



< WRAL.com

Posted Feb. 21, 2017 at 6:50 a.m.

CED Life Science presenter profile: Adaptive Risk Systems



By WRAL TechWire

Tags: Startups, Venture & Innovation, Biotech & Life Science

Editor's note: WRAL TechWire and the Council for Entrepreneurial development are partnering to present a series of profiles and Q&As featuring companies startups and emerging companies participating in the CED's annual Life Science conference coming up Feb. 28-March 1 in Raleigh. The latest profile is Adaptive Risk Systems, which is based in Raleigh.

Adaptive Risk Systems, Inc.

- Web site: www.adaptiverisksystems.com
- President: Melissa Becker
- Contact information: mbecker@adaptiverisksystems.com
- Sub-sector: Healthcare IT/Digital Health
- Headquarters: Raleigh, NC
- Year Founded: 2015



COMPANY PROFILE

Adaptive Risk Systems a women-owned business, is a cloud-based (SaaS) company that specializes in the development of products that mitigate risk. The company's president and co-founder, Melissa Becker, has spent 14 years as a clinical operations lead and auditor working on at-risk clinical studies and noticed a marketplace gap for an all-encompassing tool that utilizes the study monitor report information to identify, mitigate, and manage risks at clinical trial sites. Adaptive Risk Systems™' first product for the pharma industry is an intelligent risk monitoring assessment (IRMA™) tool that has been created for Clinical Research Associates and Study Managers to quickly identify and manage risks at both the investigative site and study levels. IRMA™ uses a proprietary rating algorithm that assigns built in corrective and preventative action plans based on the risk level assigned.

FOUNDERS/MANAGEMENT TEAM

- Melissa Becker, President
- Wes Pollard, Chief Financial Officer
- Krishna Bhupalam, Vice President Technology

KEY MILESTONES TO DATE

- Funding: To date has been internally funded by the founders for the development work and is considering investors for commercialization
- Alpha testing:
 1. Part 1 completed December 30, 2016
 2. Part 2 to be completed by March 30, 2017
 3. Beta Testing completed by Aug/Sep 30, 2017
 4. Product launch estimate Nov/Dec 2017

Q&A

- **What is the primary pain point you are seeking to address?**

In response to the FDA new guidance in August 2013, "Oversight of Clinical Investigations: A Risk-based Approach to Monitoring," Melissa Becker, the president and founder of Adaptive Risk Systems took a different approach to addressing risk-based monitoring. Instead of expounding on the current process for assessing investigative site and study risks with the use of data management and statistical programs (that take a higher-level look at study risks mainly through data entry, query metrics and protocol deviation reporting), she decided to assess the current industry study monitor report and the data that it required. This is one of the first points where the issues and root causes for critical investigative site and study issues are identified.

During Melissa's analysis of the industry study monitor report, she noticed several important aspects of the current way investigative site information is captured within the study monitor report:

Information captured by the study monitors varied dependent upon:

1. the experience of the study monitor
2. the disease indication being studied
- 3.3 the study phase.

The study monitor was not always certain what information needed to be entered into the study report (either from lack of experience and/or ambiguity of the question);

The monitor report did not allow for easy identification, tracking, and management of investigative risks identified, leading to unaddressed and unresolved issues that would continue throughout the life of the study. Thus, these issues would not be addressed until database lock, impacting study budgets and timelines due to the need for additional clean-up of issues that impacted the evaluation of the study product's safety and efficacy data.

The analysis revealed a gap in the market place for an all-encompassing tool that utilizes the study monitor report information to:

- Assess investigative site performance;
- Rank site performance in all areas assessed at the site, allowing the monitor to focus on critical areas of risk identified;
- Mitigate investigative site and study risk;
- Monitor and Manage investigative site risks;
- Perform a risk trend analysis by investigative site, group of sites, regions, countries, and protocols.

- **What sets your company apart? What's the "secret sauce"?**

Adaptive Risk Systems' 'secret sauce' is a combination of a few key factors:

- The company's co-founder and inventor of IRMA has deep industry knowledge and experience in the clinical trials space. IRMA was created to fix a clear gap in the marketplace.
 - IRMA's unique structure, algorithm, and sensibility.
 - Many follow-on products in the pipeline.
 - Seasoned management team and advisors.
- **Why should investors be interested in your company?**

It is estimated that 72% of clinical trials run behind schedule and an estimated \$660,000 to \$8 million lost for each day that the clinical trial is delayed.

Information based on large CRO experience estimates that at least 1/3 of studies end up needing repair or being rescued.

- Monitoring activities comprise approximately 30% of clinical trial costs.
- There is now a proliferation of CROs offering services for 'rescue' studies.
- Many of the study timeline delays and budget impacts can be attributed to repair costs for corrections to study data by way of the study monitor.

With monitoring activities comprising 30% of Clinical Trial costs, the impacts to study timelines and study budgets for the re-monitoring of discrepant data can be exponentially high and unnecessary if identified and addressed by the study monitor early in the study.

IRMA™ is a comprehensive risk-based monitoring report and training tool. This robust program would be the first of its kind on the market and has the potential to be an industry standard.

Recent changes in industry regulations (e.g., FDA and Good Clinical Practice (GCP) that focus more on 'quality' and risk management of clinical trials are difficult for companies to implement. The need in the market for a risk-based monitor report that is risk-based and monitors quality would address the current and future market needs saving on repair costs and commercialization timelines.

Adaptive Risk Systems (ARS) has recognized the importance and need for quality review of study data, the reporting of accurate results, and the impact or consequences that result when these are lacking. ARS has developed Intelligent Risk Monitoring Assessment (IRMA™), a tool that provides a means for the pharmaceutical industry to monitor these risks proactively. IRMA™:

- Assesses investigative site performance – utilizing our proprietary algorithm that assigns a risk score and color based on the monitors' responses to report questions;
- Ranks site performance in all areas assessed at the site, allowing the monitor to focus on critical areas of risk identified;
- Mitigates investigative site and study risk – by early identification of problem areas and assignment of actions that let the study monitor know what correction action to be implemented to correct the problem before things get out of hand;
- Monitors and manages investigative site risks – keeping clinical trials on schedule and on budget (reduce costly rescue trials) by providing a risk analysis component that can perform a risk trend analysis by investigative site, group of sites, regions, countries, and protocols.

Identification of deficiencies early on will significantly assist in the reduction of re-work or rescue trial costs while maintaining important sponsor timelines.

- **What is the potential market size?**

The global clinical trials market was estimated to reach USD 14.2 billion in 2016, and is projected to increase to USD 22 billion by the year 2021, growing at a CAGR (compounded annual growth rate) of 7.5%, during the forecast period 2016 to 2021 [online: <http://www.mordorintelligence.com/industry-reports/global-clinical-trials-market-growth-trends-and-forecasts-industry>].

As of 02Feb2014, in the U.S. alone more than 10,000 clinical trials were registered on ClinicalTrials.gov. This represents 39% of the global clinical studies market.

WRAL TechWire any time: Twitter, Facebook

Copyright 2017 WRAL TechWire. All rights reserved.

More From WRAL TechWire

- **Statewide NC gigabit Internet event to highlight fast-net solutions Tune in the event**
- **Earnings: CommScope, LendingTree beat Street**
- **Becton Dickinson to open new facility in Mebane, create 20 jobs**
- **myPhotoPipe Takes Stake in Digital Photo Application Developer**
- **CED Life Science Conference to showcase Triangle's remarkable success story**
- **CRO Celeris, Which Has RTP Office, Is Sold to Michigan Firm**

Sponsored Content

- **The 20 Biggest 401(k) Investment Mistakes to Avoid** (*Morningstar*)
- **Homeowners Are in for a Big Surprise in 2017...** (*Smart Life Weekly*)
- **Listen to VMware's Sanjay Poonen on CNBC's Fortt Knox** (*VMware Virtualization Software for Desktops, Servers & Virtual Machines for Public and Private Cloud Solutions*)
- **Haven't Tried Walmart's Grocery Pickup Service? Order Online, then Pickup for Free!** (*Walmart*)
- **Overwhelmed by Credit Card Debt? See How a Personal Loan Could Help** (*Lending Club*)
- **What The Trend Toward A Sharing Economy Means For Your Business** (*Cognizant*)

Recommended by

Editor's Blog

The latest blog posts from our WRAL TechWire and WRAL editors.

Please Log In to add a comment.