Resources:

USC Body Computing Conference 6.0

USC's Dr. Leslie Saxon and Ken Persen of Cameron Health showcase implantable defibrillation technology at the USC Body Computing Conference. Photo by USC Center for Body Computing.

To prosper as a competitive society, we have to become experts in managing data. For physicians, that data has to be clinically relevant.

Healthcare executives shared these insights and more during the annual USC Body Computing Conference, which took place last year on the USC campus. CHI is a proud supporter of the annual conference, which gathers leaders from medicine, entertainment, telecommunications, kinesiology, and the regulatory world to shape the future of wireless medical solutions.

For the sixth year, Dr. Leslie Saxon, chief of the division of cardiovascular medicine at the Keck School of Medicine and founder of the USC Center for Body Computing, led a discussion about wireless health and how it is changing healthcare monitoring and delivery.

Thomas E. Jackiewicz, senior vice president and chief executive officer for USC Health, said he expects that personalization will be the standard of care for cancer care in the next five years. Genomic medicine will outpace the federal meaningful use electronic health records incentives program, he said.

Dr. David Agus, professor of medicine and engineering with USC and co-founder of personal genetics company Navigenics, shared how far the industry has come in advancing medical treatments by reminding the audience how early pregnancy tests were administered – using rabbits.

Today, he said, we can sequence tumors and gather data that informs healthcare decision-making.

"We now have the technology to look at all the proteins in the body," he said.

Some of the technologies showcased by conference presenters included brain monitoring devices to get inside the minds of elite athletes, technology platforms that allow for better integration of the hospital patient in team discussions and treatments, and devices for wirelessly monitoring the body's vital signs in real-time.

One of the more interesting concepts on display at the conference was Nigel, a Mini Cooper equipped with 230 sensors and an iPhone app to monitor driver habits and even create specific driving games or suggest activities for each of the car's drivers. The idea could also apply to a driver's health, said Saxon, by tracking the driver's heart rate and increasing awareness about how the body responds to a song, for example. There is a "huge unmet need" for patients to be better connected with their own health, she said.

Sam Agutu says Changamka has changed the healthcare paradigm for uninsured Kenyans. Photo by USC Center for Body Computing.

Sam Agutu, managing director and CEO of Changamka Microhealth Ltd., captivated the audience with his healthcare "by the slice" approach to combining mobile money systems with prepaid health cards that allow uninsured Kenyans to pay only for the healthcare services they need, at pre-negotiated rates.

During a question-and-answer session with a senior level FDA representative, attendees asked about the various pathways for approval of these new technologies. Megan Moynahan, associate director for technology and innovation at the FDA, encouraged the audience to continue to push the boundaries of innovation so that the agency is forced to reckon with the latest cutting-edge ideas.

The USC Center for Body Computing, which runs the conference, studies, incubates, and creates wireless health products with other USC schools and corporate partners. It specializes in creating innovative solutions for chronic disease management, sports monitoring, mHealth and gaming and entertainment.

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Mobile & Digital Health Statistics

Physicians

- 85% of U.S. physicians own or use a smartphone professionally
- 81% of physicians own an iPad
- Since the end of 2012, four of five physicians use smartphones
- 50% of tablet-owning physicians have used their device at the point of care

Consumers

- The number of adults in the U.S. (ages 18+) using mobile phones for health information grew from 61 million to 75 million last year, while tablet adoption nearly doubled from 15 million to 29 million
- 80% of Internet users look online for health information
- 20% search for health-related content on mobile devices

Nearly Half of Consumers Would Use Mobile Health Technology

- 20% would like to monitor fitness & well-being
- 18% would like to allow a physician to remotely monitor a condition
- 11% would like to continue to monitor a previous condition

Source: Manhattan Research, Rock Health

"Mobile technology is the largest platform in history. The population of the world is approximately 7 billion people, and there are nearly 6.6 billion mobile connections — 3.2 billion of which are unique users. In the United States alone, there are 323 million mobile subscriptions for a population of 315.5 million."

- Robert Jarrin, senior director of government affairs for Qualcomm

Source: Testimony to House Subcommittee on Communications & Technology, March 19, 2013

Wireless Technology Promises to Rein in Costs, Improve Healthcare

Eric J. Topol, M.D.

Digital devices, such as smartphones and the iPad, have changed the world in a single generation. The technology has rearranged human routines, pop culture, marketing and politics. Those transformations, however, are likely to be dwarfed by the imminent advances wireless technologies will offer to healthcare. As mobile devices have grown smaller and smarter, so has technology for monitoring vital signs. Sensors on the wrist can collect blood pressure, heart rate, oxygen concentration in the blood, breathing rate, body temperature and more. Combining the sensors' capabilities and people's comfort with and access to cell phones, "has huge implications for healthcare delivery," according to mobile health technology pioneer Dr. Eric Topol, who serves as the director of Scripps Translational Science Institute, a National Institutes of Health-funded program of the Clinical and Translational Science Award (CTSA) Consortium focused on advancing individualized medicine.

With wireless health, physiological measurements can be taken remotely, making it possible for patients to adhere to their regular work and family schedules and for healthcare providers to assist them from miles away. For chronic diseases such as diabetes and heart disease, wireless technologies offer new ways of managing and monitoring heart rhythms and glucose levels for patients, their caregivers and physicians.

A more continuous gathering of data also better indicates the state of one's health than does the "snapshot" approach of collecting key measures only during office visits. That is especially true for cardiovascular patients, where the true indicator of heart attack or stroke risk is not high blood pressure but, rather, swings in blood pressure from high to low. Frequent or continuous monitoring may pick up the signs of an imminent incident — such as a heart attack — triggering the patient to take immediate action to prevent it.

By using a continuous glucose monitoring app, individuals at risk of developing type 2 diabetes could more easily determine their best food, exercise and lifestyle choices for attaining optimal blood sugar results — as measured by their device. By empowering patients with real-time information and immediate feedback to help them manage their disease, wireless technology could make a significant and positive difference in patients' and their caregivers' quality of life. At the same time, the cost-savings potential is enormous.

POLICY SPOTLIGHT: FDA to Issue Guidance on Mobile Health Applications

On March 21, 2013 the House Energy and Commerce Subcommittee on Oversight and Investigations held three days of hearings on mobile health information technologies and related regulatory and tax uncertainty. The hearings came on the heels of a request from committee leadership to FDA Commissioner Margaret Hamburg, M.D., seeking more information on draft guidance addressing the regulation of medical apps. In response to issues raised in the three hearings, Christy Foreman, director of the Office of Device Evaluation in the FDA's Center for Devices and Radiological Health (CDRH), testified that the FDA "would not regulate the sale or general consumer use of smartphones or tablets. It would not consider entities that exclusively distribute mobile medical apps, such as the iTunes App store or the Android market to be medical device manufacturers. It would not consider mobile platform manufacturers to be medical device manufacturers just because their mobile platform could be used to run a mobile medical app regulated by FDA. It would not require mobile medical app developers to seek Agency re-evaluation for minor, iterative product changes. And, it would not apply to mobile apps that perform the functionality of an electronic health record (EHR) system or personal health record system." The FDA expects to release final guidance before the end of the 2013 fiscal year.

HOW IT WORKS

AliveCor Heart Monitor

Considered a Class II medical device, the AliveCor Heart Monitor snaps onto the iPhone like a case and wirelessly communicates with the corresponding app. No pairing between the iPhone and the Heart Monitor is required. The EKG data is displayed in real-time on the smartphone display, saved locally in the app where it can be annotated with patient details, and wirelessly transmitted to a HIPAA-compliant cloud-based storage system where it can be analyzed by the patient's doctor from anywhere in the world. The AliveCor Heart Monitor is a powerful, easy to use, instant rate and rhythm assesment tool.

DEVICE
1

THE APP
2

THE WEBB
3
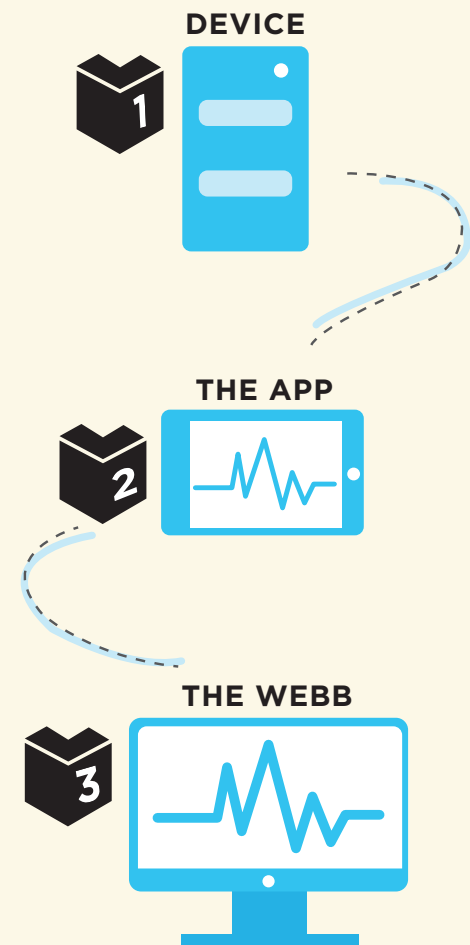
Source: AliveCor

Spotlight on Innovation
AliveCor: Bringing Health to Everyone's Fingertips

AliveCor™

Cardiovascular disease kills an estimated 17 million people worldwide every year. With new technologies and breakthrough ideas in the mobile and digital health arena emerging rapidly, the prevention, treatment and management of heart disease is becoming easier as digital health evolves. One of those breakthrough technologies is the AliveCor Heart Monitor for iPhone.

AliveCor, Inc. received FDA clearance in November 2012 to begin selling its Heart Monitor in the United States to medical professionals and prescribed patients. This revolutionary device allows you to obtain a single-lead electrocardiogram by simply placing fingers from each hand on the back of the AliveCor Heart Monitor's electrodes. This $199 solution allows for accurate screening for cardiac arrhythmias including atrial fibrillation. A-fib is is the most commonly occuring arrhythmia and carries a five-fold risk of stroke.

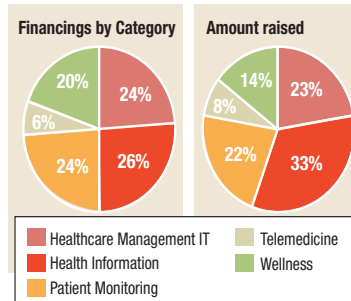AliveECG app and the AliveCor Heart Monitor

Source: AliveCor

Financing Digital Health
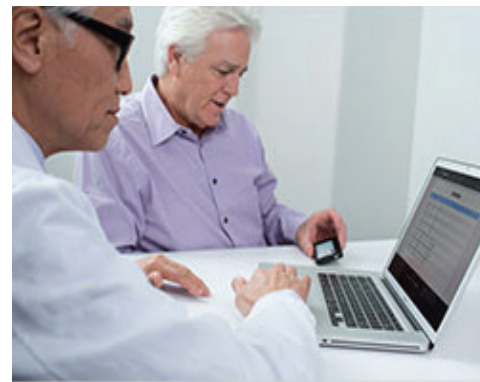
Investors and governments worldwide are keenly aware that advancements in mobile and digital health technologies will be game-changers in the delivery and markets of healthcare for years to come. Even as capital markets underwent strong headwinds in 2011, entrepreneurial investment in mobile health saw an uptick of 16 percent in overall capital raised. Overall, mobile and digital health companies closed on 46 agreements with $421 million raised from investors in 2011. The 2011 statistics are a healthy increase from 2010, as only $364 million was raised through 31 deals.
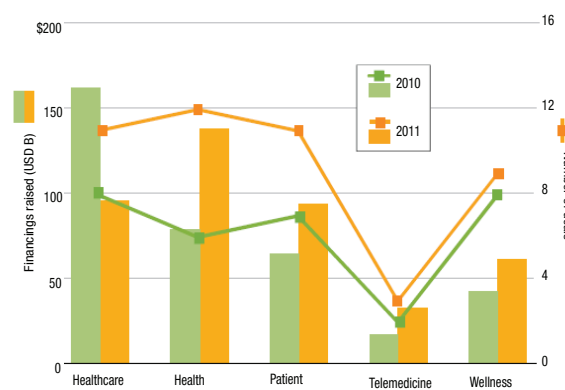
Companies Invested In:

Financings by Category

Amount raised

- Healthcare Management IT
- Health Information
- Patient Monitoring
- Telemedicine
- Wellness

Amount of financings raised and number of deals

Healthcare Management IT: 23 %
Patient Monitoring Ventures: 22%
Wellness-focused Companies: 14%
Telemedicine: 8%

Source: Burrill & Company

ADVANCES IN MOBILE AND DIGITAL HEALTH
WORKING TO BRING HEALTHCARE INTO THE 21st CENTURY

Tandem Diabetes:

In November 2011, the FDA cleared the t:slim® Insulin Pump, created by CHI member Tandem Diabetes Care. The first touchscreen insulin pump, t:slim uses a smartphone-style interface that is simpler to teach, learn, and use. Despite being the slimmest insulin pump on the market, t:slim has the largest insulin capacity (300 units). t:slim is one of the first insulin pumps to be cleared under the FDA's new Infusion Pump Improvement Initiative.

In February 2013, the FDA cleared Tandem's Mac- and PC-compatible data management application that provides t:slim pump users and their healthcare providers a fast, easy, and visual way to display data from their pump and supported blood glucose meters. The t:connect application empowers people with diabetes, as well as their healthcare providers, to easily and quickly uncover meaningful insights and patterns, allowing them to fine-tune therapy and lifestyle choices for better control of their diabetes.

t:connect

Source: Tandem Diabetes

Qualcomm Life, WebMD Partner for Cloud Based Mobile Health Data App

Qualcomm Life Inc. in partnership with WebMD, has designed a platform for mobile health data storage in the cloud, with the goal of enabling patient access to a wide collection of a data related to fitness, wellness and medical devices. This is becoming an increasingly common trend, as device manufactures, like Qualcomm, seek to collaborate with digital application designers to assist patients and consumers in monitoring their respective well-being, through digital and wireless conduits. As an example of this initiative, Qualcomm's 2net platform helps these technologies become interoperable.

The goal of the WebMD and Qualcomm Life initiative is to enable patients and consumers to be better positioned to take control of health and fitness management, through the use of biometric data. In addition, the two companies hope to increase awareness, dialogue and discussion between medical device makers and mobile health application designers, so that physicians and patients have the ability to create custom plans and platforms designed to best meet respective health needs.

Source: Qualcomm Life

23andMe:

23andMe recently released a mobile application that allows customers to access their health results on their smartphones while contributing to research. Along with reporting back genetic information, the application asks Customers survey questions. 23andMe researchers combine the answers to those survey questions with genotypic and phenotypic information to uncover the genetic associations with various health conditions and traits. The answers also help reveal how genetics affects a person's response to medication. In turn, 23andMe reports back to its customers these scientific findings helping to engage people in the research process.
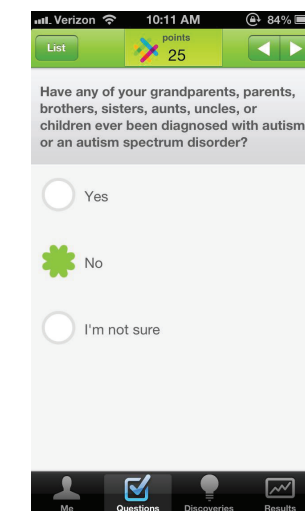
Source: 23andMe

About Proteus Digital Health:

proteus
DIGITAL HEALTH
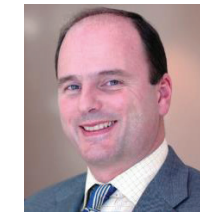
Name: Andrew Thompson
Title: Co-Founder and CEO
Company: Proteus Digital Health
Location: Redwood City, CA

Proteus Digital Health is pioneering a new category of products and services based on ingestion sensing. Its core technology, the digital health feedback system, provides an unprecedented view into an individual's personal health choices and physiologic response, allowing patients to better manage their health and more effectively collaborate with caregivers and clinicians, while enabling new information-based business models.

What impact will new technologies like yours have on the life science industry in the next five years?
Healthcare will be transformed by a new utility more available than electricity – the mobile Internet. In the 20th century we all plugged in and transformed our homes, factories and hospitals. In the 21st century we all log on, and even greater benefits are emerging. About the only thing spreading faster than chronic disease is mobile phones.

What are the factors for success for health technologies like these?
The key is creating FDA-approved digital health solutions that help consumers right away, and then deliver on longer term clinical results. This kind of immediate value means doing jobs that consumers already struggle with – like ensuring grandmas with heart failure feel safe, sons with bipolar disease sense love, daughters with diabetes understand how to stay stable, and mothers are reassured they have the tools they need to keep their family healthy.

What are the hurdles?
The most important part of a digital platform is that it creates data that can be used to deliver a much more focused and personal experience. That means you can change what you sell from a standardized product (like a pill) to a personalized solution (like an outcome). So the most important thing to change is the business model.