Cytovale Achieves FPI for Important COVID Study in Seven Days

Medrio's EDC technology enabled Cytovale to achieve FPI for a study of their rapid sepsis diagnostic in suspected COVID-19 patients eleven weeks faster than the industry average of 12 weeks.

SAN FRANCISCO (PRWEB) May 29, 2020 -- Medrio, Inc., the leading provider of eClinical technology to pharmaceutical, biotech, medical device, diagnostics, and animal health markets, has enabled Cytovale, Inc., a medical technology company dedicated to revolutionizing diagnostics for conditions like sepsis by applying cell mechanics and machine learning, to achieve their first patient in (FPI) in just seven days. The Cytovale technology will allow patients with sepsis to be identified earlier in their hospital stay.

Cytovale is conducting a pilot study to determine if its Rapid Sepsis Diagnostic System can identify sepsis "quickly and accurately" in patients in the emergency department who may have COVID-19. Patients with COVID-19 are considered to be at high risk for sepsis. Cytovale's system is designed to aid clinicians in diagnosing sepsis, providing results in less than 10 minutes, with the potential to enable precise and rapid triage in the ED.

"We initially scoped 12 weeks to FPI for this very complex study. With Medrio's easy configuration interface and attentive support team and Cytovale's dedicated UAT team, we were able to aggressively build and have the study ready for data entry in just 7 days. I've worked with Medrio on a number of studies, and on average we typically achieve FPI in six to eight weeks, some in as little as two or three weeks, but 7 days is a real achievement," said Temple Herlong, Managing Member, Study Builders, LLC.

In a time where speed is of the utmost importance, Medrio supported Study Builders, LLC to build the study and Cytovale to begin enrolling patients in the study in just seven days. The study concept was presented on March 26, 2020, with FPI achieved on April 7, 2020.

"We're faced with an unprecedented challenge in the time of COVID-19, but our collective determination and expertise enabled us to execute. Detecting sepsis early is imperative for effective treatment and would enable the clinical team to ensure that the right patient receives the right level of care at a time when resources are stretched and every moment counts. Achieving FPI in only seven days is a huge feat, and all parties involved should be extremely proud of their efforts," said Ajay Shah, Ph.D., Co-founder, and CEO of Cytovale.

A typical study with Medirio can get FPI within 6 weeks compared to the industry average of 12 weeks, due to the programming free drag and drop interface of the EDC system. "In this new normal, speed coupled with a flexible system that puts you in the driver's seat allowing changes on your timeline without coding or extra fees is critically important to getting lifesaving diagnostics, therapies, and devices quicker to market. From ICH/GCP and 21 CFR to GDPR and HIPAA, our customers are equipped with easy-to-use tools allowing them to focus on the trial with complete confidence that their data is compliant and secure. We are excited to be leading the 'new normal' of clinical trials with flexible solutions to meet participants and studies where they are. As organizations transition to more virtual operations, our hybrid and decentralized solutions are ready to help you meet accelerated timelines and changes when you need them," explained Fred Martin, Chief Product Officer with Medrio.

About Medrio

Medrio is the leading provider of eClinical technology for pharma, device, and diagnostics clinical trials. Founded in 2005, the company's cloud-based EDC, Direct Data Capture, eConsent, and ePRO solutions deliver fast, flexible, and easy-to-use tools for the collection and management of clinical data and patient-reported outcome responses. Study sponsors and Contract Research Organizations have used Medrio extensively in clinical trials across a wide array of therapeutic areas, with notable success in oncology, infectious disease, and more. Medrio has extensive experience in all study phases and leads the market in early-phase trials. The company serves over 600 customers globally, with headquarters in San Francisco and offices in numerous domestic and international locations. For more information, please visit http://www.medrio.com.

About Study Builders
Study Builders, LLC is a Southern California-based boutique CRO made up of professional consultants with years of EDC build, clinical data management, and remote monitoring expertise across numerous therapeutic areas. For more information, please visit http://www.studybuilders.com.

About Cytovale
Cytovale, based in San Francisco, Calif., is a medical technology company dedicated to revolutionizing diagnostics using cell mechanics and machine learning, and applying this first to sepsis, a condition whose early detection dramatically improves patient outcomes. For more information visit http://www.cytovale.com.

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