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Source:	WG-DAISAM		
Title:	Policy framework design for the standardization of AI-for- health assessment platform as a global digital public good		
Purpose:	Discussion		
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Abstract:	This presentation is about the project proposal for developing a policy framework for the standardization of FG-AI4H AI-for- health assessment platform to serve as a global digital public good.		

Policy Framework Purpose: To serve as a ITU/WHO 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 AI-for-health assessment platform to their country specific requirements

UN SDG Relevance: The standardization policy 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



Motivation:

Several AI regulations and policies (especially the EU AI Act) are set to take effect in 2023.

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.

 Globally, there are many efforts currently pursued in the development of regulatory sandbox models (NDHB, FDA-Software Pre-Cert, UK's NHS, etc apart from ITU-WHO-AI4H OCI Project)

Global Relevance:

The AI4H 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 as user groups.

Need for integration / portability / alignment of the digital health services platform with country specific / national health information systems

Country level (mostly LMICs) challenges and gaps:

- Reliable regulatory complaince of 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 Al4h 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*)

AI4H Assessment (OCI) 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)

Prospective partners & stakeholders

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

Proposed standardization policy framework: Specific objectives to address the following:

➢ How the ITU-WHO OCI AI4H Assessment Platform-as-a-Service can be transformed into an standards complaint cost-effective service delivery model (global public good) to member states as an alternative to the existing highly defragmented, expensive proprietary infrastructure platforms to conduct forecast based technology assessments and actual regulatory evaluations of AI4H products ?

➢How the proposed policy framework can guide and support governments and regulators with evidence based policymaking for the standardization of AI-for-health assessment platform to serve as a global public good

Policy framework design:

Policy design shall broadly cover the following:

✓ Define the policy setting (political and institutional context e.g EU to begin with)

✓ Perform stakeholder analysis, mapping by analyzing the actor type, role, interest, power , institutional structures and resources

Policy framework design(contd...):

✓ Define the analytical framework to characterize the following policy dimensions:

- Data and technology governance
- Standards Development
- Technology Infrastructure
- Interoperability
- Quality assurance
- Digital skills competency building
- Risks, Fairness and Bias
- Business models
- Institutional Framework

- Partner and stakeholder collaboration
- Regulation and legal support
- Technology transfer and Licensing
- Liability
- Change management
- 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

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

References:

- 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 : <u>https://www.orfonline.org/wp-</u> <u>content/uploads/2020/07/ORF_OccasionalPaper_261_AI-PublicHealth_FinalForUpload.pdf</u>
- 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). <u>https://doi.org/10.1007/s10676-021-09593-z</u>
- Downey, Andrea. "Regulatory Sandbox for AI Needed to Test and Build Systems, NHSX Says." digitalhealth.net, February 12, 2020.
- European Commission. (2021, April 21). Impact Assessment of the Regulation on Artificial intelligence. Retrieved from European Commission: <u>https://digital-strategy.ec.europa.eu/en/library/impact-assessment-regulation-artificial-intelligence</u>
- Gasser, Urs, &Virgilio A.F. Almeida (2017) "A Layered Model for AI Governance," 21 IEEE Internet Computing 58–62.
- 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.
- 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.
- 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
- Thomas Wiegand et al. (2020), Whitepaper for the ITU/WHO Focus Group on Artificial Intelligence for Health. Available at:https://www.itu.int/en/ITU-T/focusgroups/ai4h/Documents/FG-AI4H_Whitepaper.pdf
- US FDA, (2019, April)Proposed Regulatory Framework for Modifications to Artificial Intelligence/Machine Learning (AI)-Based Software as a Medical Device (SaMD). Available at: <u>https://www.fda.gov/media/122535/download</u>
- 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

Thank you