MD TECH REVIEW
MDTECHREVIEW.COM
JULY - 2020

LINEA System

The annual listing of 10 companies that are at the forefront of providing eClinical Trial Management solutions and impacting the industry

LINEA System

Advanced Technology for Accelerating Clinical Trial Launch

Despite concerted efforts to meet deadlines, the pharmaceutical industry routinely struggles to complete clinical trials on time. As a result, medicines are often delayed in getting to patients waiting for these life-changing treatments. In this rapidly changing world presenting numerous challenges to the industry, it is critical for sponsors to launch trials efficiently, accurately and with the decentralized teams to carry out the highest standard of processes to achieve results. Implementing an effective study start-up technology can help sponsors overcome roadblocks and delays often encountered during trial launch, and better navigate the added complexity of functioning in a virtual world. The essential parts of the start-up process are selecting optimal sites, and streamlining the activation process.

To this end, LINEA System is accelerating the launch of clinical trials with its cloud-based Study Start-up Management System (SSMS) and demonstrating that objective data and intuitive workflows are the key to advancing the clinical trial process. The company excels in site identification, feasibility, and site activation. In an interview with MD Tech Review, Kathleen Colatrella, Founder and President of LINEA System shares her insights on their proprietary SSMS, AcceleTrial™. Sponsors can optimize and automate the study start-up process with AcceleTrial™, which has been shown to reduce the time of critical activities in the site activation process. Activating the right sites ahead of schedule positions any clinical team to launch their trial with patient recruitment achieved.


Kathleen Colatrella

Why does the pharmaceutical industry need an SSMS like AcceleTrial™?

During my 15 years in the industry, I recognized that choosing the right sites for clinical trials is one of the most critical steps in the start-up process. An optimal site could enroll and retain patients quickly and collect quality data to help the sponsor prove the effectiveness and safety of the medicine. Conversely, a suboptimal site could end up costing the sponsor tens of thousands of dollars for every month the study progresses. After evaluating the problem with launching trials and thinking about how best to address this challenge, we realized that sponsors routinely lack the information necessary to validate a site that could potentially have a meaningful impact on their trial. We concluded that using objective data to assure that a certain investigator or site can unquestionably contribute patients to the trial was the key to the success of the trial. We as an industry are doing ourselves a disservice by selecting sites based on subjective data, and not leveraging technology to drive the activation process. This was the reason my team and I founded LINEA System and created AcceleTrial™, the first SSMS of its kind.

When it was founded, LINEA System executed the process manually as many sponsors and CROs do now. We started conducting research on how to improve site identification and activation by exploiting smart data and technology. From the result of this extensive research and a major technology development

project, emerged a system that objectively identifies the right sites and eases the activation process, AcceleTrial™.

We expanded our team to include statisticians, programmers, and software developers, and we created our robust Study Start-up Management System. An SSMS precedes a CTMS and differs in that it offers a built-in network of investigators, an automated workflow for both the activation process for document management, and a cloud-based structure for ease of use among decentralized team members. As the world becomes increasingly virtual, it is imperative to have information accessible in real-time for teams, regardless of location.

> **AcceleTrial™ identifies sites based on objective data validating therapeutic expertise, clinical trial experience, and access to patients that provides transparency for sponsors in choosing the right site. This model takes the guesswork out of clinical trial site identification and combined with an automated workflow, accelerates clinical trial start-up**

Our SSMS addresses all study start-up needs, and significantly reduces the time it normally takes to launch a trial. Because the biggest cause of delays for a trial is suboptimal sites, when they are ranked objectively and selected on proven past performance, they are virtually guaranteed to end up being strong contributors to the study. To illustrate, 96% of sites that AcceleTrial™ recommends are ultimately included in a study. Additionally, a sponsor can monitor and manage the activation process within the SSMS, including contracts and regulatory documentation. Within AcceleTrial™, a sponsor can also track investigator interest and screening to confirm site activation while driving the trial forward with actionable metrics.

Could you elaborate on the features and functionality of AcceleTrial™?

AcceleTrial™ offers a built-in database of over 100,000 objectively-ranked global investigators across virtually all therapeutic areas. Our proprietary database uses over a thousand sources to validate and rank investigators and sites, meaning that sites are selected based on previous experience and proven results from past clinical trials. Once these sites have been ranked, we propose a list of sites to the sponsor for site selection. AcceleTrial™ then enables teams to collect Feasibility Questionnaires and onboard sites, resulting in quick and seamless activation.

Since there are multiple parties involved in the clinical trial, i.e., the site, the sponsor, or a third party such as a CRO, real-time monitoring and accessibility is crucial to the success of the process. With AcceleTrial™, all stakeholders can keep track of each step throughout the trial start-up in one centralized location. Additionally, the functionality of AcceleTrial™ can be customized based on a clinical team's unique needs.

Moreover, AcceleTrial™ automates the entire process with built-in workflows, beginning with assessing the interest of sites, to collecting Feasibility Questionnaires, regulatory documents, getting approvals and contracts, and finally, enrolling patients. Our system is designed to help teams with a"push and pull" flow, whereby the automated nature of the process always keeps the momentum going. By continuously tracking each step and keeping the process transparent, our client can act quickly if anything has been halted. We've designed AcceleTrial™ to be an intuitive platform that will make a significant and immediate impact on a trial's launch time and cost.

Could you share a customer success story?

A large pharmaceutical company using multiple tools for site identification, feasibility, and study start-up approached LINEA to helpidentify,qualify and collect feasibility for 30 sites to support an endocrinology study. Despite using multiple tools and vendors they were still struggling to identify the right sites. Using AcceleTrial™, we identified the 30 sites and executed feasibility through the SSMS's built-in FQs. We finished this process within 2 weeks, one that typically takes about three months to complete.

Additionally, another large pharmaceutical company engaged LINEA System to support a therapeutic area, and quickly we were supporting two other areas once the client saw how quickly AcceleTrial™ sped the launch of their trials,significantly quicker than they were accustomed to. We've also worked with CROs as complementary partners driving study start-up efficiencies and enhancing trial success.

What does the future look like for LINEA System?

We are actively spreading awareness of the importance of launching clinical trials using an SSMS to identify the right sites first and quickly activate them, because we know how critical it is for patients to have access to these life-changing medicines through the sites that enroll them. Our objective has been amplified by COVID-19, and we are proud to be working on multiple COVID-19 trials. AcceleTrial™ fits perfectly into current workflows, because it can be accessed anytime, anywhere in the world and provide teams with real-time metrics. Companies have started realizing the importance of an SSMS to their trials and are considering it a necessity rather than a complementary tool. Our team is continuously educating the pharmaceutical industry about the immense benefits and value of an SSMS to their clinical trial operations. We are most proud of the opportunity to partner with companies on the unified mission to provide vital medicines to patients by accelerating the clinical trial start-up process. MD