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| ITU Logo | INTERNATIONAL TELECOMMUNICATION UNION**TELECOMMUNICATIONSTANDARDIZATION SECTOR**STUDY PERIOD 2017-2020 | FG-AI4H-L-028 |
| **ITU-T Focus Group on AI for Health** |
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| **Title:** | FG-AI4H Progress Report to ITU-T SG16 (July 2020 to April 2021) |
| **Purpose:** | Admin |
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| **Abstract:** | This document contains a copy of the FG-AI4H Progress Report for the period July 2020 to April 2021 that was submitted to the last ITU-T SG16 meeting (19-30 April 2021), for information of the FG-AI4H meeting. |

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|  | INTERNATIONAL TELECOMMUNICATION UNION**TELECOMMUNICATIONSTANDARDIZATION SECTOR**STUDY PERIOD 2017-2020 | SG16-TD470/PLEN |
| **STUDY GROUP 16** |
| **Original: English** |
| **Question(s):** | ALL/16 | Online, 19-30 April 2021 |
| **TD** |
| **Source:** | Chairman FG-AI4H |
| **Title:** | FG-AI4H Progress Report to ITU-T SG16 (July 2020 to April 2021) |
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| **Keywords:** |   |
| **Abstract:** | Since the last progress report (TD386/PLEN, 2020-06), the Focus Group on Artificial Intelligence for Health has held two meetings. The tenth meeting was held online. The eleventh meeting was also held online. The Focus Group is working towards a standardized framework for benchmarking AI solutions for health. A number of draft deliverables are being prepared and further refined. These output documents cover topics such as data acceptance and handling as well as data and AI solution assessment. The development of these documents is conducted in close interaction with actual AI for health use cases. Through these interactions, the specifics of various modalities of AI for Health solution are considered. Currently, the Focus Group has in total created 21 AI for health topic groups each containing one or more use cases, which are progressing / maturing at different speeds. Webinars are being planned to further engage new participants and to share experiences within the existing topic groups and working groups of the FG-AI4HIn order to speed up adoption, running code is being developed since October 2020 under the FG-AI4H Open Code Initiative. This will be enlarged and catalysed by AI challenges, currently being organized in coordination with the AI for good activities. An additional activity sponsored by FG-AI4H experts is the collection of best practices using AI and other digital technologies for the COVID health emergency.This progress report contains an update on the status of the work since the last progress report, and updated work plan including schedule of future meetings, a summary of contributions considered by the group and a list of attendees of the two meetings that the FG held since its previous progress report to SG16 in June 2020. |

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Attachments

1. Report of the tenth meeting ("Meeting J") of the Focus Group on Artificial Intelligence for Health (FG-AI4H), online, 30 September – 2 October 2020: [https://itu.int/md/‌dologin\_md.asp?id=T17-SG16-210419-TD-PLEN-0470!A1!MSW-E&type=mitems](https://itu.int/md/dologin_md.asp?id=T17-SG16-210419-TD-PLEN-0470!A1!MSW-E&type=mitems)
2. Report of the eleventh meeting ("Meeting K") of the Focus Group on Artificial Intelligence for Health (FG-AI4H), online, 27-29 January 2021: [https://itu.int/md/dologin\_md.asp?‌id=T17-SG16-210419-TD-PLEN-0470!A2!MSW-E&type=mitems](https://itu.int/md/dologin_md.asp?id=T17-SG16-210419-TD-PLEN-0470!A2!MSW-E&type=mitems)

# Introduction

The ITU-T Focus Group on Artificial Intelligence for Health (AI4H) was established by ITU-T Study Group 16 at its meeting in Ljubljana, Slovenia, 9-20 July 2018 with the terms of reference found in SG16-R10 Annex F. The Focus Group works in partnership with the World Health Organization (WHO) to establish a standardized framework for benchmarking AI solutions for health. Participation in the FG-AI4H is free of charge and open to all. The lifetime of the Focus Group was extended by two years at the June 2020 online meeting of Study Group 16.

Eleven meetings were held since the FG-AI4H was created, two of which since the last progress report to SG16, the main outcomes of these last two are summarized in §2. The FG-AI4H management is listed in §3. An overview of the documentation reviewed is found in §4. The immediate future plans are indicated in §10, as well as the various topic areas identified (§6).

The Open Code Initiative is implementing the digital building blocks (six software packages) that compose the FG-AI4H Assessment Platform.

The Ad-Hoc Group on digital technologies for COVID health emergency is working on collecting effective ways and cases on AI and other digital technologies to combat COVID-19 covering the entire cycle of an epidemic emergency, encompassing the following: prevention and preparedness, outbreak early detection, surveillance and response, recovery, rehabilitation, mitigation, etc. It has released its Output 1: Guidance on digital technologies for COVID health emergency: https://www.itu.int/en/ITU-T/focusgroups/ai4h/Documents/FGAI4H-DT4ER-O-001.pdf

The Working Group on Clinical Evaluation (WG-CE) held an online workshop on 14 October 2020: <https://www.itu.int/en/ITU-T/focusgroups/ai4h/Pages/ws/2010.aspx>

In October 2020 the Focus Group released an updated whitepaper, which is available on its website: <https://www.itu.int/en/ITU-T/focusgroups/ai4h/Documents/FG-AI4H_Whitepaper.pdf>

Annex A contains the list of attendees of both plenary meetings held since the previous progress report.

# Status of work

## Meeting J

The 10th meeting of the FG-AI4H took place online, 30 September – 2 October 2020. Purpose included the reporting and discussion of updates to its deliverables and sub-deliverables and of progress by the existing 20 topic groups as well as the creation of a new topic group.

The meeting noted with satisfaction that ITU-T SG16 extended the life of the FG-AI4H until September 2022.

Working group updates:

* Appointed three co-chairs for the WG on Clinical Evaluation: Naomi Lee (The Lancet, UK), Shubhanan Upadhyay (ADA Health, Germany), and Eva Weicken (Fraunhofer HHI, Germany).

Topic group updates:

* The TG-Derma Driver, Maria Vasconcelos (Fraunhofer Portugal) can no longer continue. The meeting thanked Ms Vasconcelos for her efforts in progressing TG-Derma.
* New TG on AI for Musculoskeletal medicine (TG-MSK) with Yura Perov (EQL, UK) as Topic Driver. The collaboration site for the new TG is <https://extranet.itu.int/sites/itu-t/focusgroups/ai4h/tg/SitePages/TG-MSK.aspx>. Mailing list: fgai4htgmsk@lists.itu.int (archive: <https://itu.int/ml/lists/arc/fgai4htgmsk>)

Deliverable updates:

* No new deliverables were agreed at this meeting. Future deliverables under consideration are:
* Reference software implementation (Editor: Marc Lecoultre). Initial elements: [J-045](https://extranet.itu.int/sites/itu-t/focusgroups/ai4h/docs/FGAI4H-J-045.pptx)
* Guidance on digital technologies for COVID health emergency (Editors: Shan Xu, CAICT, China), Ana Riviere-Cinnamond, PAHO). Initial draft from the AHG-DT4HE: [J-035-R01](https://extranet.itu.int/sites/itu-t/focusgroups/ai4h/docs/FGAI4H-J-035-R01.docx).
* All available deliverables were reviewed and will be shared with SG16. The latest version of the deliverables is found in the [FG-AI4H collaboration site](https://extranet.itu.int/sites/itu-t/focusgroups/ai4h/SitePages/Deliverables.aspx).

It was agreed to update the following output documents, after an editing period after the meeting:

* [J-102](https://extranet.itu.int/sites/itu-t/focusgroups/ai4h/docs/FGAI4H-J-102.docx): Updated call for proposals: use cases, benchmarking, and data (to be published once the final dates of the next FG-AI4H meeting are defined)
* [J-103](https://extranet.itu.int/sites/itu-t/focusgroups/ai4h/docs/FGAI4H-J-105.docx): Updated call for topic group participation (CfTGP) template
* [J-105](https://extranet.itu.int/sites/itu-t/focusgroups/ai4h/docs/FGAI4H-J-004.docx): Updated TDD Template
* [J-107](https://extranet.itu.int/sites/itu-t/focusgroups/ai4h/docs/FGAI4H-J-107.docx): Updated FG-AI4H onboarding document
* [J-200-R1](https://extranet.itu.int/sites/itu-t/focusgroups/ai4h/docs/FGAI4H-J-200-R01.docx): Updated list of FG-AI4H deliverables
* [FG-AI4H whitepaper](https://www.itu.int/en/ITU-T/focusgroups/ai4h/Documents/FG-AI4H_Whitepaper.pdf) ([J-002](https://extranet.itu.int/sites/itu-t/focusgroups/ai4h/docs/FGAI4H-J-002.docx))

The following documents were reconfirmed:

* [F-103](https://extranet.itu.int/sites/itu-t/focusgroups/ai4h/docs/FGAI4H-F-103.docx): Updated FG-AI4H data acceptance and handling policy
* [C-104](https://extranet.itu.int/sites/itu-t/focusgroups/ai4h/docs/FGAI4H-C-104.docx): Thematic classification scheme
* [F-105](https://extranet.itu.int/sites/itu-t/focusgroups/ai4h/docs/FGAI4H-F-105.docx): ToRs for the WG-Experts and call for experts
* [F-106](https://extranet.itu.int/sites/itu-t/focusgroups/ai4h/docs/FGAI4H-F-106.docx): Guidelines on FG-AI4H online collaboration tools

The meeting had 92 participants over the various days and reviewed 55 documents (not counting attachments). There were no outgoing LSs prepared.

A list of the 12 decisions taken at the meeting is found in [Annex E](#AnnexE) of the report.

The next meeting of the FG-AI4H will be in held virtually in 27-29 January 2021.

## Meeting K

The 11th meeting of the FG-AI4H took place online, 27-29 January 2021 to review updates to its 24 deliverables and sub-deliverables, and review progress by the existing 21 topic groups.

The following updates in leadership of FG-AI4H working groups were endorsed:

* WG-RC: Michael Berensmann and Robin Seidel replace Wolfgang Lauer Wolfgang.Lauer@bfarm.de (Federal Institute for Drugs and Medical Devices, Germany); and Liang Hong replaces Peng Liang (National Medical Products Administration, China) as WG-RC vice-chairs
* WG-O: Eva Weicken replaces Monique Kuglitsch as WG co-chair

Topic group updates:

* No new TGs were created at this meeting
* Weihong Huang (Xiangya Hospital Central South University, China) replaces Maria Vasconcelos (Fraunhofer Portugal) as TG-Derma topic driver
* Pierpaolo Palumbo (University of Bologna, Italy) steps in as interim TG-Falls driver until Sept 2021, for Inês Sousa (Fraunhofer Portugal)

Deliverable updates:

* No new deliverables were agreed at this meeting. Future deliverables under consideration are:
* Open Code Initiative reference software implementation (Editor: Marc Lecoultre, MLlab.AI, Switzerland)
* Guidance on digital technologies for COVID health emergency (Co-editors: Shan Xu, CAICT, China; Ana Riviere-Cinnamond, PAHO)
* Risk management in AI for health (Editor: Pat Baird, Philips, USA)
* All available deliverables were reviewed, their latest version is found in the [FG-AI4H collaboration site](https://extranet.itu.int/sites/itu-t/focusgroups/ai4h/SitePages/Deliverables.aspx).

No new output documents were agreed. The following updated output documents were agreed:

* [K-102](https://extranet.itu.int/sites/itu-t/focusgroups/ai4h/docs/FGAI4H-K-102.docx): Updated call for proposals: use cases, benchmarking, and data
* [K-200](https://extranet.itu.int/sites/itu-t/focusgroups/ai4h/docs/FGAI4H-K-200.docx): Updated list of FG-AI4H deliverables

The following documents were reconfirmed:

* [F-103](https://extranet.itu.int/sites/itu-t/focusgroups/ai4h/docs/FGAI4H-F-103.docx): Updated FG-AI4H data acceptance and handling policy
* [C-104](https://extranet.itu.int/sites/itu-t/focusgroups/ai4h/docs/FGAI4H-C-104.docx): Thematic classification scheme
* [F-105](https://extranet.itu.int/sites/itu-t/focusgroups/ai4h/docs/FGAI4H-F-105.docx): ToRs for the WG-Experts and call for experts
* [F-106](https://extranet.itu.int/sites/itu-t/focusgroups/ai4h/docs/FGAI4H-F-106.docx): Guidelines on FG-AI4H online collaboration tools
* [K-107](https://extranet.itu.int/sites/itu-t/focusgroups/ai4h/docs/FGAI4H-K-107.docx): FG-AI4H Onboarding document
* [FG-AI4H Whitepaper](https://www.itu.int/en/ITU-T/focusgroups/ai4h/Documents/FG-AI4H_Whitepaper.pdf) ([K-002](https://extranet.itu.int/sites/itu-t/focusgroups/ai4h/docs/FGAI4H-K-002.docx))
* [J-105](https://extranet.itu.int/sites/itu-t/focusgroups/ai4h/docs/FGAI4H-J-105.docx): TDD Template
* [J-103](https://extranet.itu.int/sites/itu-t/focusgroups/ai4h/docs/FGAI4H-J-105.docx): CfTGP template

The meeting had 140 participants over the various days and reviewed 54 documents (not counting attachments). There were no outgoing LSs prepared.

A list of the five decisions taken at the meeting is found in [Annex F](#AnnexF) of the report.

The next meeting of the FG-AI4H will be in held virtually, probably May 2021, dates TBD to be communicated in the FG-AI4H webpage and mailing list.

# Focus group management

The current FG management is as follows:

Chairman:

* Thomas Wiegand (Fraunhofer HHI, Germany)

Vice-Chairmen

* Stephen Ibaraki (ACM and REDDS Capital, USA), nominated at meeting A
* Ramesh Krishnamurthy (WHO/Health Metrics and Measurement Cluster)
* Naomi Lee (The Lancet, UK), nominated at meeting B
* Sameer Pujari (Be Healthy Be Mobile Initiative and WHO/Non-communicable Diseases Cluster), nominated at meeting A
* Manjula Singh (ICMR, India), nominated at meeting F
* Shan Xu (CAICT, China), nominated at meeting C to replace Mr Min Dong (Ljubljana)

# Summary of Contributions considered by the focus group at the last three meetings

At meeting J (online) the FG reviewed 55 documents (not counting attachments).

At meeting K (online) the FG reviewed 54 documents (not counting attachments).

All documentation is found per meeting as indicated in §1 above, or as a complete collection at: <https://extranet.itu.int/sites/itu-t/focusgroups/ai4h/docs>.

# Deliverables

During meeting G, a list of deliverables for the FG-AI4H was planned and corresponding research groups (or conference calls) was established, with nine deliverables focusing on generalized specifications including ethics, regulatory, requirement, data, training, evaluation, application, etc., and 20 focusing on use cases within specific health domains with corresponding AI/ML tasks. Initial editors were assigned to each deliverable to create initial drafts of the documents. Experts were also encouraged to contact the editors if they were interested in contributing. At meetings H and I, updates on the deliverables were presented. SG16-TD393/PLEN contains the current version of the draft deliverables for information to SG16.

See Figure 1 below to see the relationship between the different deliverables. According to different characteristics, the planned deliverables are 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 and complement each other, for a holistic view of the AI for health problem space. The arrows in the figure are intended to indicate sequential connections from the perspective of software development and implementation.
* Topic groups (DEL 10.1-10.20): focus on use cases in specific health domains with corresponding AI/ML tasks. Each case could be seen as an example of a whole process recommended by generalized specifications (DEL 1-9), and also adapt to some specific application scenarios.



Figure 1 – Deliverables structure and relationship

A table for document links and contacts information is given as below, hopefully makes it easy for collaboration and dialogues between different deliverables.

During each meeting, updates on the various deliverables are presented and are stored in the FG-AI4H Deliverables collaboration site [https://extranet.itu.int/sites/itu-t/focusgroups/ai4h/SitePages/‌Deliverables.aspx](https://extranet.itu.int/sites/itu-t/focusgroups/ai4h/SitePages/Deliverables.aspx).

# Topic areas & use cases

Meeting J:

* New TG on AI for Musculoskeletal medicine (TG-MSK) with Yura Perov (EQL, UK) as Topic Driver. The collaboration site for the new TG is <https://extranet.itu.int/sites/itu-t/focusgroups/ai4h/tg/SitePages/TG-MSK.aspx>. Mailing list: fgai4htgmsk@lists.itu.int (archive: <https://itu.int/ml/lists/arc/fgai4htgmsk>)

Meeting K:

* No new TGs were created at meeting K
* Weihong Huang (Xiangya Hospital Central South University, China) replaces Maria Vasconcelos (Fraunhofer Portugal) as TG-Derma topic driver
* Pierpaolo Palumbo (University of Bologna, Italy) steps in as interim TG-Falls driver until Sept 2021, for Inês Sousa (Fraunhofer Portugal)

Table 1 – Topic areas

| Topic group | Leader |
| --- | --- |
| 1. Cardiovascular disease management (TG-Cardio), including *risk prediction* and *clinical prediction* sub-topics
 | Benjamin Muthambi |
| 1. Dermatology
 | Weihong Huang |
| 1. Diagnoses of bacterial infection and anti-microbial resistance
 | Nada Malou |
| 1. Falls among the elderly Pierpaolo Palumbo
 | Pierpaolo Palumbo (a.i.) |
| 1. Histopathology
 | Frederick Klauschen |
| 1. Malaria
 | Rose Nakasi |
| 1. AI for Musculoskeletal medicine
 | Yura Perov, Peter Grinbergs |
| 1. Maternal and child health
 | Raghu Dharmaraju; Alexandre Chiavegatto |
| 1. Neurological disorders
 | Marc Lecoultre |
| 1. Ophthalmology (retinal imaging diagnostics)
 | Arun Shroff |
| 1. Outbreak detection
 | Auss Abbood |
| 1. Psychiatry
 | Nicholas Langer |
| 1. Radiology
 | Darlington Ahiale Akogo |
| 1. Snakebite and snake identification
 | Rafael Ruiz de Castañeda |
| 1. Symptom assessment
 | Henry Hoffmann |
| 1. Tuberculosis
 | Manjula Singh |
| 1. Volumetric chest computed tomography
 | Kuan Chen |
| 1. Dental diagnostics and digital dentistry
 | Falk Schwendicke; Joachim Krois; Tarry Singh  |
| 1. Falsified Medicine
 | Franck Verzefé |
| 1. Primary and secondary diabetes prediction
 | Andrés Valdivieso |
| 1. Endoscopy
 | Jianrong Wu |

# Working groups

Currently, after the closure of the Working Group on Health requirements (WG-HR) and the creation of the WG on Ethics at Meeting G, and of the WG on Clinical Evaluation at meeting I, the FG has six working groups, which cover issues horizontally across the various topic groups. The names and leadership are listed in Table 2, and the ToR of each WG is found online at <https://itu.int/en/ITU-T/focusgroups/ai4h/Pages/wg.aspx>.

Table 2 – Working Groups

| Working Group | Leadership |
| --- | --- |
| Data and AI solution assessment methods (WG-DAISAM) | Chair: Pat Baird (Philips)Vice-chair: Luis Oala (Fraunhofer HHI, DE) |
| Data and AI solution handling (WG-DASH) | Chair: Marc Lecoultre (MLlab.AI, CH)Vice chair: Ferath Kherif (CHUV, CH) |
| Operations (WG-O) | Co-Chairs:1. Markus Wenzel (Fraunhofer HHI, Germany)
2. Eva Weicken (Fraunhofer HHI, Germany)
 |
| Regulatory considerations on AI for health (WG-RC) | Chair: Naomi Lee (The Lancet, UK)Vice-chairs:1. Paolo Alcini (European Medicines Agency, EU)
2. Chandrashekar Ranga (CDSCO, India)
3. Khair ElZarrad (FDA, USA)
4. Wolfgang Lauer (Federal Institute for Drugs and Medical Devices, Germany)
5. Liang Hong (Center for Medical Device Evaluation, National Medical Products Administration, China)
 |
| Ethics (WG-Ethics) | Chair: Andreas Reis (WHO) |
| Clinical Evaluation (WG-CE) | Co-Chairs:1. Naomi Lee (The Lancet, UK)
2. Shubhanan Upadhyay (ADA Health, Germany)
3. Eva Weicken (Fraunhofer HHI, Germany)
 |

# Open code software project

The Open Code Initiative (OCI) was started in the FG-AI4H that aims to produce an open code prototype of the digital building blocks (six software packages) that compose the FG-AI4H Assessment Platform. The assessment platform, which can be distinguished from an AI “challenge” platforms through its consideration of regulatory guidelines and the needs of other AI for health stakeholders, supports the end-to-end assessment of AI for health algorithms. One may find more information on the [Wiki site](https://dev.azure.com/mllabai/FG-AI4H%20Assessment%20Platform/_wiki/wikis/FG-AI4H-Assessment-Platform.wiki/1/AI4H-Assessment-Platform). Currently, there are over 20 volunteer experts contributing to the OCI, that meet regularly online. The coordination of the initiative is Mr Marc Lecoultre (MLlab, Switzerland, ml@mllab.ai).

Links:

* Public: <https://www.itu.int/en/ITU-T/focusgroups/ai4h/Pages/opencode.aspx>
* Collaboration site: <https://extranet.itu.int/sites/itu-t/focusgroups/ai4h/SitePages/opencode.aspx>
* Living Document: <https://docs.google.com/document/d/1eksm8dm7MYuNjtThRp-zmwlxvFXUrjSjDnkpuMwZNJ4/>
* Azure DevOps: <https://dev.azure.com/mllabai/FG-AI4H%20Assessment%20Platform>

# Ad hoc Group on Digital Technologies for COVID health emergencies

This [FG-AI4H](https://www.itu.int/en/ITU-T/focusgroups/ai4h/Pages/default.aspx) ad-hoc group will collect effective ways and cases on AI and other digital technologies to combat COVID-19 covering the entire cycle of an epidemic emergency, encompassing the following: prevention and preparedness, outbreak early detection, surveillance and response, recovery, rehabilitation, mitigation, etc (Reference: Emergency Risk Management/ Disaster Risk Reduction of the ERF Sendai Framework). The outputs are expected to evolve towards a more generalizable mechanism on the health emergency continuum, eventually applicable to other pandemics.

Specific aspects to be addressed include:

* COVID-19
* Health emergency cycle
* Digital technologies including AI on epidemic emergencies

The group has produced one output document:

* [Output 1](https://www.itu.int/en/ITU-T/focusgroups/ai4h/Documents/FGAI4H-DT4HE-O-001.pdf): Guidance on digital technologies for COVID health emergency

The DT4HE every other week online, co-chaired by Ana Riviere-Cinnamond (PAHO, rivierea@paho.org) and Shan Xu (CAICT, China; xushan@caict.ac.cn).

# Work Plan

## Meetings

Due to the difficulty planning physical meetings ahead of time, as well as the lesser need to plan far ahead for online meetings, the management team at large has been planning FG meeting in its weekly management calls, in lieu of the Focus Group itself.

Table 3 shows the Schedule of future meetings per 2021-04-19.

Table 3 – Schedule of future FG meetings (as of 2021‑04‑19)

| Meeting | Date | Venue | Notes |
| --- | --- | --- | --- |
| L | 19-21 May 2021 | online |  |
| M | September 2021 (TBC) | TBD |  |

All activities planned are be documented in the FG-AI4H collaboration site calendar, <https://extranet.itu.int/sites/itu-t/focusgroups/ai4h/Lists/Calendar/calendar.aspx>.

The next meeting of FG will take place in online, 19-21 May 2021. Updated information will be made available on the FG webpage, <https://itu.int/go/fgai4h>.

## Webinars

The Focus Group is planning a series of webinars under “AI and Health” that will be part of the AI for Good Global Summit (2020 & 2021 “All year, always online”). Seeking out high-profile speakers that would have otherwise been approached for workshops preceding FG-AI4H plenary meetings.

## Challenges

The Focus Group is setting up a series of “AI for Health Challenges” using the Open Code platform. The intention is to run this on the “AI/ML5G Challenge Sandbox” – two deep learning servers that are being installed at ITU HQ. Initial areas of focus are: Diabetic Retinopathy, Dermatology, Malaria, and Psychiatry.

# Funding

## General activities

The FG-AI4H activities were able to secure funding from the Botnar Foundation (Switzerland), which pledged CHF 274'000 to assist with travel grants for medical and AI experts from LMIC countries, and some operational expenses. These funds became effective in July 2019 and were used to fund nine experts to travel to the meeting in Zanzibar, six experts to travel to the meeting in New Delhi, one expert to travel to the WG DASH/DASIAM workshop in Berlin, and 15 experts to travel to the meeting in Brasilia, plus travel cost of ITU staff providing secretariat services to each of those meetings. The grant was also used to cover the expenses with the use of cloud infrastructure for the running prototype of the assessment framework.

Due to the COVID-19 pandemic, all meetings after January 2020 have been online, hence the grant has been renegotiated with Botnar Foundation to also fund the Open Code Initiative, and further promotion / outreach and workshops.

## WG-RC

To further the activity of the WG on Regulatory Considerations, the U.S. FDA has pledged USD 150,000 in total to support meetings of the working group (funds managed by WHO). This aims at a more targeted effort to advance the international collective understating of the regulatory framework needed to assess and evaluate AI tools and systems.

# Outlook and next steps

After over two-and-half years of operation, the Focus Group on Artificial Intelligence for Health (FG-AI4H) made important progress towards its goals that are stated in its ToR document.

The FG-AI4H is developing into a platform to facilitate a global dialogue for AI for health. Eleven meetings have been carried out and an on-line collaboration platform has been established which has brought in several hundreds of participants with a wide range of backgrounds, interests and geographies. In addition to the general varying participants, normally interested in the various workshops organized at the start of the FG-AI4H meetings, we have seen an increase in steady participation, that delineates the *formation of a core set of experts*. The outreach campaign of the FG-AI4H has reached thousands of readers and awareness has been created through publications such as the FG-AI4H whitepaper and a paper in The Lancet, one of the most respected peer review publications for the medical sector. To ensure sustainability and cost efficiencies, we have increased use of electronic collaboration mechanisms to foster the work of the topic and working groups. We have also developed [onboarding](https://itu.int/en/ITU-T/focusgroups/ai4h/Documents/ITU_WHO_AI4H_Onboarding.pdf) material that facilitates the recruitment of new experts.

The FG-AI4H is actively working towards a standardized framework for benchmarking AI solutions for health. A number of output documents are being refined and cover topics such as data acceptance and handling as well as data and AI solution assessment and guidance to AI solution developers in areas such as ethics, regulatory considerations and clinical evaluation. It is planned to include these documents as part of the standardized framework for benchmarking AI solutions for health that is planned to be delivered and to be provided to ITU and WHO for further consideration. The implementation of the standardized framework through a benchmarking platform is being developed and open code software tools (the FG-AI4H Open Code Initiative) are being made available to conduct the actual benchmarking of AI solutions for health. Two proof-of concept benchmarks have already been considered. The AI4H challenges are expected to further help developing and testing the set of tools in the open code initiative.

The development of the output documents for the standardized framework is conducted in close interaction with actual AI for health use cases, a.k.a. *topic groups*. Through these interactions, the specifics of various modalities of AI for health solution are considered. Currently, the FG-AI4H has in total created 21 AI for health topic groups each containing one or more use cases on cardiovascular disease risk prediction, diagnoses of bacterial infection and anti-microbial resistance (AMR), dermatology, endoscopy, falls among the elderly, histopathology, malaria detection, musculoskeletal medicine, neurological disorders, outbreak detection, ophthalmology, psychiatry, radiology, snakebite and snake identification, symptom assessment, tuberculosis, maternal and child health, volumetric chest computed tomography, dental diagnostics and digital dentistry, falsified medicine, and primary and secondary diabetes prediction. This number is expected to grow as the number of participants is steadily increasing and awareness is being driven forward. The AI for health topic groups produce topic description documents, which are being refined for all 21 health topic groups in parallel. Not all of them have progressed/‌matured at the same pace, as progress is dependent on the commitment and availability of the interested experts. We expect that the earlier deliverables could become technical papers guiding the development of AI benchmarks for particular use cases; as well as a specification describing the framework for benchmarking AI-based health solutions. Moreover, the AI for health solutions in these topic groups are being expected to be the first ones to be benchmarked through our standardized framework. The audience for these deliverables will be, in addition to ITU-T Study Group work, WHO for implementation of its Digital Health Strategy, medical device regulators, medical professionals, and the various communities of machine learning experts and AI-based health solution developers.

The collaboration with WHO in developing appropriate national guidance documents for establishing a policy-enabled environment to ensure the safe and appropriate use of AI in health has been intensified. Moreover, the Working Group on Regulatory Considerations has vice-chairs from regulatory bodies of USA, China, India, Europe and Germany; more vice-chair positions to be filled by regulatory bodies of other countries are currently being discussed. The US FDA allocated some funds to help progress this activity (managed by WHO), It held two main online meetings in May and October 2020, in addition to weekly calls. The agenda items for this meeting of the Working Group on Regulatory Considerations also include the review of the output documents of the FG-AI4H.

All proceedings of the FG-AI4H have been conducted in order to generate a transparent documentation by creating reports and specifications towards enabling external assessment of the benchmarking framework and the benchmarked AI for health methods.

Working groups within FG-AI4H provide cross-group structure, for example by early exposure to regulatory considerations and in developing data acceptance and handling policies. We have established further working groups on ethical considerations, clinical evaluation and we expect to establish one on public health. These new working groups and additional activities together with the expansion of the number and reach of health topic groups will drive the activity of the FG-AI4H towards achieving its goals.

Overall, the group is satisfied with the progress and expects to start seeing some real advance in the core issues of the focus group, now that work methods and structures are more stable, after this initial term of operations and the level of participation and awareness that has been created.

# Annex A:Lists of participants at all meetings held since the previous progress report

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