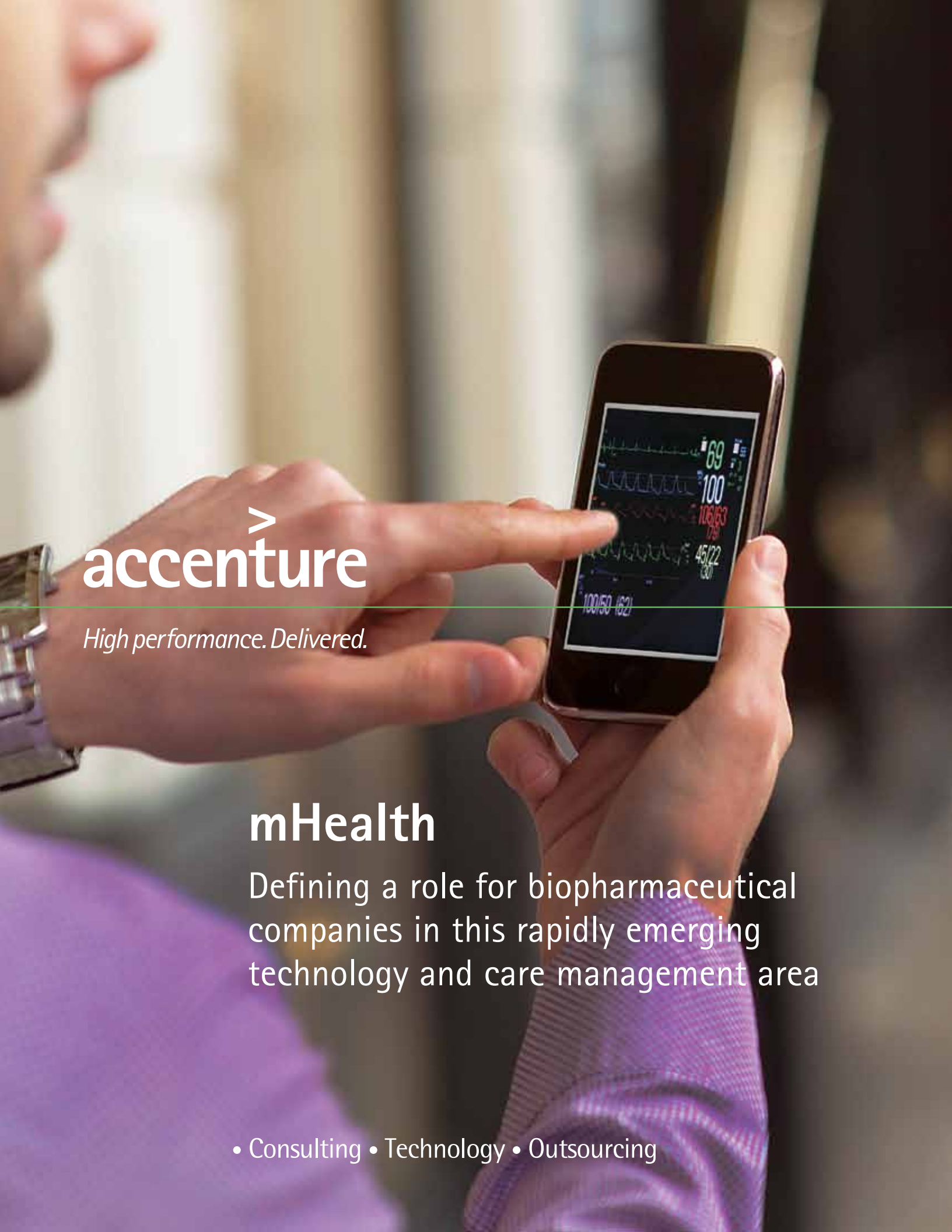

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mHealth

Defining a role for biopharmaceutical companies in this rapidly emerging technology and care management area

• Consulting • Technology • Outsourcing

Introduction

Mobile health care or "mHealth" has gained significant traction and investment from many participants, as pilots and trials evolve to substantively funded business ventures aimed at reaching broad consumer segments. Early results suggest that mHealth products and services can help meet two important goals: providing high-quality care and reducing costs, particularly in managing chronic diseases.

New health care funding (especially emerging reimbursement policies), the pervasiveness of mobile technologies and the current state of the pharmaceutical market make this an interesting time for life science companies. Should pharmaceutical companies make significant investments and establish leadership positions now? Or, should they wait and see how policies, technologies and stakeholders' strategies evolve? What options make the most sense given pharmaceutical companies critical and necessary role in improving patient health and pharmaceutical companies' need to create new value streams for key stakeholders?

This paper addresses these issues, and suggests that pharmaceutical companies should target specific tiers of mHealth opportunities based on several strategic considerations, including their relationship with payers, alignment with disease focus, extent to which services will support targeted therapeutics and likely adoption rates in selected markets.

What is mHealth?

A catchy, short phrase—mHealth—actually represents a broad spectrum of products and services, from wearable glucose monitors, to web-based fitness applications, to networks of dispersed health care professionals developing and executing daily treatment plans for chronically ill patients. Its pervasiveness and relevance to virtually all consumers strongly suggests significant health care benefits and opportunities for all key stakeholders across the health care value chain.

Over the last year there has been unprecedented media coverage, investment and product development activity as evidenced by:

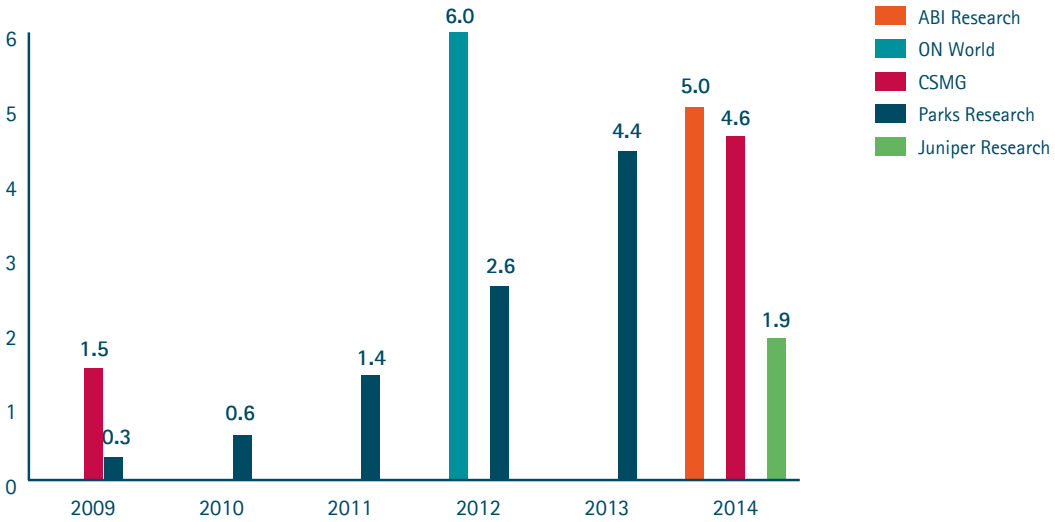
- Regulatory approval of devices and solutions that support remote health monitoring
- A stream of reports in respected press and medical journals, including the New England Journal of Medicine (NEJM), detailing the positive impact of mHealth initiatives[1]
- Numerous pilots and small-scale projects to demonstrate effectiveness and feasibility
- Clinical trials that include mHealth components
- Investments and initiatives by leading technology, device and health care firms to build these capabilities

There are widely varying forecasts of mHealth revenue and estimates of the potential of mHealth, for both patients' care and company commercial performance. The disparity is explained in part because the size of the opportunity depends upon reaching a critical mass across several dimensions, including electronic medical records (EMR), reimbursement, and technology standard convergence. However, figure 1 shows a consensus across several sources that critical mass will occur in 2014 and mHealth will be at least a $5 billion industry at that point.

Figure 1. Projected growth of mHealth

Market estimates vary, predicting growth between $2-$5 billion by 2014.

Mobile health revenue predictions, $ billions



Sources: ABI Research, ON World, CSMG, Parks Research, Juniper Research

Why mHealth now?

Several factors are converging to move mHealth into mainstream health care. First, a rapidly aging population needs options for care delivery, particularly for treatment of chronic diseases. In the United States, one study asserted that 86 percent of people over 65 suffer from at least one chronic ailment (diabetes, cardiovascular disease, chronic obstructive pulmonary disease, asthma, cancer or arthritis) with the majority having more than one.[2] Collectively and globally, treating these diseases account for about three-fourths of health care expenditures, straining financial and medical resources.[3]

Second, the shortcomings of episodic treatment and event-driven reimbursement are well known: patients delay seeing a health care professional until symptoms severely impact their quality of life and/or limit treatment options making more costly and more invasive treatment necessary. Recent studies also highlighted sporadic patient compliance as a key concern. A UCLA study of patients discharged from a hospital reveals that 73 percent failed to use at least one prescribed medication, and only 32 percent had taken all medications prescribed, resulting in "delayed recoveries, complications and costly readmissions."[4]

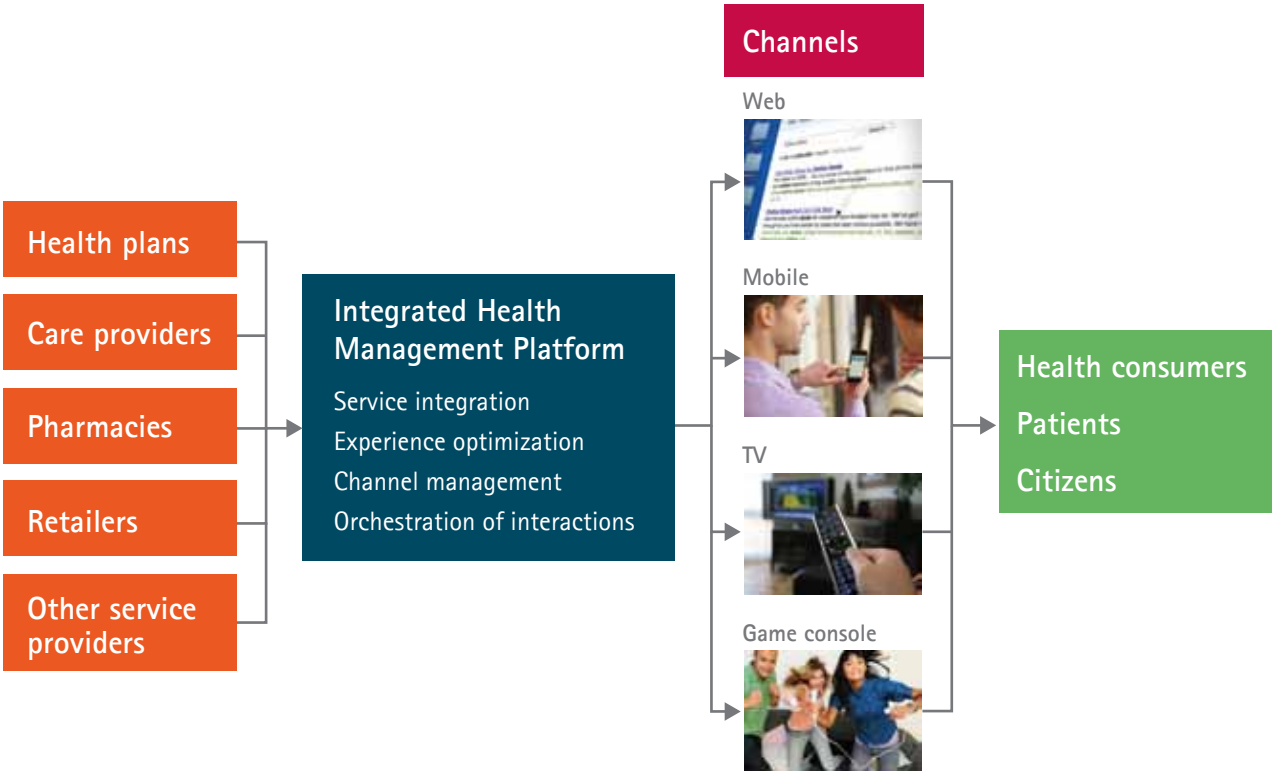
Similarly, relying on patients with chronic diseases such as diabetes to assess whether treatment adjustment is necessary can be unproductive. Recent articles on diabetes treatment summarized significant improvements in glycemic control in adults and children (who saw a drop of A1C levels from an average of 11 percent to 9 percent in the first three months) who used devices or were given text message reminders to take medications versus patients who used traditional home monitoring and reporting.[5] The evidence that mHealth makes a positive impact on improved patient outcomes is compelling. A 2009 systematic review of 25 controlled studies, by Krishna and colleagues, concluded that "interventions delivered through mobile technology resulted in both clinical and process improvements in the majority of studies." These studies covered 38,060 participants worldwide and addressed 12 different clinical areas (including diabetes, smoking cessation, HIV/AIDS, hypertension and stress management).[6]

The evolution of mHealth

Accenture believes that the evolution of mHealth will happen at different rates and through different paths, depending on a country's health care landscape and the scope of the mHealth solution. For example, we expect the United States is several years away from adopting comprehensive solutions but this timeframe will be faster than Western Europe due to private payer dynamics, political agendas and health care economic factors. We envision immediate adoption and rapid growth of narrowly focused mHealth solutions (e.g., web and mobile-enabled drug adherence solutions) due to ease of payment and limited barriers to usage.

Even as mHealth products and services continue to evolve, it is becoming clear that most will fall into two distinct categories: 1) stand-alone products and services or 2) comprehensive solutions. Stand-alone solutions and devices are focused on specific functions, diseases or data collection. Glucose monitors for diabetics or ingestible "smart pills" that track medication compliance. In contrast, comprehensive mHealth solutions have broader health care delivery applications and will include an extensive network of stakeholders to support and provide care (see figure 2).

Figure 2. Key mHealth stakeholders



The Evolution of mHealth in the United States

Mobility is a key component of a biopharmaceuticals overall digital strategy[7] and will play a critical role in connecting multiple, currently disparate stakeholders in the health care industry including patients, payers, providers, medical device companies, governments and regulators. As these entities come together, mHealth will go through a maturation process from stand-alone initiatives to the point where mHealth is pervasive throughout the industry.

	Independent	Integrated	Pervasive
Adoption	Consumer adoption of stand-alone capabilities via mobile devices, e.g., tablets, smartphones, etc. Pilots of mHealth initiatives with providers and large employers	Penetration with major payers (and IDNs) for disease areas Incorporated into clinical trials and outcomes studies	Standard of care for designated diseases; consolidation of platforms across payers and providers
Characteristics	Multiple mobile applications or capabilities for specific functions (e.g., adherence, PERS, etc.) Technology platforms that support remote monitoring for target conditions (e.g., diabetes, heart disease)	"Closed loop" capabilities supported by broad-based platforms and niche providers Integrated with electronic medical records (EMRs), reimbursement processes, predictive coaching and communications	Embedded device capabilities (e.g., implanted/ingested) that extend functionality and/or monitor behaviors
Key Issues to Address	Technological and clinical feasibility	Reimbursement for mobile platform-related activities delivering improved outcomes	Cost-effective scaling across health care stakeholders

Source: Accenture 2011

Stand-alone products or services

To date, much of the innovation and investment in mHealth relates to stand-alone solutions in large part because it is easier to bring a discreet product or service developed for an identifiable target segment to market. The value and benefits can be easier to explain and implementation can be streamlined. Current examples of stand-alone mHealth products or services include:

- A portable ECG heart monitoring device for at-home use that measures only 4" x 3" and weighs 3.5 ounces
- A smart shirt with embedded sensors that continuously monitors more than 30 physiological signs, including respiration, posture and cardiac function
- An armband that gathers detailed data about body movements, heat flux, skin temperature and galvanic skin response, from which inferences are made about important lifestyle patterns
- "Home cams" or other cheap and smart environmental sensors (e.g., motion/activity sensors, temperature sensors, webcams) that monitor and calibrate the health and safety of patients within their home environments
- Drug adherence solutions such as Vitality GlowCaps© or Health Prize© that focus on improving compliance with drug treatment

There are a wide variety of organizations devising and implementing these solutions; they are sold to a variety of stakeholders, especially patients since the costs remain relatively low.

Comprehensive solutions

In contrast to stand-alone offerings, comprehensive solutions provide end-to-end service that can encompass patient education, diagnostic services, as well as ongoing disease management and treatment. While the value delivered to patients from comprehensive solutions can be substantial, developing such solutions requires intensive effort and collaboration. Some organizations such as the Veteran Health Administration (VHA) can control end-to-end service for a captive population (i.e., military veterans with VHA health plans). The development and delivery of most comprehensive solutions, however, will require a multi-player alliance of independent companies, each bringing specialized medical, technology, or management capabilities and assets. Consequently, the development and testing of comprehensive solutions is more complex.

Nonetheless, there have been promising collaborations to deliver comprehensive solutions. Insurance providers are becoming active participants in the development of comprehensive mHealth services, with WellPoint, Humana, Aetna and Highmark launching initiatives that enable remote and/or mobile monitoring of symptoms for a variety of conditions and diseases.

Some of these collaborations are between unlikely partners. For example, Best Buy, the consumer electronics giant, was chosen by Microsoft to help advance Microsoft's HealthVault medical record initiative. Best Buy sells wireless-enabled devices that make the tracking and communication of records easier. Significa and AllOne Health have a similar collaboration. England's National Health Service has launched remote monitoring of chronic obstructive pulmonary disease (COPD) patients, and the telecom company Orange is also testing mHealth services.

The results of mHealth initiatives are encouraging, whether focused on a specific disease or patient segments. The New England Healthcare Institute found that remote monitoring for heart failure patients reduced the re-admittance rate by 32 percent following a heart failure hospitalization, resulting in net savings of more than $1,861 per patient.[8] This result was mirrored in a meta-analysis of remote heart monitoring studies involving 9,500 patients with chronic heart failure compiled by the Cochrane Review, which showed a reduction in mortality for heart patients using remote follow-up monitoring.

Taking a broader view of health care, the VHA funded a number of trials in Florida to test the concept of "aging-in-place" by providing disease management, care coordination and remote monitoring to veterans in their homes. Their results showed a 40 percent drop in emergency room visits, 60 percent decrease in hospitalizations, 64 percent decline in nursing home admissions, 88 percent reduction in nursing home bed days of care, and more than 90 percent patient satisfaction ratings.[9] Another VHA trial focused on caregiver productivity, and found that many home visits could be canceled when monitoring devices showed no abnormalities, and when visits were required, they were shortened by an average of 15 to 20 minutes because the caregiver was already informed of the test results.[10]

Given that comprehensive mHealth requires a significant information technology infrastructure and can involve development of new devices or products, companies known for their engineering like Bosch, Intel and Phillips all have begun investing in mHealth solutions, sometimes partnering with provider groups to test offerings. [See client example sidebar, Medical Device Company Pioneers Scalable Patient Web-Based Monitoring Solution]. The momentum behind mHealth is accelerating in part because these trials and pilots as well as others have shown positive results and improvements in patient care.

mHealth opportunities for biopharmaceutical companies

The question for biopharmaceutical companies is: what roles can they play in mHealth to advance patient health and improve companies' current or future business opportunities? Given the factors in health care funding, the dramatic growth in mobile technology and emerging innovations in care and disease management, biopharmaceutical companies should be motivated to answer this question now. Figure 3, mHealth Opportunities for Biopharmaceutical Companies, summarizes the opportunities and benefits of three levels of involvement pharmaceutical companies can pursue. They range from using mHealth opportunities to address basic benefits linked to improved drug compliance—something companies should be taking advantage of at a minimum—to the comprehensive benefits that enable improved patient outcomes and decreased health care costs.

Selecting the right entry level and landing point is a strategic decision—and one that must be made in the context of the company's enterprise-wide approach to the new health care landscape where biopharmaceutical companies are increasingly "going beyond the pill" to develop solutions that improve patient outcomes. In making that critical decision, the following factors should be considered:

- **Geographic focus—**e.g., market specific influence on likelihood of third-party reimbursement, consumer payment, alignment with health care landscape
- **Disease area focus—**e.g., extent to which offerings align with chronic disease areas and other attributes that influence potential impact of designated service offerings
- **Portfolio strategy—**e.g., extent to which growth and diversification objectives will be met through focus on biopharmaceutical solution versus related services

Figure 3. mHealth opportunities for biopharmaceutical companies

Level	Opportunity	Business Benefits	Required Capabilities and Likely Approaches
1	Improve drug compliance	• Increased unit sales of products • Decreased cost of patient acquisition or retention	• Low-cost solution to address funding or reimbursement issues • Stand-alone, single-purpose technology solution that meets key attributes (e.g., passive, persistent) • Distribution could be direct to patient or via third party (e.g., PBM, payer partnership)
2	Improve health outcomes	• Improved market access and/or pricing • Strengthened relationships with payers	• Ability to link biopharmaceutical solutions with care and disease management programs • Credible design and execution of studies that generate data that meets stakeholder and regulatory requirements • Integrated technology platform (devices linked to data repository with analytics) that enable info sharing across stakeholders
3	Lower health care costs and obtain target health outcomes	• Benefits from level 1 and level 2 • Revenue from services and outcomes for care and disease management	• Disease and cost management services • Funding mechanisms to support investments and obtain reimbursement • Joint venture management • Integrated technology platform (device(s) linked to data repository with analytics) to enable info sharing among stakeholders

Next steps in defining a role in mHealth

It is critical for biopharmaceutical companies to think through these opportunities and make a decision on where they want to play and how they will work with other key stakeholders to bring mHealth forward in their business. Accenture expects that most biopharmaceutical companies can successfully achieve the level 1 benefits described in figure 3. At a minimum, biopharmaceutical companies should be using mHealth to improve drug compliance. Fortunately, pursuing this level of opportunity does not require a great deal of effort or financial outlay. Key steps include: 1) determining which products have the most issues with adherence; 2) determining which methods and technologies best support various patient segments; and 3) implementing a program and monitoring the results, adjusting as needed.

However, moving to a level 2 or 3 approach, biopharmaceutical companies have some harder questions to answer including:

- Do we have the competencies that are required to provide care/disease management offerings linked with mHealth services?
- What is our ability to achieve critical mass with patients, especially compared to payers who typically already have this type of influence?
- What is our ability to influence providers to adopt new platforms, especially if we have little influence over their reimbursement?
- What is our company's credibility among consumers and health care providers in providing mHealth services?
- If we don't offer services relevant to the new health care model, will we be relegated to providing commodity products?
- Would access to information obtained through mHealth offerings substantially change our insights into treatments?

In pursuing a level 2 approach, biopharmaceutical companies serve as catalysts in bringing together a community of providers, payers who will be able to influence care delivery and achieve targeted patient outcomes. We would expect most biopharmaceutical companies to take this approach, particularly in markets where payers have the edge with established patient networks and influence on providers through reimbursements.

If choosing this approach, biopharmaceutical companies need to quickly evaluate with which payers and providers they want to create ventures and teaming arrangements to deliver mHealth solutions. Biopharmaceutical companies bring important funding and clinical trial experience to this type of collaboration—but there is limited time and space to establish these relationships so they must begin now.

Biopharmaceutical companies opting for a level 3 approach will effectively enter a new business area that involves risks/rewards associated with achieving patient outcomes at established per patient costs. They will compete with existing providers of these services, including payers that are extending their footprint in this space in developed markets. A level 3 approach is best suited in areas and markets where there is a specialty disease state where the biopharmaceutical company has close relationships with providers. In Europe, we may see biopharmaceutical companies enter this domain to gain direct access to real world outcomes data that is otherwise not available. And while single payer environments are attractive in terms of scale, they carry a higher risk in terms of ability to influence or achieve desired outcomes.

For both level 2 and 3 approaches, the most important success factor for biopharmaceutical companies will be to craft the right value proposition and obtain reimbursements required to pay for upfront investments and ongoing provider participation. Each market will require different approaches. For example in Europe, most people are simply not going to pay for additional mHealth services out of their own pocket. In Western Europe, payers are the only potential buyers of these services. But, in Eastern and Southeastern Europe, some corporations could be additional targets as many cover the health care costs of their employees and would benefit from health care cost reductions from improved prevention and health outcomes. However, some countries such as France, the United Kingdom and Netherlands have started to change their reimbursement and are beginning to recognize Telehealth and mHealth services as part of their regular health care provisions making them obvious targets for a level 3 approach.

There is, of course, the fourth option that is not reflected in figure 3: Wait until these systems reach maturity levels and then incorporate them into trial design and health outcomes studies. But the risk of waiting is high, leaving the market open for others to develop, own and dominate.

Client Success Story

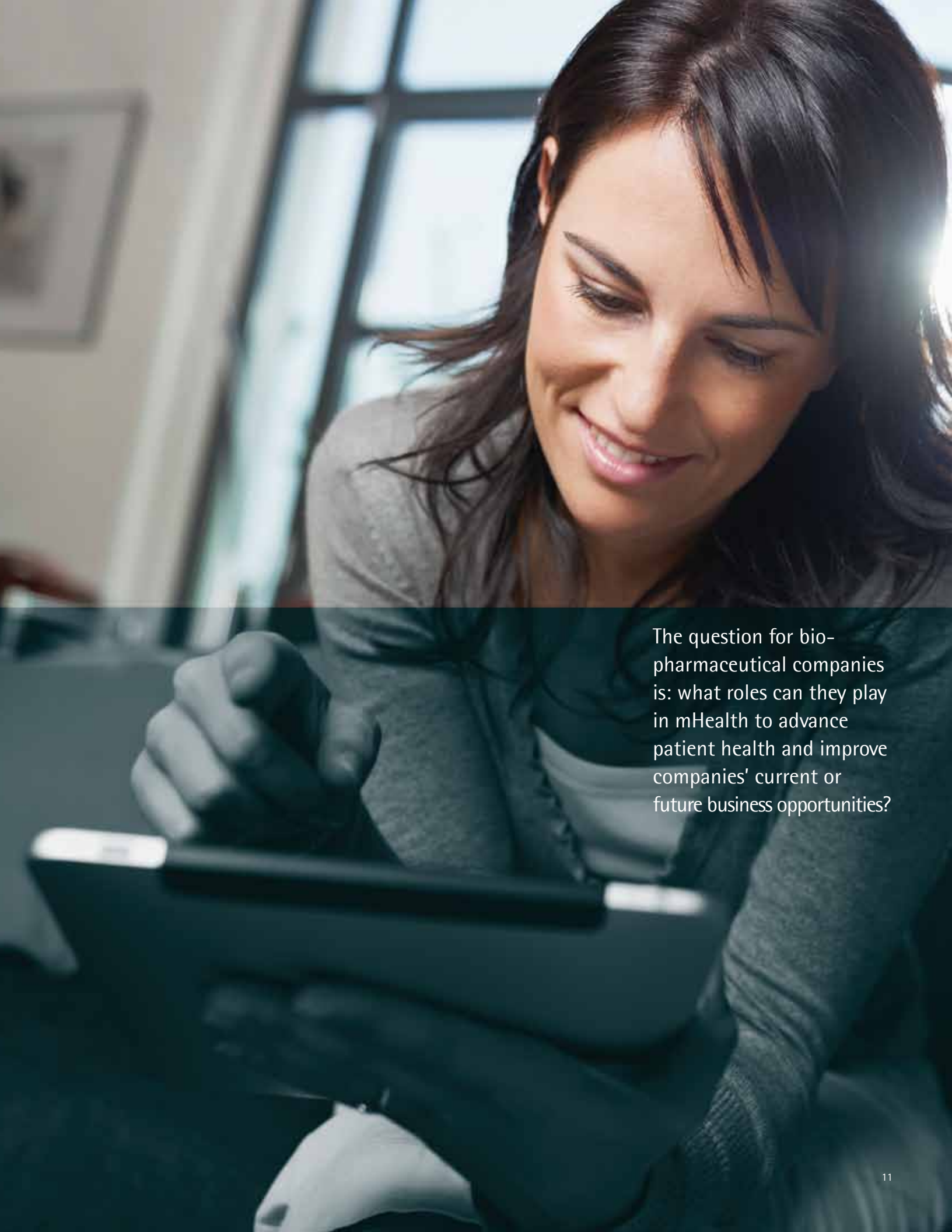
Medical Device Company Pioneers Scalable Patient Web-Based Monitoring Solution

In 2006, when mHealth initiatives were in their infancy, a leading North American medical device company turned to Accenture to help plan, manage and build an implantable cardiac defibrillator—a remote patient monitoring solution that could run over the internet and mark the first wireless device patient monitoring solution in the industry. The program had to meet two goals: enable a seamless 24x7 view of patient clinical status to provide a continuous view of a patient's clinical status with alerts for medical triage if needed, and generate data that could be easily integrated with electronic medical record (EMR) solutions.

Accenture developed the system and sub-systems for the monitoring capability, which integrated with the company's ERP and inventory management systems, and also integrated data privacy and security access controls and methods to protect physicians and patients. The system, classified as a Class III Medical Device Accessory, has a number of functions and capabilities that promoted quick and easy adoption:

- The N-tier web application architecture and user interface easily manages and integrates continuous receipt of device payloads, patient/device alert processing, and system transaction view/edit requests by physicians on patient data.
- The open system-enabled development of the first market wireless device monitoring solution as well as a wand-based inductive monitoring solution that supports legacy devices already implanted and in the field.
- The solution is built on a common, flexible platform for initial use in the United States and the United Kingdom, which can be transferred and scaled for major markets in Europe, Asia, Australia and Canada.

After the United States roll-out, Accenture worked with the company's R&D team to transfer critical knowledge to enable the company to develop future releases, including developing the prototype format for data collection and interfaces to facilitate submission of the data to EMRs. To date, over 150,000 patients are monitored with the device. Accenture continues to work with the client on additional remote monitoring solutions.



The question for bio-pharmaceutical companies is: what roles can they play in mHealth to advance patient health and improve companies' current or future business opportunities?

Challenges to the Adoption of mHealth

As with any new technology and capability, adopting mHealth is not without its challenges. A few of the more pressing challenges are outlined below:

Evolving business models

While innovation on the technical front is advancing, the marketplace moves more cautiously, stymied by a health care business model where the interests of medical practitioners, health insurers and patients are often uncoordinated. Remote, in-home monitoring can threaten traditional revenue streams of practitioners and institutions. What's more, health insurers are holding the line on new treatment methods until they are proven medically effective and cost effective. This has created a Catch-22 where new technologies won't be funded until proven, and can't be proven until funded. The other issue is consistent reimbursement and payment policy. This will vary across markets and systems, yet ideally should be consistent to support larger scale and basic availability, whether someone is treated by Kaiser Healthcare or at the Mayo Clinic or through a local network.

Incompatible technology standards

There are also unresolved technical issues with respect to standards, security, privacy and other regulatory matters. The industry's slow progress in agreeing to standards is problematic as comprehensive solutions typically call for diverse devices and systems to work together to address the unique and complex needs of an individual patient. Health care executives interviewed for an Accenture study of mHealth correctly noted that while there are device class standards and end-to-end standards, there are no standards for Wi-Fi or the wireless personal area network. However, since 2006 Continua Health Alliance has begun to organize this market and coalesce more than 200 companies around a set of industry-selected standards with a certification program. This has currently led to three Releases of Continua guidelines and more than 40 certified products/services in the market-place. There is an education effort that still remains to help them become aware that Continua has enabled a set of personal area network standards that allow for a fixed location, mobile, and high-security connectivity.

Prohibitive regulatory restrictions

Privacy is also a concern of patients and regulators. While social networking sites like PatientsLikeMe or Facebook fan pages for medications and brands encourage users to share medical details, that disclosure is voluntary. User-managed repositories for medical records such as Microsoft Healthvault have had some success, but HIPAA regulations in the United States are still a barrier to efficient exchange of health information among networks of third parties.

All of these challenges can be addressed with concerted effort. Networks of mHealth providers that are flexible, well funded and clear about the added value they deliver in improving care will be able to gain regulatory approval and market traction to overcome these barriers.

The early part of the mhealth evolution will be primarily characterized by independent, stand-alone solutions but will evolve to a more integrated approach with a blend of stand-alone and comprehensive and will eventually move to a stage where comprehensive solutions that improve patient outcomes will be pervasive.

Conclusion

There are a myriad of opportunities and levels of involvement for pharmaceutical companies to participate in mHealth. The examples and options discussed here can help companies begin developing or refining mHealth strategies and tactics to better serve patients, respond to stakeholder business concerns and secure the right collaborators and partners. Most mHealth products and services will fall into two types of categories—stand-alone and comprehensive. The early part of the mhealth evolution will be primarily characterized by independent, stand-alone solutions but will evolve to a more integrated approach with a blend of stand-alone and comprehensive and will eventually move to a stage where comprehensive solutions that improve patient outcomes will be pervasive. Biopharmaceutical companies have the relevant capabilities, resources and market reach to play a key role in this evolution. Now is the time to decide what that role will be—to derive the most benefit from related changes and investments.

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References

1 New England Journal of Medicine; 364:1078-1080, March 17, 2011, *Telemonitoring in Patients with Heart Failure.*

2 Centers for Disease Control and Prevention, *National Health Interview Survey*, 2008. http://www.cdc.gov/nchs/health_policy/adult_chronic_conditions.htm

3 United States Census Bureau, *Census Bureau reports world's older population projected to triple by 2050,* June 2009. http://www.census.gov/newsroom/releases/archives/international_population/cb09-97.html

4 Beers MH, Sliwkowski J, Brooks J. *Compliance with medication orders among the elderly after hospital discharge*, Hospital Formulary, 1992; (27(7): 720-724.

5 MobiHealthNews, *Texting improves type 1 diabetes adherence*, August 10, 2010. http://mobihealthnews.com/8599/texting-imrpoves-type-1-diabetes-adherence/

6 Krishna S, Boren SA, Balas EA (2009). *Healthcare via cell phones: A systematic review.* Telemed e-Health, 15, 231-40. p. 238.

7 *Digital: The new connector in life sciences*, Accenture, 2011.

8 New England Health Care Institute, *Remote physiological monitoring: Innovation in the management of health failure*, July 2004.

9 Centers for Medicare and Medicaid Services, *Minimum nurse staffing ratios in nursing homes*, April 2002.

10 Meyer M, Robb R, Ryan P. *Virtually healthy: Chronic disease management at the home.* Disease Management, 2001, 5(2): 87-94. See also Center for Technology and Aging, *Technologies for remote patient monitoring in older adults,* December 2009. http://www.techandaging.org/RPMpositionpaperDraft.pdf