CLINTEX WHITEPAPER → 2020

New Medicine: Faster, Safer, Smarter.

ClinTex Clinical Trials Intelligence

Disclaimer

The ClinTex CTi whitepaper (the “Whitepaper”) serves as an introduction to our de-centralised clinical trials platform (Clinical Trials Intelligence– CTi) which is designed to address the key challenges for pharmaceutical companies in initiating and conducting clinical trials. This whitepaper has been created for informative purposes only and does not represent any offer or solicitation to sell financial instruments or unites of any collective investment schemes and any such potential offer or solicitation of financial instruments may only be made by ClinTex by means of a prospectus or other offering documentation in terms of any applicable Maltese or UK law. By reading this Whitepaper document you acknowledge that design and images of the platform are at a development stage. ClinTex reserves the right to change design and any images included in the project at any point during the design or development cycle without prior notice. The whitepaper does not establish any relation between You and ClinTex. Contribution to the project/Acquiring tokens is available only after accepting all the Terms and Policies on our website. Information provided in this Whitepaper may contain “forward-looking data”. Forward-looking data may include “among others, articulations with respect to the plans, costs, destinations or execution of ClinTex Platform. In this Whitepaper, words, for example, “may”, “would”, “could”, “will”, “likely”, “accept”, “expect”, “plan”, “assess”, “estimate” and comparative words and the negative shape thereof are utilized to distinguish forward-looking articulations, which shall not be relied on. Forward-looking explanations ought not to be perused as assurances of future execution or results, and won’t really be exact signs of whether, or the times at or by which, such future execution will be accomplished. The genuine after-effects of Clinical Trials Intelligence, the ecosystem, the system could fluctuate from the forward-looking data contained in this, including because of such hazards as a crumple in the market for cryptographic forms of money, unfriendly administrative advancements, and rivalry from different stages. Forward-looking proclamations/Statements and data depend on data accessible at the time as well as administration’s great confidence conviction as for future occasions and are liable to known or unknown risk, vulnerabilities, presumptions and other unusual elements, huge numbers of which are beyond ClinTex’s control. ClinTex does not expect, nor does ClinTex embrace any commitment, to refresh or update any forward-looking data or articulations contained in this Whitepaper to reflect consequent data, occasions or conditions or something else, except for if required by relevant laws. This white paper depicts our present vision for the ClinTex Platform stages. While we expect to endeavour to understand this vision, it would be ideal if you perceive that it is reliant on a significant number of variables and subject to a significant number of dangers.

Risk Statement

Acquiring CTi tokens involves various risks. Please don’t use our platform if you do not understand these risks. In particular, that ClinTex may not be able to launch its operations. Therefore, and before buying ClinTex tokens, any future token holder should carefully consider the risks, costs, and benefits of acquiring those tokens within the crowdsale, and, if necessary, obtain independent advice in this regard. Any interested person who is not in the position to accept nor to understand the risks associated with the crowdsale or any other risks should not acquire CTi tokens, at this stage or later. Market conditions and the price of any virtual currency, including Bitcoin/ Ethereum/Ripple and others may fluctuate. It is uncertain what the price of certain cryptocurrencies will be in the future. The value of Crypto Currencies could permanently be reduced to zero. This would result in token holders being left with the CTi token having no value. Please keep in mind that virtual currency, including the CTi token can be subject to cybercrime. By proceeding to read this document, you acknowledge and agree that you shall access and use the Services at your own risk. The risk of loss in trading Digital Asset can be substantial. You should, therefore, carefully consider whether such trading is suitable for you in light of your circumstances and financial resources. You should be aware of the following points: Internet transmission risks. You acknowledge that there are risks associated with utilizing an Internet-based trading system including, but not limited to, the failure of hardware, software, and Internet connections. You acknowledge that ClinTex shall not be responsible for any communication failures, disruptions, errors, distortions or delays you may experience when trading via the Services, howsoever caused.

Contents

Abstract

ClinTex's primary mission is to speed up the delivery of new medicines to market, and to drive down the cost of medicine for the people who need it.

ClinTex will achieve this by disrupting the clinical trials process: making it faster, more efficient and more cost effective for the pharmaceutical companies that engage in the research of new medicines for market With this mission in mind, ClinTex are proud to introduce CTi – Clinical Trials Intelligence, a clinical trials collaboration and data analytics platform that leverages the benefits of distributed ledger technology (blockchain), machine-learning and AI to drive significant quality and operational improvements in the running of trials; the sharing of clinical trial data across the industry; and the first-ever predictive data analytics in clinical trials.

At current, the clinical trials industry faces several persistent issues that make trial operations overtly costly, time consuming, complex and inefficient. Resulting costs are spiralling as pharmaceutical companies invest more to do less (>$2.5 billion per new medicine), while difficulty in patient recruitment and retention means that 80% of clinical trials are delayed by an average of 10.8 months.

By developing a range of key applications that focus on the specific key pain-points and bottlenecks outlined in this document, ClinTex seek to revolutionise not only the way pharmaceutical companies collaborate on clinical trials, but also the way they set-up, conduct, and oversee the operational and clinical effectiveness of their trials.

Applications of CTi Phase 1 – 3

- → CTi-OEM: Operational Efficiency
- → CTi-PDA: Predictive Analytics
- → CTi-CDV: Clinical Data Visualisations (including Statistical Monitoring of Data)
- → CTi-PRR: Patient Recruitment & Retention:
- → CTi-RBM: Risk Based Monitoring
- → CTi-SIM: Site Investigator
- → CTi-VMM: Vendor Management

The heart of the Clinical Trials Intelligence lies in the creation of an interoperable ecosystem that delivers a secure environment for the storage and analysis of clinical data views, while addressing historical privacy and security concerns.

CTi will align the incentives of stakeholders and improve their ability to collaborate, thus improving the bottom line for pharmaceutical companies while enabling them to meet increasingly stringent regulatory standards in the conducting of clinical trials.

CTi will be the first clinical trials software solution to leverage the advantages of distributed ledger technology and smart contracts, and the first software solution to apply data analytics and machine learning to monitor and control clinical trial costs, and it is through these tools that ClinTex will deliver on their mission: to improve the quality and speed to market of new medicines, and drive down the cost of medicines for the patients who need them.

This section should only be read as an introduction to the Whitepaper and any decision to purchase any token issued by ClinTex should be based on the consideration of the whitepaper as a whole.

This Whitepaper does not constitute an offer or solicitation to sell financial instruments and any such potential offer or solicitation of financial instruments may only be made by ClinTex by means of a prospectus or other offering documentation in terms.

The ClinTex Team mentioned further below in this Whitepaper is collectively responsible for the contents of this Whitepaper and collectively declare that to the best of their knowledge, the information contained in this Whitepaper is in accordance with the facts as relevant on the date of the publication of this Whitepaper and that this Whitepaper makes no omission likely to affect its import.

Clinical Trails — The Current Landscape

Pharmaceutical and Biotech Companies conduct clinical trials to demonstrate safety and efficacy of new and promising treatments with the objective of gaining regulatory approval from the Food and Drug Administration (US), the European Medicines Agency (EU) and other relevant regulatory authorities in various geographical regions.

Phase 1

Clinical trials assess the safety of a drug in the initial phase of testing, which can take several months to complete, and usually includes a small number of healthy volunteers (20 to 100), who are generally paid for participating in the study. The study is designed to determine the effects of the drug or device on humans including how it is absorbed, metabolized, and excreted. This phase also investigates the side effects that occur as dosage levels are increased. About 70% of experimental drugs pass this phase of testing.

Phase 2

Clinical trials test the efficacy of a drug or device, can last from several months to two years and involve up to several hundred patients. Most phase II studies are randomized trials where one group of patients receives the experimental drug, while a second “control” group receives a standard treatment or placebo. Often these studies are “blinded” which means that neither the patients nor the researchers know who has received the experimental drug. This allows investigators to provide the pharmaceutical company and the FDA with comparative information about the relative safety and effectiveness of the new drug. About one-third of experimental drugs successfully complete both Phase I and Phase II studies.

Phase 3

Clinical trials involve randomized and blind testing in several hundred to several thousand patients. This large-scale and often global testing, which can last several years, provides the pharmaceutical company and the FDA with a more thorough understanding of the effectiveness of the drug or device, its benefits, and the range of possible adverse reactions. 70% to 90% of drugs that enter Phase III studies successfully complete this phase of testing. Once Phase III is complete, a pharmaceutical company can request FDA approval for marketing the drug.

Phase 4

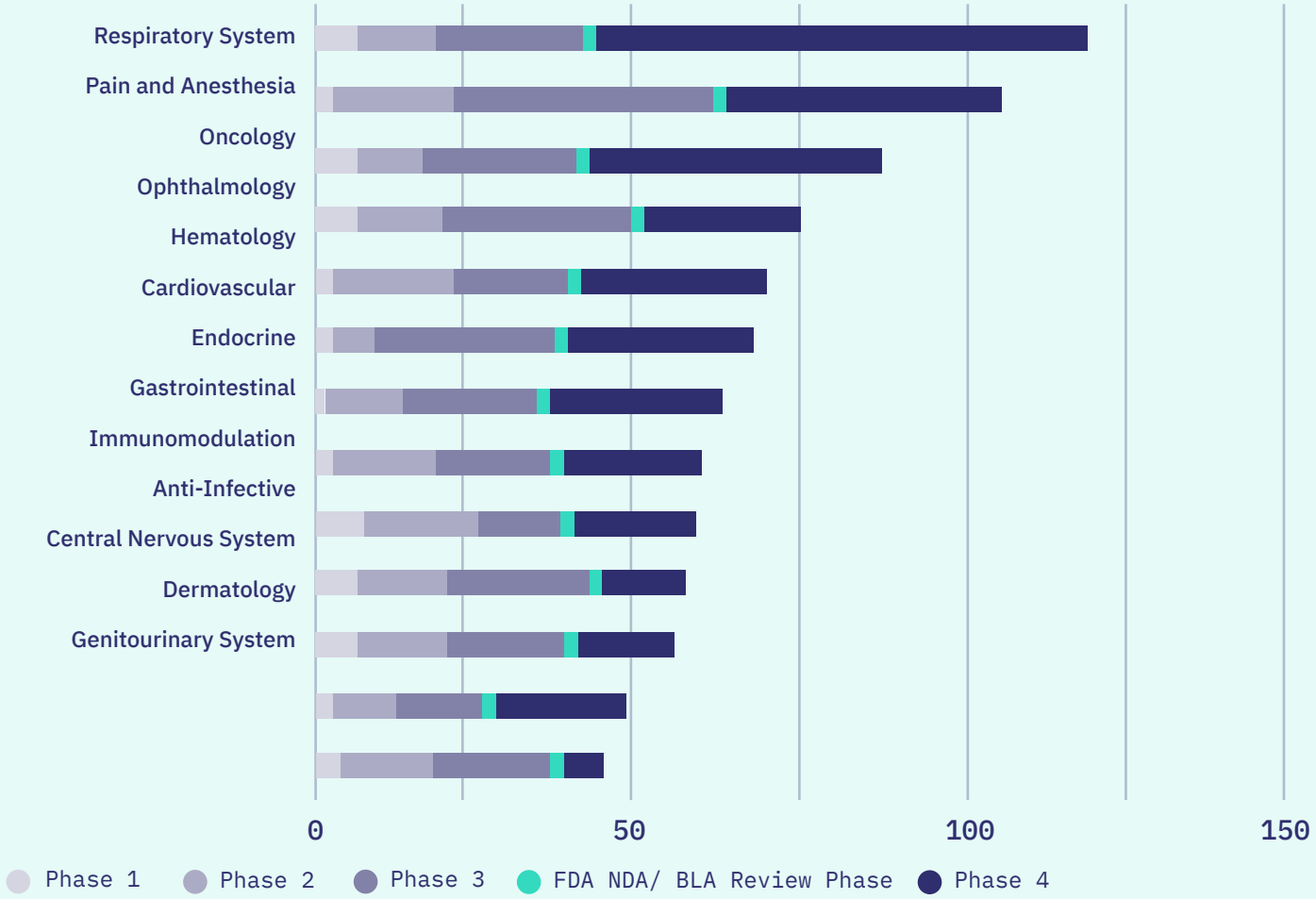
Studies, often called Post Marketing Surveillance Trials, are conducted after a drug or device has been approved for consumer sale. Pharmaceutical companies have several objectives at this stage: (1) to compare a drug with other drugs already in the market; (2) to monitor a drug’s long-term effectiveness and impact on a patient’s quality of life; and (3) to determine the cost-effectiveness of a drug therapy relative to other traditional and new therapies. Phase IV studies can result in a drug or device being taken off the market or restrictions of use being placed on it.

The Problem: Huge Cost and Timeline Overruns in Clinical Trials

The cost of running these clinical trials is now higher than ever, with expenses running at between $30 million and $70 million for a single Phase III trial (see figure 1). Considering that multiple trials are required to achieve regulatory approval, the average cost to bring a drug to market is $2.5 billion. A large portion of these enormous costs exist within “data-driven” elements that can harness the power of data analytics and machine learning, such as:

01. Data Management and Analysis
02. Data Acquisition
03. Investigator site (e.g. hospital, clinic) recruitment and retention
04. Investigator site monitoring (e.g. by pharmaceutical company)
05. Patient recruitment and retention
06. Central laboratory
07. Other external vendors e.g. ECG providers, eDiary
08. Study procedures (e.g. cost of scans etc.)

Figure 1: Analysis of Clinical Trial Costs (in Millions)
(Wong et al., 2014)



The Opportunity for Clinical Trials Intelligence

With the annual number of registered clinical trials increasing from 3,294 in 2004 to 23,384 in 2013 (Viergever and Li, 2015), and the average cost of a clinical trial across all phases running at about $15 million, delivering even small efficiencies in data handling during clinical trials has the potential to save billions.

Furthermore, during the last 20 years, the average number of trials per New Drug Application has increased from 30 to more than 70, and the number of patients required in a typical submission has also increased from 1576 to more than 4200 (Parexel International Corporation, 2005). This continued evolution of the clinical trial landscape represents significant opportunity for pharmaceutical companies to benefit from the unique ClinTex Clinical Trials Intelligence which will help them to curb and control spiralling costs with a "data-driven" and "risk-based" approach to running their trials.

For example, a 1% average cost reduction across all trials running today would generate a saving of $3.5 billion across the industry (based on the averages above). At ClinTex, we believe that our innovative platform has the potential to meet and exceed these savings on a per trial basis.

The ClinTex CTi Approach

The common "Value Item" that runs through all aspects of drug development is data. Data is used at the macro level after a trial is complete to determine if a drug is safe and effective, and if a marketing authorisation should be granted (e.g. submissions to FDA).

Clinical Trials Intelligence will be the first to bring a blockchain solution to the clinical trial process, enabling pharmaceutical companies to maximise end-to-end efficiencies through the use of smart contracts, data sharing, and an immutable audi-trial, along with operational & clinical visualisations and predictive

Equally important and always under-utilised, is the use of real-time data during an ongoing clinical trial. Distributed Ledger Technology (blockchain) offersmassive potential to aggregate previously disparatesources of data into a unified "in stream" data sourcethat can drive effective decision-making in real time.This will streamline clinical trial efficiency, reduce costs and improve data sharing across the pharmaceutical industry without compromising commercially sensitive data.

Whilst the FDA in partnership with IBM's Watson Health is actively exploring the use of blockchain to share medical information (Mearian, 2017), Clinical Trials Intelligence will be the first to bring a blockchain solution to the clinical trial process. This decentralised ecosystem enables immutable audit tracking, and the sharing and protection of clinical trial data whilst facilitating interoperability across diverse systems. When clinical trial data is made available in this way, the potential for novel analysis of the data is greatly expanded in comparison to the status quo. Pharmaceutical companies using our applications can maximise end-to-end efficiencies through the use of data sharing and the statistical monitoring and predictive analytics enabled by it. The Clinical Trials Intelligence will offer the additional processing of raw data into practical operational and clinical visualisations, as well as allowing for secure transactions likeinvestigator payments to be managed and executed efficiently. In this way the new ecosystem will have a global impact on clinical research.

The Basics of Blockchain

At its core, blockchain is a distributed system of recording and storing transaction records. More specifically, blockchain is a shared, immutable record of peer-to-peer transactions built from linked transaction 'blocks' that are stored in a digital ledger. It is considered immutable because any change to a record (previously recorded block) must be agreed upon by a consensus of validators. In other words, information that has been recorded can only be changed if everyone agrees. Blockchain relies on established cryptographic techniques to allow each participant in the network to interact (e.g. store, exchange, and view information), without the need for a third party. In a blockchain system, there is no central authority; instead, transaction records are stored and distributed across all network participants. Interactions require verification by the network before information is added, enabling collaboration between network participants whilst recording an immutable audit trail of all interactions.

Our blockchain-powered clinical trial analytical tools unlock the true value of interoperability, significantly reducing the current cost of intermediaries.

When is a Blockchain solution needed?

INITIATE	DESIGN	STRENGTHEN	IMPLEMENT
Do pre-conditions for using blockchain technology exist?	**What applications are relevant for us?**	**Do we need to enforce contracts automatically?**	**What blockchain will we use to implement our solution**
Multiple parties generate transactions that change information in a shared repository **Parties need to trust that transactions are valid** **Intermediaries are inefficient or not trusted** as arbiters of truth **Enhanced security is needed** to ensure integrity of the system If these conditions are not met, or are only partially met, a standard database or other solution may be more suitable	**Transfer and authenticate information** Parties use the distributed ledger to validate whether data is valid (Note: this requires some trust that data is accurately stored).	**Transfer value** Parties buy, sell and transfer value without an inter-mediary (eg. medical claims data, cryptocurrency payments, intellectual property, etc.) **Increase trust through smart contracts** Parties rely on contracts that are automatically enforced when pre-determined conditions are met.	Permission-less blockchain for interoperability, open innovation, enhanced security and access to greater, distributed computing power to verify transactions through proof-of-work. Public blockchains currently handle fewer transactions per second. Permission or consortium blockchain for restricted access, authorised innovation and greater number of transactions per second, which are verified through proof-of-stake.

Source: Deloitte — Blockchain Opportunities for Healthcare

Why a Blockchain Solution for Clinical Trials?

Clinical Data Security

Blockchains run on networks of many personal computers (or other devices), and every record is held by multiple devices. If there is an attempt to alter a specific record such as to change or erase clinical data, the record or transaction is immediately flagged in the chain as potentially fraudulent, and will not be saved. Therefore, the Clinical Trials Intelligence offers a secure, confidential and incorruptible way to store clinical data and clinical analytics.

Immutable Transaction Ledger

Audit trails are a required procedure and control for all clinical data. The FDA and other regulatory authorities need to be able to verify the quality and integrity of the data (FDA, 2017) and a pharmaceutical company must, in accordance with Good Clinical Practice (GCP), record all changes to the data, who made the changes and when. A blockchain ledger is the perfect record keeping tool because it does exactly that. With the Clinical Trials Intelligence, data and changes to data can be stored immutably. This allows the platform to evolve from a visualisation and analytics tool, to a workflow management tool that maintains transparency while automatically providing audit trails of actions taken. Therefore, CTi will act as a single, regulatory-compliant workflow management tool to deliver cost and efficiency savings through optimum risk-based deployment of resources.

Historical Data

Further to the immutable nature of the blockchain, the complete history of clinical data views stored on a blockchain allows the creation and evolution of powerful machine learning algorithms that increase in potency over time, providing a powerful predictive tool for clinical trials that introduces hitherto untapped opportunities for efficiency and quality in the conduct of clinical research.

Payments

Blockchain technology also offers the ability to perform the secure execution of contracts and payments based on triggers and milestones in the clinical data. For example, a payment to an investigator can be automatically triggered as pre-set milestones are reached based on data entered and verified.

Interoperability

As a blockchain can operate seamlessly across diverse systems and data formats, this allows for sharing of CTi metrics across multiple clinical trials, whatever the source. This allows the creation of a perpetual learning platform.

Protection of privacy

A foundational idea in blockchain solutions is zero-knowledge proof—i.e., the ability to verify the data in a record or transaction without ever actually seeing the contents of the record. This makes it possible for people and machines to act on sensitive health, financial, or in this case clinical data, without actually revealing the content of the data. This is an absolute essential in the clinical trials industry.

Control of access

According to FDA 21 CFR Part 11 Regulations, access to clinical data must be limited to authorised individuals and each user must have a unique access key. Blockchain technology offers the perfect solution. Clinical Trials Intelligence uses encryption keys to access the records in the blockchain. There are two encryption elements—a private key and a public address. The public address makes the existence of the record visible. The private key reveals the contents within the record to the key holder. This basic formula creates great flexibility for controlling access to records and the data they represent.

Taken individually, the benefits of each of these blockchain enabled elements are evident. However, taken together, they open the door to an entirely new paradigm. Clinical Trials Intelligence will deliver a new way of thinking that will create huge advantages and a fundamental shift for clinical trials management and oversight.

Immutability of Transactions

Blockchain's cryptographic hash functions and distributed nature ensure that stored information is time-stamped and tamper-proof.

Validation

Transactions are validated through a consensus mechanism: the network itself ensures that the transactions being added to the chain are genuine and authentic.

Disintermediation

Blockchain creates a decentralised database that is synchronised via the Internet and makes seamless data sharing possible across platforms and stakeholders.

Removal of single node of failure

The shared and replicated nature of Blockchain ensures that there is no central authority that manages the database, mitigating the possibility of hacking attacks and improving system security.

Source: Everest Group

Documented Calls for the Application of Blockchain & AI to Healthcare and Clinical Trials

In a paper entitled "How Blockchain Can Transform the Pharmaceutical and Healthcare Industries" published in April by medical data management industry brain trust PhUSE, researchers stated that "blockchain is a disruptive technology...and a cultural movement that our industries would be wise to embrace." The authors specifically cited the technology's unique ability to effectively negotiate the tension between patient data privacy and data sharing as well as the inherent capability of blockchain technology to improve trust, transparency, auditability, and security of transactions. The technology should finally allow the construction of a secure platform for keeping health records unified instead of having all kinds of medical data from various providers stored in different formats and scattered across different systems with varying levels of security.

The researchers concluded that with blockchain technology "... a drug can potentially be available 3–5 years sooner than with a traditional drug development process." Such an improvement would translate, according to research from the Manhattan Institute, into a savings of $23B per year (80% of which would be accrued to patients), for each year sooner a single high-value treatment like the HIV/AIDS active antiretroviral treatment (HAART) could be made available.

The benefits of the application of Blockchain to clinical trials specifically, and Pharmaceutical R&D in general is well documented, with examples of the business use-cases and benefits provided below;

- → "How Blockchain Can Transform the Pharmaceutical and Healthcare Industries" https://www.phuse.eu/documents//working-groups/deliverables/phuse-blockchain-white-paper-version-1-final-18746.pdf
- → "Blockchain Technology for Improving Clinical Research Quality" https://trialsjournal.biomedcentral.com/articles/10.1186/s13063-017-2035-z
- → "Reinventing Healthcare: Towards a Global, Blockchain-Based Precision Medicine Ecosystem" https://www.researchgate.net/publication/317936859_Blockchain_Healthcare_-_2017_Strategy_Guide

Furthermore, The US Food and Drug Administration (FDA) see big things for AI in healthcare. "We're implementing a new approach to the review of artificial intelligence," FDA Commissioner Dr. Scott Gottlieb said. As one example, he pointed to the agency's approval earlier this year of new clinical decision support software that uses AI algorithms to help alert neurovascular specialists of brain deterioration faster than existing technologies. "AI holds enormous promise for the future of medicine, and we're actively developing a new regulatory framework to promote innovation in this space and support the use of AI-based technologies," Gottlieb said. "So, as we apply our Pre-Cert program — where we focus on a firm's underlying quality — we'll account for one of the greatest benefits of machine learning — that it can continue to learn and improve as it is used."
https://www.mobihealthnews.com/content/fda-chief-sees-big-things-ai-healthcare

ClinTex Clinical Trials Intelligence will be the first to bring a decentralised solution to the clinical trial process, enabling pharmaceutical companies to maximise end-to-end efficiencies through the use of smart contracts, data sharing, operational and clinical visualisations.

Introducing the Clinical Trials Intelligence platform

ClinTex's primary mission is to drive down the cost of medicine for the people who need it.

Through Clinical Trials Intelligence, ClinTex will achieve this by making the clinical trials process faster, more efficient and more cost effective for the pharmaceutical companies that engage in the research of new medicines for market. By developing a range of key applications that focus on specific key pain-points and bottlenecks in the clinical trial process, ClinTex seek to revolutionise not only the way pharmaceutical companies collaborate on clinical trials, but also the way they set-up, conduct, and oversee the operational and clinical effectiveness of their trials.

Clinical Trials Intelligence will be the first blockchain-enabled clinical trial ecosystem, and the first platform to apply data analytics and machine learning to monitor and control clinical trial costs. In this section you will find a complete breakdown of the initial 7 Application's in the platform's eco-system (including examples of how they will work and add significant value in a live trial scenario), the USP's of Clinical Trials Intelligence itself, and the advantages of linking all clinical trial sponsors together on a common platform.

Clinical Trials Intelligence consists of 7 applications that specifically target the key pain points of clinical trials, incorporating blockchain and machine learning into the end-to-end clinical trial process for the very

APPLICATION

CTi-OEM

Operational Excellence

Providing data driven insight into waste minimisation in clinical trials.

APPLICATION

CTi-PDA

Predictive Analytics

Using historical clinical trial data to predict future performance and proactively address issues before they arise.

APPLICATION

CTi-SIM

Site Investigators

Identifying and recruiting medics to conduct clinical trials, and managing payments for their participation.

APPLICATION

CTi-PRR

Patient Recruitment and Retention

Selecting the right patient and help to ensure patient completes clinical trial by monitoring patient activity and alerting when patient is at risk.

APPLICATION

CTi-VMM

Vendor Management

Managing data quality from clinical trial vendors e.g. labs and third party payments based on data driven KPIs.

APPLICATION

CTi-RBM

Risk Based Monitoring

In stream monitoring of data in order to ensure resource is efficiently deployed to areas of greatest risk.

APPLICATION

CTi-CDV

Clinical Data Visualisation

Providing medics with visual analytics and dashboards to support faster decision making.

Unique Selling Points

Clinical Trials Intelligence aims to drive cost efficiency by providing affordable clinical data analytics services. Pharmaceutical companies will now be able to gain deep insight into the operational and clinical aspects of their trials without the necessity of major investment into backend technical infrastructure and data science expertise, all whilst benefitting from the security of blockchain architecture.

The Clinical Trials Intelligence distinguishes itself from other tools used in clinical trials by;

- → Bringing machine learning to clinical trial management.
- → Allowing for workflow management that "closes the loop."
- → Enabling full audit-trail functionality to identify, action and resolve issues detected by the tool.
- → Eliminating the need for hardware costs to be borne by the client.
- → Introducing an attractive pay-per-use model for clients.
- → Applying powerful and insightful data analytics functionality across administrative, operational and clinical functions in clinical trials.
- → Exploiting the immutability and interoperability of data filtered through the blockchain to create an ecosystem that fosters collaboration across the entire pharmaceutical industry.
- → Being the first ever collaboration platform for clinical trials.

Clinical Trial Data hub

"An increasingly complex clinical trial landscape is driving the life sciences industry to support broad collaborations to define and implement common approaches that make running a trial easier. These collaborations are becoming a strategic priority for many companies hoping to create greater efficiencies in the race to deliver innovative therapies, drugs, and medicines to market faster"
- Jennifer Goldsmith Senior Vice President of Veeva Vault Strategy

Linking all clinical trial sponsors together on a common platform provides greater visibility across the end-to-end trial process. Enabling real-time access to information, and the ability to share knowledge more easily will foster greater collaboration.

Clinical Trials Intelligence will enable the delivery of inter-company collaboration across clinical trials through the creation of a clinical trial data hub populated from the key clinical trial source systems. Furthermore, advanced data analytics and machine learning will transform this data hub into insightful and actionable data to drive efficiency and quality in clinical research.

With the Clinical Trials Intelligence's library of metrics and measures, the ability to extract quality insight and identify trends across the industry is greatly improved. For example, a pharmaceutical company can identify whether a problem is isolated to one clinical trial, one hospital site, one therapeutic area, or another common denominator. This type of information will become a "strategic asset", stored securely on the Clinical Trials Intelligence. Predictive analytics can be performed using current clinical data and historical operational metrics to better inform trials moving forward.

Data Capture & Management

The Clinical Trials Intelligence will also provide for further expansion of the ClinTex eco-system to support the evolving needs of the pharmaceutical industry including:

- → Electronic health records/source data.
- → Clinical trial safety monitoring (pharmacovigilance).
- → Data capture and storage directly from clinical trials.
- → Data cleaning.
- → Statistical analysis plan and execution.
- → Regulatory authority (FDA) submissions.

Applications

Operational Efficiency Application (CTi-OEM)

This module is designed to provide a single snapshot of clinical trial progress, allowing the clinical trial professional to immediately identify areas of concern that require further action. Issues requiring attention will be flagged and action plans will be recorded and monitored on the ClinTex blockchain. These snapshots will then be integrated into the Predictive Analytics application (CTi-PDA) to allow for emerging trends to be identified before they impact overall clinical trial efficiency.

Clinical Data Visualisation Application (CTi-CDV)

Traditionally, medical review of clinical data was performed based on "line listings" of data generated from clinical trials. After line by line reviews, issues identified are manually raised with the investigator site in question. Queries and other corrective actions are then manually resolved. Data quality is monitored similarly with programmed checks and controls, the output of which is reviewed manually. This approach leads to missed issues during data reviews and delays in the clinical trial (waiting for corrective actions to be completed). With the CTi-CDV, medical review will be significantly enhanced through the use of data visualisations output from information contained in ClinTex's blockchain. These visualisations will enable the improved identification and sharing of issues that may impact on trial integrity and safety of patients. Data quality will be monitored using visualisations (e.g. identification of outliers) and statistical monitoring. Furthermore, CTi-CDV will facilitate flagging of these issues as well as corrective actions to be recorded and monitored.

Predictive Data Analytics Application (CTi-PDA)

The broad range of data collected during a clinical trial creates huge opportunity to predict the probability of key events that impact the ability of a clinical trial to deliver the clinical data that regulators accept as proof of efficacy and safety of the drug being tested. The CTi-PDA application will combine all operational and clinical data sources and use predictive modelling to forecast issues and events before they happen. This is the risk-based approach supported by the FDA (FDA, 2013), but to date it has not been utilised to its full potential as predictive modelling is not yet routinely used to forecast risk. Utilising the KPIs generated from the CTi-CDV and CTi-OEM application, the CTi-PDA application will reveal hidden correlations across all datasets, thereby enabling the pharmaceutical company to take pro-active actions. For example, being able to predict that a patient will withdraw from a clinical trial would enable the pharmaceutical company to take pre-emptive action around patient retention so that the cost and time-delays as a result of patient withdrawal are avoided.

Risk Based Monitoring Application (CTi-RBM)

Site monitoring accounts for an average of between 9% and 14% of total trial costs (Sertkaya et al., 2016) and involves the pharmaceutical company representative (site monitor) actually attending the site to examine site quality and data records on a regular basis (usually every 4- 8 weeks). This represents a cost of between $3 million and $10 million per average Phase III clinical trial.

Further building upon the CTi-PDA application, the Clinical Trials Intelligence will include a Risk Based Monitoring (RBM) feature. Although some RBM tools currently exist, many are based on a cumulative picture of clinical and operational data and use this data to indicate early warnings that suggest the need for a site-monitoring visit.

The CTi-RBM application works differently. Rather than reacting to signals in the data, the Clinical Trials Intelligence will combine current and historical data to predict specific risks, thereby allowing for tactical deployment of the pharmaceutical company's resources to take preventative action rather than utilising significant resources and effort to "clean-up" and deal with an issue that has already occurred. This predictive risk-based approach can significantly reduce monitoring costs through:

Workload Management

Site monitors can be deployed to the sites/hospitals with highest predicted risk rather than a one-size fits all deployment, thus reducing resource requirements.

Preventing Issues

By predicting specific risks and taking targeted preventative action, costly and time-consuming issues are avoided.

For example, a common problem in clinical trials is invaluable patients. If a patient is not evaluable in a clinical trial, it means that their data cannot be used to assess the efficacy/safety of the drug. This issue can generate significant problems for the pharmaceutical company as it needs a certain number of evaluable patients to deliver a statistically relevant assessment. Failure to do so can result in the failure of the entire clinical trial.

The causes of this are multi-fold. For example, an invaluable patient/study can result from the patient not taking the study medication correctly or not performing certain study procedures. The CTi-RBM application will utilise machine learning by applying algorithms to historical and current data to identify patients with a high risk of being invaluable, thus targeting site monitoring resources on the areas of highest need and risk.

This example will be repeated for major sources of risk in a clinical trial, thus making the CTi-RBM application a powerful proactive and predictive tool for risk-based monitoring.

Patient Recruitment & Retention Application (CTi-PRR)

Achieving clinical trial research patient enrolment is clearly essential to conducting a successful trial. Without sufficient patient recruitment and retention from the time of study initiation to closeout, the number of completing patients may prove to be too small to derive conclusive proof of the safety and efficacy of the medicine, and therefore will lead to failure in securing FDA approval/marketing authorisation. As such, there is a lot of “competition” for patients. Difficulty in patient recruitment and retention has resulted in nearly 80% of clinical trials overrunning enrolment timelines by an average of 10.8 months. (Covance, 2015). This translates into as much as $8m in lost revenue for each day a drug is delayed (Cutting Edge Information, 2005) and it also means that cutting-edge new medications are significantly delayed in their journey to the patients who need them most.

Our CTi-PRR application provides the solution.

CTi-PRR consists of two parts;

Firstly, the application manages “recruiting” patients for clinical trials by;

- → Providing a portal for clinical research sites to share patient profiles relevant to participation in a clinical trial.
- → Enabling patients to express interest in participating in a clinical trial.
- → Enabling pharmaceutical companies to search patient profiles so that suitable patients can be identified for their clinical trial.

All data is stored on the ClinTex blockchain.

Secondly, the CTi-PRR application supports patient retention.

After having identified the correct number of patients to power a clinical trial, it is essential that retention strategies are in place to ensure the patient stays in the trial and provides evaluable data. The CTi-PRR application dynamically links to the CTi-PDA application to produce a series of alerts that notify the pharmaceutical company when a patient is at risk of withdrawing from the study, allowing proactive action to be taken to preserve the evaluability of the patient and the trial.

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Site Investigator Application (CTi-SIM)

As is the case with patient recruitment, there is a lot of competition between pharmaceutical companies to recruit experienced investigators to conduct their clinical trials. The CTi-SIM application works in two ways to support the recruitment and management of clinical investigators. Secondly, investigators (clinical research physicians) are reimbursed for their participation in a clinical trial. Reimbursement to investigators can be done using cryptographic tokens, with payments triggered based on key indicators such as number of patients recruited, number of

patients reaching defined points in the study, and data quality and evaluability of patients. The CTi-SIM (in combination with CTi-PRR/CTi-CDV) evaluates attainment of these milestones and can automatically trigger payments to investigators. This will be executed by smart contract, removing the requirement and associated cost of manual intervention in the payment process, and ensuring that payments are released based on data quality and data currency.

Firstly, the tool manages recruiting investigators to run clinical trials by;

- → Providing a portal for clinical research sites to share their investigators' profiles and experience.
- → Enabling investigators to register their interest in clinical trials.
- → Enabling pharmaceutical companies to search and select suitable investigators.

Vendor Management Application (CTi-VMM)

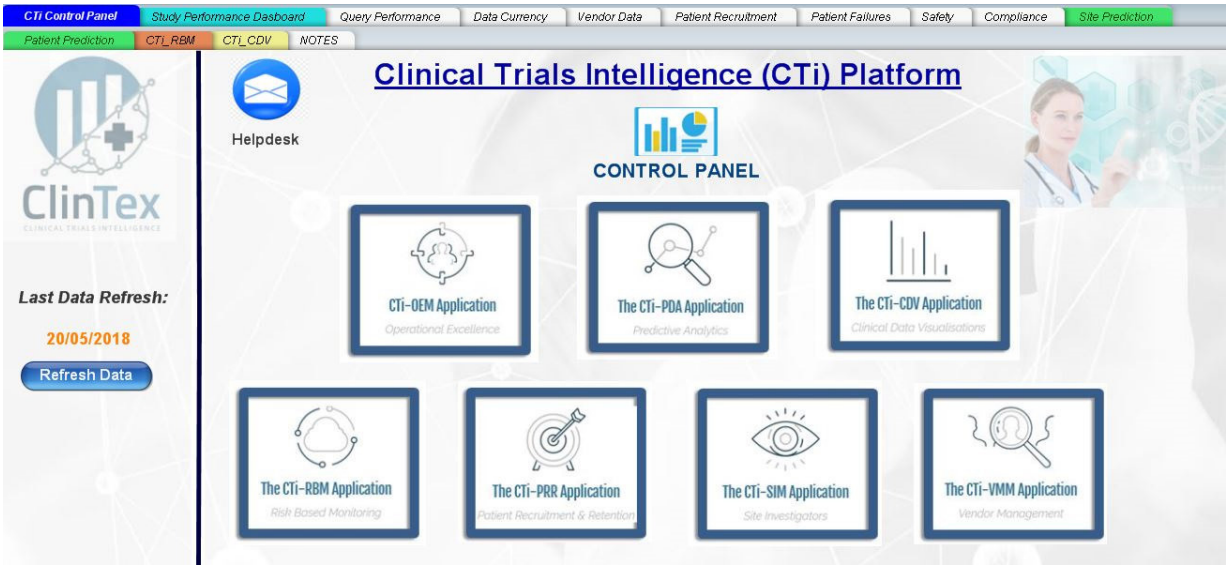
Third-party vendors manage pharmacokinetic/ pharmacodynamic, serology, stool and blood analysis, electronic diaries, ECG data etc. during clinical trials. They provide different types of services based on the specific therapeutic area being trialled. For example, serology data is important for vaccine trials. Although outsourcing these services is considered to be advantageous for clinical trials, there are some risks involved. Hence, pharmaceutical companies proactively select, track and evaluate third-party vendors on a regular basis before, during and after the completion of the contract.

This is where the CTi-VMM application has a significant role to play in effective management of third-party vendor data. CTi-VMM integrates CTi-CDV to provide oversight on data quality from third-party vendors. Furthermore, CTi-VMM manages token payment compensation by the pharmaceutical company to the third-party vendors, triggered automatically by milestones and KPIs such as number of assessments performed, data quality and data timeliness. This pay out to vendors will also be managed by smart contract within the Clinical Trials Intelligence.

Real World Application of Clinical Trials Intelligence

Note: These examples are based on sample clinical trial data in the prototype version of the Clinical Trials Intelligence. The Clinical Trials Intelligence "Control Panel" (P1) is the portal into the 7 CTi applications focused on the end-to-end management and oversight of clinical trials. Through this interface, the user can access permitted applications, depending on their token balance, and refresh data to ensure the platform is displaying the latest clinical trial data.

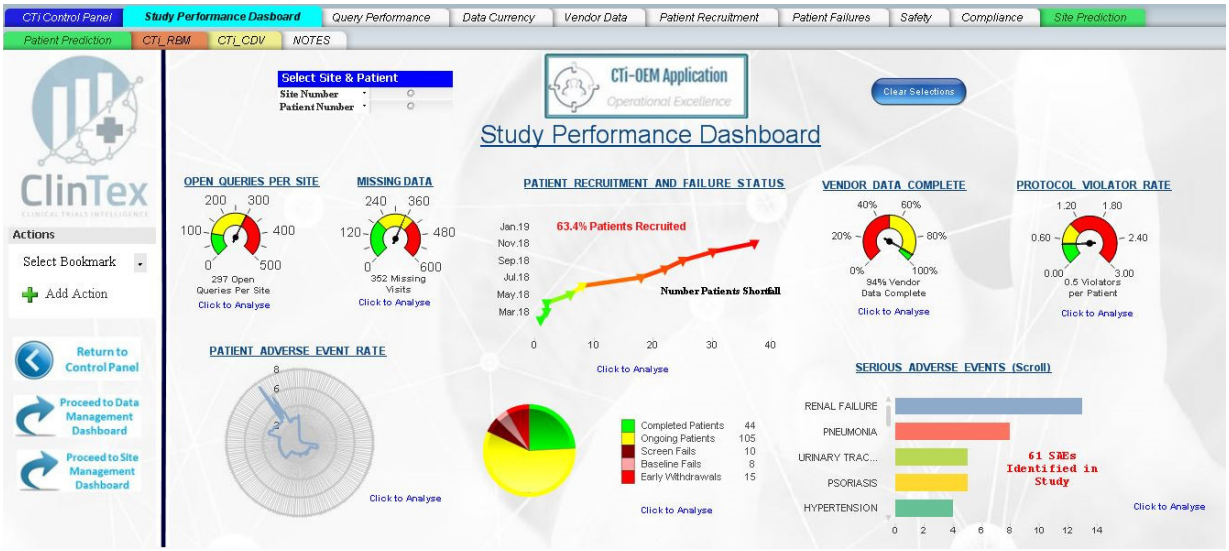
P1



Example 1: The CTi-OEM Study Performance Dashboard

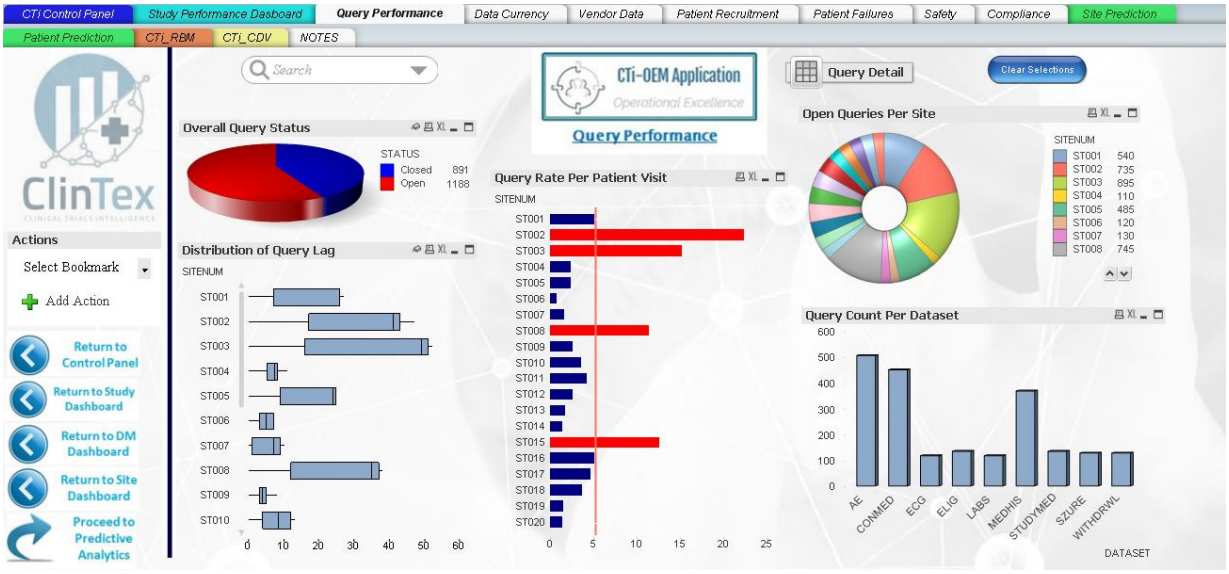
The Study Performance Dashboard (P2) provides a single snapshot of progress within a clinical trial, allowing the clinical project manager to quickly identify areas that require further action.

P2



Without having to manually pull and analyse data from source systems, this dashboard shows, for example, that while Vendor Data is almost complete (94%), there is a problem with unanswered data queries (297 Open Queries) and there are 352 missing Patient Visits. The Clinical Trials Intelligence allows rapid and seamless further analysis, so that root causes and areas where action is required can be established. For example, clicking on the Study Performance metric “OPEN QUERIES PER SITE”, further analysis is performed that provides essential information to understand what corrective action is required by the clinical trial team (P3).

P3

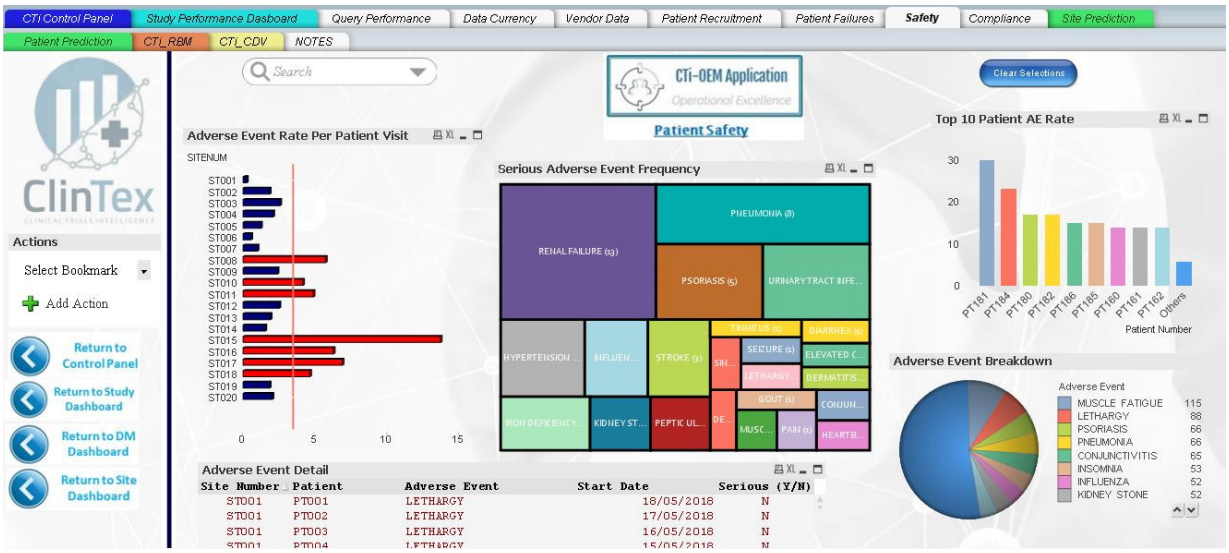


From these visualisations, overall data query rate is seen in more detail, allowing specific hospital sites that are driving this overall metric to be identified. For example; ST002, ST003, ST008 and ST015 are highlighted in Red as they are exhibiting a higher than average data query rate, which will allow the clinical trial team to develop and implement actions to address data quality issues at these sites. Query Lag (time taken to answer data queries) and queries per dataset allows the clinical trial team to further focus on root causes and to target action and resource at areas that will have the highest impact for overall clinical trial efficiency.

Example 2: Patient Safety

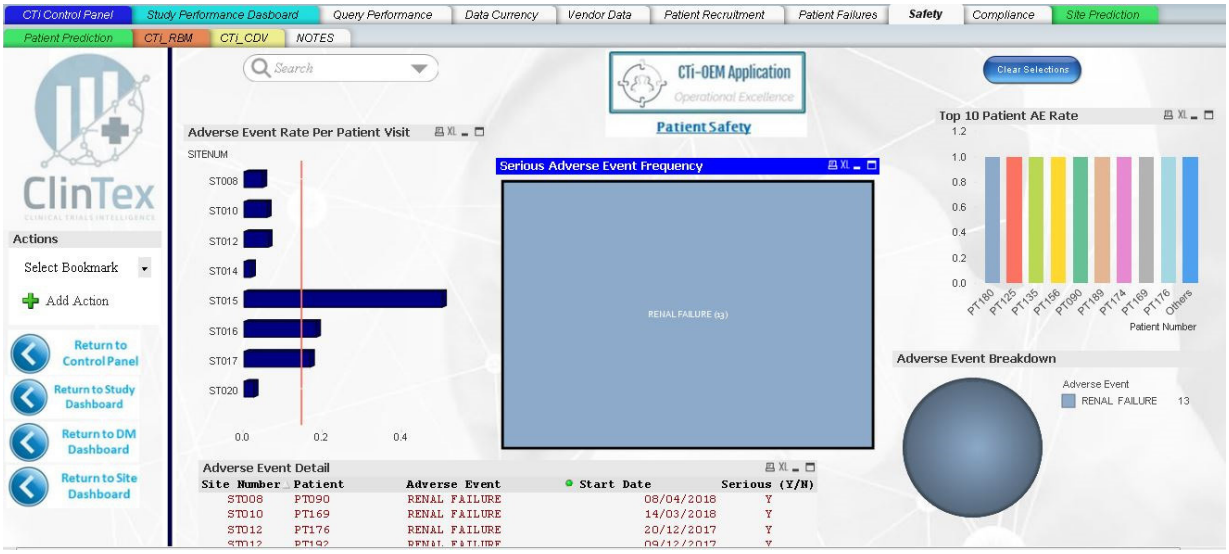
The Clinical Trials Intelligence includes a number of visualisations based on analysis of patient safety during a clinical trial. In the example below (P4), the Adverse Events experienced by patients throughout a clinical trial are represented, and allow for rapid medical review to ensure the patient is protected whilst taking the experimental medicine.

P4



Areas of interest can be rapidly investigated in the Clinical Trials Intelligence. In this example, renal failure appears to be a frequent adverse event. Hospital sites and patients experiencing Renal Failure can be rapidly identified by clicking on the “Renal failure” box (P5).

P5

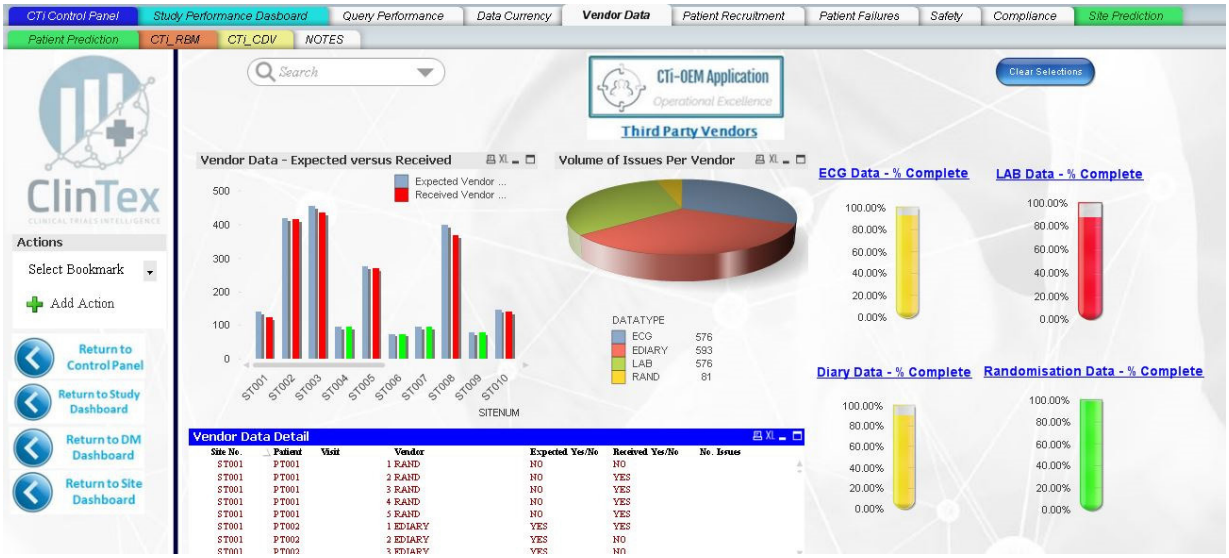


The view of this data identifies that there are 13 “Renal Failure” events, and that hospital sites ST015, ST016 and ST017 are all exhibiting a high rate of this adverse event. The patients experiencing this event are also identified in the top right of the visual, ensuring that the medical monitor for the clinical trial has all the information needed to take appropriate action.

Example 3: Third Party Vendor Data

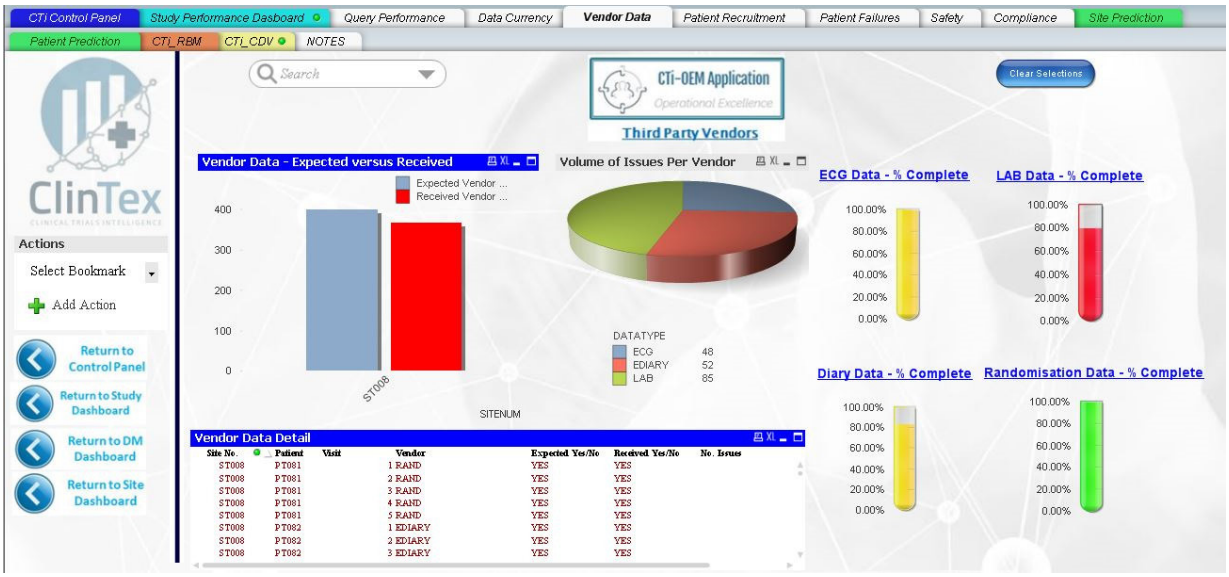
Third party vendor data is essential to complete the clinical data profile of the new medicine and prove efficacy and safety in the clinical trial. Third party data includes lab data (e.g. blood analyses) and Electrocardiogram Data (ECG). The visual below (P6) allows the clinical trial team to immediately identify gaps and delays in this data and take proactive action to ensure that data is transmitted and received.

P6



Hospital sites where expected data has not been fully received are highlighted in Red in the top left of figure 6. Clicking on these sites (e.g. ST008 below) allows further analysis to identify the details of the missing data, allowing the clinical data manager to take action to ensure this data is made available to complete the clinical data for that site (P7). In this example, Lab Data is only 80% complete (top right), representing the majority of missing vendor data for this site

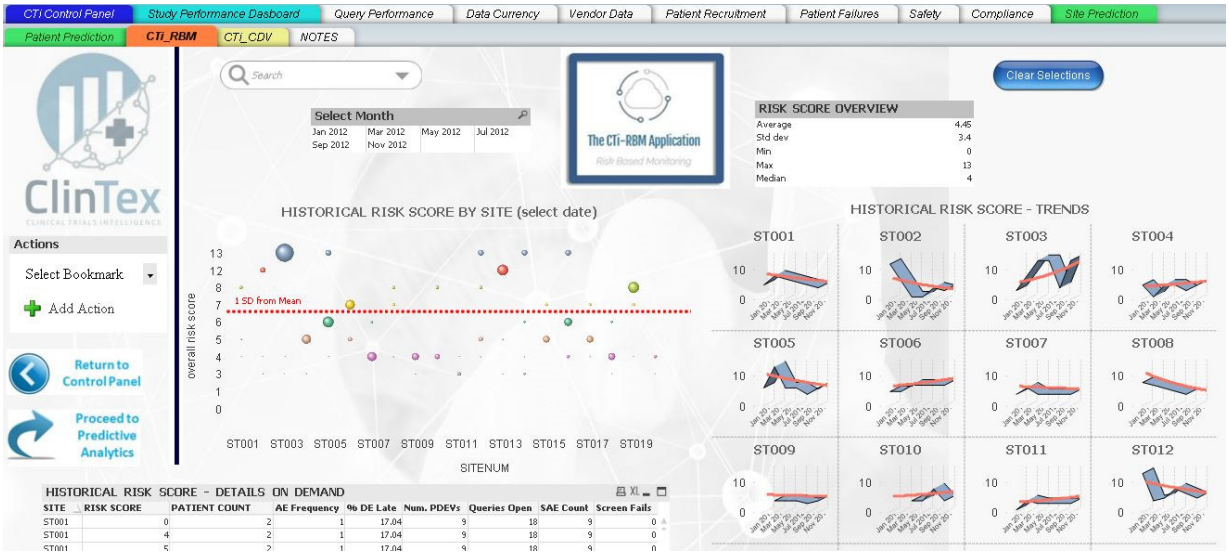
P7



Example 4: Risk Based Monitoring

Risk based monitoring is an FDA-supported initiative to encourage pharmaceutical companies to adopt a "riskbased" approach to managing sites (hospitals) conducting clinical trials on their behalf. The Clinical Trials Intelligence supports and enhances this risk-based approach through the CTi-RBM application (P8).

P8

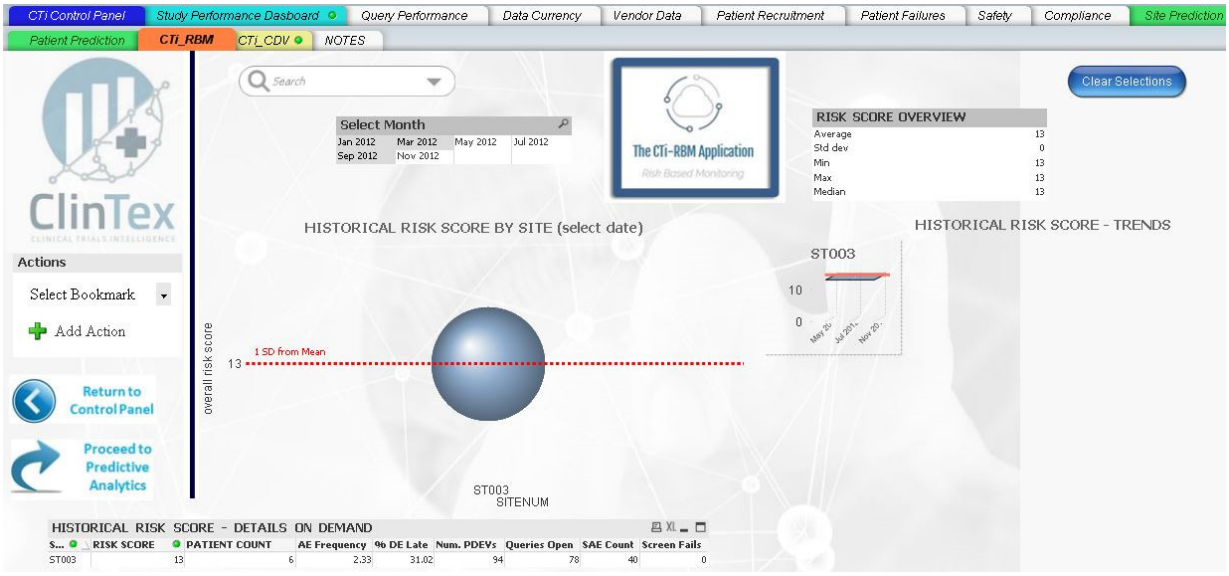


CTi-RBM application has been applied to derive a risk score per investigator site based on a number of individual risk indicators (see "Details on Demand" above). The Historical Risk Score bubble chart ranks investigator sites by the overall risk score, with the size of the bubble representing the number of patients at that site and its place on the vertical axis representing standard deviation from the average risk score (allowing "relative risk" to be visualised). For illustrative purposes, ST003 is a hospital site that represents a high risk with a significant number of patients (as per bubble chart). Also, looking at the progress of risk score for ST003 over time (see "Historical Risk Score – Trends" charts), it can be seen that ST003 risk is worsening when comparing present status to initial status.

After identifying ST003 as a site that warrants further investigation, the user can click on that site with details on demand provided that allow further analysis of the components of risk at that site and enable specific corrective action to be devised and implemented (P9 overleaf).

In this example, the user can identify that the main drivers of risk at this site are: Late Data Entry (31.02%), Protocol Deviations (94), Serious Adverse Events (40), and that there are 78 data queries open and in need of resolution before data is of sufficient quality.

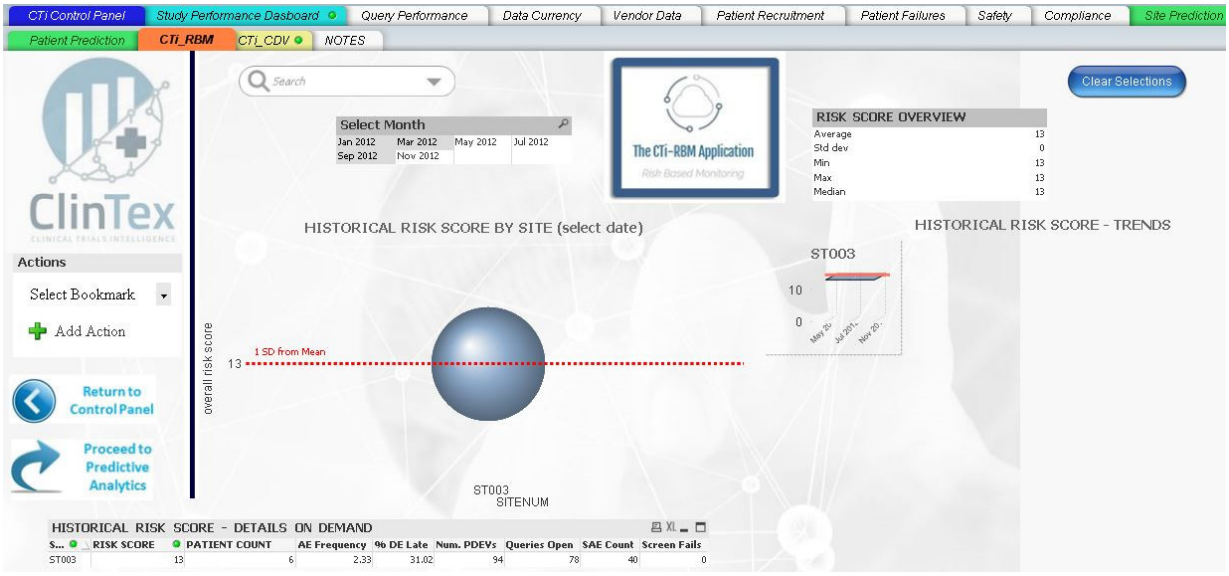
P9



Example 5: Predictive Analytics

Using historical data to predict the probability of patient, site and study level events will drive significant efficiencies in clinical trials, while protecting patient safety. The CTi-PDA application will deliver powerful and valuable predictive capabilities to provide insights to the clinical trial team that enable preventative and proactive actions to be taken to ensure success. There are a number of important events on a patient level that can be predicted from historical events e.g. Early Withdrawal, Lost to Follow-Up, Serious Adverse Events (P10).

P10



For example, it is important to take action to minimise the probability of Early Withdrawal of a patient from a clinical trial and from the Radar charts in Figure 10, Patient 041 (PT041) is showing a higher than normal probability of withdrawing early from the study. This could affect the usefulness of this patient's data to the clinical trial, and would require extra patients to be recruited, resulting is cost overruns and delays.
Being able to predict the probability of such events will have a major impact on clinical trial efficiency and quality.

Target Market & Competitor Analysis

Target Market

Clinical Trials Intelligence will enable more efficient clinical trials and is primarily targeted at the clinical trials industry currently worth $350 billion. The clinical trial industry includes pharmaceutical companies, clinical research organisations (CROs) and academic institutions conducting trials to test the safety and efficacy of new medicines. Through these various sources of clinical trial data, the Clinical Trials Intelligence will access and maintain sources of clinical trial information such as medical data, patient data, vendor data and data on researchers, facilitating collaboration across the industry and driving data insights and predictive analytics.

ClinTex have already established a partnership with Intellimed to deploy the Clinical Trials Intelligence in academic clinical research settings. Further addition to the customer base is targeted for mid-2019, when on-boarding of pharmaceutical companies conducting clinical trials will begin. ClinTex are confident of securing these valuable partnerships through;

- → Providing introductory discounted access to the Clinical Trials Intelligence for selected major Pharmaceutical partners.
- → Capitalising on the pharmaceutical industry network available to us through the clinical research background of the ClinTex core team.
- → Ongoing and significant investment in marketing and business development activities.
- → Publicising the success of CTi applications with Intellimed in academic settings.
- → Offering a “Proof of Concept” free trial in 3 large Phase III clinical trials to drive further application in industry settings.

Competitive Analysis

At the time of writing there is currently no direct competition from companies focussing specifically on the application of blockchain and AI to the whole clinical trial process. Furthermore, ClinTex offers a breadth of product features that will find application at all stages and in all key activities related to the development of new medicines using clinical trials.

While there are numerous healthcare-related blockchain projects with seemingly overlapping features, Clinical Trials Intelligence is the only one that has been designed by clinical trial professionals to address a real and current unmet need in the pharmaceutical industry that combines blockchain technology with advanced clinical data analytics to deliver more efficient medicines development.

For example, IBM Watson Health and the FDA are developing an initiative that will define how blockchain can be used to exchange healthcare data from varied sources, including electronic health records (EHR), genomic data, and health data from mobile devices, wearables, and the “Internet of things”. These data sources however are different to clinical trial data. EHR and genomic data etc. are “Real World” data collected in a normal healthcare setting, while clinical trial data is collected in an investigation of a new medicine, and is owned by the pharmaceutical company conducting the trial. Rather than being a source of competition, the work being done by IBM Watson may find application to supplement the ClinTex clinical trial data and augment analytics algorithms to improve overall clinical trial efficiency.

Additionally, DeepMind, Alphabet’s AI division, announced it will build a “Verifiable Data Audit” for health recors using a blockchain-like ledger. The company claims it will make what is being done with healthcare data both verifiable and auditable in real time. Additionally, DeepMind also seeks to use machine learning and predictive analytics to “help clinicians predict, diagnose and prevent serious illnesses”. Again, this solution does not utilise clinical trial data to improve clinical trial efficiency, but rather is focussed on collection of data in a normal healthcare setting with the goal of optimising patient treatment with existing medicines. Clinical trials by contrast focus on developing new and more effective treatments for patients.

Pfizer, Amgen, and Sanofi have recently announced they will be exploring blockchain's application in reducing the costs of the drug development process, focussing specifically on patient recruitment to make it easier for companies to find, recruit and retain patients in trials. This is a welcome and promising development for ClinTex, whose Patient Recruitment and Retention (PRR) application fits nicely with this strategy and goes further by applying predictive analytics to ensure that patients, once recruited to a clinical trial, are retained throughout the study, avoiding a major source of cost and time overruns in clinical trials. Therefore, ClinTex are well placed to deliver on big pharma's evolving interest in blockchain technology.

Start-ups like TriNetX, Patientory, Guardtime and PoktiDok are also attempting to utilise sources of "real-world" healthcare data to improve the efficiency of patient selection and recruitment. The claim is that this data aggregation can aid in the understanding of disease dynamics and patient behaviour in order to enhance the selection of best patients for clinical trials. The collection of "real-world" data, however, represents a challenge for each of these start-ups. The primary challenge is that this data is ultimately owned by the individual patient, and therefore requires individual patient consent to be utilised.

When it comes to clinical trials, however, the data is owned by the pharmaceutical company, who has already obtained consent for patient participation, and therefore is a readily available source of valuable clinical information.

In this way, the Clinical Trials Intelligence fully differentiates itself from all the competition, collecting clinical trial data exclusively across 7 distinct applications to drive efficiency in new medicines development. The ClinTex CTi proposition is unique in a market with a huge potential for growth that will benefit patients and pharmaceutical companies alike.

Source: Everest Group

CTi Development & Technology

Why Ethereum?

Basics

The Ethereum Virtual Machine (EVM) is the software that runs on the Ethereum network and allows for the creation and development of different applications all on one platform. It has an unparalleled track record in hosting decentralised applications which enable the execution of smart contracts, which parties can fulfil certain conditions and validate those conditions automatically using code. Due to smart contracts' self-executing nature, single-party manipulation is averted because control over the execution of the smart contract does not fall into the hands of a single party. Autonomy, trust, speed, and safety are Ethereum's key strengths and these will be pivotal to the CTi ecosystem.

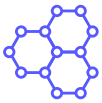
While there are other DLT platforms in the space that promise a superior transaction speed per second, these promises have not yet been realised. Ethereum's proven, viable and ready-to-use blockchain is the perfect platform on which to host the CTi eco-system.

Enter Ethereum

Advantages

- ✓ Immutable
- ✓ Corruption & tamper proof
- ✓ Secure

The Ethereum virtual machine makes the process of creating blockchain applications much easier and more efficient than ever before. Instead of having to build an entirely original blockchain for each new application, Ethereum enables the development of potentially thousands of different applications all in one platform.



The Blockchain

Blockchain technology is like the Internet in that it has a built-in robustness: copies of information are stored in many locations. However, blockchain is even more robust (immutable) because, by storing blocks of information that are identical across its network and arriving a consensus about the validity of those blocks, there can be only one agree upon version of information contained in a blockchain.

Benefits of Decentralised Networks

With end-to-end encryption and no central point of failure, applications are vastly more secured against hacking.

Source: BlockGeeks

Smart Contracts, Oracles, Data Storage and Tokenisation

Smart Contracts - Ethereum

Clincial Trials Intelligence will utilise smart contracts on the permission-less Ethereum blockchain to facilitate:

- → Assured security of access control.
- → Compensation payments within the eco-system.
- → Storage of hashed roots of clinical data.
- → Native CTi (ERC20) Token.
- → Clinical Trials Intelligence also heavily utilises smart contracts for the key tasks on its permissioned blockchain - the details of which are available in the CTi Technical Paper available at www.clintex.io.

Decentralised Oracles - Chainlink

Clinical Trials Intelligence will utilise oracles to facilitate the triggering of payments in cases where it is based off of data or occurrences on pharmaceutical source systems that are external to the CTi blockchain network, for example: payments to investigators and vendors in reward for data completion and data quality targets derived from clinical electronic case report forms (eCRF).

To achieve this, Clinical Trials Intelligence will use ChainLink as its decentralised oracle provider. ChainLink is the world's first decentralised oracle network that allows smart contracts to access key offchain resources like data feeds, web APIs, traditional payments and in our case, pharmaceutical source systems.

Decentralised Storage of Clinical Data - Storj

Clinical Trials Intelligence will use Storj as its decentralised storage provider. Storj is an open source decentralised cloud storage platform which keeps data spread across a decentralised network, eliminating the problem of having a single point of failure. Storj also encrypts all data, making it impossible for anyone to gain access to users' files without possession of the corresponding private encryption key.

The Clinical Trials Intelligence Utility Token (CTi)

CTi will have its own native token (CTi), which will have multiple utilities on the platform, each of which will be rolled out in line with the phasing outlined in our roadmap. Differing analytics access levels will apply to token holders in accordance with their CTi token balance level. The balance required for each access level will be determined in advance of live-launch. The CTi token also has a secondary use case as payment on the Clinical Trials Intelligence for investigators and third party vendors within the CTi-SIM and CTi-VMM applications.

CTi Token in Clincal Trails Intelligence Applications;

- → CTi-OEM: Operational Efficiency – CTi balance will allow access (Level 1)
- → CTi-PDA: Predictive Analytics - CTi balance will allow access (Level 1)
- → CTi-CDV: Data Visualisations - CTi balance will allow access (Level 1)
- → CTi-RBM: Risk Based Monitoring - CTi balance will allow access (Level 1)
- → CTi-PRR: Patient Recruitment - CTi balance will allow access(Level 1)\
- → CTi-SIM: Site Investigator - CTi balance will allow access. CTi tokens are used as compensation payments between parties. (Level 2)
- → CTi-VMM: Vendor Management - CTi balance will allow access. CTi tokens are used as compensation payments between parties. (Level 2)

*For information on token economics within the eco-system, please see 'Token and Ecosystem Economics' section later in this document.

Protocol

The CTi token will be ERC-20 and thus will follow the common rules of ERC-20 standard within the larger Ethereum ecosystem, including transfer between all ERC-20 compatible wallets.

The ClinTex Token (CTi) Legal Status

ClinTex have engaged with a legal partner in the UK, Sterling Law, to have the CTi token reviewed as a digital asset in relation to Securities Law, and confirmed its regulatory classification is not that of a 'Security' or 'Financial Instrument', and thus it does not fall under the FCA regulatory perimeter under the Financial Services and Markets Act 2000 (Regulated Activities). More information is available on request.

Data-Input Token

In the final phase of development, ClinTex will introduce a second native token (ERC721) to Clinical Trials Intelligence for the purposes of data-input. The CTX (ERC721) data tokens will enable the provision of data directly to Clinical Trials Intelligence's decentralised file system by external parties (such as vendors in the trial process). These tokens will be for data transmission only and will require an additional accounting and data provision mechanism for the smart contract. For more information, please see the ClinTex CTi Technical Paper.

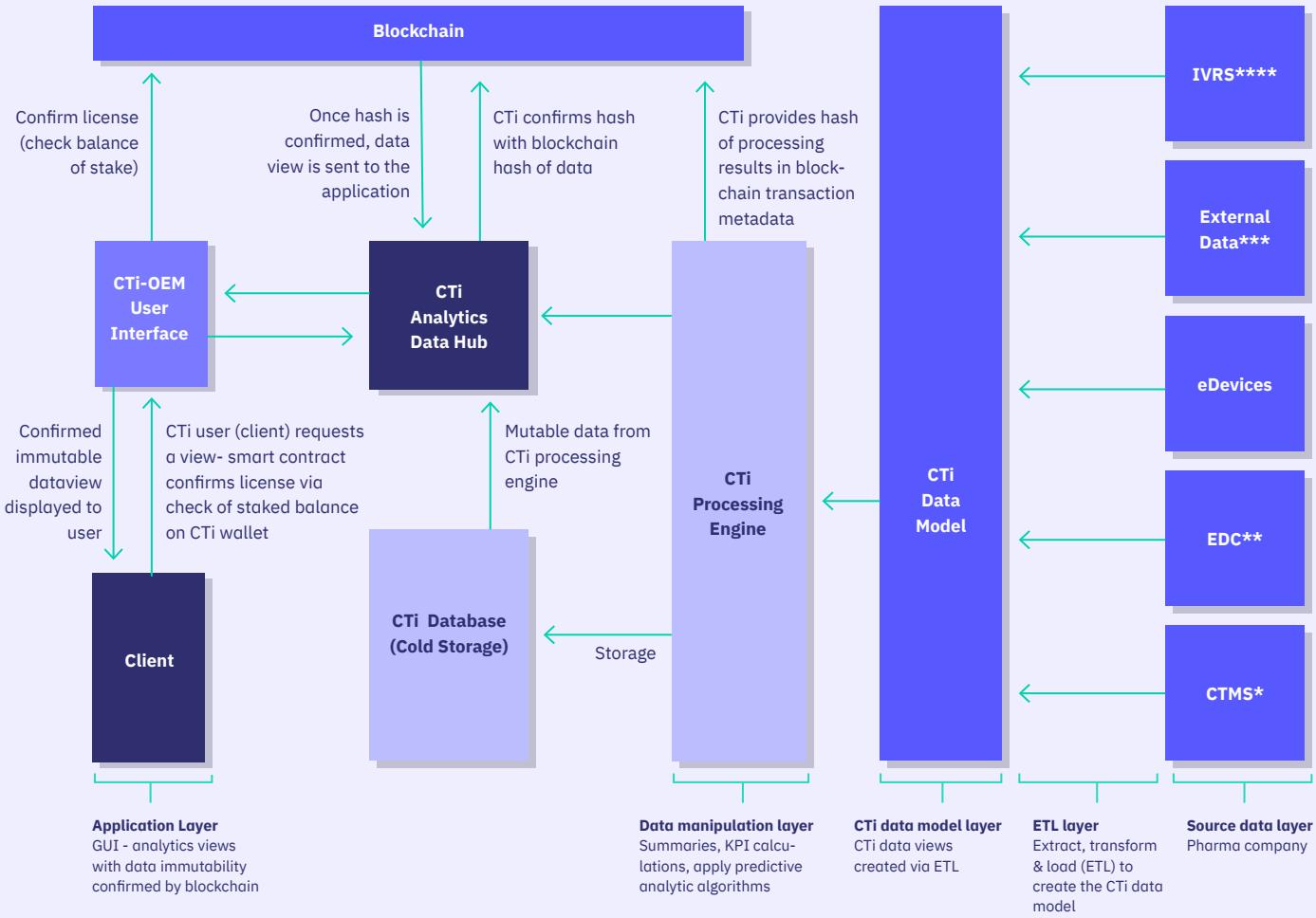
Build, Growth & Scaling

For the purpose of building out the capabilities of the Clinical Trials Intelligence in a manner that maximises eco-system growth, there are certain functionalities that will be built on-chain immediately and other functionalities that will migrate onchain in the latter phases.

Phase 1

Initially, the raw clinical data from trials will be converted into a predefined standard and stored anonymously on the cloud (in compliance with CGMP Pharmaceutical Quality standards). This pre-defined standard will include a hash of the data and timestamp, so that the processing engine can verify the cloud stored data via the blockchain. When a user requests a view from a module, the platform will receive a target index hash from the blockchain and, once a match is confirmed, retrieve the corresponding data from the cloud's database. This will ensure immutability of CTi's data.

This phase will also introduce the Clinical Trials Intelligence native token, CTi. Access to the platform will be granted via CTi balance in the platform's integrated wallet; this balance will be staked in the contract for the duration of the licence. There are also rewards in the form of CTi tokens within the CTi-VMM and CTi-SIM applications. These rewards will be deducted from the requesting clients' staked balance. (More on token economics and utility follows later in the document). The contract will also allow the use of the fabric function (automated deployment of predefined smart contracts in the Ethereum environment) to establish consortiums and/or agreements between external parties on clinical trial processes with a rewards system between them.



*Clinical Trial Management System at Pharma Company
**Electronic Data Capture at Investigator Site
***External Data e.g. from labs
****Integrated Voice Response System - Patient 'dials in' data

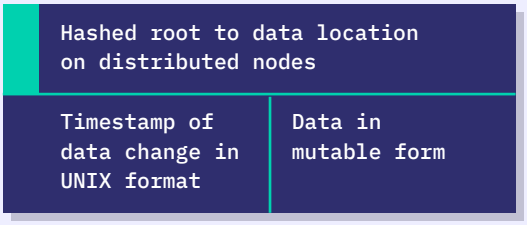
Phase 2

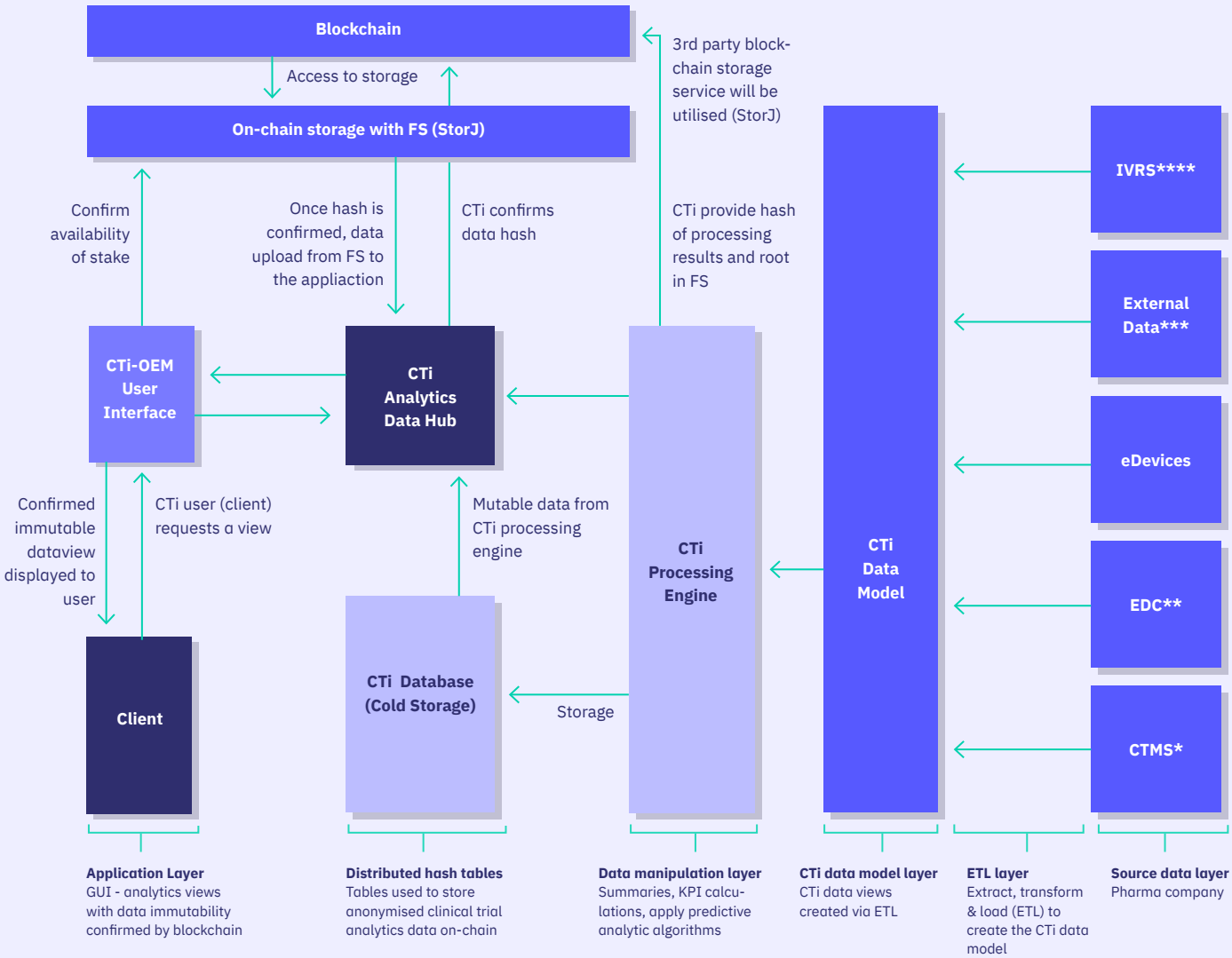
In this phase, distributed hash tables will be introduced to the ecosystem. ClinTex will incorporate a blockchain storage service for Clinical Trials Intelligence, which is where all data changes will be recorded in the distributed hash table (DHT). To ensure immutability, the indexation with the timestamp format introduced in phase 1 will remain in place on the DHT.

A concatenation will include a hash of the index and a hash of the root to the data.

Blockchain hash = SHA256(Timestamp) || SHA256(Root)

An additional element of the smart contract will also be introduced in this phase for the storage node.





*Clinical Trial Management System at Pharma Company
**Electronic Data Capture at Investigator Site
***External Data e.g. from labs
****Integrated Voice Response System - Patient 'dials in' data

Phase 3

In the final phase, the full migration of the Clinical Trials Intelligence data model to a decentralised solution will be achieved using a
sequence of smart contracts and a second native token (ERC721) for the purposes of data-input.

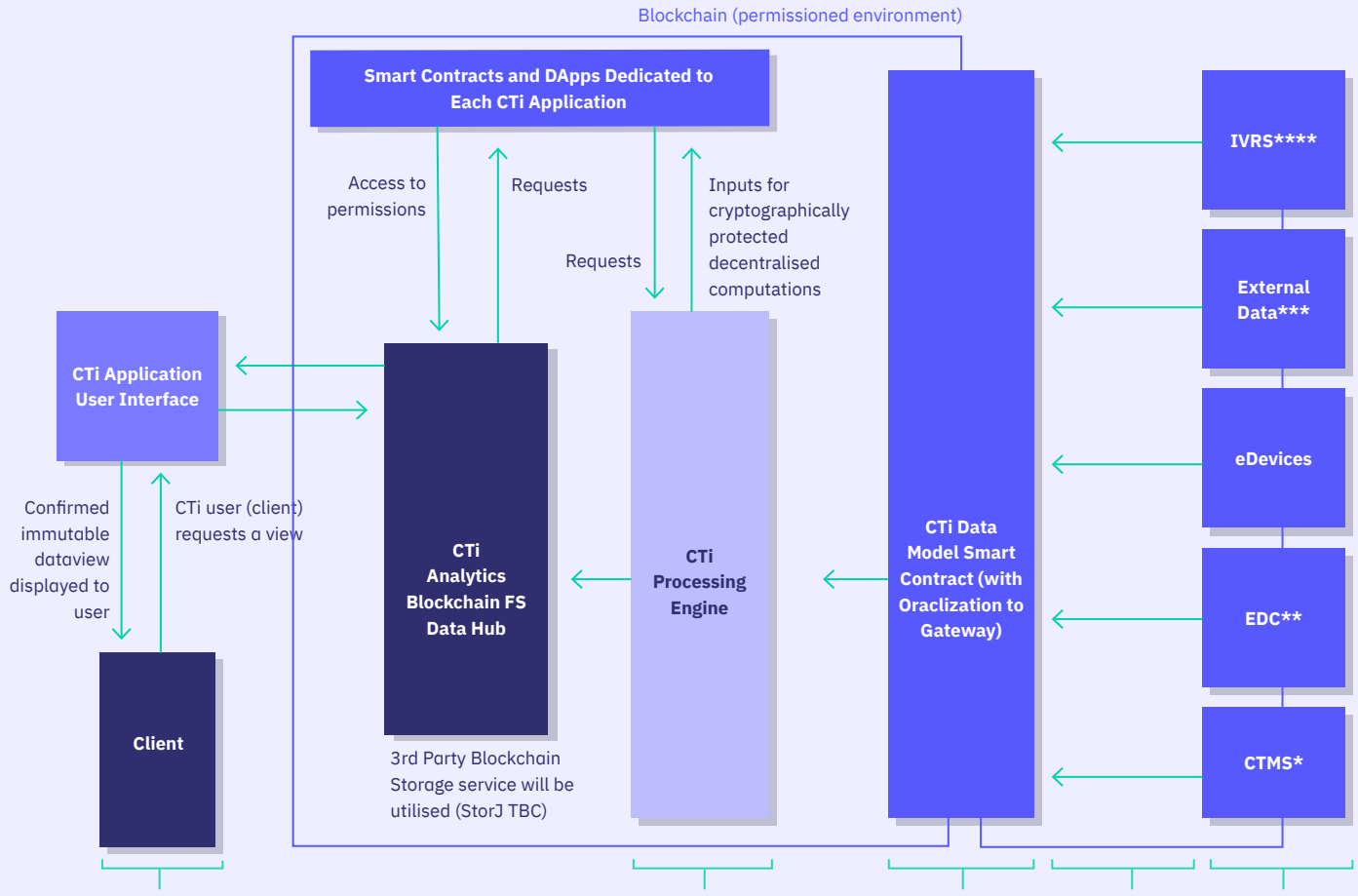
The CTX (ERC721) data tokens will enable the provision of data directly to the Clinical Trials Intelligence's decentralised file system by external parties (such as vendors in the trial process). These tokens will be for data transmission only and will require an additional accounting and data provision mechanism for the smart contract.

A further detailed breakdown of our technical plan, including diagrams of all smart contracts is available in the CTi Technical Paper which has been published separately.

Consensus

More Detail
Please see our
CTi Technical
Paper

The technical consensus protocol for the Clinical Trials Intelligence blockchain will be the Greedy Heaviest Observed Subtree (GHOST) Ethereum protocol with a Proof of Ownership of contract. At phases 1 and 2, the economic motivation for consensus over token value is derived from demand for Clinical Trials Intelligence and the pool of available tokens after staking.



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**Electronic Data Capture at Investigator Site
***External Data e.g. from labs
****Integrated Voice Response System - Patient 'dials in' data

Token & Ecosystem Economics

To access the Clinical Trials Intelligence the user will require a licence, which will be granted by smart contract when a predefined amount of CTi tokens is staked in the users balance on the platform's integrated wallet. These tokens will need to be purchased on the open market and, once a licence is granted, will remain staked in the Clinical Trials Intelligence wallet for the duration of the licence period (12 months minimum).

Value Driven Growth

An initial allotment of CTi tokens (5%) will be reserved for growing the platform and ecosystem by providing discounted access to selected major Pharmaceutical partners from the off-set. ClinTex will work with these selected partners in the early trials of the live platform to prove the model and value to industry, nurture growth, and refine the platform's analytic algorithms to client needs.

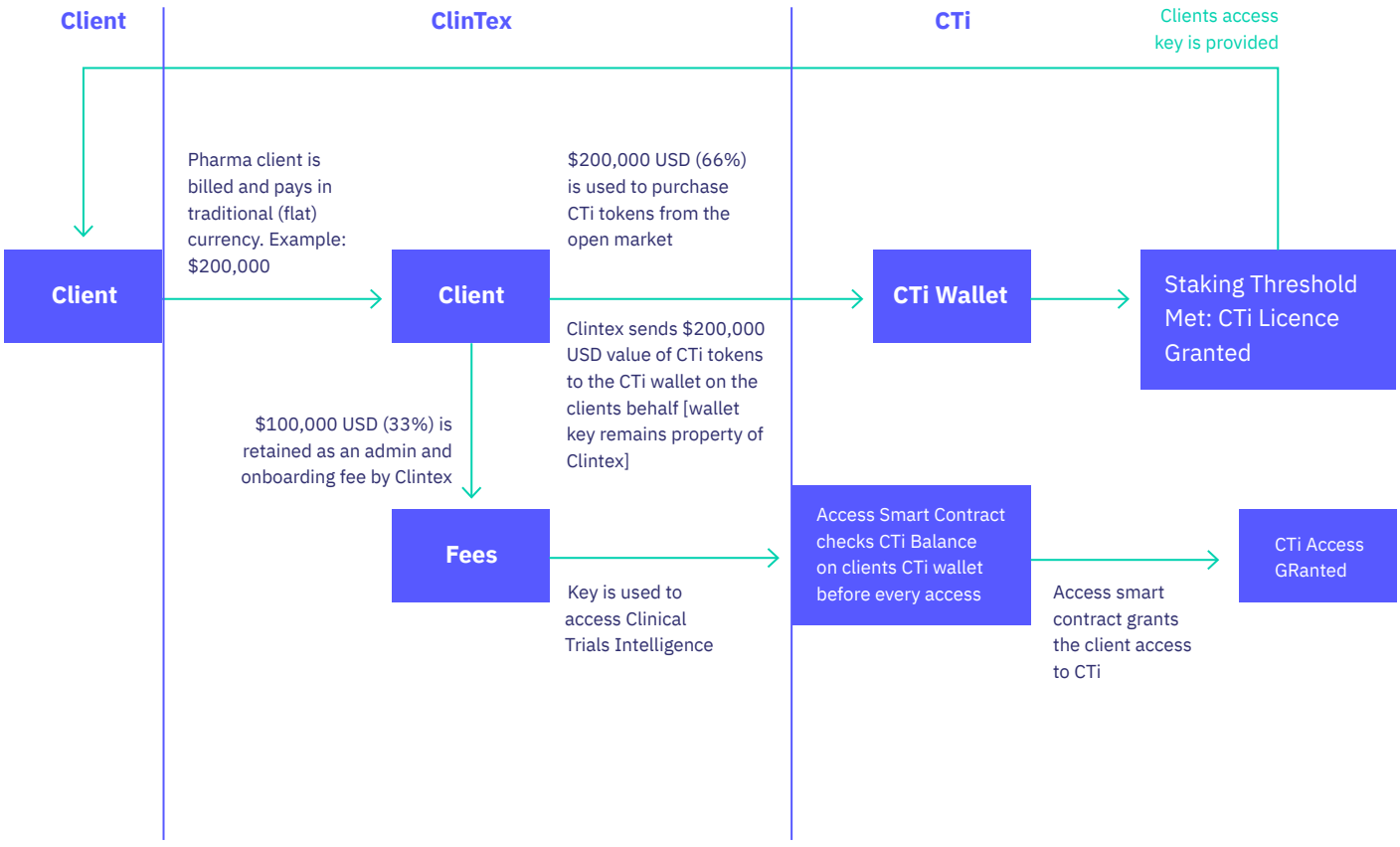
This industry adoption will be the driver of a network effect of usage of the Clinical Trials Intelligence, and long term value of the CTi token.

Brokerage Service for Major Pharmaceutical Clients

To facilitate larger pharmaceutical clients, a ClinTex subsidiary will offer to act as a brokerage service by taking payment through traditional gateways, which it will then use to purchase CTi tokens from the circulating supply on public exchanges on the clients behalf.

ClinTex will charge a fee for this service, which is one of the primary revenue generation models of ClinTex's' ongoing business plan.

Example process for pharmaceutical client on-boarding, using the ClinTex brokerage service:



Reducing Supply

ClinTex intend to heavily market to industry through the launch and roll out of CTi's seven applications, and it is envisioned that demand for licenses will experience rapid and expansive growth during this period. As tokens will need to be constantly acquired from the circulating pool each time new Clinical Trials Intelligence access license is granted, the supply of CTi will reduce significantly as the project matures.

Loyal Base

As the Clinical Trials Intelligence will be the first to market with best-in-class clinical trial analytics, it is envisioned that the majority of the customer base will renew their license after the initial 12-month period, on an on-going basis.

Furthermore, large value clients will be incentivised by ClinTex to do so when approaching the end of their license period.

For token holders, this will mean that the staked CTi tokens for pharma clients will not be returning to the supply pool at the end of the initial 12 month term of the clients license, and will stay out of circulation indefinitely.

Token Burn

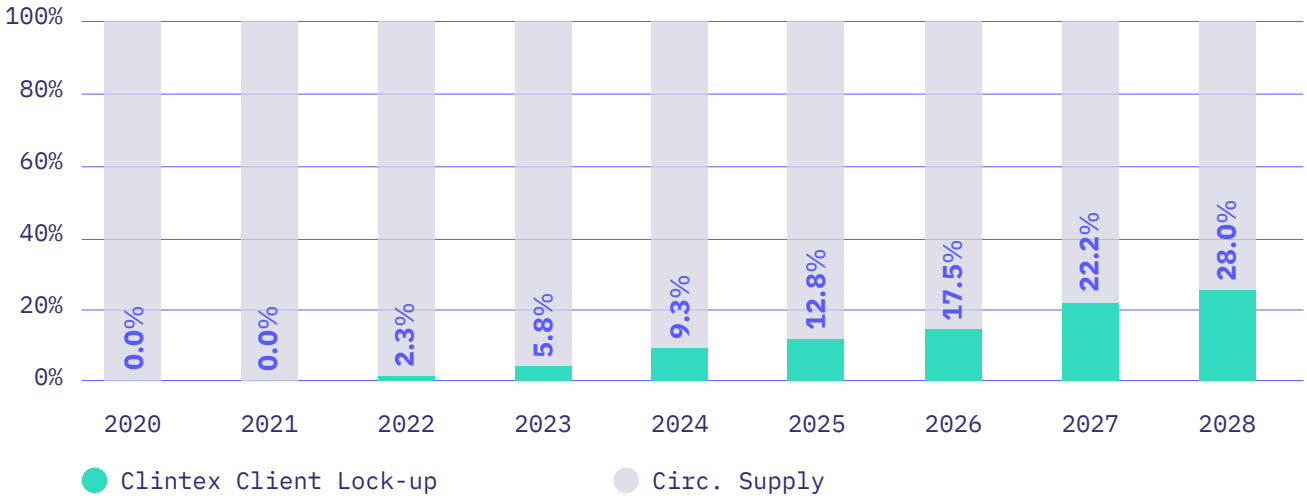
In the event that a pharmaceutical client chooses not to renew their Clinical Trials Intelligence vaccess, the CTi tokens that were staked for that license will be returned to ClinTex. As part of our commitment to continuously reduce the CTi supply pool, 20% of those tokens will be destroyed permanently. This token burn will be performed by smart contract and verifiable on the Ethereum public blockchain.

The remaining 80% will remain property of ClinTex and will act as a cancellation fee. This will be a part of the service contract that the pharmaceutical client signs with ClinTex.

Reward Payments

At phase 3, further demand for CTi tokens is driven by the reward mechanism in the CTi VMM and CTi-SIM applications. As the reward contract will transfer CTi from the client's wallet to the data owner's wallet, this will have the effect of the client being required to 'top-up' their stake at the end of the licensing period in order to renew access.

Clintex Clients Staked CTi Tokens as a % of Supply (Projected)



Our Team

Combining the best of expertise from across the pharmaceutical, clinical, software and data analytics spectrum.

Brendan O'Mainnin
Director of Operations

Brendan is a highly experienced project manager and business analyst with extensive experience in financial operations, telecommunications & consumer marketing. Successful proven leadership skills, he enjoys working with people to solve problems. Brendan has had an interest in the blockchain space since 2013 and intertwines this experience with his business expertise regularly in his role as a director in ClinTex

Ethan Diamant
Director of Clinical Data Services

Ethan is leading the Clinical Trial Services function, responsible for building partnerships with the pharmaceutical industry, and ensuring that evolving customer require-ments are built into ClinTex's products and services. Ethan has 19 years experience working directly in clinical trials including clinical data monitoring, study optimization and global operational excellence.

Andre Byrne
Director of Marketing

Andre is a an experienced marketeer with a strong technical background spanning two decades in the technology sector, including experience in banking, finance and graphic design.

A self starter with an entrepreneurial mindset, Andre is highly enthusiastic progressing technological developments that can change the world around us for the better.

John McCabe
Head of Legal & Regulatory

John holds a BA (Hons) in Business Law and is a licenced solicitor in England, Wales and Ireland after being admitted into the Law Society of Ireland in 2013. John has been working in law for over eleven years and has a keen interest in all things blockchain. He is excited to be bringing his focus to the cryptocurrency legal and regulatory landscape.

Neill Barron
Director of Clinical Data Analytics

Neill leads the requirements specification, design and development of the Clinical Trials Intelligence, ensuring it meets current and future real-world challenges for the pharmaceutical industry. He has over 20 years' broad clinical development experience through a blend of senior roles in clinical data management, data analytics, technical/process improvement and site data monitoring.

Sean Flanagan
Head of Business Development

Sean has 12 years extensive experience in the Financial Services industry and brings to the team a valuable knowledge of corporate client management, wealth management and securitisation. His track record in the cultivation of investor and client relations will help ClinTex deliver their development roadmap and generate value for all stakeholders.

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Ed Burke
Senior Developer

Edward earnt his Master of Engineering (Meng) in Dublin City University in 2007 and boosts a wealth of software engineering experience from his 10+ years' experience in senior design roles with companies such Paddy Power Better, Citi, and Fidelity. Ed specialises in C#, Java, Python and Solidarity and his strong focus and passion for scalable solutions makes him a most welcome addition to the ClinTex team.

Roman Tsivka
Blockchain Developer

Roman is an experienced blockchain architect specialising in Solidity, with rich experience in Ethereum smart contracts and distributed ledger technology. He has previously worked on the successful implementation of blockchain solutions within the public and private sectors, including extensive work with various Fortune 500 companies. Roman has responsibility for smart contract development, audit, and deployment within the CTi project.

Victoria Boychuk
Developer

Victoria is a qualified software engineer and has been working with Solidity since early 2018, when she took on her first Solidity Developer role with blockchain development agency, Applicature. As a member of the technical team, Victoria will support the design, development and roll-out of the CTi project through phases 1, 2 & 3.

Ian Arden
Blockchain Development Advisor

Ian is a partner at Applicature – a boutique Blockchain development agency focused on strategic consulting and implementation of Blockchain, smart contracts, ICO wallets and payment gateways and consumer applications. His expertise and experience in helping blockchain enterprises build and grow makes him a valuable advisor to the ClinTex team.

Sean Comiskey
Technology Engineering Advisor

Sean is highly motivated software engineer with experience covering the full software development life cycle, with particular specialisation in event sourcing and CQRS. He brings excellent understanding of modern software development principles, practices and paradigms to the ClinTex advisory board.

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