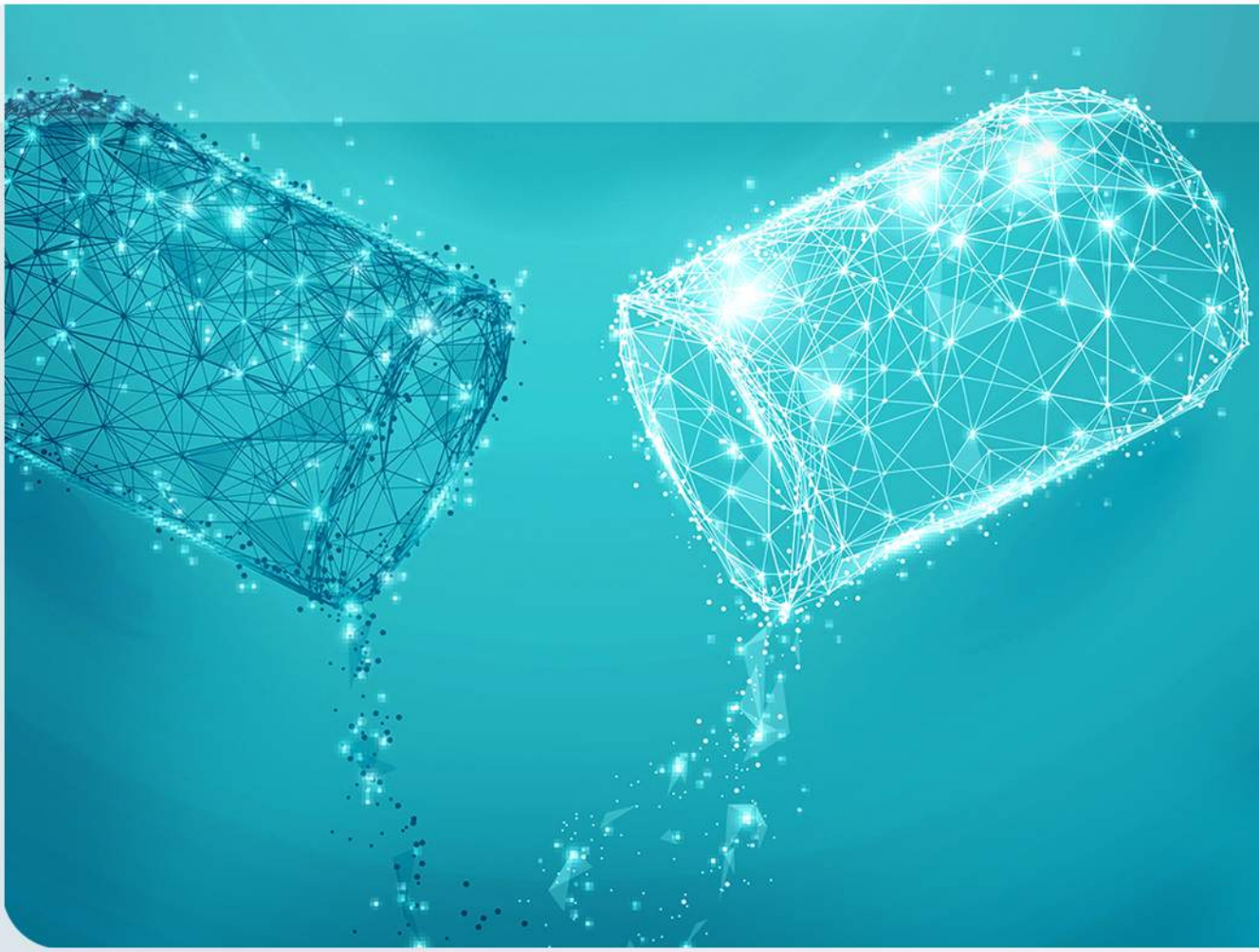

WHITEPAPER V2 APRIL 2021

A digital ecosystem for clinical trials

Vision, approach and design

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Triall Whitepaper

Version 2.1.3 | August 2021

Authors: Raymond van der Waal, Joost Flach, Mark van der Waal

Reviewers: Niels Klomp, Hadil Es-Sbai, Rob Posthumus, et al.

Design: Mark van der Waal

Change log

Since Version 1

This version of the Triall whitepaper reflects our latest insights, plans, and visions. Key changes include alterations to our token system and token allocation, which, among others, include the introduction of a secondary token (T-CRED), the Triall Community Fund, and a staking program.

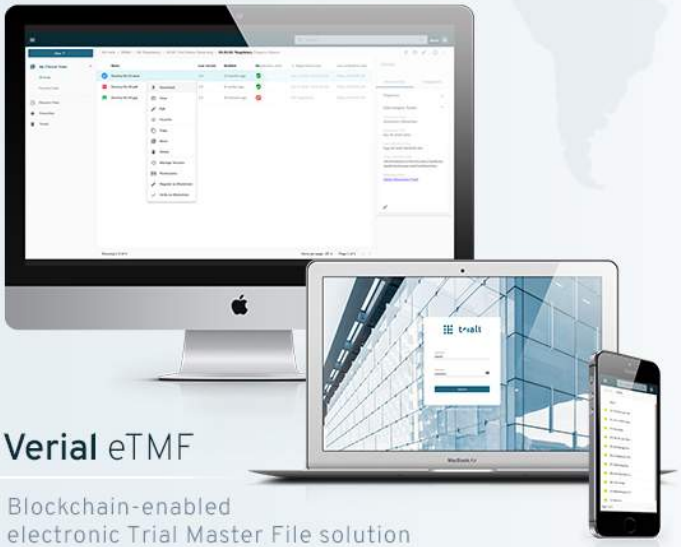
Moreover, we have updated the roadmap, partners, and advisor sections, to display the growth and developments made in 2020.

GRAPHICAL ABSTRACT

Triall in a nutshell

Industry Experience

Triall's team has **deep understanding** of industry needs and trends. Combined, they have **managed 100+ clinical trials** across 30+ countries, and sucessfully developed clinical and software companies through all stages of growth. Our developers, headed by **CTO Niels Klomp**, have a proven track-record in decentralized technology solutions.



Verial eTMF

Blockchain-enabled
electronic Trial Master File solution

- Awarded **Seal of Excellence** by Horizon 2020 (European Commission) for underlying concept
- Blockchain-secured **verifiable proofs** of clinical data
- World's first implementation of blockchain in **live and running** clinical trials—to be onboarded by more

Double-Digit Growth Market

Our target market is characterized by rapid digitalization, decentralization, globalization, and double-digit growth (**CAGR of 13,8%**). **High upside** is projected for players that can facilitate safe and reliable data. Our architecture is **designed to underpin the emerging digital ecosystem** of clinical trials and medical R&D.

Venture Backed

After bootstrapping the first 2 years, Triall's software development efforts are now **venture backed and ready to grow** in the rapidly expanding market of clinical trial software (eClinical) solutions.

Global Network

Years of industry operations have gained us a **rich value network** of **partners** and **potential customers** that stretches the globe. Our network includes leading 'big pharma' manufacturers, globally recognized academic research centers, and a host of smaller industry players working on the next breakthroughs in medical technology.

Market Validation

In collaboration with our network, we have been developing blockchain-enabled software solutions that respond to **actual industry pain points**. Leading stakeholders in our customer domain have **expressed interest** in our first product, **Verial eTMF**.

Working Product

Verial eTMF is in production and **currently being onboarded** by **6** commercial clinical trial projects across **3** countries and **15** investigative sites, involving an approximate total of **2500** participants. More projects are lined up.

First Mover

With Verial eTMF being used by clinical researchers since July 2019, we believe to be the **world's first** organization to implement blockchain in real-world clinical trial settings.

Thought Leader

Our team has published **250+ peer-reviewed papers** on innovation in clinical research and the Life Sciences at large. In May 2020, Triall-affiliated research on the applicability of blockchain, decentralized identity (DID), and verifiable credentials for global R&D cooperation was published in **Science**.

Summary

Clinical trials are complex, lengthy, and resource-inefficient

The clinical research industry is responsible for the delivery of medical solutions to society by systematically evaluating their safety and efficacy in humans during so-called **clinical trials**. As exemplified by the COVID-19 pandemic, a steady and efficient influx of vaccines, therapeutics, and other innovative medical solutions is critical for meeting society's current and future medical needs. Unfortunately, the industry faces several persistent issues that make clinical trial operations overly complex, lengthy, and resource-inefficient.

1 **Fragmentation**
Data is scattered across sites and systems.

2 **Lack of oversight**
Reported by virtually all clinical trial professionals

3 **Recordkeeping failure**
Causing significant delays, costs, and safety risks.

4 **Data integrity issues**
A growing concern according to authorities globally.

Accelerating access to novel medical solutions

Triall develops blockchain-integrated software to target these issues. Our core mission is to accelerate the introduction of novel medical solutions to society by enabling a future of smarter, safer, and more-efficient clinical trials.

Bringing together a consortium of clinical operations experts, enterprise IT specialists, and blockchain developers, we are building towards the world's first digital ecosystem for clinical trials that connects all types of clinical trial stakeholders: the **Triall Ecosystem**. It offers a series of modular applications that each tailor to identified unmet needs of clinical trial professionals, working with an API-driven infrastructure to selectively apply the strengths of blockchain and related technologies where these truly add value.

Spearheading the implementation of blockchain in clinical trials

Credited as the world's first implementation of blockchain in a live and running clinical trial, Triall's blockchain-integrated clinical document management solution **Verial eTMF** has been in use by real-world clinical trial projects since 2019, with more paying projects being onboarded. The Triall Ecosystem will be built out gradually by developing a core series of modular, but complementary and interoperable 'eClinical' applications, committing to an agile, user-centered development approach.

Proof of reliable clinical data & Safe and efficient cooperation

Uniquely, the ecosystem's infrastructure enables verifiable proof of the existence, integrity, and authenticity of clinical trial data. This fully answers to growing calls for auditability and data traceability by authorities across the globe, and promises to improve the reliability and efficiency of clinical trials throughout the drug development chain.

Moreover, through blockchain-enabled cryptographic access control and service discovery, Triall's infrastructure allows for consolidating the now severely fragmented landscape of eClinical applications into an integrated, multi-sided platform. Facilitating secure and efficient data exchanges, systems and users may start to act in concert, streamlining clinical trial operations.

A community project, leveraging open blockchain standards

The non-profit **Triall Foundation** functions as the ecosystem's governing body and public service provider, responsible for the development and maintenance of the infrastructure and its functionalities. Triall's applications are blockchain-agnostic and currently integrated with well-established, proven public blockchains, including **Bitcoin** and **Ethereum**. As its primary data logging and authentication layer, Verial eTMF has been using the **Factom Protocol**: an open-source data integrity protocol optimized for enterprise adoption, with a proven track record of industrial and governmental application.

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1. Background

1.1. Today's medical innovation process

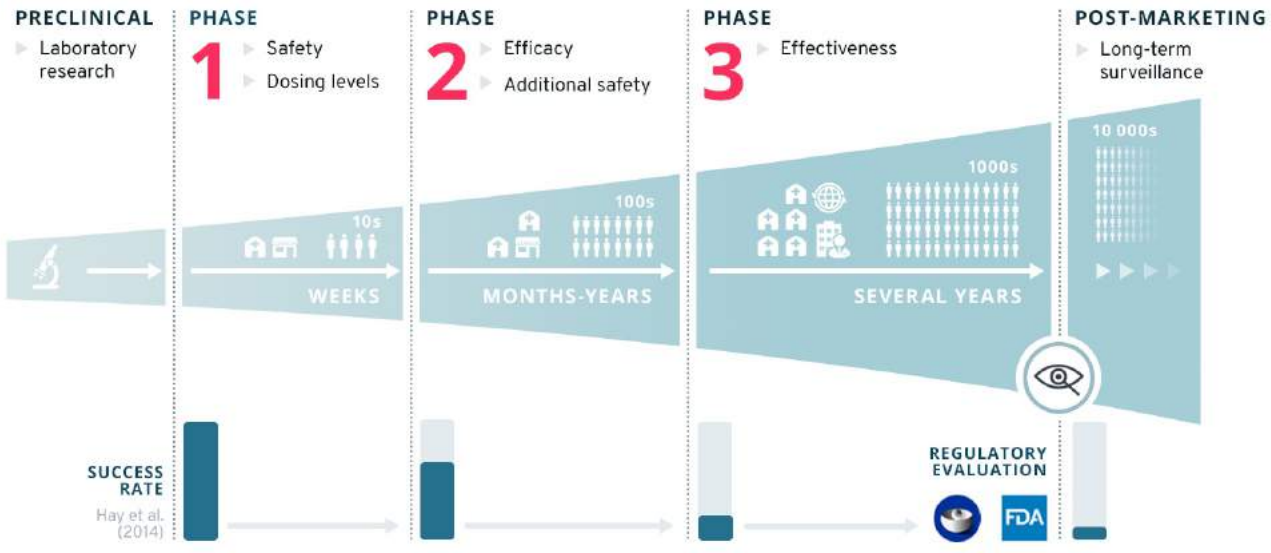
1.1.1. A brief introduction to clinical trials

With the introduction of organic chemistry and our ability to isolate, examine, and systematically measure the effects of chemically active ingredients in the body, society has transitioned into the era of modern medicine. Since then, the world has witnessed the introduction of increasingly sophisticated medical technologies and approaches that have realized the eradication of previously 'unbeatable' infectious diseases and raised global life expectancies and well-being to unprecedented levels. While these achievements are impressive, the COVID-19 pandemic demonstrates that society will continue to be challenged by emerging or re-emerging medical emergencies. Moreover, coming up with a solution to a medical problem often means shifting from one unmet medical need to another. For instance, converting diseases that once were untreatable into chronic conditions requires society to come up with innovative treatment approaches. Therefore, a steady and efficient influx of medical solutions is critical to ensure that society's unmet medical needs can be addressed. These solutions take the form of new and improved treatment approaches and technologies, such as drugs, diagnostics, or vaccines. To ensure their safety and efficacy, candidate medical solutions are subjected to a carefully regulated process of systematic evaluation in humans—so-called **clinical trials**.

1.1.2. Clinical trial phases

Clinical trials are divided into several consecutive phases, starting with **Phase 1** trials that are aimed at examining the product's safety and dosing levels in around 20 to 100 healthy human volunteers. According to recent estimates,

approximately 65% succeed to the next phase.[1] **Phase 2** clinical trials involve up to several hundred patients and are aimed at establishing 'Proof of Concept' for the medicinal candidate. In other words, these trials evaluate a product's efficacy and assess its side effects ('adverse events'). Approximately 33% of the Phase 2 candidates pass onto **Phase 3** of clinical development,[1] the purpose of which is to gather evidence on efficacy and side effects to an even greater extent. Ultimately, these trials aim to investigate whether the novel treatment offers an added benefit to the patient and the health care system compared to existing approaches. Phase 3 trials typically include 300-3000 patient subjects and take several years to complete. Approximately 60% of Phase 3 candidate products move on to the stage in which the gathered evidence is formally reviewed by the applicable market regulator, such as the **US Food and Drug Administration (FDA)** or the **European Medicines Agency (EMA)**. To this end, a 'registration dossier' is submitted that ought to contain all gathered data on quality, safety, and efficacy of the candidate product for its intended use. After deliberate evaluation, approximately 83% of the submissions are authorized for market introduction.[1] To conclude, **Phase 4** clinical trials may be conducted after a novel treatment has been approved. These post-marketing surveillance studies monitor long-term effects in the patient population at large.



1.1.3. Clinical trial stakeholders

A clinical trial is initiated by a **sponsor**: typically a pharmaceutical company or an academic institution that aims to evaluate the safety and efficacy of a new or improved medicinal product. Before starting a trial, the sponsor often conducts a vendor selection process to outsource some or all of its tasks and duties to one or more specialized service providers; **contract research organizations (CROs)**. CROs can be contracted for data monitoring, manufacturing of the investigational drug, regulatory affairs, or overall trial management. The trial can then be initiated, but only after formal approval from **regulators** in the form of an independent **ethics committee** and the national **competent authority** in the country where the trial takes place (multiple committees and authorities in the case of multi-country trials). After approval, the bulk of trial activities take place at research **sites**, which are hospitals or dedicated clinical research centers. These sites are typically responsible for recruiting **patients** or healthy volunteers, who after enrollment visit these sites to receive the treatment over the course of the trial. Throughout a trial, sponsors, CROs, sites, patients, and regulators need to interact and collaborate in a broad range of trial-related activities, such as study approval, site monitoring, data management, safety reporting, regulatory filing, medical writing, and research dissemination.

1.1.4. Clinical trial data volume

Clinical trials are becoming increasingly data intensive. To indicate, a typical Phase 3 trial now collects over 1 million data points. This is roughly double the amount observed 10 years ago and this trend is likely to increase. Whereas simple paper and electronic forms used to be the only sources of clinical data in the past, the emergence of electronic health records, wearables, and other smart mobile devices is spurring the number of data inputs in a trial.[2] To safeguard the safety and quality of medicinal products, strict guidelines and regulations stipulate that all data events are documented meticulously.

1.1.5. Guidelines and regulations

The evaluation of candidate medicinal products in human subjects has become highly regulated as a consequence of catastrophic events in the past, such as the performance of involuntary medical experiments during World War II or the 'thalidomide tragedy' of the late 1950s. In 1964, the **Declaration of Helsinki** was established by the World Medical Association, defining a set of ethical principles to protect the rights of human subjects involved in medical research. Today, clinical trials ought to comply with **Good Clinical Practice (GCP)**, an international ethical and scientific quality standard for designing, conducting, recording and reporting trials that involve the participation of human subjects. GCP compliance provides public assurance that the rights, safety, and well-being of trial subjects are protected and that the collected data are credible.[3] GCP standards have been translated into regulations in the European Union through the EU **Clinical Trials Directive** (soon the **Clinical Trial Regulation**), and in the United States through FDA regulations.

1.1.6. eClinical solutions

Today, a plethora of clinical information technology (IT) applications are offered to smoothen and optimize the management and conduct of clinical trials. These are referred to as **eClinical solutions** and aim to replace the manual, *ad hoc* and paper-driven procedures of clinical trial operations. Clinical trial professionals use on average six different eClinical solutions side by side[2].

The following major functional categories can be distinguished:

Electronic Trial Master File (eTMF)

solutions to store and manage essential trial-related documents.

Clinical Trial Management Systems (CTMS)

for monitoring trial progress and performance.

Electronic Data Capture (EDC)

solutions to record clinical data from trial participants.

Randomization & Trial Supply Management (RTSM)

solutions for double-blind randomization of participants, and supply of investigational products or placebos accordingly.

1.1.7. Clinical trial market figures

$233 billion will be spend on pharmaceutical research in 2026, coming from $186B in 2019. Majority of this budget is allocated to clinical trials. [6]

The global CRO market is projected to surpass 91B by 2026, coming from 38,4B in 2018, as R&D outsourcing to contract research organizations continues to increase. [7]

Rapid digitalization spurs double-digit market growth for eClinical software (valued $12B by 2025). High upside projected for those who can underpin this new digital playing field. Our solutions are designed to do so. [8]

Over 30.000 new clinical trials are initiated each year. Roughly 70% take place in the US and Europe, where we have a strong footprint. [4]

The average cost of a Phase 3 clinical trial falls between $11,5 and $52,9 million. [9]

Triall's solutions target major cost drivers [9] of clinical trials.

1.2. Current issues in clinical trials

A steady and efficient influx of medical solutions is critical to ensure that society's (re)emerging medical needs are effectively met. Despite today's advancements in science and technology, drug development speed, costs, and success rates have not improved over the years and in some instances operating conditions have gotten worse. Ongoing research shows that the cost of drug development continues to rise with an average of 9% each year.[10] Moreover, development cycle times have become longer and less predictable, indicated by the increasing incidence of project changes and delays. This has resulted in a situation where success rates for new candidate medicinal products entering clinical development are at an all-time low, with only 11% ultimately making it to the market.[10] Key identified issues are summarized over the following sections.

1 FRAGMENTATION

Clinical trials involve many different specialty stakeholders, often spanning organizational and national boundaries. To illustrate, a typical 'Phase 3' clinical trial comprises over 50 research sites across more than 15 countries. Clinical trial stakeholders operate in relative isolation, each applying their own software systems, data formats, workflows, and organizational structures. Furthermore, these stakeholders are reluctant to share data and documents in fear of security and privacy breaches.

In the past decade, numerous eClinical solutions (clinical trial software applications) have emerged, aiming to smoothen trial operations. Ironically, the majority of these function-specific solutions are unable to communicate with each other, and indeed, a recent industry-wide survey concluded that the majority of clinical researchers experience issues with keeping track of the status of documents and processes in their clinical operations.[11]

2 LACK OF OVERSIGHT

Though all-encompassing eClinical platforms exist, these are typically accessible only to a small number of large, wealthy pharmaceutical developers ("Big Pharma") because these are prohibitively expensive, often operate on legacy infrastructure, and offer limited options for external integration. As roughly 65% of trials are performed by academia, hospitals, and smaller industry stakeholders with limited resources,[12] it follows that the vast majority of clinical researchers are hampered by a lack of oversight, and significant time and resources are wasted. Moreover, lack of oversight is also a burden for regulators, who experience difficulty in auditing research data as there is no easy and secure way of viewing the complex network of data exchange, no real-time access to results as they are being produced, and no easy way to trace data back to its original source.[13,14] Therefore, the FDA has listed lack of traceability as one of the top data issues in clinical trials.[15]

3 RECORDKEEPING FAILURE

All stakeholders involved in clinical trials are required to maintain and store 'essential' documents in compliance with GCP guidelines and applicable regulations. These essential documents may be audited and inspected by monitors and regulatory authorities at any time to confirm the validity of the trial and the integrity of the collected clinical data. To support the correct and effective management of all of these filing responsibilities, GCP requires essential documents to be collected in a Trial Master File (TMF), today an electronic variant, the 'eTMF'. The essential documents contained within the eTMF should enable regulatory authorities to reconstruct trial activities and key decisions made, providing conclusive evidence that a medicinal product candidate is safe and effective, and qualifies for market introduction. The organization and maintenance of the eTMF can be difficult, especially in multi-country trials that involve many research sites. Consequently, failure in adequate recordkeeping is a persisting industry pain point, leading to fines, trial delays, longer development timelines, and higher development costs. Ultimately, this drives up the cost of new medicines, and even translates into safety risks for patients and consumers.

4 DATA INTEGRITY ISSUES

The aforementioned issues are at the source of a growing number of data integrity issues being detected during clinical trial inspections, as reported by regulators globally. Moreover, fabricated or concealed clinical research data continues to be a concern.[17,18] Over recent years, marketed drugs have been recalled for lacking safety or efficacy on several occasions, underlining that inadequate recordkeeping can put trial subjects and health care consumers at risk. Whereas the industry was once held in high regard for its pivotal role in the advancement of human health, these cases of error or misconduct are reducing trust in the clinical trial industry among patients, consumers and regulators.

Trust issues have led to even more stringent regulatory requirements, adding to the burden of documentation for clinical trial professionals.

5 REITERATIONS

Data integrity issues lead to costly reiteration of research activities.[16] To illustrate, while academia and smaller industry typically perform the early stages of clinical trials (Phase 1 and 2), Big Pharma's involvement is essential for completing the later stages and bringing a candidate treatment to market. Taking over projects from smaller stakeholders, Big Pharma are typically seen to reiterate research activities to compensate for documentation inadequacies in upstream trial phases. This results in an enormous amount of unnecessary costs, and ultimately delays time to market and drives up the price of the medicinal product under investigation.

6 LOW PATIENT ENGAGEMENT

Safeguarding patient engagement throughout the full length of a clinical trial (ranging from several months to multiple years) is considered another major industry challenge. With an average drop-out rate of 30%, around 85% of all clinical trials fail to retain enough patients, often resulting in costly delays.[19] Moreover, issues related to patient retention can have a significant negative impact on the outcome of a clinical trial, and thereby add to the already considerable risks in today's clinical development process.

> Triall's solutions are specifically designed to tackle these persisting issues, and thereby aim to advance clinical development towards meeting unmet medical needs.

See Chapter 3

1.3. How blockchain technology can address issues in clinical trials

What is a blockchain?

Blockchain technology involves a distributed network of computer servers ('nodes'), each maintaining an identical copy of the same database ('ledger'). A blockchain ledger enables indisputable verification and authentication of data. Data entries are processed into hash codes*, authenticated with a digital signature, and organized into blocks. New blocks are only timestamped in the ledger if the network has reached consensus on the validity and authenticity of its data contents, applying a predefined and network-specific consensus protocol. As newer blocks include a cryptographic reference to their consensually verified predecessors, the ledger evolves as a chain—the blockchain. Once timestamped, entries cannot be altered or removed without being noticed, making the blockchain tamper-proof by design.

* A hash code is a unique cryptographic identifier for a certain dataset. If entries in a dataset are altered in any way, the code will have a different output. Hashing is a one-way function, meaning there is no way to 'reverse engineer' the dataset from a hash code (contrary to encryption, which can be reversed). Identical datasets will produce identical hash codes.

1.3.1. Data integrity, traceability and auditability—Assuring reliable clinical trial evidence

In accordance with GCP standards,[3] the many stakeholders involved in a clinical trial are required to store trial-related documents and keep a record of document changes. These may be subject to inspections by sponsor representatives (independent monitors) and regulatory authorities at any point during a trial to verify the quality and integrity of trial operations. Ultimately, the clinical trial documents combined should provide regulators with conclusive evidence that the investigational product is safe and effective and qualifies for market introduction.

A blockchain ledger can function as an immutable and cryptographically secured reference log, against which trial-related documents or other data objects can be compared whilst remaining safely stored in their original, secure (private) repositories. If hash codes match those previously recorded and timestamped into the blockchain, this indisputably proves that documents have remained the same, whereas deviating hash codes prove document alterations.

Since the significance of clinical trial data becomes clear only after all data is collected (at which point the data is 'de-blinded', showing how the investigational product and the placebo product were distributed over the research subjects), malicious actors wanting to beautify or otherwise manipulate the data to better meet their stakes would find it near impossible to do so. In other words, blockchain technology becomes a tool to assure data integrity and clinical trial reliability over entire clinical development timelines.

Once registered in the ledger, entries cannot be altered without notice, establishing an immutable audit trail of documents or other data entries and their evolution throughout the timeline of clinical development. This functionality can revolutionize clinical trial data management by enhancing the traceability, auditability, and quality of clinical trial data and recordkeeping. It also fits perfectly within clinical research guidelines and regulations, which emphasize the importance of version control and state that previous entries are not allowed to be obscured under any circumstance.[3] Moreover, it offers to strengthen the value proposition of especially smaller industry players, who can now indisputably and without additional effort prove to potential partners, acquirers, or other stakeholders when and under which conditions their clinical trial data has been recorded.

1.3.2. Cryptographic access control—Integrating applications and devices in complete confidentiality

As stipulated in FDA 21 CFR part 11 regulations, access to clinical data must be restricted to authorized individuals in all clinical studies.[20] A tamper-resistant and regulatory compliant infrastructure for digital identity and access management is required for secure, trustworthy, and therefore efficient digital interactions between clinical trial stakeholders. This can be realized using **Decentralized Identifiers (DIDs)**, which are a new type of identifier for decentralized, digital identity management.

DIDs can be assigned to any type of object or entity and revolutionize the means by which organizations exchange and govern data. A DID-enabled access control manager enables peer-to-peer communication in complete confidentiality. Working with DIDs, a provider of an eClinical solution or any other data providing stakeholder (e.g., patients participating through a mobile app) could selectively choose which data points they are willing to share with other entities within a network, while also choosing how this data can be accessed (service discovery). In this scenario, all data is stored behind service endpoints that are under the control of the DID subject (e.g., an eClinical provider), where DIDs can facilitate a privacy architecture in which data may be exchanged on a private, peer-to-peer basis using communication channels identified and secured by the public key descriptions associated with the DIDs. Such a system aligns perfectly with the 'right to be forgotten' as prescribed in the GDPR, since no personal data is stored on a blockchain ledger. Authorization permissions can be defined in smart contracts and restricted to specific public keys, amendable by the sharing party, and viewable to both the sharing and receiving party. This approach excludes the need for a centralized repository shared between the data-providing and -receiving parties, and enables a situation where authorization permissions can be defined in smart contracts and restricted to specific DIDs. It allows for near real-time and specific

integration of different eClinical solutions and realizes a situation in which function-specific and previously isolated eClinical solutions may start to act in concert.

1.3.3. Smart contract automation—Governing data exchange and protocol compliance

Smart contracts open a way for new forms of automation, with the blockchain functioning as an underlying, coordinating layer that governs data exchange between different off-chain repositories. For clinical trials, smart contracts can be used to govern data transactions within a clinical trial consortium, implementing and enforcing the rules set out in the clinical trial agreement and protocol as well as those in individual contracts and standard operating procedures (SOPs). Smart contracts can function as a valuable tool in enforcing protocol compliance and at the same time can track key events in near real-time, thereby preventing that protocol deviations or violations remain undetected until long after they have occurred or remain undetected forever. These contracts help enforce procedural rules and agreements in key activities such as collecting informed consent, enrolling patients, and reporting safety events. They can determine what data is required at each point in the chain, and can help ensure that data entries are complete, immutable, and viewable only to those with the right permissions. Moreover, in the case of protocol amendments, smart contracts can help enforce the updated set of rules of the new protocol version. In doing so, they automate part of the trial monitoring responsibilities, often an accountability of the involved CRO, detecting and registering any occurring protocol violation over the course of the clinical trial, and may thus decrease the costs associated with conducting clinical trials. Collecting and reporting these violations in a timely manner is essential for a correct interpretation of the trial's results. This process will also create a transparent, traceable, and immutable event log for regulatory authorities.

1.3.4. Smart contract automation—Streamlined and trustless collaboration between clinical trial stakeholders

Lacking effective tools to monitor and insist on payments, many stakeholders involved in clinical trials face payment delays and uncertainties. For smaller clinical trial sites with often only a couple of months of operating cash on hand, this represents a major pain point. Payment uncertainty is even recorded as one of the key reasons for sites and their employees dropping out of a clinical trial consortium. Delays can also be particularly burdensome to patients who are left unsure when they will be reimbursed for participating in the clinical trial. As the industry is currently struggling to retain patients throughout the full length of a trial (the average drop-out rate is 30%)[19], certainty and timeliness of payments can be a significant step towards improving patient engagement.

When integrating blockchain with an online payment solution, smart contracts can enable automated payments between sponsors, CROs, sites, and patients based on specific trial milestones (e.g., first patient recruited, last patient visit, etc.) and the collection of data sets as soon as this information is logged on the blockchain. In this regard, smart contract-enabled automated payments can be applied for reducing manual labor, limiting the role of a third-party middleman and further streamlining clinical operations. Moreover, this approach facilitates trust between trial stakeholders, knowing payments will automatically arrive according to the agreed terms and timeline.

2. The Triall Ecosystem

2.1. The first global digital ecosystem for clinical trials

Triall is building the world's first, blockchain-enabled clinical trial ecosystem, serving and connecting clinical research professionals across traditional organizational boundaries and domains. Our mission is to enable a future of smarter, safer, and more-efficient clinical trials, where workflows are integrated, and research data integrity is assured. Our overarching and holistic approach is therefore focused on consolidating the unconnected and authenticating clinical research data globally. We believe we can distinguish ourselves by fully committing to a governance structure, strategy and roadmap that each support our core mission.

> We believe state-of-the-art Information Technology and scientific insights make a difference. Our passion lies in advancing clinical development, consolidating the unconnected, and fostering a global ecosystem that promotes trust and reliability throughout all phases of clinical development.
>
> **Hadil Es-Sbai, CEO Triall**

2.2. A multi-sided platform

The Triall Ecosystem is designed to serve the needs of all stakeholders involved in clinical trials, and has a variety of interrelated network participants. We've grouped them into the following stakeholder types:

1 RESEARCHERS

All stakeholders involved in the conduct of clinical trials, including sponsor representatives, CRO staff (e.g., project managers, clinical research associates, monitors, and data managers), site staff (e.g., investigators, research nurses, and pharmacists) and other parties that want to make use of the applications offered in the Triall Ecosystem.

2 PATIENTS

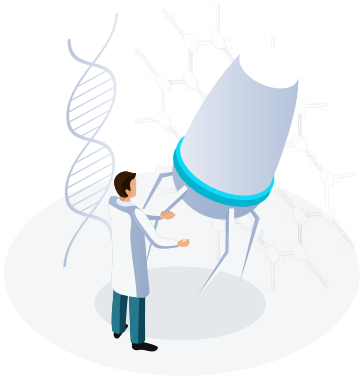
These are the research subjects (either patients or healthy volunteers) that participate in clinical trials. They can be connected to the Triall Ecosystem through our patient-level eHealth applications that aim to actively inform, recruit, engage, and empower this key stakeholder group throughout clinical trial lifecycles.

3 PROVIDERS

The organizations that provide software solutions for clinical trial operations and data management. By connecting to the Triall Ecosystem, they can leverage blockchain-enabled data logging and authentication functionalities and other microservices, and they can offer their solutions within our multi-sided digital marketplace.

4 CONTRIBUTORS

Organizations and individuals who provide technical services for the ecosystem and its community. They write, run, and audit smart contracts or provide specifications, applications, or APIs for systems and their users. These smart contracts, APIs, and applications provide additional functionalities for other stakeholders.



6 MAINTAINERS

These are the organizations or individuals responsible for providing the underlying infrastructure on which the Triall Ecosystem operates, such as node operators and (cloud) storage providers. Factom's independent Authority Node Operators* for instance ensure network integrity by verifying data blocks and writing to a blockchain ledger. They provide strength, speed, and security to the network by adhering to a shared governance system, being fully decentralized and running full nodes with strict hardware requirements.

5 TRIALL FOUNDATION

The Triall Foundation is the non-profit organization governing the ecosystem, empowered by the Triall Community. The foundation is a public service provider that acts on behalf of the community, and is responsible for the daily operations, management, development, and maintenance of the Triall Ecosystem. **

7 TRIALL COMMUNITY

The Triall Community comprises all organizations and individuals that want to support the growth and development of the Triall Ecosystem, for instance, by participating in decision-making, panels, discussions, development, or outreaches. Community members can be part of the stakeholder groups mentioned above, but any party or individual with a genuine interest in the ecosystem is welcomed.

* By default, Triall applications are connected with various blockchains including the blockchain infrastructure of the Factom Protocol (Chapter 4 addresses Triall's digital infrastructure and our reasons for choosing the Factom Protocol for use in Verial eTMF). Triall applications can be regarded as **blockchain agnostic**, since they are designed to easily integrate with other blockchain platforms.

** Chapter 5 addresses Triall's governance model.

2.3. Competitive landscape

The market for eClinical solutions is growing rapidly (13,8% CAGR) due to the increased digitalization, decentralization, and globalization of the clinical trial industry. This growth is likely to be even higher due to the effects of the COVID-19 pandemic, which has forced many stakeholders to work remotely and digitize key trial procedures. According to recent estimates, companies involved in clinical trials use on average six different eClinical solutions side by side.[2] Though many clinical researchers still apply local file systems, general-purpose solutions (e.g., SharePoint), or even paper files (hard-copies) to meet their recordkeeping duties, purpose-built software applications are becoming increasingly vital to the industry. Currently, the market for purpose-built eClinical solutions is highly fragmented with many small vendors at the bottom—who offer function-specific and often siloed eClinical solutions— and a handful of large vendors at the top—who offer all-encompassing eClinical platforms that comprise a range of different solutions for streamlined data management and recordkeeping. These large vendors mainly serve the largest of corporations ('Big Pharma') due to being too expensive for smaller to medium-sized (SME) stakeholders. Moreover, these vendors offer closed-system platforms that are often built on legacy infrastructure and relatively limited in modularity and interoperability. Nonetheless, virtually all users of current solutions indicated experiencing issues with keeping track of their documents and data in their clinical operations.[11]

2.3.1. Competitive advantage

Triall significantly improves on the market's state of the art. Primarily, we are a first mover in applying blockchain technology to the clinical trial domain, as demonstrated by the deployment and use of Triall's Verial eTMF (see section 3.1), which was credited as the world's first implementation of blockchain in a live and running clinical trial. Since the prime objective for this domain is to

establish a sound, reliable, and auditable evidence base that proves the safety and efficacy of candidate medicinal solutions, blockchain technology provides ample opportunities. Triall is a first-of-its-kind initiative, bringing blockchain-enabled data verification utilities to clinical trial data management and recordkeeping. Second, our complementary APIs promise to offer the plethora of existing eClinical solutions an easy entry to blockchain functionalities and other microservices within our infrastructure. This approach allows us to connect, rather than compete with existing solutions, ultimately turning competitors into collaborators. This represents a radical, yet much-called for 'ecosystem approach' in the clinical trial industry, given the severely fragmented landscape of stakeholders and eClinical solutions. Moreover, in due time, this approach of connecting eClinical solutions with our open specifications and modular blockchain microservices using APIs allows us to introduce the advantages of an all-encompassing, modular, and interoperable platform to the common clinical researcher, while continuing to tailor to diverse user types, budgets, needs, and need-nots.

Triall is a venture-backed B2B software startup that has built and commercialized a blockchain-integrated clinical trial document management solution (Verial eTMF) over the past years. This solution is currently in production and being used in multiple commercial projects, with more to follow.

Triall distinguishes itself by its experienced and entrepreneurial team, comprising a group of clinical operations experts, enterprise IT specialists, and blockchain engineers, which together have managed 100+ trials and founded 20+ ventures in Life Sciences and B2B software. Our experience has left us with deep roots in the clinical trial industry and strong ties to blockchain and IT standards groups (W3C, DIF, IEEE), providing us with the insights and network to continue operating at the forefront of industry developments.

Furthermore, Triall's team is supported by an international value network of 10+ partner organizations, including VC firm Dizer Capital and industry-leading blockchain development agency Applicature, as well as a global advisory board consisting of 13 industry experts and Key Opinion Leaders. Lastly, exemplifying the thought leadership of our team and partners, academic work on the promises and challenges of blockchain and related technologies by Triall team members and academic partners was recently published in renowned scientific journal *Science*.

2.3.2. Turning competitors into collaborators

Triall aims to foster the use blockchain technology in the Life Sciences industry and will therefore assist other companies, that already have an established range of software solutions, in connecting to the Triall Ecosystem and blockchain platforms such the Factom Protocol and Ethereum. We expect to attract eClinical providers and other innovators to the ecosystem by:

1. Providing them with the **tools, specifications, knowledge, and APIs** that make it easy to implement blockchain-enabled data integrity and auditability functionalities into their product offerings.

2. Helping them to '**jump the innovation curve**' in clinical development and be on the forefront of using technologies like blockchain and AI/Deep Learning-enabled automation.

3. Offering them an **easy and secure way of integrating** with other eClinical providers via the ecosystem.

4. Offering them additional **opportunities to generate new business** through our ecosystem, for instance through our Partner Selection & Management Platform (see next chapter).

3. Applications

This chapter describes the first range of core applications that will be offered inside the Triall Ecosystem. These applications specifically target issues and bottlenecks faced by the clinical research industry and will be developed in collaboration with a consortium of expert partners that each bring their own unique know-how and capabilities. Since development is an ongoing and iterative process, and as Triall also aims to foster and facilitate innovation originating from external parties, additional applications and functionalities may arise as the ecosystem grows in adoption and usage.

Verial eTMF

Clinical document management solution with blockchain proofs of data integrity and authenticity.

Verial APIs

Microservices for third-party eClinical solutions, enabling them to integrate data integrity functionalities in their own product offerings.

Triall CTMS

Clinical trial management dashboard, reading metrics from blockchain API-connected eClinical solutions.

Triall Connect APIs

Microservices for third-party eClinical solutions, enabling to communicate with other systems in the Triall ecosystem through decentralized identity and access management.

Atena PRM

Multi-sided partnering directory, vendor selection and management platform with blockchain proofs of fair tender and bidding procedures.

Trialwiki

Public clinical trial knowledge vault, offering and overview of the latest regulations and SOPs, providing document templates, and sharing insights from experts and the clinical trial community.

3.1. Verial eTMF: blockchain-enabled electronic Trial Master File solution

Failure in adequate recordkeeping is a persisting industry pain point, leading to costly reiterations and significant trial delays. Triall has built a blockchain-enabled document management solution, specifically designed for the generation and management of the eTMF: the compulsory collection of documents that allows for the reconstruction and inspection of clinical trial operations, and their compliance with international rules, regulations, and quality guidelines. Verial eTMF is the ecosystem's first application and demonstrates its proof of concept by enabling clinical trial professionals to establish verifiable proof of the integrity of their clinical data and documents. The first version of Verial eTMF has been used in live and running clinical trials and is therefore the world's first application to implement blockchain technology in clinical research. Currently, Verial eTMF v1.0 is used in multiple commercial clinical trial projects, and more paying customers are in line to be onboarded. We are extending the application's value for proposition by implementing automatic document conversion, authentication, and

translocation functionalities, as well as mobile, on-the-go document scanning and automated filing. Using tested and validated user interface (UI) components and services, Verial eTMF application is designed to be easy to use for both experienced and first-time clinical research professionals. Finally, to streamline document management even more, Triall will provide free and standardized templates of essential trial related documents.

3.1.1. Proof of existence and authenticity

Verial eTMF enables users to create verifiable proof of the existence, integrity and authenticity of any trial-related document by creating a signed hash of the document, which is subsequently submitted to the Factom servers (or any blockchain of choice). As such, the blockchain represents an immutable and cryptographically secured reference database against which documents, and data can be compared. In this design, privacy and confidentially issues are mitigated, as only a hash of the documents is stored on-chain while the documents themselves remain within a private cloud environment. Ultimately, this functionality provides an immutable audit trail of essential documents and changes over the entire timeline of clinical development (often spanning up to 10 years) and guarantees that documents have not been tampered with after registration. We will release an accompanying **Verial API** library to offer specific blockchain functionalities to third-party eClinical solution providers, enabling them to integrate with our blockchain-based infrastructure.

3.1.2. Data recognition functionalities

Verial eTMF will be able to extract data from paper and digital documents using Optical Character Recognition (OCR), barcode, QR-code, and handwritten data recognition (ICR). These functionalities enable the application to recognize and classify documents as soon as they get scanned or when a picture is taken using the mobile version.

3.1.3. Automatic classification through AI

Applying Deep Learning techniques, Verial eTMF can teach itself to recognize and classify trial-related documents that are uploaded after which they are automatically structured, named, and stored in the corresponding folder. This utility promises a breakthrough in the way clinical research professionals conduct their day-to-day clinical operations by optimizing workflows and reducing manual workload significantly.

3.1.4. DID-signing functionality

Finally, Verial eTMF allows users to assign a DID to any document stored in its repository. Multiple business rules can be associated to this DID, such as the possibility to sign a document in parallel using the DID-enabled digital signatures of different users (e.g., investigators, research nurses). This on-chain signature feature can be used to sign any type of file (instead of being limited to PDFs) and does not require expensive Hardware Security Modules (HSM) or an external Certificate Authority.

3.2. Triall CTMS: blockchain-enabled Clinical Trial Management System

The clinical research industry is increasingly expressing the need for unifying the plethora of function-specific eClinical solutions currently offered on the market. This need is driven by a demand for better visibility, more proactive risk mitigation, and better study analytics and reporting. Triall will address growing market needs by offering tailor-made APIs (see 'Triall Connect API' on the previous page) that make it possible for existing and upcoming eClinical solutions to communicate with each other in a secure and effective manner. To reap the benefits of this integration, Triall will offer a dashboard application, Triall CTMS, that integrates and visualizes the data being recorded by different eClinical solutions, providing clinical research professionals with a near real-time and traceable overview of all their clinical trial activities.

Ultimately, the dashboard provides superior planning tools and oversight, helping clinical research professionals in making faster and better-informed decisions (e.g., early Go/No-go) regarding trial management, risk-based

monitoring, and resource allocation. The following section will provide examples of the core functionalities of this application.

3.2.1. Traceable log of study metrics and KPIs

Triall CTMS offers a dashboard overview of trial progress and activities. Uniquely, it also reads and integrates data points from connected eClinical solutions, such as Verial eTMF, other Triall solutions, or API-connected third-party solutions. Recording and storing data from multiple systems in one place will lead to higher quality data that provides a more clear and complete overview of the trial's progression and performance. In this regard, Triall CTMS will provide a birds-eye view of the data being recorded and shared between Triall applications and external eClinical solutions (if these provide the appropriate access permissions).

Applying AI and predetermined risk indicators, Triall CTMS can quickly detect arising issues. This feature helps clinical research professionals to take timely and appropriate action to safeguard the credibility and conduct of the trial. For example, by visualizing data from multiple research sites, the responsible CRO can identify low-performing or deviating sites, and subsequently send monitors to visit these 'higher-risk' sites and to uncover the issues at hand. This functionality aligns with risk-based monitoring principles and ultimately promises to optimize resource allocation and shorten clinical trial timelines.

3.2.2. Safety management powered by AI

As the amount of data grows, our AI functionality will increasingly be able to help clinical research professionals respond to issues *before* they occur. This functionality is particularly significant for safety management (i.e., tracking and recording possible drug-related adverse events), where patient health or well-

being can be at risk. Furthermore, it again supports a risk-based monitoring approach that facilitates efficient use of time and resources. As more eClinical solutions are connected and as the amount of data grows, Triall CTMS will become a tool that not only promotes operational oversight and management, but also helps lead to novel insights regarding clinical trial procedures and activities.

3.2.3. eTMF tracker for document oversight

As Triall CTMS is also connected to Verial eTMF, the dashboard will give a near real-time overview of the progression of the eTMF's document repository. This allows sponsors and clinical operation leaders to visualize which documents have been logged and whether essential trial-related documents are lacking or incomplete. Again, this feature will support researchers in taking timely and appropriate action and ensure a constant state of inspection readiness.

3.2.4. Contract and budget management powered by smart contract-enabled automation

Integrating Triall's blockchain infrastructure with online payment solutions will enable automated payment functionalities, in which payments can be triggered by contractual terms and study milestones as soon as these are registered on the blockchain. Such payment automation can ease and streamline the various payment processes between Sponsors, CROs, Sites, and patients. It promises to reduce a great amount of the current manual administrative work and supports clinical trial stakeholders in tracking and managing their payments. Furthermore, it helps to promote trust between trial stakeholders, who will now be assured of their payments arriving according to pre-agreed terms and timepoints.

3.2.5. Delegation and training management powered by DIDs

Another section of the dashboard is a training and delegation manager, which provides sponsors and operational managers with an overview of all staff per research site, including their credentials and received training. In this application, training documents, new protocol versions, and other relevant documents can easily be shared with staff members, who are assigned a personal DID-enabled user account (a **Triall ID**). After training, staff members can confirm they have read the document (or received the training) using the signature associated to their Triall ID. Training activities and hashes of the related training documents are automatically logged on the blockchain and expiration dates for training documents and certificates will automatically trigger queries send out to those required to re-train.

Next to providing an overview of the credentials and training history of all the staff involved in the trial, study tasks and activities can also be linked to each of the staff member's personal user accounts. In this way, investigators can easily delegate their tasks to their study team, while also being able to update or change delegation after changes occur (like staff turnover). Currently, this procedure is often still done using a paper form, called the 'Authorization log', on which site staff members write their task, name, and signature. This method is very inconvenient and can, depending on the length of the trial, get very messy and difficult to comprehend. Triall's training and delegation environment addresses this burden by allowing individuals to authenticate themselves using their Triall ID, promoting accountability and responsibility on a single-person level.

3.2.6. Drug accountability and reconciliation

Guidelines and regulations require accountability of the investigational medicinal product to be demonstrated, by having full traceability of the product from initial release, ordering, allocation, dispensation, and intake, to return, reconciliation, and (where needed) destruction. Inadequate accountability in any of these areas can put subject safety and the reliability of trial results at risk.

Currently, a variety of blockchain projects are building NFC and/or RFID chips connected to the blockchain, able to measure temperature and humidity of pharmaceutical and food products throughout production and shipment processes. Such supply chain solutions for pharma and food are revolutionary but tend to stop at the door of the pharmacist. Triall is looking to collaborate with these initiatives to extent their scope into the clinical research space, thereby guaranteeing the quality of the product under investigation in a clinical trial, and thus improving the quality of the trial and the safety of research subjects.

3.3. Atena PRM: partner selection & management platform

In today's clinical trials, complexity and globalization require clinical trial stakeholders to partner ups. For instance, sponsors outsource a substantial part of their trial activities and duties to regional, specialized service providers. Partner selection can have a profound impact on the quality and efficiency of clinical trial operations. However, an inclusive and objective overview of regional service providers is lacking, hampering partner identification and selection processes. Having such an overview would increase the simplicity and inclusivity of clinical trial partnering, thereby stimulating healthy competition, clinical trial quality and efficiency. Triall will offer a one-of-a-kind partnering solution that assists clinical trial professionals in finding the right funding partner, CRO, consultant, and eClinical provider to support their trial activities. In the Atena partnership relationship management (PRM) platform, established and upcoming vendors are lined up to serve both experienced and first-time clinical trial professionals. The platform offers a range of functionalities that streamline and standardize communication and contracting for both outsourcer and vendor.

3.3.1. Study info and proposal templates

Triall's partnering platform provides harmonized templates for the purpose of exchanging study info, proposals, and company evaluation forms. These templates provide vendors with a comprehensive overview of the clinical trial's requirements and allow outsourcers to make an honest and equitable comparison between the proposals they receive.

3.3.2. Keeping track of your proposals

Furthermore, the platform enables service providers to keep track of their proposals by keeping them informed about any status updates, invites, and contracting details on a single or multi-trial level. This reduces the need for an, often expensive, customer relationship management (CRM) system and allows service providers to concentrate their business development activities.

3.3.3. Proof of a fair bidding/tender process

Finally, our partnering platform will provide the option to log the information exchanged in the bidding process on the blockchain. This provides indisputable proof of a fair and reasonable vendor selection procedure, demonstrating 'best value for money', which is often a requirement for publicly funded research. Subsequently, the platform provides sponsors with an automatically generated report of the selection procedure that can be shared with the grant provider or public funder.

3.4. Trialwiki

Trialwiki is Triall's public knowledge vault consisting of document and budget templates, SOPs, and other relevant clinical trial knowledge and insights. Furthermore, it will contain white papers, presentations, webinars from both the Triall team and other community members. It offers clinical trial professionals around the world a source for improved efficiency and operational excellence.

3.5. eHealth solutions

3.5.1. Patient recruitment & retention application

Patient recruitment is considered a challenging component of clinical trials. Failure to recruit patients may significantly delay the trial's timeline and can lead to tremendous costs. After recruitment, another major hurdle is retaining the patient throughout the entire study.

As part of our first 'patient engagement' incubator program, TriaII will develop a patient recruitment & retention application, together with its partners Link2Trials and Nyenrode Business University. This application will incorporate a novel methodology developed by Prof. Sjaak Bloem known as the Subjective Experienced Health Methodology (SEHM).[22] SEHM is a patient-centric approach that promotes communication and interaction with research subjects by focusing on their individual wants and needs. Insights on the subjective health experience of patients can help to predict and control their health-related behaviors and can therefore help to stimulate both recruitment and retention rates. To this end, SEHM will be incorporated in a unique patient recruitment and retention application, offered exclusively in the TriaII Ecosystem.

3.5.2. Patient treatment adherence application

Today, treatment adherence is primarily assessed by reviewing patient diaries or by asking research subjects whether they took the prescribed medication at the agreed timepoints. Digital technologies can be used to improve patient care and promote treatment adherence throughout the entire length of a clinical trial.

Triall will be developing a mobile application together with its partner NeLL (National eHealth Living Lab) as part of its incubator program. This mobile app will send automated notifications to research subjects reminding them to take their medication and provides trial-specific instructions on dosing and administration. In addition, the app will be able to answer questions and can help research subjects to schedule their site visits. All these features aim to make participating in a clinical trial more convenient for the patient, thereby improving treatment adherence and reducing drop-out rates.

3.6. Future applications

As the Triall Ecosystem grows, more applications will be developed, and follow-on incubator programs will be initiated. Advancing clinical development and meeting unmet medical needs will always be a primary focus in this process.

4. Infrastructure

4.1. A blockchain-agnostic infrastructure

Triall builds on top of existing blockchain infrastructures. Opting for established blockchain platforms provides Triall with network strength and security right from the start and allows us to fully focus on the development and commercialization of applications for clinical research professionals and the onboarding of key stakeholders. Triall applications can be regarded as '**blockchain agnostic**': our applications can be integrated with any blockchain of choice or combinations of multiple blockchains. By default, our current APIs are integrated with the **Factom Protocol** (see section 4.1.1), **Bitcoin**, **Ethereum**, and several other well-established blockchains. On request of clients or community members, other blockchain platforms may be utilized as well. The Factom Protocol provides an enterprise-grade blockchain infrastructure that is optimized for data logging. Due to its unique efficiency and cost-predictability, Factom has been our preferred blockchain platform of choice. Therefore, at the time of writing, all clinical trials that onboarded Verial eTMF have used the Factom Protocol as a data logging and authentication layer.

4.1.1. Factom

The Factom Protocol[21] is an open-source data integrity protocol that is fully optimized for enterprise adoption and has a track-record of industrial and governmental applications (e.g., Bill & Melinda Gates Foundation, US Department of Homeland Security). The protocol (initiated in 2014) is designed to tackle some of the core constraints found in blockchains like Bitcoin and Ethereum. It provides high-throughput and secure data entries at a low fixed cost, unrelated to the volatile cryptocurrency market. Factom knows a two-token system consisting of **Factoids (FCT)** and **Entry Credits (EC)**. FCT can be

traded externally like regular cryptocurrencies, while EC is used to pay for data entries to the blockchain and is non-transferable. Users can burn FCT to create EC with a conversion rate fixed at $ 0,001 and can therefore easily predict the cost of using Factom for their applications, thereby stimulating business use and adoption. Furthermore, Factom has an efficient way of organizing data, which greatly reduces the time and costs usually associated with storage of data on and retrieval from the blockchain. This is accomplished by allowing data entries to be grouped into separate chains, making it easy to examine what data does and does not exist within a specific chain. To further improve the security levels of its blockchain infrastructure, Factom implements a data anchoring policy where 'Merkle roots' of the Factom blockchain are periodically registered on Bitcoin and Ethereum, thereby taking advantage of the security levels of these public blockchains.

4.1.2. Ethereum: ERC-20

Triall's two-token system (see section 4.2) will be developed on Ethereum using the ERC-20 standard. Currently, Ethereum has the most widely distributed infrastructure for generating tokens, as demonstrated by the thousands of ERC-20 tokens issued, used, and traded to date in a reliable manner. Leveraging Ethereum allows Triall to distribute access to a wide audience while using an infrastructure that has been proven to be scalable and secure (e.g., wallets, (decentralized) exchanges, smart contracts).

4.2. Two-token system

4.2.1. Triall utility tokens

Triall is spearheading the use of blockchain in clinical research and will be the first to build a tokenized, multi-sided platform for clinical trials: the Triall Ecosystem. To fuel the micro-economy of this ecosystem and facilitate fair and equitable sharing of benefits and access among all stakeholders, we introduce our main utility token called **TRL** and its counterpart the Triall Application Credit (**T-CRED**). T-CRED gives the right to enter- and use the services in the Triall Ecosystem. It is the only token that can be used to pay for Triall applications, can only be created by converting TRL, and is intended for use and adoption within the clinical research sector. Clinical research professionals that lock up their T-CRED receive a membership status that provides unique rewards and benefits, and token holders who lock up their TRL are provided with community rewards (see section 4.2.3). We believe this token system is vital for ecosystem growth, network-fostering effects, and long-term sustainability.

An overview of envisioned token utility is provided below.

ACCESS TO ECOSYSTEM UTILITIES

TRL offers access to the applications and APIs offered within the Triall Ecosystem, facilitated through the conversion of TRL to T-CRED.

DIRECT P2P COMPENSATION

Both TRL and T-CRED can function as a common currency in the ecosystem. They enable fast and secure reimbursement of stakeholders for their contributions to the ecosystem as well as automatic milestone-based payments to multiple parties involved in a trial consortium, such as clinical research sites or patients/participants.

ECOSYSTEM GOVERNANCE

TRL functions to engage stakeholders in setting the course for the ecosystem (e.g., which apps to build, what community initiatives to support) to foster long-term sustainability. Voting rights are based on individual TRL (or T-CRED) holdings and are increased through membership tiers.

COMMUNITY ENGAGEMENT

TRL offers access to the applications and APIs TRL is used to compensate and incentivize the community for contributions to the ecosystem, e.g.: (1) Clinical quality experts sharing best practices with our public knowledge base environment (Trialwiki); (2) Academic Institutions sharing 'big data' for improved analytics and risk-based management. (3) Developers contributing to the infrastructure, such as bug bounty hunting or user experience testing; (4) Community members building wallets, APIs or promotional websites.

MEMBERSHIPS & REWARDS

Contrary to most industry associations, memberships are not charged through recurring membership fees within the Triall Ecosystem, but enabled through token lock-up schemes. Those who lock their T-CRED and/or TRL receive unique benefits, such as premium features and additional voting rights, that stimulate community growth and network effects. We differentiate between memberships for clinical research professionals and community rewards for token holders.

4.2.2. Token Economics: a 2-token system with deflationary design

4.2.2.1. T-CRED under a tokenized SaaS subscription model

Triall applications are offered under a Software-as-a-Service (SaaS) subscription model, where T-CRED is used to pay subscription fees. Clients wishing to use any of the Triall solutions need to 'charge' their account with sufficient T-CRED, which are then periodically released to the corresponding SaaS provider (e.g., Triall or a connected third-party solution provider). A proportion of TRL tokens is hence effectively removed from the circulating supply for all active subscriptions. Initially, a pre-payment period of 6 months is maintained, but Triall may choose to alter the pre-payment period as agreed upon contractually with clients.

T-CRED is created by converting TRL at a fixed price of $ 100 through a smart contract and oracle. The token is transferable, not burned by use, and can be converted back to TRL. This two-token system is designed to not expose end users to the volatility of TRL. It makes the costs of using Triall solutions predictable, and thereby limits continuity risks and promotes adoption.

T-CRED can only be converted back to TRL at a reduced rate, where a percentage of tokens is permanently burned (see figure below). Initially, Triall will implement a 2,5% token burn policy for converting TRL back to T-CRED, but this percentage may be altered at any time depending on market supply and demand. This token burn policy serves to mitigate conversion of T-CRED to TRL by individuals for potential 'trading' purposes (i.e., due to the token burn, such individuals are more likely to use public or decentralized exchanges and (pegged) fiat currencies). Examples of this token model in practice are detailed on below.

Triall two-token system

4.2.2.2. Implications for supply and demand

The total supply of TRL is not fixed, but rather fluctuates around an equilibrium point with an estimated downtrend over time. Initially, a total of 175 million TRL will be created at time of ITO. When TRL tokens are converted to T-CRED, the total supply of TRL is temporarily reduced. As soon as T-CRED is converted back to TRL, the (previously reduced) supply of TRL tokens is restored again. In the time between conversions, the value of TRL (measured in $) may (1) increase, (2) remain the same, or (3) decrease. The new TRL price will determine how many TRL tokens are issued when T-CRED is converted back to TRL, and will thus affect the total TRL supply. Over time, the total TRL supply is likely to decrease for the following reasons: **(1) every time T-CRED is converted back to TRL, a percentage of TRL tokens is burned permanently**, and **(2) as the ecosystem grows, the demand for TRL and the associated token value is likely to increase, thereby lowering the TRL conversion rate and reducing the total supply**. Furthermore, token lock-up schemes (and associated incentives) are introduced to reduce the circulating supply of TRL, thereby creating additional network stability, as detailed in the following sections.

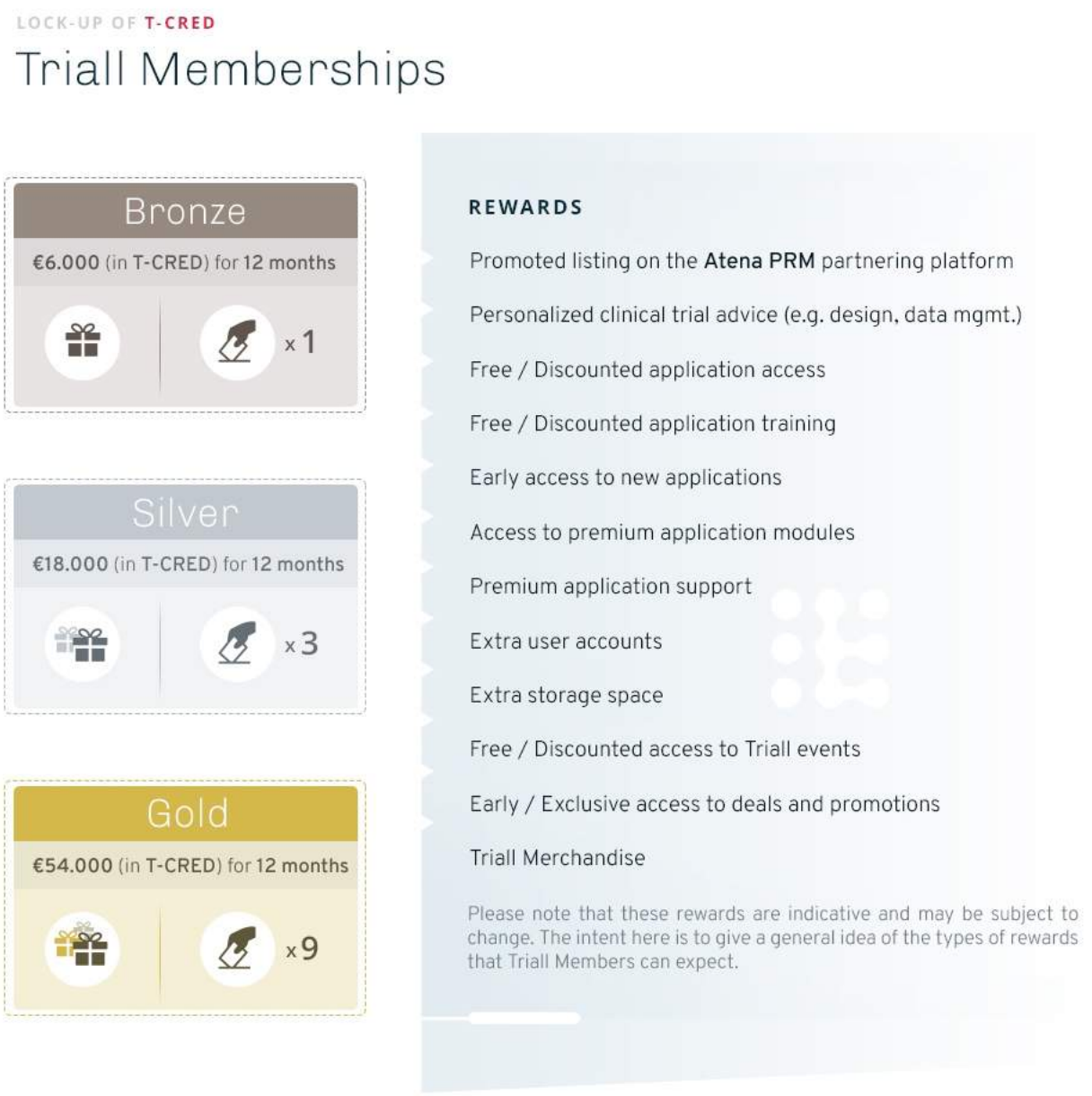
4.2.3. Token lock-up reward system

Early adoption and token holding are incentivized in the Triall Ecosystem by awarding memberships and community rewards to those who lock their tokens over time.

4.2.3.1. Lock-up of T-CRED (“Triall Memberships”)

Entities can qualify for **Triall Memberships** by locking up their T-CRED. These memberships come with rewards, designed with clinical research professionals (as typical T-CRED holders) in mind. Clinical research professionals could, for instance, be individuals or entities such as Sponsors (pharmaceutical or biotech companies), CROs or academic hospitals. Triall Memberships are divided into three tiers, depending on the amount of T-CRED in lock-up. An indicative list of rewards is provided on the next page. Triall Memberships and associated lock-up schemes are settled in T-CRED to mitigate exposure to token volatility for the end user. Over time, Triall may choose to adjust membership tiers to retain fit with the ecosystem’s size and scope.

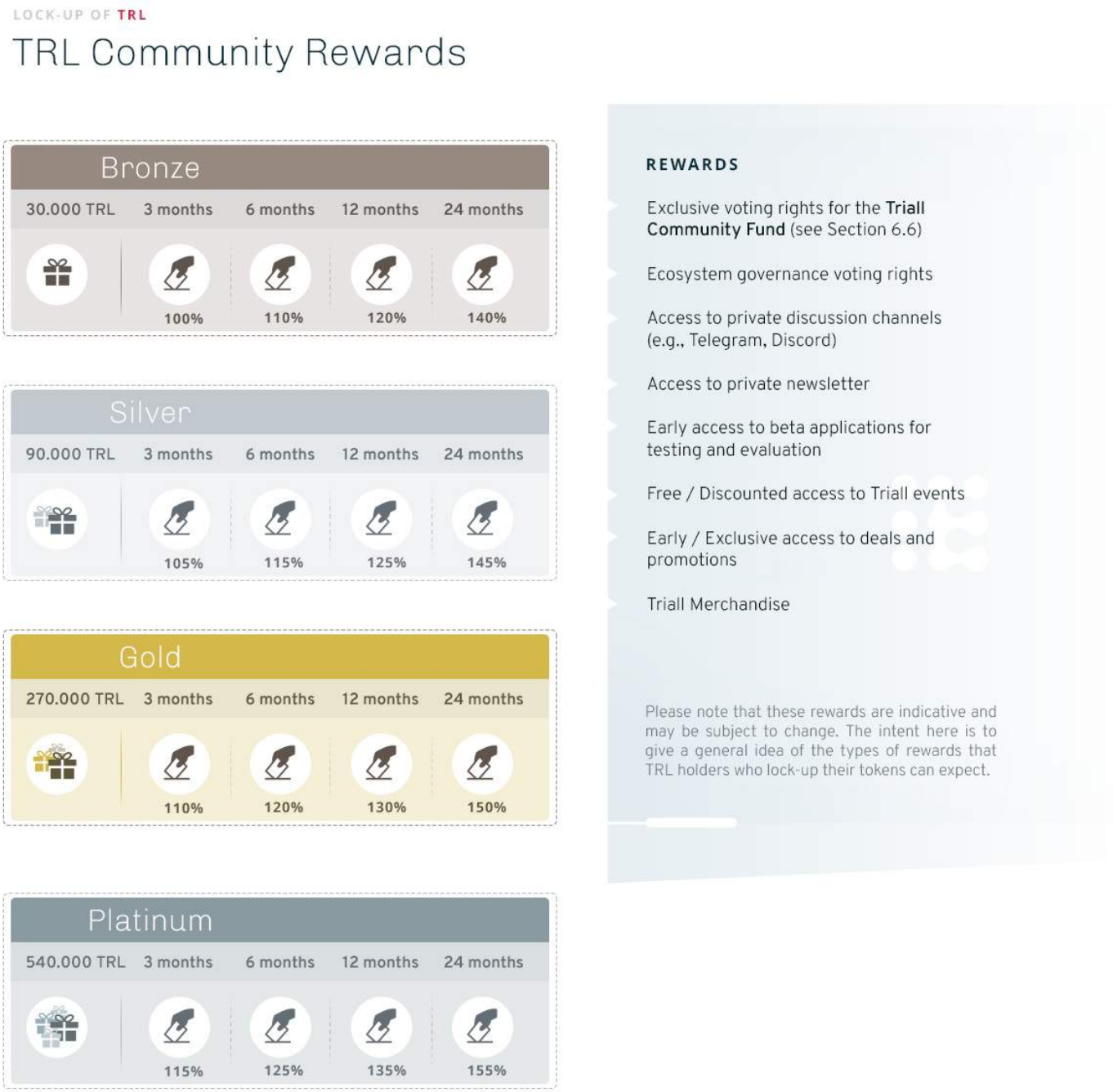
- Clinical research professionals who lock T-CRED for at least 12 months receive Triall Membership status.
- Triall Members are entitled to rewards and voting rights.
- Rewards are increased with tiers, depending on the number of T-CRED in lock-up.
- After the lock-up period has expired, Triall Members can choose to use the T-CRED at their discretion. They may, for instance, use these to pay for subscription or membership renewals.



4.2.3.2. Lock-up of TRL ("TRL Community Rewards")

In addition to the Triall Memberships, aimed at end-users of ecosystem applications (i.e., clinical research professionals), a separate token lock-up reward system is offered for TRL token holders (who may not wish to use Triall applications per se). Holders who lock-up their TRL tokens over a period of time (see figure on the next page), are rewarded with unique benefits, such as: (1) exclusive admission and voting rights for the Triall Community Fund (see section 6.6), (2) ecosystem governance voting rights, (3) access to Triall

meetups and conferences, (4) access to private chat groups (e.g., Telegram or Discord), (5) access to private newsletter, (6) priority access to beta applications for testing and validation prior to general release (Gold tier and higher only), and (7) Triall merchandise & discounts. We are continuously looking to improve and reiterate the benefits and rewards for token lock-up and remain open for input from the community.



Voting weight = amount of TRL * relative voting power.

Voting mechanisms for ecosystem governance and the Triall Community Fund are further detailed in section 6.5 and 6.6.

4.2.4. TRL value drivers

Triall will pursue the listing of TRL on a growing number of centralized and decentralized crypto exchanges to promote the liquidity of our main utility token. As a publicly tradable token, the value of TRL will be determined by market supply and demand. Therefore, the token economics of TRL are designed to limit supply and drive demand.

4.2.5. Lowering the (crypto) barrier to entry for end users

To ease adoption for the end-user, Triall offers the option to pay in fiat currencies for the use of Triall applications. In this scenario, TRL tokens are (always) purchased on behalf of the client. This will effectively remove a major barrier to entry for certain users who do not want to deal with fiat-to-crypto conversion or adopt crypto storage solutions in their business conduct. Triall (or a service provider) will in this case purchase the TRL tokens on behalf of the

client (e.g., from the public market) and convert them to T-CRED, to further ensure sustainable demand for TRL. Nevertheless, paying directly in T-CRED is encouraged as product pricing is discounted for those that do so.

4.3. Open specifications and designs

The Triall Ecosystem will provide specifications of data structures and open-source components where applicable, allowing all parties to interface with Triall solutions. This means you can use open-source components, Blockchain as a Service (BaaS) solutions or create your own integrations and applications for the Triall Ecosystem. It is one of our key objectives to create an ecosystem that is inclusive, where all stakeholders can integrate and have a seamless experience.

4.4. Network integration

The Triall Ecosystem comprises a network that enables secure and efficient data sharing between third-party eClinical providers. By using our specifications and tailor-made APIs, providers can connect their eClinical solutions to the ecosystem, using their own solutions or our underlying microservices and blockchain infrastructure. Connecting to the ecosystem enables these providers to authenticate their data using blockchain and, moreover, creates the possibility to exchange data with other connected eClinical solutions in a secure environment. In this respect, Triall's DID-enabled decentralized identity and access management layer, comprises a cryptographic access management and service discovery protocol that allows eClinical providers to: (**1**) choose which data points they want to share, (**2**) authorize the eClinical solutions of other providers to read these data points, and (**3**) define how they can access this data (service discovery). This way of integrating different eClinical solutions is powerful, since decisions regarding authorization permissions and access lie with the corresponding provider instead of a centralized administrator. Hence,

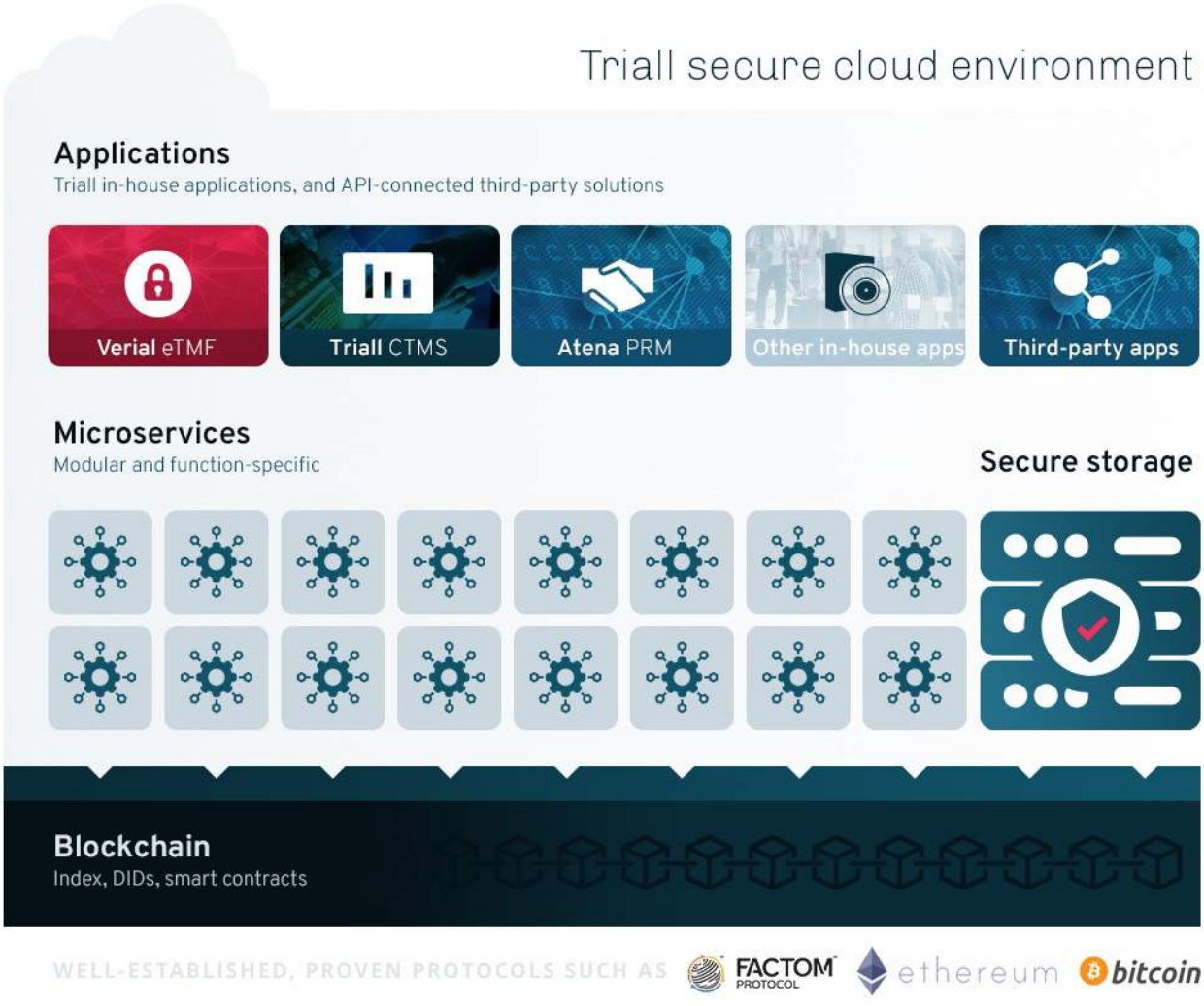
an eClinical provider can be rest assured that its data remains confidential and can only be read by those parties it authorized to do so. A CTMS provider, for example, could exchange data with another provider's EDC or eTMF system, giving the CTMS a completer and more comprehensive overview of the clinical trial's overall performance and process. In this scenario, both providers are free to negotiate terms for financial compensation as they see fit. Moreover, compensation can be automated in smart contracts using TRL. All data recorded on the blockchain using the Triall APIs will be hashed (and metadata may be recorded or hashed) to preserve confidentiality in line with international quality standards and privacy regulations such as the European General Data Protection Regulation (GDPR) and U.S. Health Insurance Portability and Accountability Act (HIPAA). As such, the blockchain operates as a data governance layer that preserves data integrity and enables stakeholders to stipulate access permissions in a decentralized manner, while sensitive and personal identifiable information remains in its original private (cloud) environment.

4.5. Microservices architecture

The Triall Ecosystem and its applications will function on a modular configuration of different underlying microservices which communicate over interfaces through a uniform network of APIs. Microservices are independent pieces of software that run separately from each other in code envelopes ('containers'), where each microservice performs a single specific function (e.g., blockchain registration) and is interchangeable and scalable on its own (e.g., you can remove/replace one container, while leaving the rest of the system intact). Each microservice can be developed, updated, managed, and scaled separately, which greatly increases the time-to-market, cost-efficiency, and simplicity of product development and infrastructure management compared to monolithic applications. In contrast, monolithic applications run processes that are dependent on each other, meaning failure in one process impairs the entire

application. Moreover, if one process faces an increase in demand, the entire application needs to be scaled up. Monolithic applications are also known for becoming increasingly complex over time as new features are added, leading to various cost-inefficiencies and delaying time-to-market.

Due to its microservices architecture, the Triall Ecosystem is highly scalable by design and allows for easy and rapid expansion as usage increases. Depending on needs, eClinical providers connected to the ecosystem's infrastructure can choose to leverage one or more microservices. This modular design enables a highly flexible value offering where microservices can be utilized under a subscription-based model and users will be charged in T-CRED. The microservices architecture allows for both on-premises and cloud-based offerings.



5. Governance

5.1. Philosophy

Triall envisions an inclusive digital environment that is accessible to all parties involved in clinical development. This vision is also embedded in our governance model as we strive to engage and empower stakeholders in key decisions regarding the development and strategy of the ecosystem.

> We commit to a transparent, accountable, and equitable governance model in line with our vision and values.

5.2. Governance model

5.2.1. Triall Foundation

Stichting Triall Foundation ('Triall Foundation' or 'the foundation') is the non-profit organization responsible for the governance and maintenance of the Triall Ecosystem. Its Board of Directors ('the board') will be responsible for the strategic and general management of the foundation. The board's composition will represent the appropriate expertise and subject-matter knowledge for the effective management of the foundation in compliance with quality standards and applicable regulatory requirements. The board will be transparent in its decision-making and will operate in the interests of Triall's stakeholders and community.

The primary responsibilities of the Triall Foundation's Board of Directors concern:

- Decisions regarding the foundation's strategy
- Decisions regarding the foundation's annual budget and use of proceeds
- Decisions regarding the development of new applications and functionalities
- Decisions regarding incubator and charity schemes
- Selecting new board members
- Proposing voting topics

The foundation's board will initially consist of 7 members, including an appointed chair ('President') selected from the group of our main partners. At the time of the ITO, board seats will be filled by founding members, but these will gradually be replaced until at least 50% of the initial seats are filled by members coming forth out of the group of our main partners and stakeholders. Each 12 months, one seat will be open for (re)appointment, in which a board member may be replaced or re-elected based on his or her performance. The founding members expect that new external knowledge will be required as the blockchain space is moving rapidly. As the ecosystem grows, the number of seats will be re-evaluated by the board. Regarding decision-making, the board's chair will be 'primus inter pares' (i.e., will have the deciding vote in the occurrence of an indecisive vote).

5.2.2. Managing partner Clinblocks B.V.

Clinblocks B.V. is a Dutch business entity that will operate as managing partner of the foundation. This entity will provide continuity to the growth of the ecosystem by being fully engaged in organizational support to develop and operate the ecosystem. Financial arrangements between the Foundation and Clinblocks B.V. will be in line with market prices and targets met and will be bound in the form of a master service agreement. The foundation holds the right to extend the contract or choose another party as it sees fit.

5.3. Revenue streams

Triall aims to establish a range of business models to support long-term growth of the foundation and ecosystem. In this regard, Triall holds the right to offer and outsource the services and activities listed below:

- **eClinical solutions.** Triall will offer applications and APIs within the ecosystem under a subscription-based model.
- **Product-related services.** Triall will offer product-related services such as support with integration, customization, training as well as general consultation on configuration, analysis, and reporting.
- **CRO related services.** Triall's team consists of highly experienced clinical research professionals. Triall is therefore uniquely positioned to provide CRO services in addition to its software solutions, such as research monitoring, data management, pharmacovigilance, and many other clinical trial services.
- **API development and network integration services.** Triall will license out APIs that allow industry players to connect to Triall's infrastructure and utilize specific microservices of the ecosystem. The foundation will also assist parties throughout the network integration process as a fee-for-service.

- **Advertising (partner selection and management platform).** Triall charges a premium for promoted content.
- **Technology auditing and consulting.** Triall will offer auditing and consultancy services, to support the development activities of innovators on the platform.
- **Incubator program.** Triall is facilitating applications and initiatives through its incubator program that support eHealth and eClinical innovation.
- **Token management service.** Triall may offer to facilitate network transactions with TRL and T-CRED on behalf of its users. This allows users to pay Triall in fiat currency, while Triall pays for their subscription and services in cryptocurrency.

5.4. Socially responsible operations

Despite impressive achievements in many areas of medicine, countless serious diseases and conditions remain to be addressed. Especially in the case of diseases with either extremely small or extremely poor patient populations, treatment options are limited due to lacking private economic incentives to invest in their development. To address these unmet medical needs, alternative funding strategies are needed to facilitate medical innovation. While there are philanthropic schemes, subsidies, and grants, the current funding landscape for promising medical solutions remains scarce and the competition for obtaining funds is fierce. As socially responsible foundation, Triall aims to give back to the medical and clinical research community by investing parts of its (sustainable) operating income into incubator and charity schemes, supporting research and innovation towards meeting unmet medical needs.

5.5. Voting system – Ecosystem governance

The foundation will engage stakeholders in the decision-making process and governance of the ecosystem, by putting topics up for voting to the Triall community. Topics that may be put up for voting are major alterations to the ecosystem, preferred incubator programs, token (lock-up) incentives, community programs, and the structure, compensation, and annual evaluation of the relationships with the Foundation's main partners. The Board may also decide to put other subjects up for voting if deemed necessary. Voting is only available to those who have locked their tokens (see section 4.2.3). The foundation will decide per topic which individuals and entities are eligible for voting. For instance, topics related to the contents and features of applications may be best voted on by Triall Members (end users), whereas topics related to token (lock-up) incentives and community programs may be best voted on by TRL token holders. Votes are non-binding: the foundation aims to engage all stakeholders and values input from the community, but retains the right to develop and grow the ecosystem as the board deems fit.

5.6. Voting system – Triall Community Fund

To further engage the community in the development of the Triall Ecosystem, 10% of the total TRL token supply is reserved for the Triall Community Fund (TCF). The TCF is established to help the Triall Ecosystem grow globally through community-sponsored projects. Examples of such projects may include a TRL (mobile) wallet, applications, token integration with other networks, marketing campaigns, websites promoting Triall, bounty programs and competitions, or any other initiative that reaches a majority vote. After the initial pool of 10% of TRL tokens has been depleted, part of the sustainable operating income from Triall may be reinvested into the TCF. Votes in the TCF are non-binding, but guide the selection of top community initiatives in the following way:

PHASE 1 SUBMISSION

In phase 1, anyone can propose a development idea to be (co-)funded by the TCF. To qualify for the admission program, one needs to have locked their TRL tokens (as specified in section 4.2.3). All projects need to provide details on their problem statement, solution, technical specifications, funding goal, use of proceeds, team, past experiences, and previous grants (proposal templates will be provided by Triall).

PHASE 2 OPEN VOTING

Eligible proposals will be put up for voting. In this phase, token lock-up is not required for voting. Anyone who is a TRL token holder can vote for their favorite community proposals.

PHASE 3 SHORTLIST

After all votes are tallied, the top 5 community initiatives (receiving the most votes) will be shortlisted. These projects will be given the opportunity to showcase their initiative, for instance through interviews or AMA sessions hosted by Triall.

PHASE 4 FINAL VOTING

From the 5 shortlisted projects, a winner will be chosen based on a final community vote. In this phase, only token holders who have locked their tokens* can cast their votes on their favorite shortlisted initiatives (see section 4.2.3).

PHASE 5 WINNER

The initiative receiving the most votes in Phase 4 will be declared the winner. This initiative will be sponsored and (co-)funded by the TCF.

* This lock-up will also give access to all other incentives as reported in section 4.2.3 (e.g., priority access and discounts, Triall merchandise, meetups, conferences, and private newsletter for stakeholders).

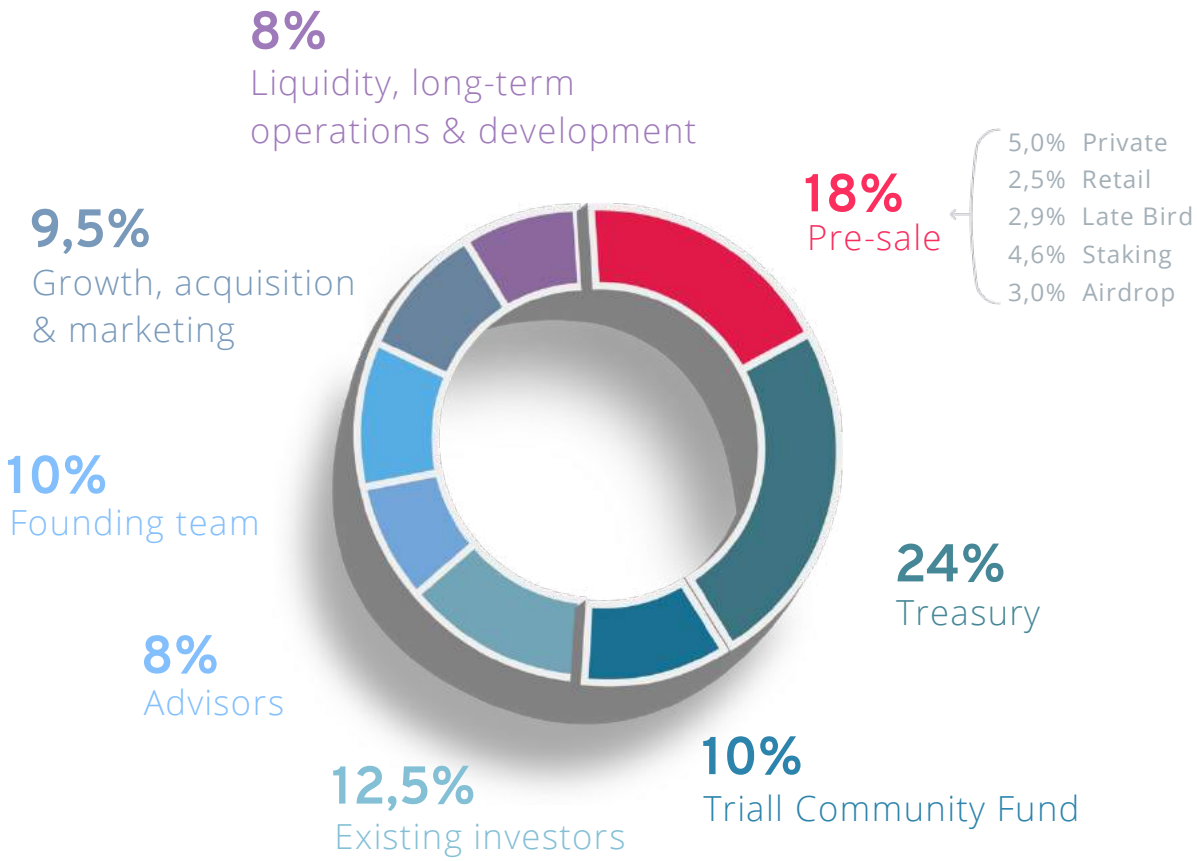
6. Initial Token Offering

Triall will offer **52%** of the total TRL token supply to the community through its ITO and the Triall Community Fund (see section 6.6). This ITO serves to distribute early access to the Triall Ecosystem and will support in funding its development. TRL tokens are issued using the ERC-20 standard on Ethereum and are available for anyone meeting our legal requirements.

6.1. ITO structuring

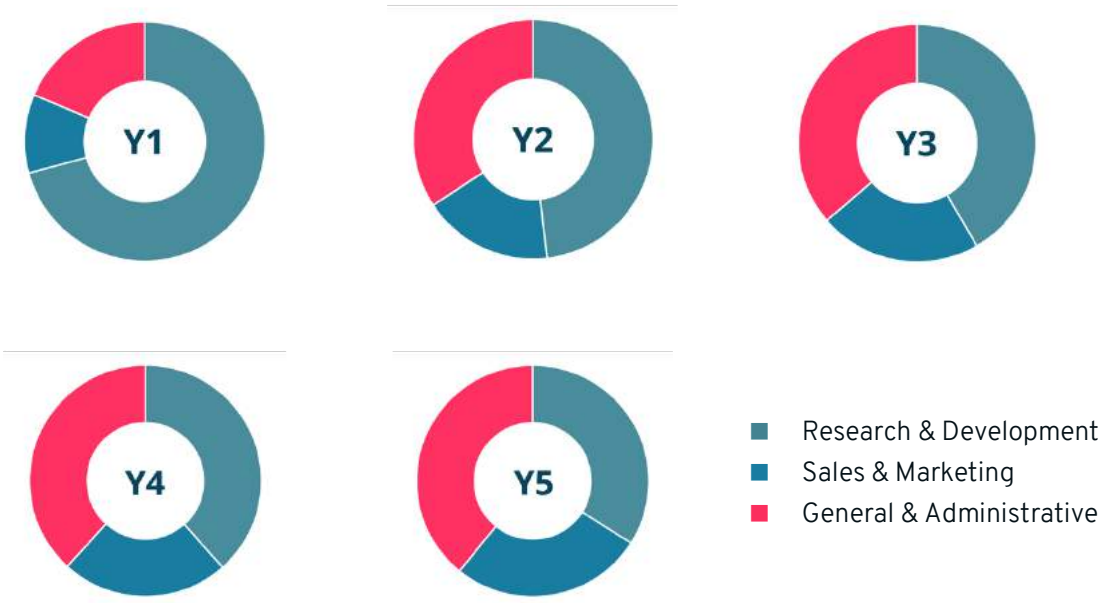
- The **total TRL token supply** at ITO will be **175 million**.
- A total of **91 million TRL (52%)** will be distributed to the community, of which **31,5 million (18%)** will be allocated to the Pre-sale, **42 million (24%)** to the Treasury, and **17,5 million (10%)** to the Triall Community Fund.
- Any **unsold tokens** from the Pre-sale will be **burned**.
- The **Pre-sale price** of 1 TRL will be **$ 0,125** in the Private Pre-sale round (5%), **$ 0,20** in the Retail Pre-sale round (2,5%), and **$ 0,20*** in the Late Bird Pre-sale round (2,9%*). * *Edited: previously was $ 0,23 and 7,5%.*
- The **listing price** of 1 TRL will be **$ 0,25**.
- The **hard cap** will be **$ 1.093.750** in the Private Pre-sale round, **$ 875.000** in the Retail Pre-sale round, and **$ 1.025.000**** in the Late Bird Pre-sale round. ** *Edited: to reflect the updated token price and allocation size.*
- All token allocation pools are bound to a **vesting schedule** (see section 7.6).
- **Circulating supply** at the time of our token generation event (TGE) will be **$ 935.312** (2,14%). *** *Edited: previously was $ 916.563; updated to reflect ProStarter.io IDO vesting.*

6.2. Token allocation



6.3. Use of proceeds

The funds raised during our ITO will enable full-scale development and timely release of the Triall Ecosystem as envisioned and portrayed in this whitepaper, supported by a global marketing and sales campaign. The visuals below provide an overview of the use of proceeds for the 5 years post ITO.



6.4. Growth and sustainability of the Triall Ecosystem

6.4.1. Growth, Acquisition, and Marketing

To support sustainable growth and adoption of the Triall Ecosystem, 9,5% of the total TRL token supply is reserved for the Growth, Acquisition & Marketing pool. These tokens are intended to support global marketing outreach programs and facilitate onboarding of new stakeholders and users for the Triall Ecosystem, which will further stimulate adoption and usage of TRL. In this regard, TRL tokens may also be used as an incentive for vendors and CROs who bring news users to the platform, or reward individuals and companies who provide substantial contributions to the ecosystem.

6.4.2. Liquidity, Long-term operations & Development

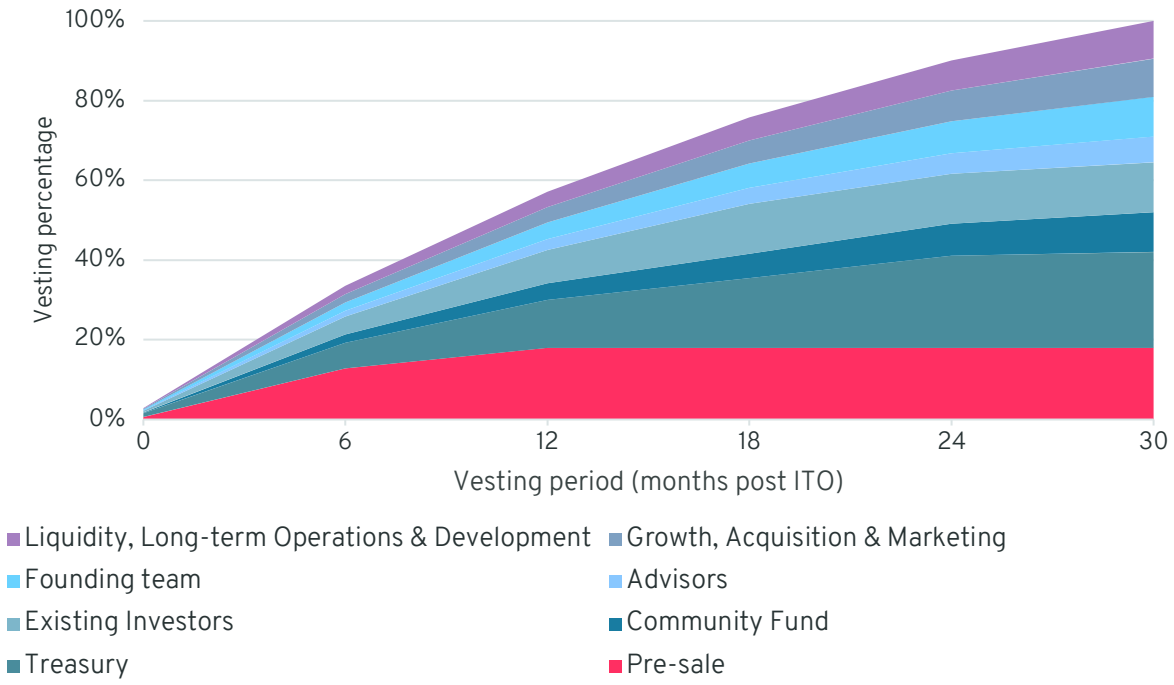
The Liquidity, Long-term Operations & Development pool is intended to help sustain the Triall Ecosystem over the course of multiple years (in addition to its own revenue schemes) and grow the ecosystem beyond the scope described in this whitepaper. For instance, Triall may opt to develop new applications such as EDCs (Electronic Data Capture) and ePROs (Electronic patient-reported outcomes) in the future, either in-house or through its incubator program, if the scope and needs of the ecosystem call for it at that time. Similarly, the fund may be used to grow the core team and its strategic advisors.

6.5. Vesting schedules

All of the tokens issued by Triall are bound to a vesting schedule. This serves to drive the sustainable growth of the ecosystem and the token value of TRL. Moreover, vesting schedules help promote accountability of the founding team and investors. Founder and advisor tokens in lock-up and vesting are abstained from voting.

Token pool (% of total)	Vested at ITO (% of total)	Vesting period *
Private Pre-sale (5%)	3% (0,15%)	6 months
Retail Pre-sale (2,5%)**	10% (0,25%)	5 months
Late Bird Pre-sale (2,9%)***	0% (0,00%)	12 months
Staking (4,6%)***	0% (0,00%)	12 months
Airdrop (3%)	0% (0,00%)	12 months
Treasury (24%)	4% (0,96%)	25 months
Triall Community Fund (10%)	0% (0,00%)	30 months
Existing investors (12,5%)	3% (0,38%)	18 months
Advisors (8%)	2% (0,16%)	30 months
Founding team (10%)	2% (0,20%)	30 months
Growth, Acquisition & Marketing (9,5%)	0% (0,00%)	30 months
Liquidity, Long-term operations & Dev. (8%)	0% (0,00%)	30 months
Total token supply (100%)	**2,10% (2,10%)**	**30 months**

*Linear vesting every month. **0,29% of the Retail pool is allocated to the ProStarter.io IDO, which knows a 25% initial unlock and 3 months of vesting. *** Late Bird pool (7,5%) has been split between Late Bird (2,9%) and Staking (4,6%) pools.



6.6. Accepted currencies

The Triall Foundation intends to offer its tokens to a wide audience to ensure a fair initial distribution. Fiat currencies, Bitcoin, Ethereum will be accepted at the time of the ITO. A final list of accepted currencies will be specified on the ITO platform website.

6.7. Compliance with financial authorities

All token buyers will have to go through a whitelisting procedure, compliant with Know Your Customer (KYC) and Anti-Money Laundering (AML) laws and regulations. For our token sale event, we plan to only offer TRL tokens to those who (1) are authorized and have full power to purchase TRL tokens according to the laws that apply in their jurisdiction of dominance, (2) are compliant with local, state and national laws and regulations when purchasing, selling and/or using TRL tokens, and (3) have a nationality and live/have their seat in a jurisdiction that allows the Triall Foundation to sell tokens through a crowd sale without requiring any local authorization. Details on the ITO procedures will be provided at the ITO platform website.

7. Roadmap

Please note that the roadmap, milestones and deliverables are indicative and may be subject to change.

8. Partners

New partners added since April 2021 are listed on **triall.io**. Full partner descriptions can be found in the **Appendix** to this whitepaper, which is available for download at **triall.io** under 'Resources'.

9. Team

The team behind Triall unites profound knowledge of the clinical research landscape with in-depth understanding of the promises offered by blockchain technology. Combined, it has managed over 100 phase I-IV clinical trials in over 30 countries and published over 250 peer-reviewed papers on pharmaceutical innovation, including articles in top-tier academic journals such as Nature and Science. The team has experienced the challenges of managing Life Sciences companies through all different stages of growth and innovation, and can draw on a strong combination of academic, entrepreneurial, and industrial experience in the target market.

Our Management Team

Niels Klomp, MSc
CTO
Experienced blockchain and SaaS developer; Director of the Factom blockchain.

Rob Posthumus, LL.M.
General Counsel
Corporate lawyer; Deal-maker; Extensive experience as legal counsel in healthcare and pharma.

Dr. **Joost Flach**
Head of Clinical Affairs
Clinical researcher; Medical writer; Project manager.

Hadil Es-Sbai, MSc
President | CEO
Empathetic leader and team-builder; Extensive experience in managing clinical trials.

Dr. **Linda van de Burgwal**
CFO
Founder of two successful industry consultancies; Cum laude PhD in science commercialization.

Mark van der Waal, MSc
Head of Product Design
PhD candidate and management consultant in health technology innovation; Graphic designer.

Ray van der Waal, MSc
Head of Marketing
Researcher; Consultant and copywriter focusing on complex tech and R&D.

Hadil Es-Sbai, MSc
President | Chief Executive Officer

hadil.es-sbai@triall.io
hadilessbai

Hadil majored in analytical chemistry, and has a background of **20+ years in clinical development**. He assumed several roles within the pharmaceutical and clinical contract research industries, and acquired **extensive experience managing international clinical trials** (phase I-IV) across a wide range of therapeutic areas. Hadil **co-founded and managed several service-driven pharmaceutical companies**, including the contract research service providers Herakles Life Sciences Group in 2007 and CR2O in 2008. He is described as an empathetic and tireless leader, who gears all his entrepreneurial initiatives towards making innovative treatments accessible to those in need.

Niels Klomp, MSc
Chief Technology Officer

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niels-klomp

Niels is a serial tech entrepreneur with **18+ years of experience in various CTO roles**, including CTO of Sphereon where he **leads the development of a completely new cloud-based Content Services API Platform** that includes **blockchain and decentralized identity technology**. He has over 20 years' experience with GNU/Linux system administration, including high availability, clustering, and (enterprise) software development. His expertise furthermore includes **cloud and microservices architectures**, continuous integration/delivery to release management, **blockchain development**, business process modelling, enterprise integration, DMS integrations, and databases. As one of the former moderators of the largest Dutch tech community (Tweakers.net) and due to his active involvement in the Factom Protocol, Niels has extensive experience in online communities and their dynamics. He was one of 5 worldwide **elected Guides of the Factom Protocol blockchain**, and was recently appointed as interim **Director of the Factom Protocol**, where he will drive the adoption and impact of the blockchain.

Dr. **Linda van de Burgwal**

Chief Financial Officer

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lindavandeburgwal

Linda is an academic entrepreneur working on the interface of science and business and holding a **cum laude PhD in science commercialization**. Her main areas of expertise are innovation and entrepreneurship in the Life Sciences industries. As an entrepreneur, she **co-founded several companies**, including ttopstart in 2009, and FFUND in 2016. She has developed **strategic business plans** and synthesized both early- and late-stage **investment propositions** for various profit and non-profit organizations. She is known for her energy, passion in achieving an impact, and ability to initiate and develop partnerships with diverse actors.

Rob Posthumus, LL.M.

General Counsel

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robposthumus

Rob is a **corporate lawyer and deal-maker** with more than 30 years' experience in drafting, negotiating and managing contracts in the pharmaceutical and healthcare industries. He **headed the legal department of Erasmus University Medical Center** (ErasmusMC) in Rotterdam, was legal counsel with Royal Nedlloyd Group and the Erasmus University of Rotterdam, and held several management and advisory functions within the Erasmus University and ErasmusMC, where he has been **supportive of a range of startups** and the realization of the Erasmus MC Incubator in the Rotterdam Science Tower.

Mark van der Waal, MSc
Head of Product Design

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mbvanderwaal

Mark combines a practical and academic background in health technology innovation. As a **PhD candidate**, he has developed models to leverage 'hidden' **intangible resources and intellectual property (IP) rights** in processes of biomedical innovation. His thinking on a blockchain-enabled model for international cooperation and data-sharing to accelerate R&D response to infectious disease outbreaks was published in *Science*. Prior, he investigated **science-based product and service innovation** in neurosciences, vaccines, and microbiota, designing peer-reviewed **management tools to address identified innovation barriers** in these domains. Besides his research, Mark has worked as a management consultant, assisting biomedical innovators in communicating value propositions, building strategic value networks, mapping the optimal route for growth, and for staying on track for successful innovation. Mark is a passionate (self-taught) graphic designer, and has been involved in **UI / UX design** projects for business and academia for years.

Dr. **Joost Flach**
Head of Clinical Affairs

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joost-flach

experienced clinical project manager and research scientist. He manages and consults on clinical trials for industry and academia. He has an academic background in neuropharmacology and business management and **holds a PhD in microbiology**. Throughout his career and PhD research, Joost has built ample experience in clinical operations, medical writing, and regulatory approval strategies. As Head of Clinical Affairs, Joost sets out to advance medical innovation by bringing the promises of emerging technologies, such as blockchain, to end users within the clinical research community. Joost ultimately ensures that the needs of clinical research professionals are met by the software solutions developed by Triall, paving the way for novel therapeutics with positive societal impact.

Raymond van der Waal, MSc
Head of Marketing

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raymond-van-der-waal

Ray has a background in Biomedical Sciences and in Management & Entrepreneurship within the Life Sciences. Over the past 4 years, he built experience as a researcher, consultant, and entrepreneur. His research focused on the impact of market research, intangible assets, and emerging technologies on medical R&D. As a consultant, he **co-authored a number of successful European Grant proposals** for technology-driven ventures. Within his role at Triall, Ray has been involved in the design, marketing and communication of Triall's value offering. He has a passion for **making complex technologies resonate** with a broad audience.

Prof. **Eric Claassen**, PhD
Vrije Universiteit Amsterdam
Advisor Strategy

Yassin Mobarak, MSc
Dizer Capital
Advisor Technology

Sina Djali, MSc
Janssen (J&J)
Advisor Product Design

Prof. **Niels Chavannes**, MD, PhD
NeLL | Leiden University Medical Center
Advisor Product Design

Dr. **Po Chi Wu**
UC Berkeley | HKUST | FutureLab Consulting
Advisor Strategy

Prof. **Sjaak Bloem**, PhD
Nyenrode Business University | Janssen (J&J)
Advisor Product Design

Danielle Bradbury
Galera Therapeutics
Advisor Quality & Compliance

Moses Ma
FutureLab Blockchain Lab
Advisor Business Development

Cari Jacobs-Blom, MSc
CR2O
Advisor Quality & Compliance

Maarten Boender
Sphereon
Advisor Technology

Allan Bukuya
TrialDocs International
Advisor Product Design

Nick van den Bulk, MSc
CR2O
Advisor Product Design

Rob Helmich, MSc
Herakles Life Sciences Group
Advisor Human Resources

Bios for all of Triall's team members can be found in the **Appendix** to this whitepaper, which is available for download at the Triall website.

10. Legal Disclaimer and Disclosures

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We shall have no liability for damages of any kind arising out of the use, reference to or reliance on the contents of this White Paper, even if advised of the possibility of damages arising.

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No regulatory authority has examined or approved any of the information set out in this White Paper. No such action has or will be taken under the laws, regulatory requirements or rules of any jurisdiction. The publication, distribution or dissemination of this White Paper does not imply that applicable laws or regulatory requirements have been complied with.

This document is intended for people who have experience purchasing blockchain tokens. If you have not regularly participated in prior token sales, nor fully understand risks associated with it, we strongly advise against participating in the TRL sale. Each participant fully accepts any risks associated in the process of the token sales, distribution and accepts that no guarantees will be made for the tradability of the token, nor protection against the exposure of volatility which may occur, resulting in a large difference in the value between the purchase date and the date TRL are tradable. By participating in the Triall Ecosystem and by acquiring TRL you acknowledge that the primary function of the TRL is enabling the Triall Ecosystem, and not being a value storage asset. Also, you accept that blockchain tokens inherently come with great risks, such as loss of value, theft, hacking or other complete loss of tokens, loss of usability and security and other weaknesses in Triall or third-party software. Please be aware that it is your own responsibility to adequately hold, store and trade the TRL tokens, for instance by choosing a compatible wallet. If you do not fully understand these risks and obligations, we encourage you to get informed or obtain relevant counsel or to abstain from any involvement.

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