principles, and recommendations. Minds and Machines, 28(4), 689-707.
9. Gagliardi D., Psarra F., Wintjes R., Trendafili K., Pineda Mendoza J., Haaland K., Turkeli S., Giotitsas C., Pazaitis A., Niglia F., Cox D., (2020), New Technologies and Digitisation: Opportunities and Challenges for the Social Economy and Social Enterprises. European Commission, Executive Agency for SMEs
10. Gasser, Urs, &Virgilio A.F. Almeida (2017) “A Layered Model for AI Governance,” 21 IEEE Internet Computing 58–62.
11. Kazim, E., Almeida, D., Kingsman, N. et al. Innovation and opportunity: review of the UK’s national AI strategy. DiscovArtifIntell 1, 14 (2021). https://doi.org/10.1007/s44163-021-00014-0
12. Muller, C. (2017). Artificial intelligence–The consequences of artificial intelligence on the (digital) single market, production, consumption, employment and society. Opinion. European Economic and Social Committee.
13. Oala Luis, Andrew G. Murchison, Pradeep Balachandran, ShrutiChoudhary, Jana Fehr, AlixandroWerneckLeite, Peter G. Goldschmidt et al. "Machine learning for health: algorithm auditing & quality control." Journal of medical systems 45 (2021): 1-8.
14. Stefano NATIVI, Sarah De Nigris, AI Standardisation Landscape: state of play and link to the EC proposal for an AI regulatory framework, EUR 30772 EN, Publications Office of the European Union, Luxembourg, 2021, ISBN 978-92-76-40325-8, doi:10.2760/376602, JRC125952
15. Thomas Wiegand et al. (2020), Whitepaper for the ITU/WHO Focus Group on Artificial Intelligence for Health. Availableat:https://www.itu.int/en/ITU-T/focusgroups/ai4h/Documents/FG-AI4H\_Whitepaper.pdf
16. US FDA, (2019, April)Proposed Regulatory Framework for Modifications to Artificial Intelligence/Machine Learning (AI)-Based Software as a Medical Device (SaMD). Available at: <https://www.fda.gov/media/122535/download>
17. US FDA, (2021, January), Artificial Intelligence/Machine Learning (AI)-Based Software as a Medical Device (SaMD) Action Plan.Availableat : https://www.fda.gov/media/145022/download
18. Wiewiórowska-Domagalska, A. (2017). Online Platforms: How to Adapt Regulatory Framework to the Digital Age? European Parliament Briefing, Internal Market and Consumer Protection. doi:10.2861/645636

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