

Home-Based Drug Monitoring Device for Measuring Personalized Dose Optimization, Drug-Drug Interaction and Toxicity



Pam Randhawa
CEO & Founder
Empiriko

CEOCFO: Ms. Randhawa, would you tell us the concept behind Empiriko?

Ms. Randhawa: The concept behind Empiriko came about because much of the extensive testing and clinical trials required to bring a drug to market focus on how the drug is metabolized in the liver. Metabolism profiling is one of the most commonly used means of identifying toxicity, potential side effects, and selecting the best pharmaceutical compounds for further study. However, despite major spending on testing, 43 drugs have been withdrawn from the market since 1997 due to safety issues. Others have required special “black box” labeling due to adverse reactions, underscoring the critical role metabolism plays in causing adverse reactions and fully understanding pharmacological processes. Many of these failures are due to variability between animal species in pre-clinical drug toxicity testing and the lack of sensitive biomarkers.

The pharmacokinetics of drug-drug interactions -- the effect of one drug on the metabolic clearance of a co-administered drug -- is also a major mechanism of adverse drug reactions. Regardless of the reason, the relationship between drug metabolism, a patient's response to therapy and potential toxicity cannot be overemphasized. These factors contribute significantly to morbidity/mortality and serve as a driver of healthcare costs worldwide. Avoidable healthcare costs account for over \$200 billion in the U.S. annually, with direct medical costs of adverse drug reactions at \$130 billion. These challenges result in a segment of the population experiencing adverse reactions or not getting the full benefit of the drug -- which can lead to noncompliance and \$105 billion in avoidable costs.

Our first objective was to improve drug research and development processes by testing drugs earlier in the drug lifecycle (prior to animal testing) and helping pharma companies design drugs more effectively and safely. Our second objective was to improve patient treatment and outcomes by measuring a patient's physiological and clinical functions on a continuous and real-time basis for early intervention and effective treatment. Many drugs are studied in controlled environments, such as clinical trials, where patients are selected to meet specific criteria and monitored closely. Unfortunately, controlled trials do not always detect what happens in the general population. Genetics provide a patient's risk level but do not explain how that patient would respond to a specific therapy which is dependent on environmental factors (such as age, health, the effect of multiple medications, compliance, dosing levels, diet, alcohol ingestion, non-prescription drugs and other chemical agents). Our goal is to address environmental and clinical factors with an eye to personalized treatment.

CEOCFO: Have people tried to address both of these objectives?

Ms. Randhawa: There have been some improvements on the drug discovery side. However, since seventy or eighty percent of the drugs tested on animals do not equate to humans, there has been a concerted effort in harvesting and studying human liver cells and other biological systems. In terms of personalized patient treatment, there have not been significant improvements. Patients are typically assigned a caseworker, enrolled in a disease management program or provided rudimentary monitoring devices.

CEOCFO: How are you working to get things done?

Ms. Randhawa: We developed our patented technology -- Biomimiks™ -- that closely mirrors the in vivo metabolism of liver enzymes (cytochrome P450) by incorporating chemical catalysts, biological processes and in silico modeling. The power of these “chemosynthetic livers” is that they closely mimic the liver's metabolic reactions to drugs, targeting areas

where a more granular assessment of hepatic function, metabolism, toxicity, drug level monitoring and environmental toxicology are important concerns. Initially, this technology was developed as the foundation for our focus on drug metabolism profiling and pharmaceutical industry applications. However, recent advances in chemistry, nanotechnology and materials sciences have positioned Biomimiks™ to be leveraged into the rapidly expanding field of biosensors and personalized medicine. This has opened doors for Empiriko to develop a home-based drug monitoring device for personalized patient treatment. Currently, our R&D focus is dedicated on developing this device.

CEOCFO: Are many pharmaceutical research people taking advantage today?

Ms. Randhawa: Researchers in drug discovery were initially skeptical about a chemical-based (in vitro) system that mimics biological functions. However, we were able to apply our technology and present findings on marketed drugs where human studies have already been completed and published. Our in vitro results were similar to those human studies. Since then, there has been significant interest from pharmaceutical and biotech companies.

CEOCFO: What is the current customer base?

Ms. Randhawa: Since the Biomimiks™ platform serves as the foundation for both R&D and personalized patient treatment, we decided to invest all our resources into developing the device. This allows us to capitalize on emerging technologies and trends related to nanotechnology, mass spectroscopy, biosensors, and microfluid technology – allowing the company to scale its technology onto a range of exciting platforms including personalized health monitoring. This device would provide physicians the patient personalized information needed to optimize drug dosage, detect drug-drug interactions and determine potential drug toxicity (adverse reactions) – in real time.

“This home-based drug monitoring device would assess liver function, metabolism, toxicity, drug level monitoring and environmental toxicity. The device’s clinical intelligence engine would analyze and translate actionable information necessary for physicians to treat their patients more effectively and in a personalized manner.”- Pam Randhawa

CEOCFO: Would you tell us more about this second side of Empiriko’s business?

Ms. Randhawa: Initially the device targeted at patients who have chronic conditions and are at risk because the therapeutic window for drugs they take is narrow, their individual response is highly variable and drug interactions are more prominent. It’s important to understand that sophisticated instruments and scientific analysis are used to study new drugs and those instruments cost thousands of dollars. We are applying the same scientific and clinical rigor to the patient market. A good analogy would be the transformation of super computers to personal computers and now smart phones. This home-based drug monitoring device would assess liver function, metabolism, toxicity, drug level monitoring and environmental toxicity. The device’s clinical intelligence engine would analyze and translate actionable information necessary for physicians to treat their patients more effectively and in a personalized manner. Our first version would target neurological disorders (e.g., strokes, depression, epilepsy, addictive disorders) and oncology.

CEOCFO: Why pay attention to Empiriko?

Ms. Randhawa: Empiriko stands out because our technology would enable physicians for the first time, to obtain quantifiable, clinically actionable and personalized patient information in real time. In addition, this changes the role of patients to be more proactive in their own care. This takes the bias out of patient reported data or retrospective analysis. By measuring the concentration of drugs in plasma, profiling metabolites and other clinical measures at the point of care, this device would represent a paradigm shift in improved patient compliance, chronic disease monitoring, risk management, cost-effectiveness and clinical outcomes. Collectively, this breakthrough in evidence-based medicine would verify for all stakeholders in the care continuum that treatment was delivered and optimized as it was originally intended.

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

For more information visit: www.empiriko.com

Contact: Pam Randhawa 617 340-3082 (work) pam.randhawa@empiriko.com

