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Tapping The Potential Of The Mobile Health Application Revolution

by

Mobile health applications have the potential to significantly change drug development, clinical trials and the administration of health care. In this article, Dr Bill Hanlon, vice president, head of global regulatory affairs at Covance, and Scott Thiel, associated director at Navigant Consulting take a look at the opportunities and challenges of this growing field. *Content paid for by Covance.*

Mobile health applications have the potential to significantly change drug development, clinical trials and the administration of health care. The industry has grown rapidly, with roughly 45,000 identified mobile health publishers and more than three billion app downloads in 2015. By some projections, the global market will reach \$10.2 to \$11.8bn by 2018 with a compound annual growth rate of 39-41%. Currently, less than one-fifth of health care providers currently use mobile health apps with their patients, but nearly half say they will start in the next five years.

This expanding industry has created new opportunities for developers ranging from small start-ups to established companies. But many of these firms will face similar challenges entering this evolving field. Regulations are still emerging, and the US Food and Drug Administration (FDA) has not yet provided definitive guidance on some types of products. Expectations for precision and accuracy can be as high as those for traditional medical devices, and users are starting to demand more reliable performance. While mobile health apps hold promise for reducing the cost of clinical trials, concerns about issues such as validation, logistics and data security must be addressed.

To succeed, companies will need to keep pace with changing guidelines, make informed design decisions and develop quality systems that ensure patient safety.

A Cost-Effective Platform for Supporting Health and Wellness

Mobile health apps provide a strong platform for managing chronic diseases, helping people age independently and offering therapy and diagnosis support. For example, a provider could monitor a hip fracture patient's mobility by asking the person to use a device with an accelerometer instead of requiring frequent visits to the clinic. Individuals also can track important health-related conditions on their own; for instance, a patient with asthma could rely on an app that detects whether the user has entered an area with high pollen levels. From a manufacturing perspective, mobile health apps are attractive because they are cost- and energy-efficient.

Mobile health products can be categorized as follows:

- ► Consumer health apps record or monitor activities such as eating, stress and relaxation, strength training and sleep.
- ► Sensor-enabled wearables are voice or movement-controlled, always on and environmentally aware; these products automatically connect and alert the user through alarms.
- ► Non-invasive monitoring apps can employ an accelerometer to detect falls and changes in activity patterns.
- ► Pervasive monitoring apps track activity, heart rate, blood pressure, ECG, glucose, injections, inhalation, body weight and body temperature in real time.
- ► Physiological sensors are incorporated into a pill; the sensor sends a signal to a skin patch electrode that transmits wireless information about vital signs, body position and medication ingestion.

Increasing Acceptance Among Health Care Providers

Technology improvements have helped drive the mobile health revolution. The number of mobile devices worldwide jumped from 0 to 7.2 billion in three decades, and users now benefit from improved batteries, advanced sensors and faster data networks and computer chip processors. In addition, miniaturized devices for measuring biomarkers have emerged.

As with any new technology, some early adopters have embraced mobile health, while others are more cautious about switching to new products. However, these apps are likely to become more pervasive. Providers are beginning to view mobile health as part of the solution for value-based care and chronic disease management.

According to a 2015 survey of 500 professionals¹:

- ► 16% of health care providers currently use mobile health applications in their practice

- ▶ 46% say they will start using them in the next five years
- ▶ 86% believe that mobile health apps will help them better understand their patients' conditions
- ▶ 46% say that the apps will improve provider-patient relationships

According to a 2014 study²:

- ▶ Half of doctors think that e-visits could be substituted for more than 10% of in-person visits
- ▶ About two-thirds say they would prescribe an app to improve patients' chronic disease management

Key Players and Challenges in Mobile Health Development

The marketplace is primarily occupied by four types of companies: start-ups, traditional medical device firms, pharmaceutical companies and established organizations that are new to health care. Their levels of activity in various industry areas can be summarized as follows:

	Start-Ups	Medical Device Companies	Pharmaceutical Companies	Established Companies
Local				
Applications on hand-held devices such as smartphones or tablets	High	High	High	High
Remote				
Most data sent to cloud or Internet server farm for processing	High	Medium	Medium	High
Device Design Change				
Modification to existing device	Low/None	Medium	Low/None	Medium
Combination Product				
Interface between medical device and pharmaceutical product	Low/None	Medium	High	Low/None

One market limitation is reimbursement. The Centers for Medicare & Medicaid Services will not reimburse for many mobile health products because of the lack of associated clinical outcomes studies showing a benefit. Conducting these studies is very costly, and companies will need to determine whether they can recoup the expenses once the app is on the market. In some cases, developers may invest in a trial to build goodwill with customers; one solution is to join a consortium that might fund such studies.

Connectivity and data security represent another critical challenge. Apps must interact with other devices to maintain consumer interest, but privacy of health care data is a primary concern for users and federal agencies. Interoperability and security between devices will be essential for the market to grow. Companies can refer to interoperability design guidelines, such as those issued by the Personal Connected Health Alliance, to ensure secure communication protocols.

The Need for a Quality System

Stakeholders expect fair and balanced information in marketing claims for mobile health apps. In some cases, the precision and accuracy are expected to be on par with those of traditional medical devices. Whether the app collects, moves, analyzes or reports data, a mobile health product requires a quality system and risk management process that considers patient safety.

Data Activity	Development	Key Risk Management and Quality System Considerations
Collect	• New device/sensor • Change device to collect more data • Add user input interface	• Design control • Usability • Verification and validation (V&V) studies
Move	• Interface development • Partnerships with other companies • Information storage	• Supplier controls • Standards compliance • Audits
Analyze	• Evidence that algorithm works • Software verification • Data security and privacy	• V&V studies • Design control • Standards compliance
Report	• Present on new or existing platform • Real-time or retrospective	• Design control • Usability • FDA pre-market discussions

Navigating A Complex Regulatory Environment

Mobile health apps present a challenge to regulators and industry. Many of these systems are assembled or configured by the health care provider or user; for example, the patient may add a weight scale or blood pressure cuff. From a regulatory standpoint, this added complexity makes it more difficult for agencies and developers to ensure safe and effective use.

Several federal entities share jurisdiction over mobile health regulation or have shown interest in mobile health apps:

- ▶ Food and Drug Administration focuses on regulating the subset of products that claim to be a medical device or are used as an accessory to a medical device.
- ▶ Federal Trade Commission has scrutinized marketing claims and charged companies with making unsubstantiated statements about functions such as treating acne, improving children's school performance, sharpening users' vision and slowing cognitive decline.
- ▶ Federal Communications Commission is involved because the apps are on mobile devices.
- ▶ Office of the National Coordinator for Health Information Technology has shown interest in the subset of products that interface with electronic medical records.

The FDA has not made a definitive statement about how it intends to regulate certain types of products. For instance, developers are still waiting for a guidance document on clinical decision support software. Because the agency categorizes products based on intended use, seemingly minor changes in software design or marketing language can alter how a device is regulated.

Developers should be aware that the FDA has substantial experience with regulating software. In the 1980s, software problems caused a device to deliver incorrect doses of radiation to cancer patients; in response, the agency issued a software draft policy that is still used by industry. According to FDA data, software failures caused 24% of the medical device recalls in 2011, and that figure could easily be higher today.

Rules in the US may not align with those in other countries. For example, the European Commission's medical devices directive states that standalone software with a "medical purpose" must comply with the regulations – a term that could be interpreted multiple ways. National authorities can then apply the directive and other guidance to local laws and, in some cases, may tighten the regulations. Mobile health companies will need to closely examine international guidelines to avoid designing a product that cannot be used in other countries.

Enabling Integration into Clinical Trials

Mobile health apps have the potential to benefit clinical trials by maintaining data quality and lowering the cost. Because apps can capture information automatically, trials that employ these products may have fewer data gaps that require follow-up with investigators. The use of mobile health apps also could reduce the chances that errors will occur when information from a medical record is entered into a database. Innovative companies such as Apple have made large investments in this area, and the technology is becoming smaller, cheaper and more durable.

Signs of growth are already emerging. The number of clinical trials using mobile apps increased from 135 in 2013 to 300 in 2015. The majority of the studies use interventional therapies, and the devices are being employed to report effectiveness and safety. As monitoring with mobile health apps becomes part of everyday medical practice, companies will increasingly need to incorporate these products into clinical trials as well to ensure accurate comparisons.

However, several barriers still remain. Pharmaceutical companies tend to be cautious about adopting unfamiliar devices because errors or false claims could force them to repeat studies. Mobile health developers will need to address the validation process and logistical issues, such as how to integrate their data with electronic medical records. Payers are reluctant to reimburse for the devices, and physicians and patients may have concerns about data confidentiality and security. Finally, elderly patients may not be comfortable using the apps, although this problem is likely to decrease with time.

The Future of Mobile Health

As mobile health continues to expand, developers should expect regulations to be clarified and to become more consistent across countries. Interoperability of health care systems and seamless information flow will be a key focus. As more data are collected, artificial intelligence also will play a larger role in clinical decision support.

Covance provides regulatory and validation services for mobile health developers, supported by expert partners such as Navigant. As an experienced CRO, we can manage relationships between mobile health companies and biopharmaceutical clients interested in trying these products in clinical trials. With our reputation for quality and commitment to innovation, Covance can help developers navigate a rapidly changing field.

References

¹ Are mobile medical apps good for our health? A new study by Research Now reveals that doctors and patients say yes. Research Now. March 2015. <https://www.researchnow.com/mobile-medical-apps-good-health-new-study-research-now-reveals-doctors-patients-say-yes-infographic> (accessed 27 June 2016).

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