

# CREATING A HEALTHCARE APP

After reading this factsheet you should:

- Have a basic understanding of the steps involved in creating a healthcare app.
- Have links to related resources.

## Introduction

The [World Health Organisation \(WHO\)](#) defines mHealth or mobile health as medical and public health practice supported by mobile devices, such as mobile phones. The mHealth market has also grown rapidly, valued at more than [111.5 billion USD](#) in 2022. Innovators should become familiar with the following steps when creating a healthcare application.

## What is the purpose of the app?

Establish the main goal of your healthcare app and identify the need it aims to address. Validate with the intended users that this is a need worth solving. Identify what category of app you want to create.

Wellness apps (Diet and Nutrition, Lifestyle and Stress, Exercise and Fitness) form the majority of mobile health apps with the other main category being health condition management apps (Providers/Insurance, Medication reminder, Women's Health and Pregnancy, Disease Specific). The top rated wellness apps and the top rated health condition management apps can be seen [here](#).

## What is the target market?

It is important to conduct some early market research. Any new app should be meeting an unmet need. Research potential competitors and understand what the existing apps provide to the market. Establish any areas of opportunity or gaps that your app can take advantage of. Identify your target audience and consider their age, their income if they have any health issues or chronic diseases. Try to understand your users' routines, habits, and expectations.

## What is the monetisation model?

Prior to beginning development, you must decide on your app's monetisation strategy as this will have a significant influence on the development of the app.

Some strategies are listed below. More info can be found [here](#).

- Paid product: onetime payment for access to the app.
- Freemium model: basic aspects of the app are free, but premium features must be purchased.
- Subscription model: enables users to access your software via a paid subscription.
- In app advertising: partner with advertising providers to imbed relevant adds within the app. The app is free but offering ad space earns you money.
- In app purchases: incorporate marketplace features that offer customers relevant goods and services.





## How are healthcare apps classified in the EU and US? What are the regulations for a healthcare app?

US: FDA implements regulatory monitoring if the app meets the [FDA definition for a medical device](#) or if it could pose risk to a patient if it malfunctioned. Healthcare apps fall into one of three categories: Class I, Class II, or Class III, with Class III devices carrying the most risk.

Examples of how the FDA might regulate particular device software functionalities are given in this [guidance document](#). More info can be found on the [FDA website](#).

EU: MDR implements regulatory monitoring if the app meets the [MDR definition for a medical device](#) or if it could pose danger to a patient if it malfunctioned.

The EU categorises Software as a Medical Device (SaMD) into four different classes based on the level of risk they pose to the patient: Class I, Class IIa, Class IIb, or Class III, with Class III devices carrying the most risk. Guidance on Qualification and Classification of Software in Regulation (EU) 2017/745 can be found [here](#).

More information on medical device classification and regulation in the EU and US can be found on the HIHI factsheet on Software as a Medical Device – classification – US vs EU [here](#).

## Are there any other legal requirements?

Patient privacy and confidentiality.

US: The Health Insurance Portability and Accountability Act ([HIPAA](#)) is a US governmental regulation that settles rules for sharing personal health information.

Read more about HIPAA here [\\*link HIPAA factsheet\\*](#) EU: The General Data Protection Regulation ([GDPR](#)) is the EU governmental regulation that settles rules for sharing personal health information. Read more about GDPR [here](#).

## How do I develop the app?

- User interface and user experience (UI/UX): Work with a designer to create an inviting user interface (UI) and consider usability, accessibility, and creating a streamlined user experience (UX). Some design tips can be found [here](#).
- Select the development strategy: Establish if you are creating a native (iOS or Android) or a cross platform app.
- Development: Assemble a development team or work with an app development company. Ensure the software complies with the intended functionality, security standards, and legal requirements.
- Security and Privacy: Implement user authentication, access controls, and strong data encryption while adhering to all applicable data protection laws.
- Launch app: Create a marketing plan to advertise your healthcare application. Interact with customers and collect feedback to continuously develop and improve the app.

