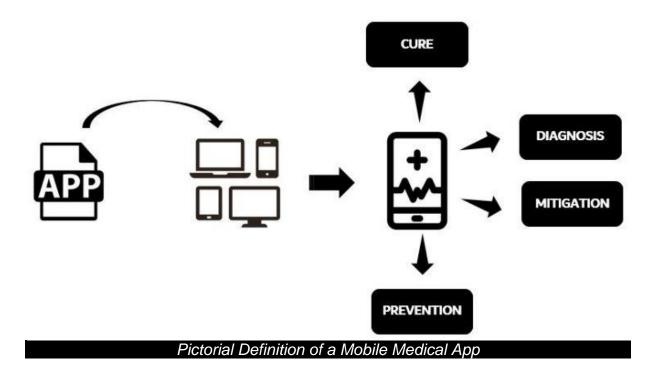


Mobile Medical Applications: The Regulatory Framework in the U.S. and the EU



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The medical device market is one of the largest industries in the healthcare sector, which has seen significant growth in the last 15 years. Harnessing the benefits of the digital revolution and medical technology, the industry is in a state of continuous transformation. Mobile medical applications (MMA) represent one such transformative invention the industry has provided to healthcare professionals. An MMA is a piece of software that runs on a smartphone and/or other mobile communication device, transforming the mobile platform into a medical device to perform a specific healthcare function.

According to Research and Markets, the global market for mobile health applications is currently valued at approximately \$28.32 billion and is expected to reach \$102.35 billion by 2023. Complex data analytics and mobile technologies are enabling and driving the integration of mobile devices into the healthcare sector, which in turn are catering to the requirements of healthcare professionals, patients, and general consumers as well. They have also contributed to simpler remote monitoring; better communication; and care

coordination among doctors, nurses, and other specialists involved in the diagnosis and treatment of diseases.

Depending upon the functionality, MMAs can be broadly segmented into one of several categories....