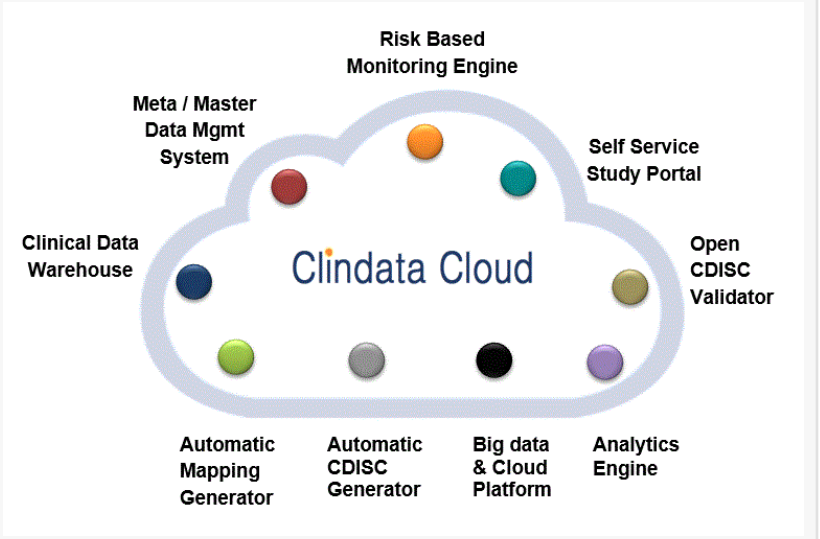
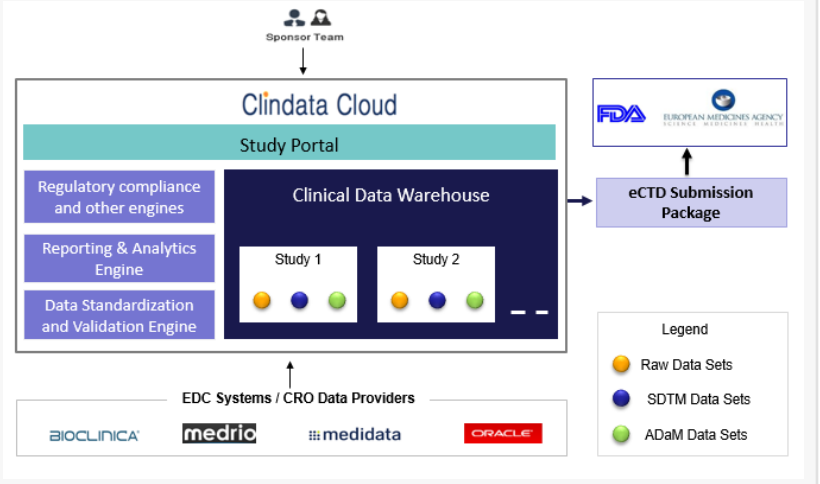
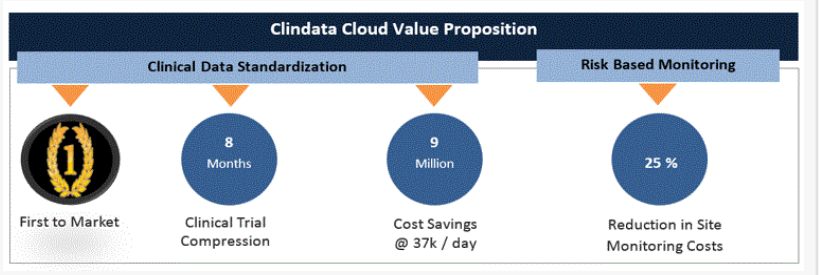
New Life Saving Drugs May Finally Become Affordable, With A Disruptive Clinical Platform by Clinical Data Inc.

"Clindata Cloud" a Clinical Data Standardization & RBM Platform reduces drug development costs by 5 % and accelerates the product launch by 8 months.



Clinical Data Standardization & Risk Monitoring Platform





MO - 3rd March, 2016. The cost of new drugs and medical devices is skyrocketing making them unaffordable to many in dire need. Bio-Pharma companies are required to conduct extensive clinical trials (studies); to get their new drugs approved for launch by FDA and other global regulatory agencies. The high cost, duration and risk of conducting clinical trials, are a major driver in making new drugs unaffordable.

NORTH WALES, PENNSYLVANIA, UNITED STATES, March 11, 2016 /EINPresswire.com/ -- "Clindata Cloud" a disruptive Clinical Data Standardization & Risk Monitoring Platform enables biotech, pharma and medical device companies reduce their drug development costs by 5 % and accelerate product launch by 8 months; by eliminating data related FDA rejections and providing real time big data insights across disparate data sources. The built-in pattern recognition, machine learning and predictive analytics algorithms, recognize and alert of risk patterns that could indicate possibility of serious adverse events or death; thus driving subject safety on clinical trials.

Conducting clinical trials to launch a new drug costs about $1.2 billion over 10 years with a success rate of less than 1 % and requires several complex regulatory compliant IT systems. Many smaller bio-pharma and medical device companies cannot afford to have IT expertise or applications in-house and instead heavily depend on their Contract Research Organizations (CROs) creating data silos across the clinical trial. This resulting

To help lower the cost and risk of new drug development and shorten review time, FDA has mandated compliance with CDISC data standards beginning October 2016. FDA is also recommending a Risk Based Monitoring (RBM) approach to Clinical trials to reduce site monitoring / oversight costs by 25 % and increase the safety of the subjects in the study.

“We are glad to remediate these chronic problems, with our disruptive Clinical Data Standardization & Risk Monitoring Platform, Clindata Cloud. Offered in an affordable Software-as-a-Service (SaaS) model, it helps companies of all sizes to compress their clinical trials by 8 months and overall study cost by 5 % and eliminate clinical data related FDA rejections. It also drives regulatory compliance and subject safety, all contributing to lower the cost of new drugs.” stated Sujan T, the founder of Clinical Data Inc.

“Architected on big data and cloud computing platforms, Clindata Cloud sits on top of disparate data sources, such as Oracle Clinical, Medidata Rave and Medrio EDC systems and consolidates / harmonizes disparate data into unified subject (patient) centric data sets and housed in its Clinical Data Warehouse. It then standardizes the datasets to FDA mandated CDISC data standards at a blazing speed of 1 Million records per 10 mins in real time. This speed now makes it possible to analyze standardized data in real time unlike in the past. Clindata Cloud, empowers the clinical operations teams, with real time data insights and predictive analytics to drive safety and performance” said co-founder & CTO Paddy K.

Specifically designed for clinical trials, it eliminates the need for a large IT landscape to run clinical trials. The platform is compliant with FDA CFR-Part 11, HIPAA and GCDMP regulatory standards and is hosted on a secure private cloud. With its unprecedented scalability it can host hundreds of clinical trials in one clinical data warehouse dedicated to a client and makes cross study analytics possible in real time.

For more, log on to http://www.clindatainc.com

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