Revolutionizing Clinical Trials with Data, Technology & Blockchain

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Clinical Trial Process Background

To get a drug approved requires lengthy and costly clinical development programs involving multiple trials. The drug approval process spans over 10 years on average and can cost upwards of $2 billion. Despite concerted efforts to meet deadlines, the pharmaceutical industry routinely struggles to complete clinical trials on time mainly due to delays with patient recruitment.

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 to meet their recruitment targets in order to execute clinical trials.

Sites (also known as Investigators or Doctors) enroll patients into clinical trials. In order for the Sites to support a trial they must be evaluated, selected and onboarded by the Sponsor (Pharmaceutical Company). In the onboarding process, numerous delays are experienced due to lengthy budget and contract negotiations between the Sponsor, Sites, 3rd party vendors and IRB/Ethic approvals.

The payment process is a pain point for all stakeholders running global trials and very difficult to manage as there are many moving parts globally with different currencies.

Being able to speed the clinical development time by selecting/onboarding the right Sites could offer a key competitive advantage and reduce development costs leading to more affordable drugs to patients.

LINEA System Background

ACCELETRIAL

SITE IDENTIFICATION > ACTIVATION – *PERFECTED*

LINEA System, LLC was founded in 2007 by Kathleen Colatrella based on her 15+ years of experience in large pharma and biotech companies running clinical trials from beginning to end. In 2016, LINEA conducted extensive research on how to improve Site identification, feasibility and activation by leveraging big data and technology. Using our hands-on experience, we have developed a platform technology that accelerates clinical development program timelines by fast-tracking the startup of the clinical trials — **perfecting Site identification and Site activation to speed patient recruitment.**

LINEA SYSTEM

We developed AcceleTrial™, a cloud based study startup management system (SSMS) that has a built-in database of over 100,000 Sites to match the right investigative Sites to the trial and then having an automated workflow which sets up these Sites to quickly start the trial and have them contribute patients.

O ur AcceleTrial™ solution is based on the foundation of pairing the right Sites to clinical trials using objective data and not self-identification. AcceleTrial™ puts at your fingertips a database of thousands of Sites globally that are ranked and indexed based on; Objective Site-specific Therapeutic Expertise, Objective Site-specific Clinical Trial Experience and Objective Patient Data. LINEA is accelerating the launch of clinical trials with its cloud-based Study Start-up Management System (SSMS) AcceleTrial™ 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. 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 **including the payment process**. Activating the right Sites ahead of schedule positions any clinical team to launch their trial with patient recruitment achieved.

LINEA
Opportunity

The global market for drug trials is projected to grow to $70 billion by 2027 with $40 billion spent in phase 3 trials. Sponsors running large phase 3 trials requiring large patient pools and many Sites need a platform like AcceleTrial™ to save time and money. LINEA has secured MSAs and has repeat business with three major pharmaceutical companies. In a given year, these three companies launch up to 400+ trials in different therapeutic areas. There are over 34,000 trials launched globally each year. 1000+ trials per year will be using AcceleTrial™ within 5 years.

The Opportunity/Application of LINEA Token

Many opportunities are possible as we are working with large global sponsors supporting their clinical trials. Our strategy is to introduce a LINEA Token on the Energi Blockchain as a means for obtaining access to LINEA's startup application AcceleTrial™ and services.

The goal is to bring the LINEA Token to Pharmaceutical companies and have these tokens be exchanged for services. The anticipated outcome is that the LINEA Token will start the process of Pharma using tokens with various stakeholders in exchange for services and collaboration in executing clinical trials. This could also expedite the contract and budget negotiations reducing needless delays in the trial launch.

We look to incentivize the teams we work with to think futuristic and consider different ways of engaging especially in the current environment in the wake of the pandemic. Introducing new ways to collaborate with varied forms of payment would bring new opportunities. Our goal is to help clinical teams efficiently and cost effectively conduct clinical trials and speed the trial cycle time to get medicines to patients faster. We believe that introducing another form of payment that would allow for quick exchange of services offers tremendous growth and would be beneficial for all the stakeholders involved.

LINEA Token use case

Sponsors would earn LINEA Tokens when they contract with LINEA to use our startup platform AcceleTrial™ to Identify and Activate Sites for Clinical trials.
Initially, these sponsors can use these LINEA Tokens to obtain Professional Services, user licenses, application customization and access to advance features. Our Professional Services involve engaging our Medical Research Analysts (MRAs). The MRAs are Professional resources that LINEA offers to Sponsors who might not have the resources to drive the AcceleTrial™ application or just wants to additional expertise to expedite the process.
Our goal is to get Big Pharma to use the LINEA Tokens for these services and add more services down the road.

Token Name	LINEA Token
Ticker Name	LINEA
Amount of tokens generated	5,000,000
Amount of tokens we want to bring into circulation on EnergiSwap	500,000
10% circulation	LINEA would be roughly .10 NRG

Pharmaceutical companies are global in nature and the payments to and from stakeholders and other big Pharma is a slow and involves different currencies.

We believe the future of payments among Global Pharmaceuticals companies is through blockchain and pharma tokens. We would like to start this revolution by introducing a LINEA Token on the Energi Blockchain.

Our long-term goal is to have all big pharmaceutical companies use LINEA tokens as a pharmaceutical currency.
We will start with the three Global Pharma giants that we have Master Service Agreements (MSA) with. These three Global giants have a combined market capitalization of over $500 billion. We also work with several other mid-size pharmaceutical companies as well as several Contract Research Organizations (CRO) who work with various large and mid-size Pharma.

We will initially grant these clients LINEA Tokens when they contract with us for Site Identification for their clinical trials. Per study protocol, they will look for X number of sites and will use our AcceleTrial™ database to find and activate those Sites (Investigators, Doctors).

Our goal is to capture 5% (within 5 years) of the Global Clinical Trial market for our Study Start-up Management System (SSMS). There are over 20,000 Phase 3 trials launched globally each year. 1000+ trials per year will be using AcceleTrial™ within 5 years. The average trial is looking for 50 Sites.

Subject to change based on the price of the LINEA Token, we will give the Sponsors 100 tokens per Site contracted. For example, if the Sponsor does a trial with 50 Sites, they will receive 5000 LINEA Tokens. If they do 10 trials of that size, they can accumulate 50000 LINEA Tokens. Every 1500 LINEA Tokens has the value of using our Professional Services to help them find one Site with executed CDA and Feasibility. The current cost of engaging our Professional Services is $1000/site so the LINEA Token would have initial value to the Sponsors of $.67/token which would be more than the initial value on EnergiSwap (based on the current price of NRG), the initial value of the LINEA Token would be approximately $.39.

As we continue to develop AcceleTrial™, we will come up with new features that can help the Sponsors accelerate Site identification, activation and patient recruitment even further. Instead of charging the sponsors more upfront, they can unlock new features with LINEA Tokens.

Eventually the price of the coin will be equal or more than the value to engage our Professional Services. At some point, we'll have to change how many tokens to engage with our Professional Services.

L INEA System engages with many Sites (Investigators, doctors) globally that conduct the clinical trials to pre-qualify them to participate in specific clinical trials. Initially, we can give LINEA Tokens to the Sites for filling out important surveys to give us key data points that would help qualify them for future Sponsor trials. Once the sites see the value in the token, they will be willing to accept LINEA Tokens as payment from the Sponsors for participating in the clinical trial.

LINEA System will engage with it's Technology partners to implement the LINEA Token features into AcceleTrial™.