

with no larger follow-on studies.³⁶

MOBILE TECHNOLOGY FOR RESEARCH AND DEVELOPMENT

Apple iOS

Apple HealthKit: Apple created the HealthKit, a software development kit (SDK) for iOS and the WatchOS. These application programming interfaces (APIs) integrate a new app with the phone's health and activity data. Extensive videos, sample code and guides are included on the website.³⁷

CareKit: is the open-source SDK to help patients manage their own health.³⁸ For example, Corrie Health app from Johns Hopkins University monitors a patient's recovery from a heart attack by tracking vital signs, medications and physical activity.³⁹ Johns Hopkins is using this app as part of the Myocardial Infarction Combined Device Recovery Enhancement (MICORE) Study.⁴⁰

Apple ResearchKit: is an open-source framework that enables an iOS app to be used for medical research.³⁸ The workflow for research, such as enrollment, consent and patient surveys is part of the Kit. ResearchKit is integrated with HealthKit so that health and activity parameters (steps, calories burned and heart rate) can be included in the study. For example, an app could be developed to measure activity in a population at risk (e.g. Parkinson's Disease) and that data, along with patient input is made available to researchers. Such an app has already been developed (mPower) by the University

Figure 13.4: mPower app for Parkinson research

Android OS

Google Fit: is an app but also includes an Android software SDK, similar to Apple HealthKit for building apps using the activity sensor's application programming interface (API). Data is transmitted to a central web repository known as Google Fitness Store.⁴²

ResearchStack: is a SDK framework for creating research apps using the Android OS, analogous to the Apple ResearchKit.

Research Droid: is an Android port of the ResearchKit launched in November 2015 to add Android smartphones to the research platform. The first app America Walks was developed that is available on both Android and iOS and can integrate with ResearchKit.⁴³ A study (sponsored by TrialX) started and ended in 2016 to collect data from volunteers.⁴⁴

REGULATORY REQUIREMENTS

In the United States, the Food and Drug Administration (FDA) for many years did not have a clear statement on the regulation of mobile health. Now some clarification has come to distinguish between devices and apps which are used for treatment or clinical decision support and those which have not.⁴⁵ Those devices and apps which are directly involved in treatment or that provide clinical decision support are regulated and must get through