

Accreditation Guide for Health and Wellness Apps

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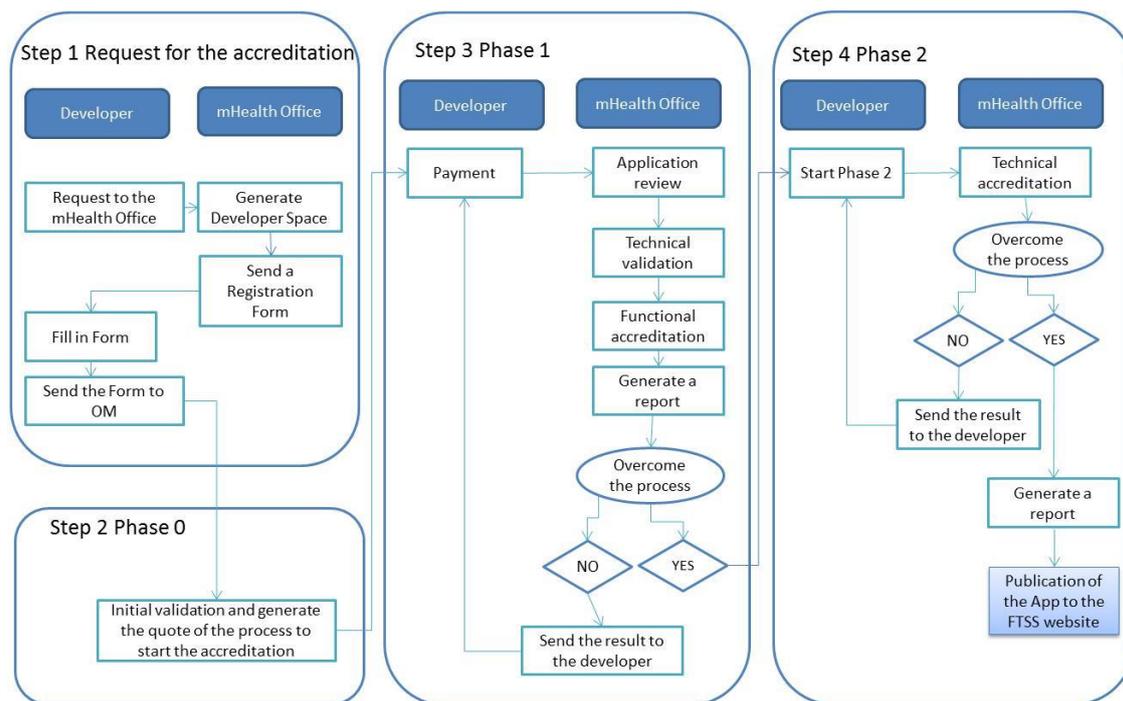
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Introduction

The purpose of this document is showing the steps to follow to carry out the accreditation of a Health or Wellness App and obtain the accreditation stamp of TIC Salut Social Foundation.

Accreditation process

The diagram of the accreditation process is shown below:



To start the accreditation process it is necessary that the owners / developers of the application send an email to oficinamobilitat@ticsalutsocial.cat showing your interest in the accreditation of their App.

Once the mHealth Office receives the request, it will send an email to the applicant with the New App Form that must be completed with technical and functional data of the App. This form must be returned to the mHealth Office duly completed.

When the mHealth Office receives the completed form, it will prepare the quote corresponding to the accreditation of the App. To elaborate the budget, the classification level of the App will be checked as well as the data filled out in the form sent.

The form will allow the mHealth Office to determine the minimum accreditation criteria that the App must meet, and will allow the beginning of the process.

The accreditation process has been differentiated into three phases:

- Phase 0: Review of the application.
- Phase 1: Technical validation and functional accreditation.
- Phase 2: Technical accreditation.

Once the three phases have been passed, owners / developers will be informed of the result of the evaluation through a report of results for each criterion.

The fact of proposing an App in the accreditation process of the Fundació TIC Salut Social implies that this application must pass the following phases:

- **Phase 0: Review of the application.**
 - Check the request
 - Checking the information provided in the form
 - Economic quote of the accreditation process
- **Phase 1: Technical validation and functional accreditation.**
 - Initial technical validation where the application is tested.
 - Functional accreditation of the application by the Functional Experts Committee of the mHealth Office (entities such as [COMB](#), [COPLEFC](#), [COIB](#), [SCEPC](#), [AIFICC](#) and [CAMFIC](#)) reviewed the App and the content criteria is evaluated.
- **Phase 2: Technical accreditation.**
 - Technical accreditation. Specifically, the usability block, the technology block and the security block are reviewed.

The accreditation process ends once the mHealth.cat Office has evaluated the three phases and their corresponding blocks. In case of not having passed any of the phases, the developers will be informed through a report and the steps to be followed to overcome the process will be indicated.

You can check the accreditation rates in the document "*Accreditation rates for Health or Wellness Apps*" at www.ticsalutsocial.cat.

Accreditation blocks



FUNCTIONALITY AND CONTENT

A Committee of Experts, made up of professionals from different professional associations in the sector such as [COMB](#), [COPFLEFC](#), [COIB](#), [SEPC](#), [AiFICC](#) and [CAMFiC](#), evaluate 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 AND ACCESSIBILITY

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.



TECHNOLOGY

We determine whether the app functions efficiently and reliably 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

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

Within the accreditation process, a classification of the App is obtained that allows determining the requirement of the process. It should be noted that this classification will not affect the economic cost of accreditation.

All Apps will be classified in one of the two levels of demand, which will mark the criteria to be used for the accreditation process of the App. The two levels of demand are determined according to whether the risk is evaluated from a technological or functional point of view (clinical):

- Technological criteria: usability and security (registration and management of the information collected)
- Functionality and Content criteria (Information provided)

To classify the app in one of these three levels, first you have to select one of the following options to check their correspondence in the next tables:

- A. **Sensitive information:** The App manages private information, which in case of suffering any security threat could put the patient's privacy at risk. On the other hand, those who interact with the health system will also have a high risk consideration.
- **Low** → The App does not collect data.
 - **Moderate** → The information has a local treatment or the collected data can be transmitted in aggregate form.
 - **High** → The App collects user data that is transmitted outside the application.
- B. **Information or recommendation of Health:** The information provided may provide erroneous information. A lot of attention with the applications that evaluate the health status of the user.
- **Low** → The App does not provide information of the patient's health status and does not make any recommendation of health or provides specific information about the current status of the user or activity.
 - **Moderate** → The App provides information but this is decontextualized. It is general information or that it has its origin in protocols and standard recommendations.
 - **High** → The App provides information or specific recommendation for the user, based on the data collected by the application or entries by the user.
- C. **Impact:** Possible number of users who will use the App. The impact can be calculate depending on the kind of platform and the number of users and the penetration of the use of this type of applications in the population.
- **Low** → The App has a very reduced target audience, less than 2% of the population of Catalonia. (<100k).
 - **Moderate** → Potential users of the app are between 2% and 10% of the population of Catalonia. (users between 100k and 1M).
 - **High** → Potential users of the App exceed 10% of the population of Catalonia (>1M).

Once the result of the three indicators (**A, B and C**) is obtained, you can use them in the next tables to obtain the results that determine the two levels of risk (*technological level and content level*):

Technological Level:

	Impact		
Sensitive information	Low	Moderate	High
Low	LEVEL 1	LEVEL 1	LEVEL 2
Moderate	LEVEL 2	LEVEL 2	LEVEL 2
High	LEVEL 3	LEVEL 3	LEVEL 3 + SECURITY

Content Level:

	Impact		
Information or recommendation of Health	Low	Moderate	High
Low	LEVEL 1	LEVEL 1	LEVEL 2
Moderate	LEVEL 1	LEVEL 2	LEVEL 2
High	LEVEL 2	LEVEL 3	LEVEL 3

The accreditation criteria and the requirement of each criterion can be found in the document "Accreditation criteria for Health or Wellness Apps" at www.ticsalutsocial.cat .

Final result

The fact of successfully overcoming the accreditation process involves publishing the App on the TIC Salut Social website with the corresponding accreditation stamp, specifically in the section of the Catalog of Accredited Apps, a news item will be published on the website informing of this accreditation and will be disseminated in different social networks. The corresponding accreditation certificate will also be delivered together with the detailed results report of the accreditation made.

In the case of not satisfactorily overcoming the accreditation process, the corresponding "results report" will be delivered where the points not exceeded are detailed and pertinent comments will be made. If in a maximum of three months the changes are presented, the application will be revised again, bearing in mind that if the App fails in more than three criteria of a block, 50% of the price of that block must be paid.

Random audits

Once the App has successfully passed the accreditation process, random audits are performed to ensure that they keep meeting the criteria. If an App is not accomplishing this is identified, it will be unpublished from the site immediately. The developer must always inform the mHealth Office on the potential sensitive changes that may affect the performance of non-accreditation criteria.