

## Automated Recruitment Is the New Face of Clinical Trials

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In this age of Twitter, Kindle and the iPhone, the idea of a healthcare system in which 90% of hospitals still use paper processes feels about as dated as a punch line from "Leave It to Beaver." And yet, it's standard practice in the U.S.

An innovative startup out of San Francisco, Calif., KDH Systems, is working to modernize the healthcare process, beginning with clinical research and clinical trials. The company's largest project to date is a partnership with the Neurological Emergency Treatment Trials, which is funded by the National Institute of Health. In the next 18 months KDH Systems will connect 150 emergency rooms via its Global Healthcare Network for the purpose of recruiting patients for clinical trials related to neurological conditions.

Each participating hospital will host a server dedicated to KDH Systems that is directly connected with the hospital's internal patient registration system. The software, which has a patent pending that will make it HIPPA compliant, combs through the hospital's internal system, automatically identifying patients that meet the right set of criteria for a specific study. The software then sends an alert to the head of trial protocol.

"The beauty of it is people don't have to register for trial," Susan Brown, the Chief Marketing Officer of KDH Systems, says. The trial finds them.

The potential is enormous: While it's fairly easy to find candidates for trials for diseases such as Rheumatoid Arthritis or Type-2 Diabetes, there are many others, such as the diseases the Neurological Emergency Treatment Trials is studying, which just don't have enough public visibility to recruit the number of patients they need.

"Clinical trial patient recruitment is one of the biggest roadblocks in getting clinical trials approved," Brown says. "The FDA mandates that they have a certain number of trial candidates that go through each phase, and that can lengthen or even completely blow up the trial if they don't get the right number and the efficacy is not proven." KDH Systems helps fill that gap, filtering through preexisting patient files to find candidates that are already in the system.

But it's taken years of testing and revision — a clinical trial for the system, if you will — to get this far.

KDS Systems began as an information system for hospitals, intended to automate a range of hospital processes. Co-founders David Haddick and Kris Durski, who have a combined 50 years' experience in software and product development for the healthcare industry, spent an untold number of hours customizing a prototype for the Emergency Department at the University of California at San Francisco before running into a dead end. "There was just no traction as far as getting it sold — there's so much fragmentation and confusion in the healthcare market," Brown says. "We were just beating our heads against the wall."

The setback was not without insight: "Doctors loved the reporting aspect of the software. [They thought] it was amazing that with a tap of the key they could get complete reports," Brown recalls. "That was the leading indicator that there was a real need for this kind of automated process."

Back at the drawing board, Durski and Haddick adapted KDH Systems for clinical research, transforming the system into a patient identification platform. Working closely with a few key proponents at UCSF, including clinical researcher John Stein, who used the system exclusively to populate his medical research for several years, the team found its niche. To date, KDH Systems has recruited 15,000 patients from UCSF and Stanford databases, which total more than 300,000 patients.

As KDH Systems expands into hospitals and clinical trial settings across the country, one factor that bodes well for its success is the software's ability to be completely customized. And while we expect no less from our email interface, the flexibility of the system is a revolutionary proposition in healthcare.

"Let's say you have 10 different trial sites, and you want to see the enrollment statistics for each site. We can provide that on the dashboard, at one central location," Brown says. With trials, the software allows for doctors to

# Medical Devices eBulletin

*A quarterly eBulletin from the people who bring you the Medical Devices Executive MindXchange*

Growth Dynamics and Insights into the Changing Industry Landscape

*March 2009 Vol 2 / Issue 1*

shape their own requirements, customizing trial criteria and qualifications, exclusion and inclusion criteria, and trial forms.

KDH Systems also has the potential to conduct an unlimited number of non-competing trials at the same time — it's just a matter of setting the criteria for the database. Brown likens KDH Systems to a customer relationship management tool like Sales Force.com that automates multiple companies on a hosted platform. Single companies can share information across distributed locations, if needed, but that data is password protected and remains encrypted until users authenticate it on either end.

"The big dream is that it [KDH Systems] becomes the standard [system] for all usage for all clinical trials because it will save time and certainly money. That's a huge plus in automation," Brown says. "Eventually this will lead to a whole different process that will streamline clinical trials and, if you want to know the vision, it can make drugs cheaper, better, faster, to market."