

Khale Completes NIH-Funded Study on SMART™ Adherence Monitoring System

Khale, Inc. announced today the successful completion of an NIH-funded study of usability on its SMART™ Medication Adherence Monitoring System.

Gainesville, FL July 26, 2012 -- Khale, Inc. announced today the successful completion of a study sponsored by the National Institutes of Health (NIH) to assess the usability of the SMART™ Medication Adherence System.

SMART™ is being launched as a clinical trials tool and a service platform for the pharmaceutical industry, to address the very significant problem of noncompliance of participants in drug trials. Studies and reports have estimated that between 25% and 50% of study participants are either not taking the study drug per protocol, or not taking it at all. The result of noncompliance and unknown compliance rates in drug trials is flawed data and, ultimately, failed studies and failure to gain approval for important drugs. SMART™ definitively monitors who is taking the medication and who is not, in real-time, allowing intervention within a short period of time after a dose has been missed, driving compliance rates higher and generating superior data sets.

The NIH sponsored study was designed to assess the usability of SMART™ technology by subjects with disease (HIV/AIDS) in real-world environments (home). In the SMART™ system, a subject swallows a capsule containing FDA-designated direct food additives, termed adherence-enabling markers (AEMs). After being absorbed in the upper GI tract including the stomach, the AEMs rapidly generate volatile breath compounds, termed exhaled drug ingestion markers (EDIMs), which can be detected in the breath. The subject exhales directly into a small handheld SMART™ device, and the breath sample is analyzed for the presence of EDIMs. SMART™ devices in development will transmit data to a central repository in a HIPAA-compliant manner. The presence of EDIMs in exhaled breath coupled to a positive biometric authentication (i.e., facial recognition) indicates “definitive” subject adherence to the medication on a dose-by-dose, time-stamped basis without the expense and burden of directly observed therapy (DOT).

In response to interview questions, 100% of study participants generally liked the idea of a system documenting adherence, and 92% indicated that they would be willing to use the SMART™ device again in a clinical study if asked. Overall, subjects were willing to use the SMART™ Adherence System and generally satisfied with its operation. Subjects effectively used the SMART™ Adherence System during the observed initial interactions with the device and throughout the 10-day study period. Future SMART™ devices are expected to increase usability even further.

Khale is a medical technology innovator, developing products that transform healthcare and save lives. The company is a world leader in the use of sensors that analyze vapor and exhaled breath and is focused on novel patient-centric monitoring solutions. Its two current product lines under development include SMART™, the world’s only definitive medication adherence monitoring system, and Assurance™, a replacement for conventional finger-based pulse oximetry which will monitor multiple patient parameters from a single-point-of-contact sensor, more comfortably and conveniently than finger-based pulse oximetry with fewer false alarms.

For more information, please visit www.khale.com or contact the company at 352.371.8488.
