Accreditation Guide for Health and Wellness Apps

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Content

Introduction

The mHealth Office promote the use of health and social welfare activity practices centred on the person and supported by mobile devices, sensors and other wireless solutions that act as digital assistants in remote mode and that at the same time, they can interact with other technologies such as virtual reality or artificial intelligence.
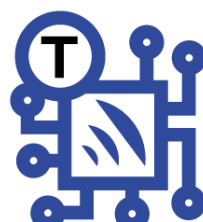
The mHealth Office is working to promote the development of solutions that improve personal care processes by redefining the relationship between professionals and patients in terms of efficiency and effectiveness.

In 2017, the mHealth Office developed the certification process for mobile applications for health. Due to the growing need in the health sector to regulate and classify the different solutions developed in mobility for citizens and professionals, appears the need to promote the use of trusted applications for patients and professionals. With this intention, the assessment framework were set up, called, "Certification seal for mobile health applications of the TIC Salut Social Foundation".

This guide show the different stages of the App's assessment framework and determine their actions performed in the different steps and phases of the process.

The certification scheme consists in review a total of 120 criteria distributed in four certification blocks, in this sense, the four blocks reviewed in the assessment framework are: **Clinical content** and functionality of the App, **Technological** aspects, **Security** and Data privacy and **Usability** of the App.

With the purpose of guaranteeing an accurate assessment of each criterion, there are stablished two levels of classification for the App: **Technological Level and Content Level**. Each level can be rated in three levels (1, 2, or 3), being level 1 being the least demanding and level 3 being the most demanding regarding how strict the assessment framework will be.

Each assessment criterion has a label depending on the classification level of the App, for instance:

As it's shown in the following table, the criterion T.06 will be compulsary for the Apps rated in level 3, meanwhile, for the Apps rated in level 2 this criterion is recommended.
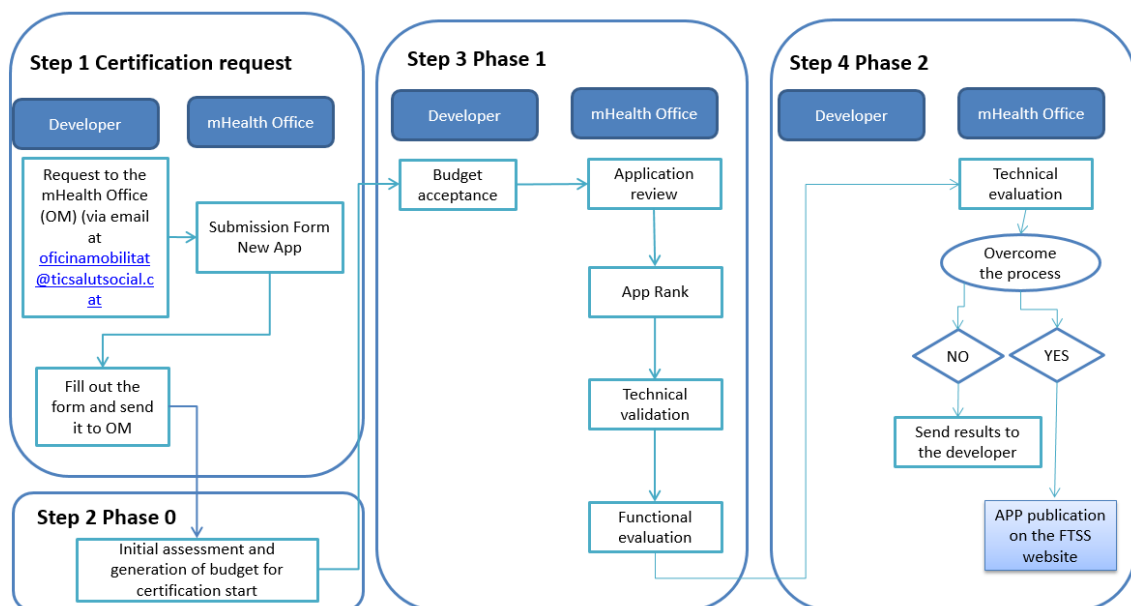
	Criteria	Level 1	Level 2	Level 3
T.05	**It does not fail immediately during its use (blocks, etc.)**	Compulsory	Compulsory	Compulsory
	The App works and does not have constant failures which force to close it.			
T.06	**It is retrieved correctly in context changes (switch to other App and return), external interruptions (incoming call or message, etc.) and switched off the terminal**	Desirable	Recommended	Compulsory
	If the user switch to another App or receives an incoming call, he may resume to the previous App screen.			

Certification scheme

The certification scheme has four steps:

Step 1 – Certification request. The manufacturer of the App sends an email to the mHealth Office, at the address oficinamobilitat@ticsalutsocial.cat, indicating their interest in starting the certification process for their health app.

The mHealth Office sends a form (**New App Form)** to the developer for being returned completed to the Office.

Step 2 – Phase 0. Review of the application and budget. With the completed form, the mHealth Office will review the information provided and prepare the corresponding budget.

Step 3 – Phase 1. App classification, technical validation and functional evaluation. This phase consists of classifying the App in the two levels of demand required for certification (functional and technological), once the App has been classified, a general technical validation of the application is carried out and finally the Committee of Functional Experts reviews the App and evaluates the criteria corresponding to the Content Block.

Step 4 – Phase 2. Technical evaluation and preparation of the final report. In this phase, the criteria corresponding to the rest of the certification blocks are assessed: Usability, Security and Technological Block. Also a final report is delivered, specifying the non-conformities found and the certificate of the evaluated App is delivered.

The certification process ends once the mHealth Office has evaluated the three phases (0, 1 and 2) and their corresponding blocks. In the case of not successfully passing any stage of the process, the developer of the App is informed in the report indicating the following steps.

The criteria can be check in the Tic Salut website: https://ticsalutsocial.cat/wp-content/uploads/2021/09/2021_Criteris-certificacio_ENG_v3.0.pdf

Accreditation categories

CLINCAL CONTENTS

A Committee of Experts, made up of professionals from different professionals associations in the sector such as CoMB, COPLEFC, COIB, SCEPC, AiFICC and CAMFiC, assess the quality of the content and the utility of the functions offered. Their review includes the usability and design of the application and whether it notifies the user of any software updates.

USABILITY

The application must have an intuitive interface, with a design suited to its intended function and it must ensure universal, inclusive access to people with functional diversity to maximize the benefits offered by the technology.

TECHNICAL REQUIREMENTS

We determine whether the app functions are efficient and reliable from a technological point of view. The application must adapt to a minimum of functionality acceptable to the end user ensuring robustness and consistency.

SECURITY AND PRIVACY

We ensure robust mechanisms are in place to preserve the privacy of the data generated by the users and the utmost confidentiality in the transmission of said information. It is necessary to ensure proper storage of information and establish mechanisms for encryption when registering passwords.

Classification levels

One of the stages of the certification process is to classify the App according to two levels of risk (level of technological risk and level of content risk) by the user who will use it. This classification allows determining the requirement applied to the criteria of the certification process, that is, whether the criterion is compulsory, recommended or desirable. It should be noted that this classification would not affect the economic cost of certification.

The two levels of demand determine the risk posed by the user in using the App; from a technological or functional point of view (clinical):

- **Technological level:** Corresponds to the level of requirement applied to the technological, usability and security criteria.
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- **Content level:** Corresponds to the level of requirement applied to the content criteria.

In order to know which are the levels of requirement established by each application submitted to the certification process, it will be necessary to answer the three questions (A, B and C), which will determine the three parameters used to classify the App in both levels:

A. **Sensitive information:** *Does the App manage private information, which, in the event of any security threat, could put the patient's privacy at risk? On the other hand, those Apps that interact with the health system will also be considered high risk.*
   - **Low** → The App does not manage data.
   - **Moderate** → The information has a local treatment or the collected data can be transmitted in aggregate form.
   - **High** → The application collects data about the user that is transmitted outside the application.

B. **Health Information or Recommendations:** Can the information provided by the application on aspects related to health provide misinformation? *Close attention to applications that assess the user's health status.*

- **Low** → The App **does not** provide information about the patient's health status does not provide health recommendations or provide specific information about the status of the user or the activity of the user.
- **Moderate** → The App provides health information but it is out of context, it is general information or it has its origin in standard protocols and recommendations.
- **High** → The App provides specific health information or recommendations for the user based on the data collected for the application or input by the user.

C. **Impact**: *What is the possible number of users who can use the application in Catalonia? Generic applications, without a specific scope, will have an impact that can be considered depending on the platform and the share of users and the penetration of the use of this type of application in the population.*

- **Low** → The application has a very small potential target audience below 2% of users (<100k)
- **Moderate** → The potential users of the application are between 2% and 10% of the population (device user between 100k and 1M)
- **High** → The potential users of the App exceed 10% of the population (< 1M)

Once the answer to the three questions (A, B and C) is obtained, the following matrices can be used to obtain the result of the App for each level (technological level and content level).

Technological Level:

In the case of the technological evaluation that implies evaluating the blocks of security, technology and usability, the following two parameters are used to be able to determine what risk it entails for the patient in terms of the use of the application:

- **Impact of the solution** potential volume of people who can use the technology)
- **Sensitive information managed by the App** (that puts the health system at risk or of a character that will not interact with the system)

The following matrix indicates the technological level of the App based on the two previous parameters:

Sensitive information	Impact		
	Low	Moderate	High
Low	LEVEL 1	LEVEL 1	LEVEL 2
Moderado	LEVEL 2	LEVEL 3	LEVEL 3
Alto	LEVEL 3	LEVEL 3	LEVEL 3

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Content Level:

In the case of the clinical evaluation that involves evaluating the content block, the following two parameters are used to determine what risk it entails for the patient when using this application:

  - Impact of the solution (potential number of people who can use the technology)

  - Health information or recommendation that entails a risk for the person

The following matrix indicates the content level of the App based on the two previous parameters:

Information or health recommendation	Impact		
	Low	**Low**	**Low**
Low	LEVEL 1	LEVEL 1	LEVEL 2
Moderado	LEVEL 1	LEVEL 2	LEVEL 2
Alto	LEVEL 2	LEVEL 3	LEVEL 3

Final score

Successfully passing the certification process implies publishing the App on the Tic Salut website with the corresponding certification seal, and made dissemination on the different social networks. The manufacture receives the final report with the results of the certification process and the certificate in case of overcoming the process.

In the event that not overcoming the certification process, manufacture receives the final report, detailing the disagreements.

Random audits

Once the application has successfully passed the certification process, random audits are performed to ensure that the criteria continue to be met. If an application is identified that does not meet any of the criteria, it will be unpublished from the Foundation's website immediately. The company that owns the App will always have to inform the mHealth Office of potentially sensitive changes that may affect non-compliance with the certification criteria.