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Smartphone-Based Data Gathering for Clinical Trials



Interview conducted by: Lynn Fosse, Senior Editor, CEOCFO Magazine

CEOCFO: Dr. Sterns, what is the basic concept for iRxReminder?

Dr. Sterns: We are a smartphone-based data gathering for clinical trials. The same technology can be used for supporting self-management of chronic conditions, as well as recovery from intense procedures with complex medication regimens.

CEOCFO: Is most data or is much data gathered for trials electronically on smartphones today or is that still a little bit newer concept?

Dr. Sterns: It is definitely, a newer concept.

CEOCFO: Who is using your services? Where are you in rolling out the services?

Dr. Sterns: We have a number of customers now. We have a medical device trial with Metro Health in Cleveland. We have an ulcerated colitis study with the University of Wisconsin Medical School and we have had a number of projects that include universities like Kent State University, Case Western Reserve University, and others. We have a new project we are initiating with Akron Children's Hospital focused on bone marrow transplant recovery.

CEOCFO: How do you reach potential customers?

Dr. Sterns: We have a national presence and an international presence from my work as a researcher. We attend trade shows. We will be at the mHealth Summit. We will be at HiMSS '14 and probably the American Telemedicine Association meeting this year. We participated at those meetings last year.

CEOCFO: What were some of the challenges in putting together your offering?

Dr. Sterns: I think one of our early challenges was establishing that smartphones are universally usable by all age groups. We have done numerous pilots over the last decade, becoming experts in educating quickly and efficiently participants to utilize the smartphones from stem to stern, completely. That training used to take some time. It now takes about 20 to 25 minutes. The training ensures they can use the entire device so that they want to carry it with them, use the radio, use the e-mail, get notes from their grandchildren, things like that. The medical applications are incidental to why they carry the smartphone with them. But having it, they adhere better to the study protocols and stay engaged in the study.

CEOCFO: Has the training gotten easier because people are much more familiar with smartphones now or have you figured out a way to streamline that process?

Dr. Sterns: It is probably a combination of three things. We are experts in that training and have streamlined it, but phones, particularly those with touch screens, have gotten easier to see and use. Then there are more and more individuals who have this equipment on a daily basis prior to our introducing it. There was a time when we were always introducing it. That is no longer the case. Pew indicates 17% of people 65 and older have smartphones, for example, and now a majority of people using mobile technologies have a mobile device that connects to the internet.

CEOCFO: How does it work?

Dr. Sterns: Our system consists of three components. We have our control center used by the researcher to set up and deploy the studies. That is cloud-based. Then the participants utilize our smartphone app. We also have a new component, a medication-dispensing system, called the iLidRx.

CEOCFO: What is the goal?

Dr. Sterns: It is designed to provide a cognitive prosthetic for complex medication schedules. It consists of a box, on the inside of the lid is a display, and inside the box are what we call pods that resemble perhaps a ten-foot tape measure. That pod is the equivalent of a 90-day bottle of pills you would get from the pharmacy except when you opened the lid, you would see an LED on the top that tells you that you need to take that particular pod now. When you pick up the pod,

on the display you would see a picture of the pill why you're taking it, all the warnings, directions for taking it, such as you need to eat food with this medication. You place this pod on your hand, tilt it and out comes a pill. There is no opening anything and you get the correct dosage and when you place it back, it reports back to the system confirming the medication's been dispensed. We have had pharmacists refer to it as a personal Pixus.

**"iRxReminer is an important solution because it will help have a dramatic impact on health care tomorrow as well as being able to save \$20M per study in clinical research today."
- Dr. Anthony Sterns**

CEOCFO: *Would that handle one pack of medication at a time?*

Dr. Sterns: You can have many of these tape measures within the container. For the bone marrow transplant project for example, we are using up to 20 medications that are taken 7 to 10 times a day.

CEOCFO: *Would you hook up and all the medications in one spot?*

Dr. Sterns: That is right. We also have a patented cellphone case that is designed to carry your phone and your pills with you for your midday pills. If you're a school age child, for example, you would take your morning medications. You would dispense your midday medications, place them in your case along with your smartphone, head off to school, and the smartphone tells you with a pulse, reminding you, to take your medications. What we find with most people is that they get in the habit of taking their meds on time. Another unique feature of our system is it supports rather than nags. With the one-way text reminding service for example, you will always get that every day and you learn to ignore it. It is not all that helpful because most of the time you do take your meds particularly early on. With our system, you take your meds and you do not get bothered, but if you do not remember, you do get that alert. That alert is much more meaningful and appreciated when it occurs.

CEOCFO: *Where is that in development?*

Dr. Sterns: The control center and app have been used since 2011 in research. For the iLidRx, the pill dispensing system, the Akron Children's Hospital project will be the first project to be used in the field. We just received funding in that project from the Great Lakes Innovation Design Enterprise (GLIDE) Innovation Fund here in Ohio. I should mention, we have support in developing our product from the National Institute of Health, National Institute on Aging through the Small Business Innovation Research Program.

CEOCFO: *Are you funded to tackle all the areas that you would like or will you be seeking funding and additional partnerships?*

Dr. Sterns: The best investment in us is by customers at the moment but we are looking for angel investors or strategic partners. In fact, we have a recent partnership with InterSystems who is participating in the Akron Children's Hospital project. As I said, we have received investment from the Innovation Fund. We received support from the National Institute of Health's SBIR program. We have received funds and support from TiE Ohio.

CEOCFO: *Why is this the right time?*

Dr. Sterns: There are probably three trends that are making a difference. First of all smartphones will be the de facto device for mobile health management which is certainly another benefit. There is the Affordable Care Act and Accountable Care Organization and the movement towards Accountable Care organizations are also a trend that has worked in our favor because there's now an incentive for people and interests, to remain healthy and self-manage their conditions. The third thing is that the cost of medical research has just exploded. A new drug will cost about \$4B now. The research itself, those trials typically run an average of \$60M and the amount of dropout that has been going on in those trials has been increasing from 20 to 30% over the last 4 years, from 2008 to 2012. Our research has shown that the new marketing calling and text reminding methods are contributing to that dropout. Our technologies, in our pilot studies, have shown 0 to 5% dropout. By eliminating dropout in a \$60M study, you can save \$15M to \$20M. As the cost of research has increased, finishing on time and doing it with less dollars has become paramount.

CEOCFO: *You certainly seem to be getting great results in all of the areas of focus. What might be on the back-burner?*

Dr. Sterns: We are focused on two areas. One is medical devices, which tend to have smaller numbers of people in their trials. For example, if you have a new surgical technique and the person goes home for recovery and is depressed, stays in bed for three weeks and does not do their rehab, the fault of that is then attributed to the surgery. Now, with our techniques, you will be able to follow their recovery, see that they are taking their medications correctly and that they are working and they could be adjusted if they are not. You can walk the person through their rehab routine, measure their

pain before and after their exercise. Then when they come back, you can distinguish between someone who has fully embraced their recovery regime and someone who has not and account for that in the study. Now you can say, "With surgery and full embracing of the regime you succeed this much faster," or "You recover that much faster, whereas, if you do nothing afterwards, you don't recover any better." Those are good things.

CEOCFO: *Why pay attention to iRx Reminder? Why does iRx Reminder stand out as an exceptional company?*

Dr. Sterns: I think we solved a very difficult problem, which is helping people be highly compliant with their medications. We have done that because health behavior is first and always our focus and being technologists is second. We have understood the human side of the equation. Really, while the rest of our industry has been focused on supporting health care professionals, we have been in the business of supporting patients and connecting them to health care professionals. Medication is a \$320B problem today. Medication non-compliance accounts for half of the 60-year olds who show up in the ER every year, 700,000 people in 2012. iRxReminder is an important solution because it will help have a dramatic impact on health care tomorrow as well as being able to save \$20M per study in clinical research today.



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