|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| ITU Logo | INTERNATIONAL TELECOMMUNICATION UNION  **TELECOMMUNICATION STANDARDIZATION SECTOR**  STUDY PERIOD 2017-2020 | | | FG-AI4H-L-049 | |
| **ITU-T Focus Group on AI for Health** | |
| **Original: English** | |
| **WG(s):** | | Plenary | | E-meeting, 19-21 May 2021 | |
| **DOCUMENT** | | | | | |
| **Source:** | | ITU-T FG-AI4H | | | |
| **Title:** | | Draft reply LS on invitation to review artificial intelligence standardization roadmap and provide missing or updated information ([SG13-LS196](https://www.itu.int/ifa/t/2017/ls/sg13/sp16-sg13-oLS-00196.zip)) [to ITU-T SG13] | | | |
| **Purpose:** | | Discussion | | | |
| **LIAISON STATEMENT** | | | | | |
| **For action to:** | | | ITU-T SG13 | | |
| **For comment to:** | | | – | | |
| **For information to:** | | | – | | |
| **Approval:** | | | FG-AI4H meeting (Online, 21 May 2021) | | |
| **Deadline:** | | | 15 January 2022 | | |
| **Contact:** | | Thomas Wiegand Fraunhofer HHI (Germany) Germany | | | Tel: +49 (30) 31002 617  Fax: +49 (30) 392 72 00  Email: [thomas.wiegand@hhi.fraunhofer.de](mailto:thomas.wiegand@hhi.fraunhofer.de) |

|  |  |
| --- | --- |
| **Abstract:** | The ITU/WHO FG-AI4H informs SG13 of its current planned deliverables and request inclusion into their artificial intelligence standardization roadmap. |

The ITU-T Focus Group on AI for Health (FG-AI4H) in partnership with WHO thanks ITU-T SG13 for its liaison statement on an invitation to review artificial intelligence standardization roadmap and provide missing or updated information (your [SG13-LS196](https://www.itu.int/ifa/t/2017/ls/sg13/sp16-sg13-oLS-00196.zip), our [FGAI4H-L-027](https://extranet.itu.int/sites/itu-t/focusgroups/ai4h/docs/FGAI4H-L-027.docx)).

In the goal to establish a standardized assessment framework for the evaluation of AI-based methods for health including diagnosis, triage or treatment decisions, the FG is working on the deliverables listed in Table 1 hereinafter. We would appreciate if the respective entries are added to your roadmap, as they will provide important guidance to implementers of software as medical device (SaMD) that use AI methods.

We remain at your disposal for further clarifications and look forward toward fruitful collaboration.

List of deliverables of the ITU/WHO Focus Group on AI for Health (status of 2021-05-21)

| Name | Title | Abstract |
| --- | --- | --- |
| [DEL00](https://extranet.itu.int/sites/itu-t/focusgroups/ai4h/Deliverables/DEL00.docx) | Overview of the FG-AI4H deliverables | This deliverable provides an overview of the various FG-AI4H deliverables. To establish a standardized assessment framework for the evaluation of AI-based methods for health, a series of deliverables is planned, including 9 generalized specifications on ethics, regulatory, requirement, data, training, evaluation, application, etc., and 20 topic description documents on specific use cases with corresponding AI/ML tasks. This document is to give a comprehensive understanding and overview on the structure, relationship, progress, and corresponding scopes on those deliverables, and improve possible collaborations. |
| [DEL01](https://extranet.itu.int/sites/itu-t/focusgroups/ai4h/Deliverables/DEL01.docx) | AI4H ethics considerations | This initial draft of the abstract describes the topics to be addressed in the forthcoming deliverable “AI for Health Ethics Considerations” to help seed future content. Digital technologies, machine learning and Artificial Intelligence (AI) are revolutionizing the fields of medicine, research and public health in an unprecedented manner. While holding great promise, this rapidly developing field raises a number of ethical, legal and social concerns, e.g. regarding equitable access, privacy, appropriate uses and users, liability and bias and inclusiveness. These issues are trans-national in nature, as capturing, sharing and using data generated and/or used by these technologies goes beyond national boundaries. The tools, methods and technologies used in “Big Data” and AI are being applied to improve health services and systems. However, many questions remain unanswered concerning the ethical development and use of these technologies, including how low- and middle-income countries will benefit from AI developments. A number of government agencies, academic institutions, NGOs and National Ethics Committees have started to address the ethical issues and challenges posed by digital technologies in general, but there remains no international guidance on the specific case of health. There is an urgent need to develop harmonised ethics guidance for the design and implementation of AI in global health. Moreover, to secure AI benefits at the global scale, a new collaborative research agenda should be established. |
| [DEL02](https://extranet.itu.int/sites/itu-t/focusgroups/ai4h/Deliverables/DEL02.docx) | AI4H regulatory best practices | This document is the current draft of the deliverable 2 on “Regulatory considerations for AI for health”. The presented document is a high-level, educational overview of some of the key regulatory considerations that can be used as a preliminary framework that can be further developed by the WG-RC together with other stakeholders. |
| [DEL02\_1](https://extranet.itu.int/sites/itu-t/focusgroups/ai4h/Deliverables/DEL02_1.docx) | Mapping of IMDRF essential principles to AI for health software | This document contains a mapping of the IMDRF Essential Principles to related aspects of AI for health software. |
| [DEL02\_2](https://extranet.itu.int/sites/itu-t/focusgroups/ai4h/Deliverables/DEL02_2.docx) | Good practices for health applications of machine learning: Considerations for manufacturers and regulators | This document contains the latest draft of the FG-AI4H deliverable DEL02.2 "Good practices for health applications of machine learning: Considerations for manufacturers and regulators". This deliverable defines a set of guidelines intended to serve the AI solution developers/manufacturers on how to do conduct a comprehensive requirements analysis and to streamline the conformity assessment procedures to ensure regulatory compliance for the AI based Medical Devices (AI/ML-MD). |
| [DEL03](https://extranet.itu.int/sites/itu-t/focusgroups/ai4h/Deliverables/DEL03.docx) | AI4H requirement specifications | This document represents the latest version of the project deliverable FG-AI4H DEL03 "AI4H requirement specification" and supersedes the previous version of the document (FG-AI4H-K-040). |
| [DEL04](https://extranet.itu.int/sites/itu-t/focusgroups/ai4h/Deliverables/DEL04.docx) | AI software life cycle specification | This document contains the proposed initial structure for the FG-AI4H Deliverable 4, "AI Software Life Cycle Specification". This document was first submitted as G-204 at the FG-AI4H meeting G in New Delhi, 13-15 November 2019. |
| [DEL05](https://extranet.itu.int/sites/itu-t/focusgroups/ai4h/Deliverables/DEL05.docx) | Data specification | The present document proposes an outline for the future deliverable "Data Specification". Background: The ITU/WHO Focus Group on Artificial Intelligence for Health (AI4H) has proposed a list of deliverables at meeting "G" in New Delhi in November 2019, including this "Data Specification", which combines a set of four deliverables as umbrella. |
| [DEL05\_1](https://extranet.itu.int/sites/itu-t/focusgroups/ai4h/Deliverables/DEL05_1.docx) | Data requirements | This initial draft describes the objectives and proposes an initial outline of the planned deliverable “Data Requirements” to help seed future content. This document lists acceptance criteria for data submitted to the FG-AI4H and states the governing principles and rules. These principles are crucial because the core of the benchmarking framework for AI for health methods will be an undisclosed test data set – per use case of each topic area to be defined – that will not be made accessible to the AI developers. |
| [DEL05\_2](https://extranet.itu.int/sites/itu-t/focusgroups/ai4h/Deliverables/DEL05_2.docx) | Data acquisition | This document contains the proposed initial structure for the FG-AI4H Deliverable 5B, “Data Acquisition”. It presents a framework for public healthcare data acquisition and management model based on standard protocol for its easy adoption by any country or international health organizations. This paper assumes basic digitization of electronic health record (EHR) at basic health facilities. There is a gap in developing an integrated and comprehensive framework that addresses the use of EHR in a standardized way for public health, privacy issue by anonymizing patient specific information, fusing multiple records with slight changes in the same information, augmenting a broad spectrum of contextual data, and so on. |
| [DEL05\_3](https://extranet.itu.int/sites/itu-t/focusgroups/ai4h/Deliverables/DEL05_3.docx) | Data annotation specification | This document describes the topics to be addressed in the forthcoming Deliverable 5.3 "Data Annotation Specification". Data annotation would be one of the most dependable factors on model performance, it serves as one important aspect of data quality control on Artificial Intelligence for health. This document is addressed to give a general guideline of data annotation specification, including definition, background and goals, framework, standard operating procedure, scenario classifications and corresponding criteria, as well as recommended metadata, etc. A questionnaire is attached to seek input and collaboration with topic groups in FG-AI4H regarding data annotation. |
| [DEL05\_4](https://extranet.itu.int/sites/itu-t/focusgroups/ai4h/Deliverables/DEL05_4.docx) | Training and test data specification | This document contains the draft version 2.0 of the project deliverable FG-AI4H DEL5.4 on "Training and test data specification". This belongs to a set of four deliverables under the umbrella of the deliverable FG-AI4H-DEL05.1 "Data specification". |
| [DEL05\_5](https://extranet.itu.int/sites/itu-t/focusgroups/ai4h/Deliverables/DEL05_5.docx) | Data handling | This document outlines how data will be handled, once they are accepted. Health data are one of the most valuable and sensitive types of data. Handling this kind of data is often associated with a strict and factual framework defined by data protection laws. It is important to set a strict data policy which will ensure confidence in FG-AI4H not only among contributors, but across all stakeholders. There are two major issues that the data handling policy should address: (a) compliance with regulations dealing with the use of personal health data; and (b) non-disclosure of the undisclosed test data held by FG-AI4H for the purpose of model evaluation. |
| [DEL05\_6](https://extranet.itu.int/sites/itu-t/focusgroups/ai4h/Deliverables/DEL05_6.docx) | Data sharing practices | AI solution developers for healthcare understand what an important role sharing data plays in their success. In addition to patients, healthcare organizations, government agencies realize the value of sharing data when considering the beneficial outcomes. This deliverable provides guidance for existing industry best practices for the sharing of health-related data. It outlines the roles of each party with respect to the data provider, processor, and receiver while exploring traditional and novel approaches leveraging distributed and federated methods for developing privacy-preserving AI/ML models. |
| [DEL06](https://extranet.itu.int/sites/itu-t/focusgroups/ai4h/Deliverables/DEL06.docx) | AI training best practices specification | Machine learning models for AI in Health are deployed in high-impact tasks. As a result, it is important to follow best practices for training and documentation so as to achieve maximum performance and transparency. The first part of this document provides a review of best practices for proper AI model training. The second part of this document provides guidelines for model reporting. This document was first submitted as I-032 at the FG-AI4H meeting I (e-meeting), 7-8 May 2020. |
| [DEL07](https://extranet.itu.int/sites/itu-t/focusgroups/ai4h/Deliverables/DEL07.docx) | AI for health evaluation considerations | This introduction with considerations on the evaluation of AI for health sets the scene for the five related documents DEL07.1-5 that describe the evaluation process (DEL07.1), the technical tests (DEL07.2), the test metrics (DEL07.3), the clinical evaluation (DEL07.4), and an assessment platform (DEL07.5) in detail. In this document, an overview of the deliverables DEL7.1-5 is given, preliminary considerations on the evaluation process are being made, characteristics of health AI validation and evaluation that are novel are identified, and the concept of standardized model benchmarking is introduced. Moreover, requirements for a benchmarking platform are considered in detail and best practices for the health AI model assessment are collected from selected sources. This document was submitted as L-036 at the FG-AI4H meeting L (e-meeting), 19-21 May 2021. |
| [DEL07\_1](https://extranet.itu.int/sites/itu-t/focusgroups/ai4h/Deliverables/DEL07_1.docx) | AI4H evaluation process description | The AI4H evaluation process description serves as overview of the state of the art of AI evaluation principles and methods and a forward-looking initiator for the evaluation process of AI4H. This process description includes a review of existing evaluation principles and methods, evaluation need and solutions specific for AI4H. It will also look into ethics and risks aspects of AI4H evaluation. Furthermore, based on the fundamentals of AI, the description will gain insights on the direction of how the current evaluation methods evolve towards the concept of real AI. |
| [DEL07\_2](https://extranet.itu.int/sites/itu-t/focusgroups/ai4h/Deliverables/DEL07_2.docx) | AI technical test specification | This document specifies how an AI can and should be tested in silico. Among other aspects, best practices for test procedures known from (but not exclusively) AI challenges will be reviewed in this document. Important testing paradigms that are not exclusively related to AI applications will also be included. |
| [DEL07\_3](https://extranet.itu.int/sites/itu-t/focusgroups/ai4h/Deliverables/DEL07_3.docx) | Data and artificial intelligence assessment methods (DAISAM) reference | This document is the reference collection of WG-DAISAM for assessment methods of data and artificial intelligence quality evaluation. |
| [DEL07\_4](https://extranet.itu.int/sites/itu-t/focusgroups/ai4h/Deliverables/DEL07_4.docx) | Clinical evaluation of AI for health | This document provides an overview of the current challenges of "Clinical Evaluation of AI for Health". It is part of the deliverable-series 7.1-7.4 that are outlined by deliverable No.7 "AI for Health Evaluation considerations". Although the performance of AI models in health is often measured by their accuracy, establishing confidence among clinicians, patients, researchers and policy makers in the safety, efficacy, and cost-effectiveness of AI solutions in health requires a more comprehensive evaluation. The purpose of Deliverable 7.4 is to outline the current best practice, the principles and outstanding issues for further considerations related to clinical evaluation of AI models for health. It serves as the output document of the WHO/ITU Focus Group on AI for Health (FG-AI4H) Working group on Clinical Evaluation of AI for Health (WG-CE). |
| [DEL07\_5](https://extranet.itu.int/sites/itu-t/focusgroups/ai4h/Deliverables/DEL07_5.docx) | Assessment platform | Since the DASH/DAISAM Workshop in Berlin in January 2020, options have been explored to implement an assessment platform that can be used to perform health AI evaluation for the different topic groups. So far, this has resulted in two code bases which we are currently working on: (a) custom assessment platform and (b) evalai-based assessment platform. This deliverable collects practical experiences and lessons-learned to guide on the implementation of assessment platforms using AI for health. |
| [DEL09](https://extranet.itu.int/sites/itu-t/focusgroups/ai4h/Deliverables/DEL09.docx) | AI4H applications and platforms | This document contains a discussion on development of AI tool for health using mobile applications and cloud-based AI applications. This document also invites Medical & AI researchers to collaborate in development of Cloud-based / Mobile Application based AI tools for Health within the International Telecommunication Union (ITU)/World Health Organization (WHO) Focus Group on “Artificial Intelligence for Health” (FG-AI4H). |
| [DEL09\_1](https://extranet.itu.int/sites/itu-t/focusgroups/ai4h/Deliverables/DEL09_1.docx) | Mobile Applications | This document contains a draft set of rules for development of AI tool for Health using Mobile Applications, their testing and benchmarking. This document also invites Medical & AI researchers to collaborate in development of Mobile Application based AI tools for Health within the International Telecommunication Union (ITU)/World Health Organization (WHO) Focus Group on “Artificial Intelligence for Health” (FG-AI4H). |
| [DEL09\_2](https://extranet.itu.int/sites/itu-t/focusgroups/ai4h/Deliverables/DEL09_2.docx) | Cloud-based AI applications | This document contains a draft set of rules for development of cloud-based AI applications, their testing and benchmarking. This document also invites Medical & AI researchers to collaborate in development of cloud-based AI applications for Health within the International Telecommunication Union (ITU)/World Health Organization (WHO) Focus Group on “Artificial Intelligence for Health” (FG-AI4H). |
| [DEL10\_0](https://extranet.itu.int/sites/itu-t/focusgroups/ai4h/Deliverables/DEL10_0.docx) | AI4H use cases: Topic Description Documents | This document provides an overview of the ITU/WHO Focus Group on AI for Health (FG-AI4H) "AI4H use cases: Topic Description Documents". Each use case is represented by a topic group that is dedicated to a specific health topic in the context of AI. The topic group proposes a procedure to benchmark AI models developed for a special task within this health topic. All members of a topic group create a topic description document (TDD) that contains information about the structure, operations, features, and considerations of the specific health topic. This document constitutes deliverable No. 10 (DEL.10\_0) and serves as an introduction to the topic groups and their topic description documents. The following Topic Groups are currently covered:   1. [TG-Bacteria: Diagnoses of bacterial infection and anti-microbial resistance (AMR)](https://extranet.itu.int/sites/itu-t/focusgroups/ai4h/tg/SitePages/TG-Bacteria.aspx) 2. [TG-Cardio: Cardiovascular disease (CVD) management using AI (multiple subtopics)](https://extranet.itu.int/sites/itu-t/focusgroups/ai4h/tg/SitePages/TG-Cardio.aspx) 3. [TG-Dental: Dental diagnostics and digital dentistry](https://extranet.itu.int/sites/itu-t/focusgroups/ai4h/tg/SitePages/TG-Dental.aspx) 4. [TG-Derma: Dermatology](https://extranet.itu.int/sites/itu-t/focusgroups/ai4h/tg/SitePages/TG-Derma.aspx) 5. [TG-Diabetes: Primary and secondary diabetes prediction](https://extranet.itu.int/sites/itu-t/focusgroups/ai4h/tg/SitePages/TG-Diabetes.aspx) 6. [TG-DiagnosticCT: Volumetric chest computed tomography](https://extranet.itu.int/sites/itu-t/focusgroups/ai4h/tg/SitePages/TG-DiagnosticCT.aspx) 7. [TG-Endoscopy: AI for endoscopy](https://extranet.itu.int/sites/itu-t/focusgroups/ai4h/tg/SitePages/TG-Endoscopy.aspx) 8. [TG-FakeMed: AI-based detection of falsified medicine](https://extranet.itu.int/sites/itu-t/focusgroups/ai4h/tg/SitePages/TG-FakeMed.aspx) 9. [TG-Falls: Falls among the elderly](https://extranet.itu.int/sites/itu-t/focusgroups/ai4h/tg/SitePages/TG-Falls.aspx) 10. [TG-Histo: Histopathology](https://extranet.itu.int/sites/itu-t/focusgroups/ai4h/tg/SitePages/TG-Histo.aspx) 11. [TG-Malaria: Malaria detection](https://extranet.itu.int/sites/itu-t/focusgroups/ai4h/tg/SitePages/TG-Malaria.aspx) 12. [TG-MCH: Maternal and child health](https://extranet.itu.int/sites/itu-t/focusgroups/ai4h/tg/SitePages/TG-MCH.aspx) 13. [TG-MSK: AI for Musculoskeletal medicine](https://extranet.itu.int/sites/itu-t/focusgroups/ai4h/tg/SitePages/TG-MSK.aspx) 14. [TG-Neuro: Neurological disorders](https://extranet.itu.int/sites/itu-t/focusgroups/ai4h/tg/SitePages/TG-Neuro.aspx) 15. [TG-Ophthalmo: Ophthalmology](https://extranet.itu.int/sites/itu-t/focusgroups/ai4h/tg/SitePages/TG-Ophthalmo.aspx) 16. [TG-Outbreaks: Outbreak detection](https://extranet.itu.int/sites/itu-t/focusgroups/ai4h/tg/SitePages/TG-Outbreaks.aspx) 17. [TG-Psy: Psychiatry](https://extranet.itu.int/sites/itu-t/focusgroups/ai4h/tg/SitePages/TG-Psy.aspx) 18. [TG-Radiology: AI for radiology](https://extranet.itu.int/sites/itu-t/focusgroups/ai4h/tg/SitePages/TG-Radiology.aspx) 19. [TG-Snake: Snakebite and snake identification](https://extranet.itu.int/sites/itu-t/focusgroups/ai4h/tg/SitePages/TG-Snake.aspx) 20. [TG-Symptom: Symptom assessment](https://extranet.itu.int/sites/itu-t/focusgroups/ai4h/tg/SitePages/TG-Symptom.aspx) 21. [TG-TB: Tuberculosis](https://extranet.itu.int/sites/itu-t/focusgroups/ai4h/tg/SitePages/TG-TB.aspx) |

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_