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| **Abstract:** | 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). |

**Introduction:**

Even after 60 years of rising of artificial intelligence (AI), its use in resource-poor countries is relatively less as compared to developed countries [1]. The use of AI in Mobile Applications is growing rapidly [2]. It was estimated in the beginning of 2019, that more than 5 billion people have mobile devices worldwide, and more than half of these devices were smartphones [3]. The healthcare mobile apps have a significant positive impact on health and health care, however, there is a challenge for patients and clinicians to find a confirmed product among infinite choice of unproven mobile applications [4]. Thus, there is a wide scope for development of reliable AI based Mobile Applications for healthcare within the sphere of International Telecommunication Union (ITU)/World Health Organization (WHO) Focus Group on “Artificial Intelligence for Health” (FG-AI4H).

**Objectives:**

The objectives of the topic groups are as follows:

1. to provide a forum for open communication among various stakeholders,
2. to clarify the technical requirements for upcoming Mobile Apps with AI for Healthcare
3. to prepare the regulatory/ethical rules for upcoming Mobile Apps with AI for Healthcare
4. to agree upon the benchmarking the Apps,
5. to coordinate the benchmarking process in collaboration with the Focus Group management
6. and working groups.

**Basic requirements for Mobile Application:**

The desired key features for a Mobile Application for implementing AI for health are as follows:

1. Functionality [5]:

The mobile applications should be validated w.r.t. the desired features of application, target audience and the distribution channel such as Google Play, Apple App store etc. Some key points are as follows:

* Verify accessibility in respect of compatibility with mobile platforms, user friendly language, easy to use and affordability
* Confirm that mandatory fields are being collected, format of data and display of data is correct
* Proper error handling and relevant error messages
* User-friendly console of the App, appropriate size of the buttons and user manual for users

1. Performance [5]:

Some key points for validation of the performance of mobile applications are as follows:

* The client server communication should work properly at peak, average and minimum user levels
* Identify the bottlenecks which prevent the application to perform at the required acceptability levels.
* Identify optimum response time of the app
* Identify the optimum mobile device requirement for the app
* Identify optimum performance of resources such as GPS, Camera, Battery etc in various situations

1. Security Validation:

The security of mobile applications should be validated. Some key points are as follows:

* Enforce secure communication by applying signature-based permissions, disallow access to your app's content, ask for credentials before showing sensitive information etc. [6]
* Apply network security measures by using SSL communication, applying network security configuration and creating your own trust manager [6].
* Use the best Cryptography Tools and Techniques [6].
* Get security audit of Mobile App
* Design App for handling data overflow

**Regulations for Mobile Apps with AI for Healthcare**

A product that meets the definition of a medical device falls within the purview of the FDA, and is then subject to regulation before and after it is marketed[7]. Section 201(h) of the Federal Food Drug & Cosmetic (FD&C) Act defines a device as “an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including a component part, or accessory which is:… intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals.. ..”. If the App is a medical device, then it must be evaluated whether the developer meets applicable regulations in offering the product to the public.

When a App draws data from a medical device, it is considered as accessory to that medical device, thus, are regulated according to regulations of parent device. If the app creates a new property or function that the parent device does not have, such apps might fall into Class-III classification and regulated accordingly.

**Ethical issues [10]**

There are 17 principles mentioned in the “ICMR - National Ethical Guidelines For Biomedical And Health Research Involving Human Participants”. According to Principle of essentiality, the use of human participants should be duly vetted by an ethics committee (EC) independent of the proposed research. According to Principle of professional competence, the app must be developed in consultation with medical experts and contain accurate medical information.

The researcher should not have conflict of interest, such as participant’s welfare or financial interest etc. Efforts should be made to communicate the findings of the research study to the individuals/communities wherever relevant. All members of a research team are expected to maintain high standards and to uphold the fundamental values of research. Unethical behaviour in scientific research can destroy the public’s trust in science and have a negative impact on the research team. The researcher must ensure that the patient records is secured and will not be shared with third parties, such as medical institutions, insurance companies, advertisers etc. An ethical framework based on equality and equity is required for international collaboration, due to different levels of development in terms of infrastructure, expertise, social and cultural perceptions, laws relating to IPR, ethical review procedures, etc. There is a need to follow all the guidelines related to Ethics issues before designing a research study.

**Call for Topic Group Participation in AI4H applications and platforms: Mobile Applications**

The International Telecommunication Union (ITU)/World Health Organization (WHO) Focus Group on “Artificial Intelligence for Health” (FG-AI4H; https://www.itu.int/go/fgai4h) seeks engagement from members of the medical and artificial intelligence (AI) communities to collaborate in development of Mobile Application based AI tools for Health.

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