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| **Title:** | | Updated DEL00: Overview of the FG-AI4H deliverables | | |
| **Purpose:** | | Discussion | | |
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| **Abstract:** | 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. This version is based on the update on FG-AI4H meeting J, 30 Sep-2 Oct 2020 (A revision marked version is found in document FG-AI4H-J-043). |

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|  | | **International Telecommunication Union** | | |
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| **ITU-T** | **FG-AI4H Deliverable** | |
| TELECOMMUNICATION STANDARDIZATION SECTOR OF ITU | | Draft 2021-01-25 |
|  |  | | | |
|  | DEL00  Overview of the FG-AI4H deliverables | | | |
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Summary

This document provides the overview of all deliverables in FG-AI4H, intended to serve a basic framework for a standardized methodology of artificial intelligence for health, including generalized consideration on ethics, regulatory, requirement, data processing, model training, model evaluation, adoption and scale-up, etc. This overview also summarizes use cases in specific domain with corresponding AI/ML tasks, such as 20 topic description documents within different topic groups. This document is to give a comprehensive understanding and overview on the structure, relationship, corresponding scopes and progress on those deliverables, and improve possible collaborations.

Keywords

Overview, deliverables, artificial intelligence, health

Change Log

This document contains Version 0.2 of the Deliverable DEL00 on "*Overview of the FG-AI4H deliverables*" [approved at the ITU-T Focus Group on AI for Health (FG-AI4H) meeting held in Draft 2020-095-2508].

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ITU-T FG-AI4H Deliverable DEL00

Overview of the FG-AI4H deliverables

Introduction

The ITU/WHO Focus Group on artificial intelligence for health (FG-AI4H) was established by ITU-T Study Group 16 at its meeting in Ljubljana, Slovenia, 9-20 July 2018.  This group is committed to establish a standardized assessment framework for the evaluation of AI-based methods for health, diagnosis, triage or treatment decisions. A list of deliverables for the FG-AI4H was planned and corresponding groups was established, with 9 deliverables (DEL 1-9) focus on generalized consideration on ethics, regulatory, requirement, data processing, model training, model evaluation, adoption and scale-up, etc., and 20 topic groups (DEL 10.1-10.20) within specific health domains with corresponding AI/ML benchmarking tasks. During the drafting process, the importance of collaboration is gradually recognized, this collaboration could be:

* Distinguish the scope of DEL 1-9, to avoid overlap and maintain specialized.
* Collect input from different use cases and generalize into applicable DEL 1-9.
* Provide structured experiences sharing between different topic groups (DEL 10.1-10.20).

Therefore, to improve the possible collaboration above, this document continuously update the overview of all deliverables in FG-AI4H, and it can also be used as a quick guild for new participants to understand FG-Ai4H activities.

# Scope

This deliverable provides an overview of all FG-AI4H deliverables, 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 gives an overall introduction on the structure, relationship, progress, and corresponding scopes on those deliverables to improve possible collaborations.

# References

<TBD>

# Terms and definitions

## Terms defined elsewhere

This document uses the following terms defined elsewhere:

**3.1.1 Artificial intelligence** [ISO/IEC 2382:2015]: Branch of computer science devoted to developing data processing systems that perform functions normally associated with human intelligence, such as reasoning, learning, and self-improvement.

**3.1.2 Machine learning** [ISO/IEC 2382:2015]: Automatic learning, process by which a functional unit improves its performance by acquiring new knowledge or skills, or by reorganizing existing knowledge or skills.

## Terms defined here

This document defines the following terms:

**3.1.1 term [reference]:** definition

**3.1.2 term [reference]:** definition

<TBD>

# Abbreviations

|  |  |
| --- | --- |
| AHG | Ad hoc group |
| DEL | Deliverable |
| FG-AI4H | Focus Group on artificial intelligence for health |
| ITU | International Telecommunication Union |
| TDD | Topic description document |
| TG | Topic groups |
| WG | Working group |
| WHO | World Health Organization |

# Conventions

DEL refers to an FG-AI4H deliverable.

# Deliverable classification

According to utilization scenario, the planned deliverables can be divided into two groups:

* Generalized specifications (DEL 1-9): focus on generalized specifications including ethics, regulatory, requirement, data, training, evaluation, application, etc. Each part is interconnected to form a whole standardized framework for AI-based methods for health.
* Topic groups (DEL 10.1-10.20): focus on use cases in specific health domains with corresponding AI/ML tasks. Each case is an example of a whole process recommended by generalized specifications (DEL 1-9), and profiled in specific application scenarios.

# Deliverable structure

To better understand the deliverables’ relationship, Figure 1 gives an overall structure of all deliverables. The arrows in the figure indicate sequential connections from the perspective of software development and implementation, including demand finding, solution (data preparation, model development and evaluation aspects), and finally scale-up and adoption. Topic groups (TGs) take charge of specific health domains with corresponding AI/ML tasks in the recommended process of the above generalized specifications. They are providing the connection of the Working Groups (WGs) with actual health topics and the specific problems involved with a number of AI for health tasks and data modalities. .

This figure will be continuously updated according to the scope change of corresponding deliverables and newly established WGs, TGs, AHGs, suggestions and comments from editors, contributors and experts are all welcome.

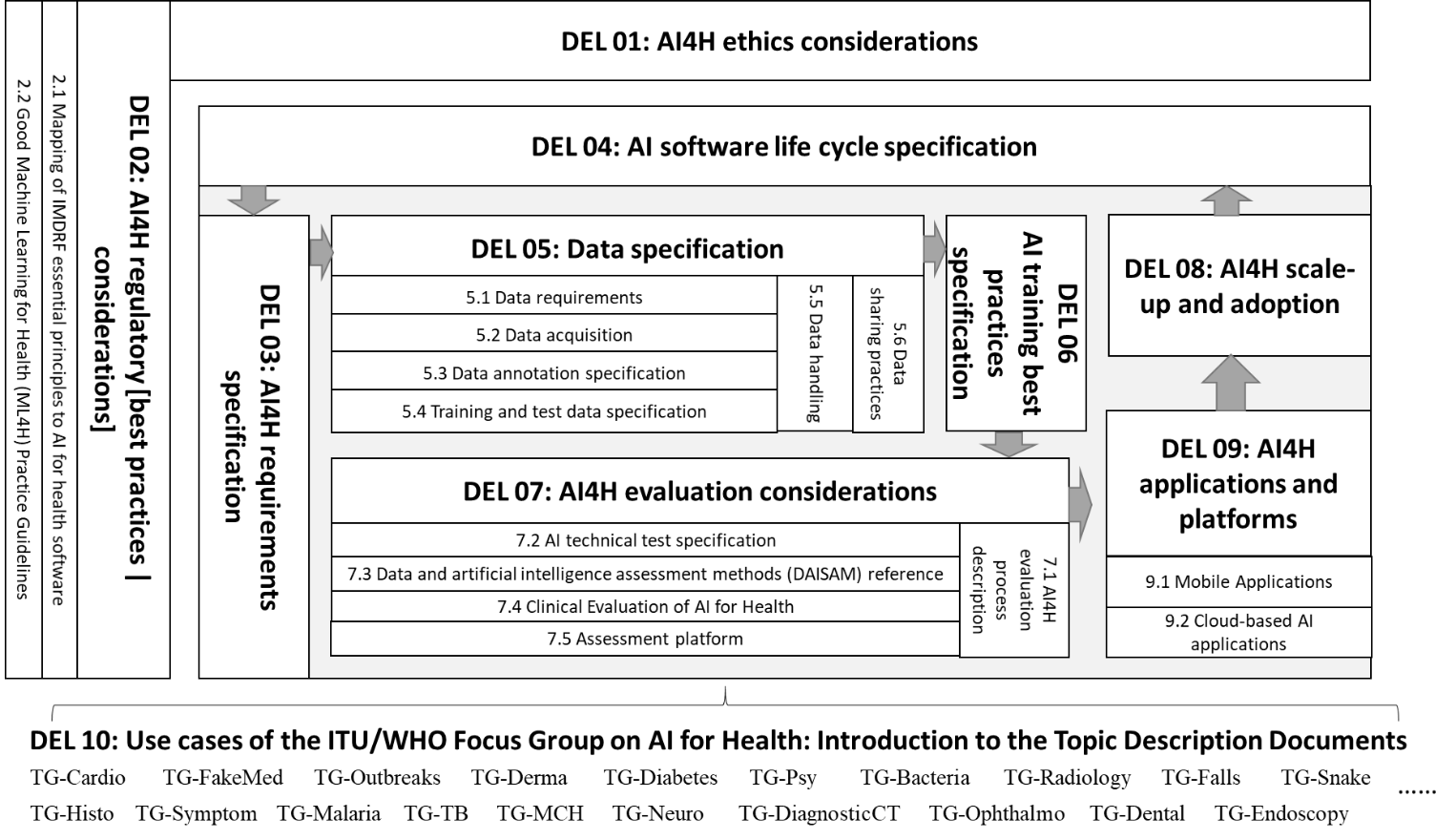


Figure 1 – FG-A4H Deliverables structure

# Deliverables index

An index of all planned deliverables is given as below. More details can be found via the link of each document, and contacts information are attached here to encourage collaboration between different deliverables.

Table 1 – Doc links and contacts for all deliverables (2020-06-08)

| No. | Deliverable | Updated draft editor | Availability\* |
| --- | --- | --- | --- |
| 0 | Overview of FG-AI4H deliverables | [Shan Xu](mailto:xushan@caict.ac.cn) (CAICT, China) | [I-211](https://extranet.itu.int/sites/itu-t/focusgroups/ai4h/docs/FGAI4H-I-211.docx) |
| 1 | AI4H ethics considerations | [Andreas Reis](mailto:reisa@who.int) (WHO) | [G-201](https://extranet.itu.int/sites/itu-t/focusgroups/ai4h/docs/FGAI4H-G-201.docx) |
| 2 | AI4H regulatory [best practices | considerations] | [Jackie Ma](mailto:jackie.ma@hhi.fraunhofer.de) (Fraunhofer HHI, Germany), [Khair ElZarrad](mailto:mohammed.elzarrad@fda.hhs.gov) & [Rose Purcell](mailto:Rosemarie.Purcell@fda.hhs.gov) (FDA, USA) | [I-038](https://extranet.itu.int/sites/itu-t/focusgroups/ai4h/docs/FGAI4H-I-038.docx) |
| 2.1 | Mapping of IMDRF essential principles to AI for health software | [Luis Oala](mailto:luis.oala@hhi.fraunhofer.de) (Fraunhofer HHI, Germany), [Pradeep Balachandran](mailto:pbn.tvm@gmail.com) (Technical Consultant eHealth, India), [Pat Baird](mailto:pat.baird@philips.com) (Philips, USA), [Thomas Wiegand](mailto:thomas.wiegand@hhi.fraunhofer.de) (Fraunhofer HHI, Germany) | [G-038](https://extranet.itu.int/sites/itu-t/focusgroups/ai4h/docs/FGAI4H-G-038.docx),  [G-038-A01](https://extranet.itu.int/sites/itu-t/focusgroups/ai4h/docs/FGAI4H-G-038-A01.xlsx) |
| 2.2 | Regulatory checklist | [Pradeep Balachandran](mailto:pbn.tvm@gmail.com) (India) and [Christian Johner](mailto:christian.johner@johner-institut.de) (Johner Institut, Germany) | [I-036](https://extranet.itu.int/sites/itu-t/focusgroups/ai4h/docs/FGAI4H-I-036.pptx) & [Nextcloud document](https://datacloud.hhi.fraunhofer.de/nextcloud/s/izz73RgE474Rq9g) |
| 3 | AI4H requirements specification | [Pradeep Balachandran](mailto:pbn.tvm@gmail.com) (India) | [I-033](https://extranet.itu.int/sites/itu-t/focusgroups/ai4h/docs/FGAI4H-I-033.docx) |
| 4 | AI software life cycle specification | [Pat Baird](mailto:pat.baird@philips.com) (Philips, USA) | [I-204](https://extranet.itu.int/sites/itu-t/focusgroups/ai4h/docs/FGAI4H-I-204.docx) |
| 5 | Data specification | [Marc Lecoultre](mailto:ml@mllab.ai) (MLlab.AI, Switzerland) | [G-205](https://extranet.itu.int/sites/itu-t/focusgroups/ai4h/docs/FGAI4H-G-205.docx) |
| 5.1 | Data requirements | [[Gupta Saurabh](mailto:drsaurabhmd@gmail.com) (AIIMS, India), [Manjula Singh](mailto:singhmanjula.hq@icmr.gov.in) (ICMR, India)]\*\* | [I-044](https://extranet.itu.int/sites/itu-t/focusgroups/ai4h/docs/FGAI4H-I-044.docx) |
| 5.2 | Data acquisition | [Rajaraman (Giri) Subramanian](mailto:kinnal@hotmail.com) (Calligo Tech, India), [Vishnu Ram](mailto:vishnu.n@ieee.org) (India) | [G-205-A02](https://extranet.itu.int/sites/itu-t/focusgroups/ai4h/docs/FGAI4H-G-205-A02.docx) |
| 5.3 | Data annotation specification | [Shan Xu](mailto:xushan@caict.ac.cn) (CAICT, China), [Harpreet Singh](mailto:hsingh@bmi.icmr.org.in) (ICMR, India), [Sebastian Bosse](mailto:sebastian.bosse@hhi.fraunhofer.de) (Fraunhofer HHI, Germany) | [I-043-R01](https://extranet.itu.int/sites/itu-t/focusgroups/ai4h/docs/FGAI4H-I-043-R01.docx" \t "_blank) |
| 5.4 | Training and test data specification | [Luis Oala](mailto:luis.oala@hhi.fraunhofer.de) (Fraunhofer HHI, Germany), [Pradeep Balachandran](mailto:pbn.tvm@gmail.com) (India) | [I-034](https://extranet.itu.int/sites/itu-t/focusgroups/ai4h/docs/FGAI4H-I-034.docx) |
| 5.5 | Data handling | [Marc Lecoultre](mailto:ml@mllab.ai) (MLlab.AI, Switzerland) | [DEL05](https://extranet.itu.int/sites/itu-t/focusgroups/ai4h/Deliverables/DEL05.docx) |
| 5.6 | Data sharing practices | [Ferath Kherif](mailto:Ferath.Kherif@chuv.ch) (CHUV, Switzerland), [Banusri Velpandian](mailto:banusrir@gmail.com) (ICMR, India), WHO Data Team | [I-046](https://extranet.itu.int/sites/itu-t/focusgroups/ai4h/docs/FGAI4H-I-046.docx) [G-205-A06](https://extranet.itu.int/sites/itu-t/focusgroups/ai4h/docs/FGAI4H-G-205-A06.docx) |
| 6 | AI training best practices specification | [Xin Ming Sim](mailto:xinming@aisingapore.org) and [Stefan Winkler](mailto:stefan@aisingapore.org) (AI Singapore) | [I-032](https://extranet.itu.int/sites/itu-t/focusgroups/ai4h/docs/FGAI4H-I-032.docx) |
| 7 | AI4H evaluation considerations | [Markus Wenzel](mailto:markus.wenzel@hhi.fraunhofer.de) (Fraunhofer HHI, Germany) | [I-028](https://extranet.itu.int/sites/itu-t/focusgroups/ai4h/docs/FGAI4H-I-028.docx) |
| 7.1 | AI4H evaluation process description | [Sheng Wu](mailto:wus@who.int) (WHO) | [G-207-A01](https://extranet.itu.int/sites/itu-t/focusgroups/ai4h/docs/FGAI4H-G-207-A01.docx) |
| 7.2 | AI technical test specification | [Auss Abbood](mailto:abbooda@rki.de) (Robert Koch Institute, Germany) | [I-027](https://extranet.itu.int/sites/itu-t/focusgroups/ai4h/docs/FGAI4H-I-027.pptx) |
| 7.3 | Data and artificial intelligence assessment methods (DAISAM) reference | [Luis Oala](mailto:luis.oala@hhi.fraunhofer.de) (Fraunhofer HHI, Germany) | [I-035](https://extranet.itu.int/sites/itu-t/focusgroups/ai4h/docs/FGAI4H-I-035.docx) & [Live version](https://docs.google.com/spreadsheets/d/1u3p5QrqkArL8_tJ8I1O5_j3qYIeycYLP0TD0siWmfM4/edit?usp=sharing) |
| 7.4 | Clinical evaluation of AI for health | [Naomi Lee](mailto:naomi.lee@lancet.com), [Rupa Sarkar](mailto:rupa.sarkar@lancet.com) (Lancet, UK) | [I-051](https://extranet.itu.int/sites/itu-t/focusgroups/ai4h/docs/FGAI4H-I-051.docx) |
| \*\*\* 7.[5] | Assessment platform | [Luis Oala](mailto:luis.oala@hhi.fraunhofer.de) (Fraunhofer HHI, Germany), [Steffen Vogler](mailto:steffen.vogler@bayer.com) (Bayer, Germany) | [I-037](https://extranet.itu.int/sites/itu-t/focusgroups/ai4h/docs/FGAI4H-I-037.docx) & [Git live version](https://gitlab.hhi.fraunhofer.de/fgai4h/assessment-platform) |
| 8 | AI4H scale-up and adoption | [Sameer Pujari](mailto:pujaris@who.int) (WHO) and Robyn Whittaker (New Zealand) | – |
| 9 | AI4H applications and platforms | [Manjeet Chalga](mailto:chalgams.hq@icmr.gov.in) (ICMR, India), [Aveek De](mailto:aveek@cms-india.org) (CMS, India) | [I-050](https://extranet.itu.int/sites/itu-t/focusgroups/ai4h/docs/FGAI4H-I-050.docx) |
| 9.1 | Mobile applications | [Khondaker Mamun](mailto:mamun@cse.uiu.ac.bd) (UIU, Bangladesh), [Manjeet Chalga](mailto:chalgams.hq@icmr.gov.in) (ICMR, India) | [I-048](https://extranet.itu.int/sites/itu-t/focusgroups/ai4h/docs/FGAI4H-I-048.docx) |
| 9.2 | Cloud-based AI applications | [Khondaker Mamun](mailto:mamun@cse.uiu.ac.bd) (UIU, Bangladesh) | [I-049](https://extranet.itu.int/sites/itu-t/focusgroups/ai4h/docs/FGAI4H-I-049.docx) |
| 10 | AI4H use cases: Topic description docs. | [Eva Weicken](mailto:eva.weicken@hhi.fraunhofer.de) (Fraunhofer HHI, Germany) | [I-030](https://extranet.itu.int/sites/itu-t/focusgroups/ai4h/docs/FGAI4H-I-030.docx) |
| 10.1 | Cardiovascular disease management (TG-Cardio), including *risk prediction* and *clinical prediction* sub-topics | [Benjamin Muthambi](mailto:brm5@caa.columbia.edu) (Watif Health, South Africa) | [G-006](https://extranet.itu.int/sites/itu-t/focusgroups/ai4h/docs/FGAI4H-G-006.docx) (general) |
| 10.1  A | Cardiovascular disease management (TG-Cardio), *risk prediction* sub-topic | [Benjamin Muthambi](mailto:brm5@caa.columbia.edu) (Watif Health, South Africa) | [I-006-A01](https://extranet.itu.int/sites/itu-t/focusgroups/ai4h/docs/FGAI4H-I-006-A01.docx) (risk prediction) |
| 10.2 | Dermatology (TG-Derma) | [Maria Vasconcelos](mailto:maria.vasconcelos@fraunhofer.pt) (Fraunhofer Portugal) | [I-007-A01](https://extranet.itu.int/sites/itu-t/focusgroups/ai4h/docs/FGAI4H-I-007-A01.docx) |
| 10.3 | Diagnosis of bacterial infection and anti-microbial resistance (TG-Bacteria) | [Nada Malou](mailto:nada.malou@paris.msf.org) (MSF, France) | – |
| 10.4 | Falls among the elderly (TG-Falls) | [Inês Sousa](mailto:ines.sousa@fraunhofer.pt) (Fraunhofer Portugal), [Pierpaolo Palumbo](mailto:pierpaolo.palumbo@unibo.it)  (University of Bologna, Italy) | [I-012-A01](https://extranet.itu.int/sites/itu-t/focusgroups/ai4h/docs/FGAI4H-I-012-A01.docx) |
| 10.5 | Histopathology (TG-Histo) | [Frederick Klauschen](mailto:frederick.klauschen@charite.de) (Charité Berlin, Germany) | [I-013-A01](https://extranet.itu.int/sites/itu-t/focusgroups/ai4h/docs/FGAI4H-I-013-A01.docx) |
| 10.6 | Malaria detection (TG-Malaria) | [Rose Nakasi](mailto:g.nakasi.rose@gmail.com) (Makerere University, Uganda) | [I-014-A01](https://extranet.itu.int/sites/itu-t/focusgroups/ai4h/docs/FGAI4H-I-014-A01.docx) |
| 10.7 | Maternal and child health (TG-MCH) | [Raghu Dharmaraju](mailto:rdharmaraju@gmail.com) (Wadhwani AI, India) and [Alexandre Chiavegatto Filho](mailto:alexdiasporto@usp.br) (University of São Paulo, Brazil) | [I-015-A01](https://extranet.itu.int/sites/itu-t/focusgroups/ai4h/docs/FGAI4H-I-015-A01.docx) |
| 10.8 | Neurological disorders (TG-Neuro) | [Marc Lecoultre](mailto:ml@mllab.ai) (MLlab.AI, Switzerland) | [I-016-A01](https://extranet.itu.int/sites/itu-t/focusgroups/ai4h/docs/FGAI4H-I-016-A01.docx) |
| 10.9 | Ophthalmology (TG-Ophthalmo) | [Arun Shroff](mailto:arunshroff@gmail.com) (MedIndia) | [I-017-A01](https://extranet.itu.int/sites/itu-t/focusgroups/ai4h/docs/FGAI4H-I-017-A01.docx) |
| 10.10 | Outbreak detection (TG-Outbreaks) | [Auss Abbood](mailto:abbooda@rki.de) (Robert Koch Institute, Germany) and [Stéphane Ghozzi](mailto:stephane.ghozzi@helmholtz-hzi.de) (HZI, Germany) | [I-018-A01](https://extranet.itu.int/sites/itu-t/focusgroups/ai4h/docs/FGAI4H-I-018-A01.docx) |
| 10.11 | Psychiatry (TG-Psy) | [Nicolas Langer](mailto:n.langer@psychologie.uzh.ch) (ETH Zurich, Switzerland) | [I-019-A01-R01](https://extranet.itu.int/sites/itu-t/focusgroups/ai4h/docs/FGAI4H-I-019-A01-R01.docx) |
| 10.12 | AI for radiology (TG-Radiology) | [Darlington Ahiale Akogo](mailto:darlington@gudra-studio.com) (minoHealth AI Labs, Ghana) | [I-023-A01](https://extranet.itu.int/sites/itu-t/focusgroups/ai4h/docs/FGAI4H-I-023-A01.docx) |
| 10.13 | Snakebite and snake identification (TG-Snake) | [Rafael Ruiz de Castaneda](mailto:Rafael.RuizDeCastaneda@unige.ch) (UniGE, Switzerland) | [I-020-A01](https://extranet.itu.int/sites/itu-t/focusgroups/ai4h/docs/FGAI4H-I-020-A01.docx) |
| 10.14 | Symptom assessment (TG-Symptom) | [Henry Hoffmann](mailto:henry.hoffmann@ada.com) (Ada Health, Germany) | [I-021-A01](https://extranet.itu.int/sites/itu-t/focusgroups/ai4h/docs/FGAI4H-I-021-A01.docx) |
| 10.15 | Tuberculosis (TG-TB) | [Manjula Singh](mailto:singhmanjula.hq@icmr.gov.in) (ICMR, India) | [I-022-A01](https://extranet.itu.int/sites/itu-t/focusgroups/ai4h/docs/FGAI4H-I-022-A01.docx) |
| 10.16 | Volumetric chest CT (TG-DiagnosticCT) | [Kuan Chen](mailto:ckuan@infervision.com) (Infervision, China) | [I-009-A01](https://extranet.itu.int/sites/itu-t/focusgroups/ai4h/docs/FGAI4H-I-009-A01.docx) |
| 10.17 | Dental diagnostics and digital dentistry (TG-Dental) | [Falk Schwendicke](mailto:falk.schwendicke@charite.de) and [Joachim Krois](mailto:Joachim.krois@charite.de) (Charité Berlin, Germany); [Tarry Singh](mailto:tarry.singh@deepkapha.ai) (deepkapha.ai, Netherlands) | [I-010-A1](https://extranet.itu.int/sites/itu-t/focusgroups/ai4h/docs/FGAI4H-I-010-A01.docx) |
| 10.18 | Falsified Medicine (TG-FakeMed) | [Franck Verzefé](mailto:fverzefe@gmail.com) (TrueSpec-Africa, DRC) | – |
| 10.19 | Primary and secondary diabetes prediction (TG-Diabetes) | [Andrés Valdivieso](mailto:avaldivieso@anastasia.ai) (Anastasia.ai, Chile) | [I-024-A01](https://extranet.itu.int/sites/itu-t/focusgroups/ai4h/docs/FGAI4H-I-024-A01.docx) |
| 10.20 | AI for endoscopy (TG-Endoscopy) | [Jianrong Wu](mailto:edwinjrwu@tencent.com) (Tencent Healthcare, China) | [I-052-A01](https://extranet.itu.int/sites/itu-t/focusgroups/ai4h/docs/FGAI4H-I-052-A01.docx) |

\* NOTE: The document numbers indicated reflect the status as of the start of the Brasilia meeting (H) and Geneva Virtual meeting (I). Colour codes indicate deliverable drafting status (as of the issuance of this document) as "active" (green) and "unclear whether active" (blue). Updates will be issued as I-200 series.

\*\* Need replacement editors.

\*\*\* Provisional number, to be confirmed.

# Summary of generalized documents (DEL 1-9)

To coordinate generalized specifications on AI4H, a summary table of all generalized documents (DEL 1-9) is given below. It displays the abstract, objectives, and score, of corresponding deliverables, to maintain specialized and avoid possible overlap. The statements were extracted from the latest documents and reviewed by editors before the virtual meeting in 7-8 May 2020. This table will be continuously updated in future activities of FG-AI4H.

Table 2 – Summary of generalized documents (DEL 1-9)

| **Deliverable** | | **Objectives/Scope/ overview** |
| --- | --- | --- |
| **1- 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. |
| **2- AI4H regulatory best practices]** | | High-level perspective and guidelines on the best practices for regulation of AI for health towards the safe application of AI solutions. It will include common elements of AI regulation across different verticals as well as some regional and country-specific regulations. |
| 2.1 | Mapping of IMDRF essential principles to AI for health software | AI for health (AI4H) software provides a number of new aspects that have not been considered when developing the regulatory framework for software as a medical device (SaMD) as described by the IMDRF Essential Principles (EPs) in  “Essential Principles of Safety and Performance of Medical Devices and IVD Medical Devices”, IMDRF Good Regulatory Review Practices Group, IMDRF GRRP WG/N47 FINAL, 31 October 2018.  This document provides a suggested mapping of the EPs to related aspects of AI4H software. Its purpose is to cover all aspects considered in the regulation of SaMDs and whether and if yes, how they are applicable to AI4H. |
| 2.2 | Guidelines for AI Based Medical Device- Regulatory Requirements | This document defines a set of guidelines intended to serve the regulators and the device manufacturers with a common understanding on the best practices and processes that support a comprehensive requirements analysis to achieve regulatory compliance for AI for Medical Devices (AI-MD)  The **regulatory scope** of AI-MD, include (a) regulated and non-regulated medical devices, (b) medical devices with or without enforcement of regulations  The **regulatory requirements scope,** in this context**,** of AI-MD pertain only to technical aspects of AI/ML products; not to commercial or business aspects, such as strategic positioning, market assessment, profitability, etc.  The **product scope** of AI-MD,   * DOES include c) Software-as-a-Medical Device (SaMD) , (d) Software-in-a-Medical Device (SiMD) and (e) healthcare applications intended to improve medical outcomes or efficiency of healthcare system * DOES NOT include software applications for (a)healthcare facility administrative support, (b) for maintaining or encouraging healthy lifestyle, behaviour and wellness   This set of guidelines are not intended 1) to be comprehensive and/or 2) to replace any regulation, directive, standard, or similar legally-binding regulatory framework or guidance document of any geographic jurisdiction. |
| **3- AI4H requirements specification** | | The purpose of this document is to define the System Requirements Specifications (SyRS) that explains the informational, functional, behavioural and operational aspects a generic AI for health (AI4H) system.   * SyRS scope includes a requirements model that defines the informational, functional, behavioural and operational aspects of the AI4H system under consideration. Specific objectives include the following:   + Best practices for defining the AI software requirements and the task that the AI should solve without any ambiguity. This includes a clear description of the intended use   + Procedure to classify AI4H software vis-a-vis existing health interventions. Important considerations include, among others: Does the AI4H software replace components in existing health intervention workflows? Does it represent a new type of intervention?   + Risk management guidelines * This SyRS is generic in nature and shall be applicable across all domain specialties/ topic groups of AI4H FG. It may be modified, customized or extended appropriately to include the specific requirements and needs of the particular topic group under consideration * Requirement specifications may be defined in terms of use cases, graphical methods, mathematical models, documentation, etc. or combination of these |
| **4-AI software life cycle specification** | | 1. Identification of all standards and best practices that are relevant for the AI for health software life cycle. Similar to other software life cycle processes, the AI software life cycle process needs to be specified. 2. Summary and critical review of the identified documents including a discussion of their limits/gaps and need for action. 3. Identification of life cycle steps that are specific/characteristic for AI for health software, such as training and test procedures based on data that potentially need to be annotated. 4. Specification of the AI for health software life cycle and definition of best practices for the different life cycle steps in one document (under consideration of a, b, and c). Overview and examples of best practices |
| **5-Data specification** | | This deliverable combines a set of six separate deliverables as umbrella, which address six important aspects related to data specification when used for artificial intelligence (AI) and machine learning (ML) models/methods for health purposes. Each editor will propose an initial outline (=Table of Contents), define the objectives of the future deliverable, and collect a bibliography of existing literature and material relevant for the development of the respective document. A short call for participation, the expertise profile of potential contributors, a time plan, and a brief characterisation of the target audience serve as preface |
| 5.1 | 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. combines a set of four deliverables as umbrella. |
| 5.2 | 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. |
| 5.3 | Data annotation specification | This document describes the topics to be addressed in the forthcoming deliverable “DEL05-A03: 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 committed 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 |
| 5.4 | Training and test data specification | This document is intended to guide the target audience with a systematic way of preparing technical requirements specification for datasets used in training and testing of machine ML models  This document explains the best practices of data quality assurance aimed at minimizing the data error risks during the training and test data preparation phase of machine learning process lifecycle  The training and test data requirement specifications follow the data integrity, data security and data safety norms of the AI data governance lifecycle process |
| 5.5 | 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. |
| 5.6 | Data sharing practices | This deliverable aims to provide an overview of the existing best practices for data sharing of health-related data. The scope of this document includes a description of all the necessary steps and requirement to enable secure data sharing. The document specifies the role of the data providers, data processors and the data receivers. The document outlines established data sharing methods and novel methods based on distributed and federated environments for privacy preserving AI/ML models. |
| **6-AI training best practices specification** | | This document comprises two parts. The first summarises challenges encountered during the training of AI models and provides some suggested best practices, while the second recommends a framework which could be used for the transparent reporting of trained AI models. |
| **7-AI for health evaluation considerations** | | In this introductory document, characteristics of health AI evaluation that are novel or otherwise essential are identified, best practices for the health AI model assessment are collected from selected sources, and requirements for a benchmarking platform are considered. This sets the scene for the four related documents DEL07.1-4 that dive into the details of health AI evaluation including a process description, technical tests, metrics and clinical validation |
| 7.1 | 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. |
| 7.2 | 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 should be mentioned too. |
| 7.3 | Data and artificial intelligence assessment methods (DAISAM) reference | Here we provide a summary of how to understand and identify algorithmic bias at different stages of the AI-based product that may have critical implications when the algorithm is applied in a real-world clinical setting. The aim is to train the most accurate model for each group without harming any minority group of patients. Furthermore, methods to mitigate bias according to the problem at hand are provided. These guidelines aim to provide a framework for technologists that build health related AI based products to investigate the presence of algorithmic bias. |
| 7.4 | Clinical evaluation of AI for health | The aim of the ITU/WHO Focus Group AI for Health is to create a faster, trusted intermediate step that can show regulators and decision makers that ‘latest versions’ are of sufficient standard\*\* and appropriate for context and use cases where they might be being planned for deployment. This requires the creation of globally representative datasets that are curated independently, of high quality and secure (i.e. that no systems have ever seen before). |
| **8-AI4H scale-up and adoption** | | TBD |
| **9-AI4H applications and platforms** | | This document contains a draft set of rules for development of AI tool for Health using Mobile Applications & Cloud-based AI applications, their testing and benchmarking. 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). |
| 9.1 | Mobile applications | This document contains a draft set of rules for development of AI tool for Health using Mobile Applications, their testing and benchmarking. The objectives of the topic groups are:   1. to prepare the rules for development of AI tool for Health using Mobile Applications 2. to discuss the regulatory/ethical rules for Mobile Apps with AI for Healthcare 3. to provide a forum for open communication among various stakeholders, 4. to develop benchmarking for the Apps, 5. to coordinate the complete process in collaboration with the Focus Group management and working groups. |
| 9.2 | Cloud-based AI applications | This document contains a draft set of rules for development of Cloud-based AI applications, their testing and benchmarking. The objectives of the topic groups are as follows:   1. to discuss on technology, security and legal issues related to cloud-based AI tools 2. to provide a forum for open communication among various stakeholders, 3. to coordinate the benchmarking process in collaboration with the Focus Group management and working groups. |

# Summary of Topic Description Documents (DEL 10.1-10.20)

Similar to above, to provide a structured overview of different health domains considered in FG-AI4H, a summary table of all Topic Description Documents (TDD) is given below, with key messages including health domain, task classification, gold standard, input data type, testing/training dataset, data annotation, algorithm, evaluation, etc. These information listed below were obtained from a questionnaire to all TG drivers (<https://forms.gle/3fYrm3SZSrNQu3eeA>), seven TGs gave response and the remaining blank will be filled through a comprehensive review of all TDDs later. This table will be continuously updated in future activities of FG-AI4H.

Table 3 – Key message of Topic Groups

| Topic Groups (Examples) | Domain (Cardiovascular/ Dermatology/ Histopathology/‌etc.) | Task (Classification/ detection/ segmentation/ prediction/‌etc.) | Gold Standard (state-of-the-art task intervention method) | Input data type (Text/ Image/ video/ audio/ numerical/‌etc.) | Testing/ Training dataset (Public dataset/ Collected by myself/‌etc.) | Data annotation (Procedure/ annotator number/ tool/‌etc.) | Algorithm (specific model used in this TG) | Evaluation (Metrics used in this TG) |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| TG-Bacteria | Diagnoses of bacterial infection and anti-microbial resistance | TBD | TBD | TBD | TBD | TBD | TBD | TBD |
| TG-Cardio | cardiovascular disease | prediction | TBD | Quantitative & qualitative data (structured) | De-identified retrospective secondary data from healthcare/EMR & research data repositories | Structured data are used, thus simple R programming is used to recode structured data to required standardized labels. | TBD | TBD |
| TG-Dental | Dental diagnostics and digital dentistry | Classification/ detection/ segmentation/ prediction | Histology, Cross-image validation, human annotations | 2D Image, 3D Image, Video, Text | Self-built | Custom made tool | TBD | TBD |
| TG-Derma | Dermatology | TBD | TBD | TBD | TBD | TBD | TBD | TBD |
| TG-Diabetes | Primary and secondary diabetes prediction | TBD | TBD | TBD | TBD | TBD | TBD | TBD |
| TG-DiagnosticCT | Volumetric chest computed tomography | TBD | TBD | TBD | TBD | TBD | TBD | TBD |
| TG-Endoscopy | Endoscopy | Classification/ detection/ segmentation | Pathological report, Cross annotation by doctors | 2D Image, Video | Public dataset， self-built | Cross annotation, Self-built annotation tool | TBD | TBD |
| TG-FakeMed | AI-based detection of falsified medicine | Classification/ detection/ prediction |  | 2D Image, Text | Self-built |  | TBD | TBD |
| TG-Falls | Falls among the elderly | TBD | TBD | TBD | TBD | TBD | TBD | TBD |
| TG-Histo | Histopathology | TBD | TBD | TBD | TBD | TBD | TBD | TBD |
| TG-Malaria | Malaria detection | TBD | TBD | TBD | TBD | TBD | TBD | TBD |
| TG-MCH | Maternal and child health | TBD | TBD | TBD | TBD | TBD | TBD | TBD |
| TG-Neuro | Neurological disorders | Classification/ detection/ prediction | Post-mortem pathology evaluation, and biological markers. | 2D Image, 4D Image, clinical scores, genetics and biomarkers (e.g. csf) | Public dataset, self-built. | Manual | TBD | TBD |
| TG-Ophthalmo | Ophthalmology | Classification/ detection/ segmentation/ | Pathological report, Cross annotation by doctors | 2D Image, 3D Image, Text | Public dataset, self-built | Cross annotation, Self-built annotation tool | TBD | TBD |
| TG-Outbreaks | Outbreak detection | TBD | TBD | TBD | TBD | TBD | TBD | TBD |
| TG-Psy | Psychiatry | TBD | TBD | TBD | TBD | TBD | TBD | TBD |
| TG-Radiology | Radiology | TBD | TBD | TBD | TBD | TBD | TBD | TBD |
| TG-Snake | Snakebite and snake identification | Classification | Snake expert (herpetologist) identification | 2D Image | Public dataset, self-built. | Expert identification, crowdsourcing | TBD | TBD |
| TG-Symptom | Symptom assessment | Classification | Average doctor opinion. | Text, semantically structured cases. | Self-built. | a new case-creation tool | TBD | TBD |
| TG-TB | Tuberculosis | TBD | TBD | TBD | TBD | TBD | TBD | TBD |

\* NOTE: Colour codes indicate TGs’ status reflected in FG-AI4H website, as “active groups" (green) and “starting groups" (blue).

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