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| **ITU-T Focus Group on AI for Health** |
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| **Abstract:** | This document contains the Call for Participation in the Topic Group on “AI-based detection of falsified medicine” (TG-FakeMed). The purpose of the Call for Participation is to call on members of the medical and artificial intelligence communities with a vested interest in the topic to become engaged in the TG-FakeMed. |

ITU/WHO Focus Group on artificial intelligence for health (FG-AI4H)

Call for Topic Group Participation: < Detection of falsified medicine>

The International Telecommunication Union (ITU)/World Health Organization (WHO) Focus Group on “Artificial Intelligence for Health” (FG-AI4H; <https://itu.int/go/fgai4h>) seeks engagement from members of the medical and artificial intelligence (AI) communities (including clinicians, technologists, entrepreneurs, potential benchmarking data providers, machine learning experts, software developers, researchers, regulators, policy-makers, companies/institutions, and field experts) with a vested interest in shaping the benchmarking process of <Detection of falsified medicine >.

# About FG-AI4H

Over the past decade, considerable resources have been allocated to exploring the use of AI for health, which has revealed an immense potential. Yet, due to the complexity of AI models, it is difficult to understand their strengths, weaknesses, and limitations. If the technology is poorly designed or the underlying training data are biased or incomplete, errors or problematic results can occur. AI technology can only be used with complete confidence if it has been quality controlled through a rigorous evaluation in a standardized way. Towards developing this standard assessment framework of AI for health, the ITU has established FG-AI4H in partnership with the WHO.

Thus far, FG-AI4H has established < G-022 > topic groups. The topic groups are: AI and cardiovascular disease risk prediction, child growth monitoring, dermatology, falls among the elderly, histopathology, neuro-cognitive diseases, ophthalmology (retinal imaging diagnostics), psychiatry, radiotherapy, snakebite and snake identification, symptom assessment, tuberculosis, volumetric chest computed tomography, and <Detection of falsified medicine >.

Each topic group agrees upon representative benchmarking tasks in a pragmatic, best-practice approach, which can later be scaled and expanded to similar tasks. Every benchmarking task should address a health problem of relevance (e.g. impacting a large and diverse part of the global population or challenging to treat) and for which AI technology would provide a tangible improvement relative to the current practice (e.g. better care, results, and/or cost/time effectiveness).

For a rigorous and sound evaluation, undisclosed test data sets must be available (or have to be collected) for each task. All data must be of high quality and compliant with ethical and legal standards. In addition, the data must originate from a variety of sources so that it can be determined whether an AI algorithm can generalize across different conditions, locations, or settings (e.g. across different people, hospitals, and/or measurement devices). The format/properties of the data serving as input to the AI and of the output expected from the AI, as well as the benchmarking metrics are agreed upon and specified by the topic group.

Finally, the AI-to-be-evaluated will be benchmarked with the undisclosed test data on FG-AI4H computing infrastructure. Here, the AI will process single samples of the undisclosed test data set and predict output variables, which will be compared with the "ground truth." The results of the benchmarking will be provided to the AI developers and will appear on a (potentially anonymized) leaderboard.

# Topic group: < Detection of falsified medicine>

A topic group is a community of stakeholders from the medical and AI communities with a shared interest in a topic. The objectives of the topic groups are manifold:

1. to provide a forum for open communication among various stakeholders,
2. to agree upon the benchmarking tasks of this topic and scoring metrics,
3. to facilitate the collection of high-quality labelled test data from different sources,
4. to clarify the input and output format of the test data,
5. to define and set-up the technical benchmarking infrastructure, and
6. to coordinate the benchmarking process in collaboration with the Focus Group management and working groups.

The primary output of a topic group is one document that describes all aspects of how to perform the benchmarking for this topic. (The document will be developed in a cooperative way by suggesting changes as input documents for the next FG-AI4H meeting that will then be discussed and integrated into an official output document of this meeting. The process will continue over several meetings until the topic description document is ready for performing the first benchmarking.)

This topic group is dedicated to <Detection of falsified medicine>.

Introduction

The presence of substandard and falsified medical products in countries and their use by patients threatens to undermine progress towards meeting the Sustainable Development Goals. Such products may be of poor quality, unsafe or ineffective, threatening the health of those that take them.

The problem of substandard and falsified medical products continues to increase, as globalized manufacturing and distribution systems grow ever more complex. That complexity heightens the risk that production errors will occur, or that medicines will degrade between factory and consumer. Increasing demand for medicines, vaccines and other medical products in almost every country, in addition to poor supply-chain management and the growth of e-commerce also creates opportunities for falsified medicines to be introduced into the supply chain.

Unfortunately, reliable information on the true public health and socioeconomic impacts of substandard and falsified medical products is sparse. A stronger evidence base is needed to help prevent, detect and respond to substandard and falsified medical products, and the public health threat they represent.

The falsified and sub-standard drugs today cause, according to the University of Edinburgh (childhood pneumonia model), the deaths of 250,000 children a year. Technological innovation, more precisely AI technology is one of the most effective means of dealing with increasingly creative counterfeiters. This topic group on AI-based Detection of falsified medicine aims to develop artificial intelligence algorithms and to collect data available on falsified drugs.

Relevance

One of the reasons for the proliferation of falsified and substandard drugs is the lack of drug analysis equipment or simply too expensive equipment for LMICsthat cannot afford a price tag of EUR 60.000 per device, many healthcare facilities and pharmaceutical depots on the continent are unable to get the technology to stop counterfeited medicine.

This lack of analytical devices leads to the lack of database that stores clean data on falsified and sub-standard drugs. Lack of high-quality data from the majority of LMICs means that first estimates will depend largely on data modelling.

AI is presented as a solution to the problem and must:

* Save life by verifying the authenticity of drugs (Customs, warehouses, pharmacies, hospitals) anywhere rapid verification is required.
* To build a database: To provide information and quantify the cost and socioeconomic impact of falsified and substandard medicines and establish the potential costs.
* To save money: An affordable solution than existing test machines on the market
* To identify the unknown chemical components: By using artificial intelligence-based technology to match collected drug data to datasets in our database stored on secure servers in the cloud.

In order to address the global challenge, the system should satisfy the following objectives:

1. Visual measurement data Devices should work with an affordable smartphone
2. Easy backup generation of database
3. Continuous operational status follow-up measurement devices
4. The system should be able to work offline and online if connection is available
5. The system should allow identification and quantification of drugs
6. The system should have two app, one for non-professional and the second for health professional
7. The system should also provide automatic reporting (weekly, monthly, yearly)
8. The system should provide simple answers and interpretation messages for non-professional

Data availability

Anonymized data will be made available by the organizers of this Topic group.

Data available:

* Data from TrueSpec Africa
* Anonymized drugs information

More details about the activities of the topic group can be found in the documents (G-022). These can be accessed with a free ITU account (cf. “Get involved”).

The topic group would benefit from further expertise of the medical and AI communities and from additional data.

# Get involved

To join this topic group, please send an e-mail to the focus group secretariat (tsbfgai4h@itu.int) and the topic driver (verzefefranck@gmail.com). Please use a descriptive e-mail subject (e.g. "Participation topic group AI for (Detection of falsified medicine), briefly introduce yourself and your organization, concisely describe your relevant experience and expertise, and explain your interest in the topic group.

Participation in FG-AI4H is free of charge and open to all. To attend the workshops and meetings, please visit the Focus Group website (<https://itu.int/go/fgai4h>), where you can also find the whitepaper, get access to the documentation, and sign up to the mailing list.

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