

mHealth and the Transformation of Clinical Trials

Harnessing data, advanced analytics, and the Internet of Things
to optimize digitized clinical trials

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Executive Summary

Currently, biopharmaceutical corporations, medical device companies, and contract research organizations (CROs) are evaluating their moves to incorporate more comprehensive levels of mHealth technology into their clinical trial programs.

mHealth has the potential to revolutionize the clinical trials industry. But, how does the industry handle and fully exploit the constantly increasing volumes of data generated and the ever-changing nature of mHealth technology?

This white paper examines the opportunities that mHealth can deliver and analyzes the challenges currently involved in mHealth R&D incorporation. It delivers insights gained from Oracle's recent collaborations with a range of pharmaceutical companies – from global drug manufacturers, to small US, EMEA, and Asia-Pacific biotechs. It then looks into the near future to imagine what digitalized trials could look like in 2020.

Through these investigations into mHealth with our life science industry partners, this paper describes the potential key benefits that mHealth technology and methodologies can offer. It also discusses how Oracle can help pharmaceutical companies take advantage of mHealth technology to improve patient engagement, optimize data quality, and gain deep insight into real world data.

Introduction

With a global market value estimate of nearly \$14 billion,¹ the mHealth space is developing at a rapid pace. This market is producing a previously unseen blurring of lines between consumers and patients, as well as between healthcare and research.

Consumers increasingly are using wearable technologies in their everyday lives to monitor aspects of their health and fitness. The significant volumes of data produced via mHealth for health monitoring has potential for use in clinical trials. Through this lens, people are becoming part of the Internet of Things, or the Internet of *Clinical* Things.

Oracle, along with its pharmaceutical and medical device partners, has explored the potential advantages and current barriers that mHealth presents for the clinical development arena. They have assessed methodologies to innovate, advance, and transform mHealth value for the industry. With its considerable cross industry experience, together with its deep expertise in cloud, data, analytics, security, and best practices, Oracle offers a number of key capabilities to deliver digital clinical trials.

DEFINING mHEALTH

No two definitions of mHealth agree exactly, although two United Nations bodies have put forward their own definitions.

The World Health Organization defines mHealth as a component of e-health, and “a medical and public health practice supported by mobile devices, such as mobile phones, patient monitoring devices, personal digital assistants (PDAs), and other wireless devices.”²

The International Telecommunication Union (ITU) suggests mHealth encompasses “all available services for delivering care or medical information using mobile equipment and networks”.³

Previously, the US Food and Drug Administration (FDA) had offered guidance only around “mobile medical apps,” as can be seen in the February 9, 2015 “Guidance for Industry and FDA Staff: Mobile Medical Applications.”⁴

More recently, however, the FDA has launched its “Digital Health” initiative.⁵ In the overview, the agency defines digital health as:

“The broad scope of digital health includes categories such as mobile health (mHealth), health information technology (IT), wearable devices, telehealth and telemedicine, and personalized medicine.”

1 Global mHealth Market Size, Share, Development, Growth and Demand Forecast to 2022. P&S Market Research. March 2016. Available at: <https://www.psmarketresearch.com/market-analysis/mobile-healthcare-market>. Last accessed 11 May 2016.

2 WHO, New horizons for health through mobile technologies Global Observatory for e-Health series. 2011. Vol.3. Available from: www.who.int/goe/publications/goe_mhealth_web.pdf. Last accessed 11 May 2016.

3 Filling the gap: Legal and regulatory challenges of mobile health (mHealth) in Europe. Discussion paper. ITU June 2014. Available from: <http://www.itu.int/en/ITU-D/Regional-Presence/Europe/Pages/Discussion-Paper-mHealth-in-Europe.aspx>. Last accessed 11 May 2016.

4 “Guidance for Industry and FDA Staff: Mobile Medical Applications,” US Food and Drug Administration. Available from: <http://www.fda.gov/downloads/MedicalDevices/.../UCM263366.pdf>. Last accessed 30 August 2016

5 Digital Health” initiative, US Food and Drug Administration. Available from: <http://www.fda.gov/MedicalDevices/DigitalHealth/default.htm>. Last accessed 30 August 2016

Even though there are many, varying definitions, it is clear that mHealth has the potential to connect patients to care providers and researchers, as well as to deliver data from real-world evidence that, traditionally, has been sparse.

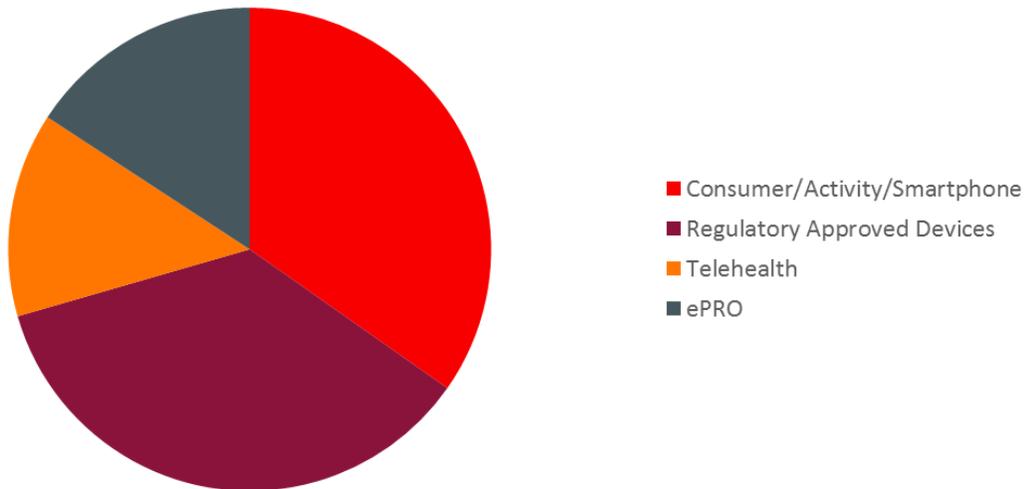
Real World mHealth Use Cases

Right now, life sciences companies are at varying stages of mHealth technology adoption in clinical trials. The majority are still exploring the possibilities. According to a 2016 industry survey by *FierceBiotech*,⁶ more pharmaceutical companies are currently planning or piloting the use of mHealth (using devices such as sensors or wearables), in their clinical trials, than actually conducting trials using the technology.

The aforementioned survey included 108 respondents from a list of trial sponsors and CROs. It found that of the trials in which devices were actually being used, two-thirds were regulatory-approved devices, while another one third was using consumer, activity, or smartphone devices.

The sizable portion leveraging consumer/activity/smartphone devices represents a growing trend toward exploring mHealth as a new operating model using the consumer device as a proxy for a true, regulated device.

What are the primary technologies your company is evaluating or utilizing for mHealth trials?



FierceBiotech survey, July 2016
n=108

⁶ *FierceBiotech* survey of 108 clinical R&D and IT representatives in North America and EMEA from trial sponsors and CROs, July 2016.

Exploring the Possibilities: Perspective from Eli Lilly & Company

Top 20 biopharmaceutical company Eli Lilly & Company is “keen to unleash the value of mHealth into clinical research,” says Katherine Vandebelt, Global Head of Clinical Innovation. The company has been looking at the potential for up to 10 years, depending on how mHealth is defined.

According to Vandebelt, “Some aspects of mobile health have been around for many years, and therefore, we have incorporated this into our clinical research. Certainly in the last five years, our use has become more extensive. In compliance with guidelines that exist in various regulatory authorities, we took opportunities to use diagnostic devices, or to collect measures, either by the healthcare provider or the patient. So these are isolated examples where that data could be collected in the doctor’s office, clinic, hospital or at home.”

“This was starting to take advantage of the e-source concept. However, within the last five years, it’s been more a case of digitizing the whole clinical development ecosystem and really starting to explore what already exists in healthcare, and understanding the effects within trials and the reliability of the data,” Vandebelt adds.

Within diabetes, Lilly has started to explore the possibility of using dosing algorithms and being able to make data available to investigators. In this way, the company could make a decision about dosing without necessarily making the patients come into the office. The company also looked at patient-reported information and mobile nursing to work with patients in different locations. In addition, Lilly is still learning how best to run a trial that’s fully digital and/or mobile.

“From our point of view, we research this a lot and we do pilots, with patients and with investigators to understand the barriers and the enablers that allow this to happen,” says Vandebelt. “But we do think that for it to become prevalent, that we really need to be running clinical research quite a bit differently than we do today.”

Key Opportunities for True mHealth in Clinical Trials

mHealth is emerging from the early adopter phase and beginning to transform clinical trials through new innovative methods and techniques. The mHealth paradigm can help to accelerate insight into efficacy and safety signals that traditional trials cannot. Acquiring such real world data is starting to show results, as shown in the results of the *FierceBiotech* survey:

The survey revealed the top five benefits of mHealth in clinical trials realized by respondents as follows:

What benefits have you actually realized from your mHealth clinical trials?

Top Five Benefits

- » Real time data capture
- » Improved data quality
- » Real world evidence from continuous data
- » Increased insight into patient adherence
- » Reduced monitoring effort via remote monitoring

FierceBiotech survey, July 2016

n=108



While improved data quality is a primary benefit, David Blackman, Director of Business Innovation at PPD, agrees that use of the technology has to bring value over and above the data that can be captured: “It needs to offer advantages for patients, investigators, and trial sites,” he says.

Ralph Russo, Director of Global Clinical Data Integration at Merck Research Laboratories, emphasizes the convenience of mHealth for trial patients, “The technology essentially brings the clinical trial to the patient. Instead of having to attend a hospital or other trial site, the technology allows day-to-day, non-intrusive collection of data.” This increased convenience for patients will benefit trial retention and adherence.

At a broad level, the technology offers sponsors and investigators greater oversight of a trial. It provides access to real-world evidence via continuous data and enables increased decision-making capabilities. Use of mHealth can also provide other benefits. These include monitoring far more about each individual patient, increased insights into adherence, improved patient retention, reduced investigator visits, improved sponsor/ CRO-to-site communication, earlier signal detection, and simplification of post-marketing studies.

The survey results and the experiences of Oracle customers mirror the potential transformational value that the FDA sees in digital health.

From the FDA “Digital Health” website⁵ referred to previously:

The use of technologies, such as smart phones, social networks, and internet applications, is not only changing the way we communicate, but is also providing innovative ways for us to monitor our health and well-being, and giving us greater access to information. Together, these advancements are leading to a convergence of people, information, technology, and connectivity to improve health care and health outcomes.

CATEGORIES OF mHEALTH TECHNOLOGIES and APPLICATIONS

Three broad and sometimes overlapping groups of mHealth technologies have the potential to be used in clinical trials. These include:

Self-care: *An ever-expanding variety of regulatory-approved and non-approved consumer products that enable patients to self-monitor aspects of their health, such as blood glucose levels, weight, and activity.*

Managed care: *Monitoring technology that feeds back data that has already been used in clinical trials in the following therapy areas:*

- *Dementia: monitoring patient visits to the refrigerator or bathroom*
- *COPD: inhaler usage*
- *Ebola: vitals monitoring*
- *Diabetes: blood glucose levels*
- *Vaccines: body temperature*
- *Hypertension/diabetes: medical and physical activity adherence*

Hospital at home: *Bluetooth devices can be connected enabling patients to be at home, rather than in hospital. Examples include intravenous (IV) administration, home dialysis, and webcams using two-way communication between patients and caregivers. The technology can also be used to link small hospitals into central hubs to provide expert care.*

According to the FDA, providers and other stakeholders are using Digital Health to:

- *Reduce inefficiencies*
- *Improve access*
- *Reduce costs*
- *Increase quality*
- *Make medicine more personalized for patients*

Patients and consumers can use digital health to better manage and track their health and wellness related activities.

The Internet of Clinical Things

Multiple smart devices, apps, wearables, and Bluetooth devices connected to the Internet are now integrated into everyday life, connecting people wherever their location into the Internet of Things. In this new world, the patient has the potential to become a “thing of the Internet,” as this technology is increasingly used in clinical trials.

Not only can the technology collect episodic and physiological data that mimics visits to the clinical trial site and/or the doctor’s office, but -- depending on the device -- the technology also enables continuous remote monitoring. This type of tracking produces a tremendous amount of data from various sources and holds huge potential. But, it also leads to a number of challenges.



Patients will be increasingly connected to the Internet – essentially becoming a “thing of the Internet” in the Internet of Things.



Exploring the Possibilities: Perspectives from PPD, a Leading CRO

PPD, a leading global contract research organization (CRO) with offices in 46 countries worldwide, has conducted a number of studies using mHealth devices.

In one such trial, PPD ran a subset of a larger study using wearable, on-body sensors to gather biometric patient data in the patient's real-world setting. While using these new technologies to capture more and better scientific data was the primary concern, it was also essential for PPD and its partners to design the study in a way that allowed examination of the patient's experience while using the technology. It was also important that PPD monitor the changes in patient interaction with wearing the sensors over time. For this study, two carefully chosen types of devices measured information about patient retention impact, data capture compliance, and data quality.

The study used a blood pressure cuff and an activity monitor connected to the patient's smartphone. In general, people were more comfortable with consumer devices, like activity and sleep monitors. With the activity monitor used in this study, patients simply charged the device so that data flowed automatically from the device into PPD's databases. In contrast, the blood pressure cuff was a less commonly used item. Patients initiated the device twice daily to capture blood pressure readings transmitted to the study databases. Not only did this type of approach provide insight into medical versus consumer type devices, but it also allowed for the cross-validation of the data points, which improved the data quality of the information captured. PPD looked at the operational metrics, early indications or signal detection data for this study.

As David Blackman, Business Innovation Director for PPD, explains, "PPD is especially interested in examining the metadata on compliance, looking at when and how drop-off occurs, and at data flow consistency. We also are building a lot of insights into the differences when patients bring their own devices and are required to download an application, versus being provided a study-specific smartphone. We believe this approach will help guide the design of future studies using this technology."

The selection of the technology and devices to be used must be carefully considered. For example, the activity monitor choice in this study was deliberate. "We had to know that the monitor produced consistent, quantitative data validation without changes in device performance for the study's duration," Blackman says. "We needed to ensure there weren't any changes in a device's algorithm, capture method, or data consistency."

PPD continues to explore complementing its studies with non-regulatory wearables like consumer-grade activity monitors. PPD sees a role for these devices in future studies in very specific circumstances. Additionally, the consumerization of wearable sensors in everyday life is likely to act as a catalyst for embedding specific types of devices and sensors in clothing.

"PPD sees the logic and value proposition around this technology to access better scientific evidence faster for real-time analysis and response," Blackman says. "It's important to work with the relevant regulatory authorities from the onset of the study to ensure they understand the benefits, importance, and collection sequence of data we're capturing to help our clients and partners bend the cost and time curve of drug development to deliver life-changing therapies that improve health."



Challenges and Barriers to mHealth Adoption

The use of mHealth technology presents a significant change for the industry and comes with costs attached. The top barriers to adoption of mHealth technology, as identified in the *FierceBiotech* survey, fall in two broad categories, business and technical. The top business-related barriers are seen as a lack of regulatory clarity and acceptance and an organizational resistance to change. The top technical barriers are defined as a lack of FDA-approved sensors/wearables and data security.

Top Five Business Barriers

- » Lack of regulatory clarity / acceptance
- » Organizational resistance to change
- » Increased cost / Lack of ROI
- » Ability to make effective use of data collected
- » Concern over ability for vendors to scale beyond pilots

Top Five Technical Barriers

- » Lack of FDA approved sensors/wearable
- » Data Security
- » Lack of integration with EDC-CDMS
- » Scalability – collecting, storing, cleaning, submitting
- » Lack of medical sensors for a therapeutic area

FierceBiotech survey, July 2016

n=108



Currently, the industry is grappling with these issues, and alongside regulatory bodies, planning the development of methodologies to optimize mHealth technology's potential.

In its September 2016 white paper, "eSource in Clinical Research: A Data Management Perspective on the Use of Mobile Health Technology,"⁷ the Society for Clinical Data Management (SCDM) defined principles for clinical data management, as well as guidelines for the impact of mHealth on all roles involved in the clinical trial lifecycle. These included:

Electronic source data (eSource) in the form of mHealth technologies used for study participant data collection is gaining momentum within the clinical research setting. To effectively adopt mHealth technologies as new data sources, we propose a principles-based approach to the evaluation of eSource, as outlined in the following key areas: technology, people, processes, and standards.

*We also outline regulatory considerations to provide general guidelines for adoption. **All roles, participants, and processes in the clinical trials enterprise will be affected by changes in technology involving new standards, data flows, and data sources.** Clinical data managers will see their roles expand and will be positioned to drive the process changes necessary for adopting successful mobile technologies.*

Mobile health will be a game changer in the conduct of clinical research — one that benefits both the trial participants and the research.

We examine some of the key challenges for the industry below.

Scale, Data Type, Volume, Speed, and Structure

The industry faces the challenges of storing, aggregating, correlating, and analyzing vast volumes of data from mHealth technologies to find what is relevant and clinically meaningful. "I do expect the volume of data to increase and to get challenges with that," notes Merck Laboratories' Russo.

Data can now be produced from multiple sources, in structured or unstructured formats, and in varying volumes, with different standards attached. Data may come from mobile applications, medical devices, clinical lab test results, patient e-diaries (covering a patient's physical or emotional responses or describing an adverse event), discharge summaries and clinician notes, electronic medical records, other free-text notes, and/or video/ imaging information.

The volume of data varies greatly depending on the frequency of reporting. Data collection frequency can vary from once or twice a day (a drug ingestion event or a blood pressure (BP) measurement), to a high-frequency basis. Data types can include such information as activity or sleep data, blood pressure monitoring, continuous heart-rate every few seconds, or other physical movements or physiological measures.

For just one patient, per day, there is the potential to create a huge volume of multiple types of real world data. By collecting the data in a real life situation, there is the opportunity to gather far richer datasets than are typically available in periodic, six weekly, physician appointments. Self-measurement of daily BP not only provides more data, but also gives a realistic picture of the true, normal BP of the patient, rather than the potentially inflated BP triggered by white coat syndrome in the physician's clinic. Collecting more frequent data points enables biostatisticians to increase the power of their analyses and helps drive a stronger conclusion, as to whether the new drug is effective and safe.

⁷ "in Clinical Research: A Data Management Perspective on the Use of Mobile Health Technology," the Society for Clinical Data Management, September 30, 2016. Available from <http://scdm.org/publications/white-papers/>. Last accessed 07 October 2016.

This richer data source provides huge opportunities and a few challenges. For example, simply measuring pulse every second produces 86,400 pulse measurements a day. So, for a two-year, 500-subject clinical trial, that would yield 31 billion data points. Exploring, visualizing, and analyzing such large data volumes is relatively new for clinical research. But, so-called, big data technologies exist across a wide array of industries to handle these volumes. By correlating this data with other clinical data in the trial and with external data, there exists the opportunity and possibility of new discoveries.

For instance, it is possible to explore relationships between pulse increases/decreases, with drug ingestion, eating habits, periods of activity, and other external factors to derive true, real world evidence. It could be that by deeper analysis of this richer data, a previously rejected drug compound could be found to be effective, if taken five minutes after food.

- 5,000 data points / per day



Blood Pressure
3xDaily
500 subjects

- 43m data points / per day



Pulse
Every second
500 subjects

Data volume comparison: blood pressure read three times per day compared with pulse readings every second

Further, advances in machine learning and artificial intelligence (AI) can help to identify new correlations and derive new potential hypotheses and patterns. While it is likely to be many years before AI becomes main stream in clinical research, the opportunity for such techniques, combined with ever-increasing, lower-cost, computing power, enable clinical data scientists to explore new pathways and relationships that were impossible to consider with the traditional, discrete, tiny datasets.

The availability of more data leads to presumably better insight and greater potential to discover any additional drawbacks that the drug or therapy might cause. A drug that looked effective and safe using the old paradigm might be exposed as unsafe and ineffective through analysis of such real world data.

This insight must be recognized by the industry as a positive and not used as a barrier to stifle innovation. Real world evidence must be leveraged as an enhanced opportunity to drive development of new, safe, and effective therapies. The ability to gather large and diverse data directly from the patient and correlate them with external data is just the start of a new digital journey. The necessary technologies exist today in other data-rich industries.

A platform-based solution is required. One that is not device-specific and that can grow and evolve as new devices are created and added into a given clinical trial.



With increasing data volume, integration becomes necessary on many levels. The technology used to capture the data has to be integrated with the technology to aggregate and transform the data. Then, that technology must integrate with the analytics engines to identify clinically relevant data. The industry needs to do this at scale across many thousands of patients and many thousands of devices.

For each clinical trial, it is not ideal to create this integration from the ground up, or as a point-to-point solution. A platform-based solution is required. One that is not device-specific and that can grow and evolve as new devices are added into a given clinical trial. With the rapid development of new sensors and devices in the market, it is critical that clinical development programs have the ability to choose the sensor appropriate to their therapy and have this available for rapid use, without any extensive IT integration effort. This is the Oracle approach, *any device, any app, one platform*.

Regulatory Reaction

In the U.S., the FDA appears enthusiastic about the potential of mobile health technology. According to Leonard Sacks, Associate Director for Clinical Methodology in the Office of Medical Policy at the FDA, the Agency is positive, albeit with the caveat that mobile devices report data of meaningful clinical benefit.⁸

In October 2015, the FDA reached out to gather input from stakeholders about the use of innovative methods and technologies in clinical trials. Leslie Kux, Associate Commissioner for Policy the FDA stated that the FDA is particularly interested in:⁹

- » Experiences of using different technologies, communication infrastructures, and innovative methods
- » What the FDA could do to encourage [the] adoption of these [innovations] in clinical trials
- » Identifying any barriers and challenges perceived by stakeholders
- » Issues around participant acceptance and privacy

Key industry players report that their experiences with the FDA are indeed positive, with other global regulators, including the European Medicines Agency (EMA), also moving rapidly to accommodate increasing demand for guidance. In 2014 the EMA Innovation Task Force widened its scope to encompass the use of mHealth technology in clinical trials.^{10, 11}

However, all are aware there are challenges with different data privacy regulations in different countries. Katherine Vandebelt, Global Head of Clinical Innovation at Eli Lilly & Company notes: “We also need to understand that there are cultural differences with patients and doctors around the world in terms of how medicine is practiced and how patients are cared for. That influences use of digitized sources, as well as the regulations around this. It makes it difficult to run a global mHealth trial.”

Adds PPD’s Blackman: “We need to demonstrate to the regulators the value proposition around using this technology, to get better, faster, scientific evidence that you can analyze and respond to in real time. As an industry, we need to reach out to regulators early enough, and generally I’ve found, they are absolutely willing to work with you.”

⁸ FDA enthusiastic about mobile health data, M Thibault, MD+DI, October 2nd, 2015. Available at: www.mddionline.com/article/fda-enthusiastic-about-mobile-health-data-10-05-15. Last accessed 07 June 2016

⁹ Using Technologies and Innovative Methods To Conduct Food and Drug Administration-Regulated Clinical Investigations of Investigational Drugs; Establishment of a Public Docket, US Federal Register, Vol.80, No. 209, Thursday October 29, 2015, Notices, p66543-5

¹⁰ Kerali, H, Clinical Trials Arena, 12 January 2016 <http://www.clinicaltrialsarena.com/news/regulations/will-the-use-of-mhealth-tech-in-clinical-trials-require-a-new-code-of-ethics-4775351>. Last accessed 08 June 2016

¹¹ Innovation Task Force, European Medicines Agency. www.ema.europa.eu/ema/index.jsp?curl=pages/regulation/general/general_content_000334.jsp. Last accessed 08 June 2016



Regulatory Status

The use of regulatory-approved devices in clinical trials is one issue. Can non-regulatory-approved devices play a role?

Russo sees a potentially significant role for non-regulatory-approved activity monitors, in particular, in cardiovascular studies: “It is a great opportunity to get real-time data, safety data, and how one patient is doing versus another patient.”

Blackman agreed: “With wearables it’s about creating an objective data point around traditionally subjective data.”

The 2016 *FierceBiotech* survey also found that companies are using an approximately equal split of regulatory-approved and non-approved devices. With non-regulatory approved devices, how the data is used seems to be a critical factor. Is the data being used for a primary endpoint? Or, is it being used to provide contextual data around a key data point?

According to surveys from SCORR Marketing and Applied Clinical Trials, the vast majority -- 95 percent (95%) -- of clinical trial industry insiders believe the positives of using wearables in clinical trials outweigh the negatives. The surveys also found that 91 percent (91%) believed that, within three years’ time, their companies would be using wearables more often in trials for a combination of monitoring, and to a lesser extent, for drug delivery purposes.^{12,13}

Concerns around device accuracy and validation are currently being debated. These concerns focus on non-regulatory-approved devices, around “bring-your-own-devices” versus provisioned devices, and around issues of patient validation. Developments in technology will improve validation moving forward, as devices incorporate biometrics and facial recognition, as well as through the use of embedded devices and sensor ‘tattoos’.

For regulatory approved devices -- which are required to go through stringent data validation -- Blackman sees them playing a role, “These devices could, should, and will become used for scientific endpoints.”

Many other regulatory implications are beginning to be worked through by the industry, such as the implications around the speed of mobile technology development. With regular updates being issued for applications and devices, as well as new devices coming onto the market all the time, the quality and reliability of the data could be compromised.

Notes Vandebelt, “There is tremendous concern that if you change the way you run the trial, then the data reliability or usability will be in jeopardy. So there is huge hesitation around using current technology or evolving technology during a trial.”

“One of the ways we could solve that problem, however, is to expedite the execution of trials, so you aren’t burdened with obsolescence or lagging technology when you complete the trial. Another possibility is to really work with regulatory authorities and individuals to truly understand what’s needed and to eliminate issues associated with evolving technology. If you have the right analytical methods and data flows, you can deal with changes,” she adds.

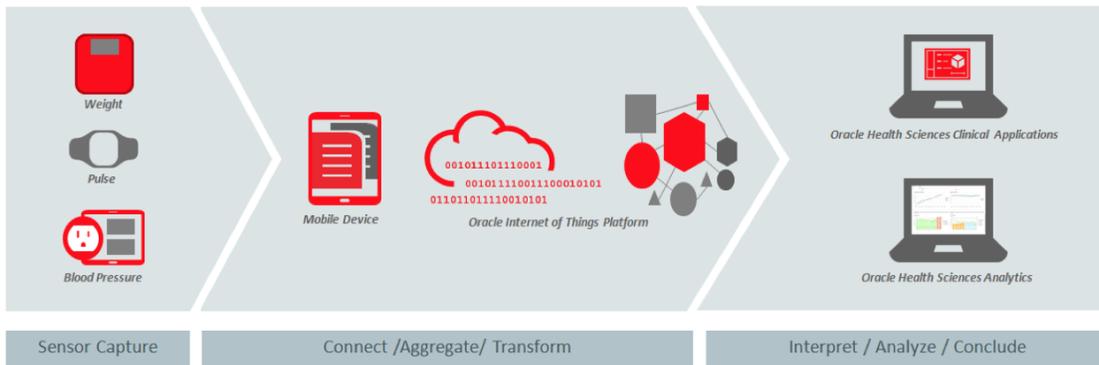
¹² Mobile health in clinical trials survey report. SCORR Marketing and Applied Clinical Trials. 2015 <http://www.scormarketing.com/resources/mobile-health-in-clinical-trials/>. Last accessed 04 May 2016

¹³ mHealth wearables Report 2016. SCORR Marketing and Applied Clinical Trials. 2016. <http://www.scormarketing.com/resources/wearables-in-mhealth-technology/>. Last accessed 04 May 2016

Oracle – Enabling Digital Trials

Any device, any app, one platform

Digital Clinical – *Simplified, Scalable, Sensor Connectivity* *Rapid acquisition of Real World Data – Any sensor, one platform*



Digital Clinical Trials with Oracle

The practical application of mHealth technology within clinical trials is still in its infancy, but it is rapidly evolving. Our discussions with key players and our 2016 survey show that, to date, the majority of pharmaceutical companies have been experimenting with using mHealth technology one pilot trial at a time, or as a sub-set of existing studies.

To help organizations adopt digital trials at scale, Oracle Health Sciences offers a number of key technologies and applications to acquire, transport, transform, explore, and analyze data from sensor to clinical submission. Our solution offerings are focused on an approach of any device, any app, one platform. This model is designed to support multiple data sources from device/sensor, mobile apps, device clouds, EHR, and other clinical sources.

Oracle's modular and scalable cloud environment helps optimize operations, moving clinical trials in a new direction and helping companies to take advantage of the opportunities presented by real world data, with the security, quality, and flexibility that the industry requires.

Oracle offers many platform service technologies, such as the Internet of Clinical Things Cloud Service, Mobile Cloud Service, and Big Data Cloud Service, alongside clinical trial applications, such as Oracle Health Sciences InForm and Oracle Health Sciences Data Management Workbench. These facilitate secure data acquisition from any device, readying the data rapidly for data exploration and analysis.

Key to the solution is the concept of Choose and Use. A clinical trial program director should be free to choose whichever sensor or device he or she prefers for a specific disease area. Additionally, he/she should have the capability to develop and finalize a protocol rapidly, without the concern that the device will take an inordinate amount of time to integrate into the corporate data infrastructure. With Oracle, new devices can be plugged into the cloud architecture and configured for patient data acquisition quickly.



Looking Ahead: Digitized Clinical Trials in 2020

As they become simpler to use, advances in mHealth technology will continue at a rapid pace and gradually will be integrated into everyday patient life. Improvements in device accuracy and quality can also be expected.

By 2020, billions of devices will be linked around the world. Estimates vary, but there could be as many as 50 billion connected devices. This will produce enormous volumes of data.

BY THE YEAR 2020, THERE WILL BE

50,000,000,000 connected devices,
creating and sharing

40,000,000,000,000 GB

worth of data across the Internet of Things.

Sources: World mHealth Market: Opportunities and Forecasts¹⁴; mHealth Market – Opportunities and Forecasts¹⁵

¹⁴ World mHealth Market: Opportunities and Forecasts, 2014 – 2020, Allied Market Research, May 2015, <https://www.alliedmarketresearch.com/mhealth-2015-market>, last accessed 28 April 2016

¹⁵ mHealth Market – Opportunities and Forecasts, 2012 – 2020, Allied Market Research, November 2013, <https://www.alliedmarketresearch.com/mobile-health-market>. Last accessed 28 April 2016



The life sciences industry has the opportunity to make use of these advances and deploy them within clinical trials. This includes innovations such as: smart contact lenses, mobile scanning devices, or dermally implantable sensors or tattoo sensors.

Industry pundits think it unlikely that one trail blazing study will suddenly open the door to widespread use of mHealth technology. Rather, a gradual process is more likely. According to Blackman: “I think we will see *book of work* build up; and regulatory authorities will become more comfortable with the data – how it’s captured, analyzed, and reported.”

Vandebelt agrees with this view. “Generally, we keep watching the healthcare market. We try to assess if we can keep pace in clinical research. Across the industry there aren’t a lot of pioneers out there, because there hasn’t been a lot of reward to be that pioneer in the clinical development space as opposed to the healthcare space. This is causing a lack of adoption and slow movement.”

Given this, what will, or what could, a truly digitized clinical trial using mHealth technology look like in 2020? Rather than be used to collect key data points, mHealth technology could become standard in trials, adding greater insights around key data points and streamlining processes.

Industry insiders, including Anita Zubak, Merck’s Executive Director, Global Clinical Trial Operations IT, see clear distinctions among therapy categories for the adoption of mHealth technology. “Certain therapy areas are always going to be more amenable to using certain types of technology. Cardiology and diabetes are the obvious ones.”

Overall, Zubak believes that mHealth technology is likely to “enhance rather than revolutionize” clinical trials. However, it could also be predicted that the mHealth revolution will be focused more in the post-marketing space and in healthcare, rather than in Phase III studies.

What will the patient, who is taking part in a clinical trial, experience in 2020? Zubak hopes that patient participation will be almost a non-event through the use of better devices and improved connectivity. “You won’t think about it because it will be so easy. You will sign-up online, have no appointments to go to, and the technology will be integrated into your everyday routine. It will be seamless, with no extra burden to participate,” adds Zubak.

By 2020, a patient will have increasing access to his/her own data and will be storing that data with the ability to take it along to his/her physician. It is also likely that the use of technology connecting physicians and patients will be widespread. However, technology must be developed to help physicians understand and utilize the data shared, as well as signal them on new, important data, or on adverse events.

As the industry evolves to adopt the new mHealth model, Oracle is working with our partners to capitalize on our breadth of technology and domain experience. Innovative technologies from Big Data, to the Internet of Things, to advanced analytics, are all being used across multiple industries, at great scale. Oracle Health Sciences combines the best, most appropriate technologies to deliver advanced, innovative solutions to accelerate clinical trials and enable the acquisition of true, real world evidence.

Conclusion

The explosion of medical sensors and devices, combined with advanced data collection, management, and analytic technologies, provide a tremendous opportunity to transform the design and management of clinical trials. Taken together, these trends can help the life sciences industry accelerate the delivery of new therapies to patients.

However, currently, the technology, regulatory, and operational mHealth-related challenges that the industry faces are large and complex. Oracle is investing heavily in combining its experience in solving highly complex, “big data” challenges for other industries with its critical, health sciences domain expertise to manage regulatory implications, data privacy, and validation concerns.



Our goal? To help the industry fulfil the promise of mHealth by bringing life-improving treatments to patients faster, more efficiently, and at lower cost.

Oracle is excited to be able to bring our global resources to bear in fulfilling this mission.

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