



Evaluating Blockchain for the Governance of the Plasma Derivatives Supply Chain: How Distributed Ledger Technology Can Mitigate Plasma Supply Chain Risks

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Objective: This exploratory study examines how distributed ledger technologies could be used within the plasma derivatives supply chain. The plasma derivatives are used increasingly in the pharmaceutical market and the supply chain is global. However, there are significant risks relating to the governance of the supply. The risks include unclear origin of plasma and the propagation of contaminated or poor-quality blood to the pharmaceutical production process. From an ethical perspective, the risk is that vulnerable individuals are exploited in the donation process. Finally, the plasma supply chain currently depends on only a few exporters of plasma, which presents a supply chain risk.

Design: The blockchain technology is piloted in other areas of pharmaceutical supply chains

and in this study we examine those solutions and conceptualize how a similar solution can be applied to the plasma supply chain. We identify risks within the plasma supply chain and discuss how blockchain-based solutions can mitigate those risks.

Results: Drawing on existing literature within the pharmaceutical blockchain arena, we introduce a solution to verify the origin of plasma. We also model how the blockchain technology can be used to tackle ethical and supply chain risks.

Conclusions: Blockchain can have a role in mitigating plasma supply chain risks. The area is, however, novel and requires more research.

Plasma derivatives are defined as pharmaceutical products that contain plasma proteins, which are separated from blood.¹ Plasma is used to produce treatments for immunodeficiency disorders and hemophilia, for example, and the market is growing rapidly—it is anticipated to be worth US\$15.5 billion by 2024.² Shortage of plasma in the market may have significant consequences, including increased mortality rates.³

Plasma may be collected as a part of the whole blood donation process or by plasmapheresis where cellular constituents of blood are returned to the donor. The plasma collected as part of the whole blood is often referred to as recovered plasma, whereas the plasmapheresis product is known as apheresis or “source” plasma. In the process, whereby whole blood is donated, three main components are separated: red blood cells, blood platelets and plasma.³ There are specific plasma collection centers in which only the plasma is collected and blood cells are transfused back into the donor.⁴ In most countries, the collection of blood is reliant on voluntary blood donors, and it is not remunerated for. Many of these countries are importers of plasma from those few countries that allow remunerating plasma donors.⁵ The United States

is the biggest exporter of plasma at 1.6% of their total exports.⁶

The current plasma supply market involves various risks (Table 1). One main risk is that relating to infections—in the late 80’s, contaminated blood entered into the supply system causing an HIV epidemic.⁶ There are also ethical risks; remunerating donors may attract those in a weaker social strata, such as the poor and drug addicts to donate frequently, while the health effects of frequent plasma donation are not clear.⁵ It is also commonsense that overreliance on one source—like the United States for plasma—exposes the supply chain to significant risks. Europe is a significant importer of plasma, and it has been suggested that plasma collection within the region must be increased to mitigate the supply chain risks.⁷

Another issue is the counterfeiting and falsification of medicinal products. By definition, a falsified medicinal product mimics the real product, whereas counterfeit medicinal products are illegal copies of real products, which breach the intellectual property rights.⁸ It is suggested that the global counterfeit drug market is valued at \$200 billion.⁹ Falsification can take forms such as improper storage and poor manufacturing practices.¹⁰ Plasma derivatives are not immune

Table 1. Plasma derivative supply chain risks.

Risk	Description
Ethical	Frequent donors are those in a socially weaker position, such as addicts or the homeless.
Contamination	Contaminated blood is transmitted to the plasma supply chain. The risk is reportedly low due to rigorous testing and cleansing process; however, falsification can undermine this.
Falsification	Falsification can take many forms (e.g., the origin of plasma can be blurred or testing procedures can be forged).
Supply chain	Relying on a single sourcing partner introduces a single point of failure in the system.
Regulatory	Regulations are getting more stringent and non-compliance can result in fines and sanctions.
Reputational	Any of the above risks materializing will lead to reputational consequences and eroded trust in the market.

to this, and it is suggested that counterfeiting is increasing in the plasma market.¹¹ The testing of plasma and the viral inactivation process may be expensive.⁶ This may lead to false testing processes, which means plasma that is not properly tested or processed can be transmitted to the supply chain, exposing significant risks in terms of infection and poor quality of plasma. It is common sense that one of these risks materializing would have a significant reputational impact and the trust in the system would erode rapidly.

Regulators are paying increased attention to the counterfeiting and falsification problem, and they are launching more stringent measures to curb it. U.S. Food and Drug Administration (FDA) introduced Drug Supply Chain Security Act (DSCSA), which defines requirements relating to the tracing of medicinal products across the supply chain.¹² DSCSA is being rolled out in a phased manner between 2014 and 2023. In addition, the European Union is regulating the field heavily. For example, good distribution practice (GDP) places requirements for the tracking of the logistics chain.¹³ Directive 2002/98/EC mandates certain practices in terms of the testing of blood products, as well as tracing of the blood components, all through the donor, and maintaining this information for 30 years.¹⁴ Other jurisdictions are also hardening regulations. One example is Taiwan, which aims at curbing the counterfeiting of medicinal products, including plasma derivatives, with a new requirement for tracking and tracing systems across the supply chain.¹⁵

METHODS

This is an exploratory study based on design science research (DSR) approach, whereby our intention is to create a new understanding and theoretical basis for further research and prototyping. Hevner et al.¹⁶ describe the goal of design science as building artifacts to solve

relevant business and organizational problems. Our aim is to build a concept, which can be evaluated and implemented in further studies. The artifact in this case is the top-level analysis and the concept; this is aligned with design science guidelines and the definition of artifact.¹⁶ We also consider that the requirement for problem relevance is met due to the many risks the plasma supply chain is currently facing. Failures in the plasma supply chain will undoubtedly have grave consequences.

We base our concept on existing literature. In the first phase of the study, a literature review was conducted through finding sources with targeted searches, whereby we queried academic databases, Google Scholar and Google with key words, such as “blockchain,” “medicine,” “drug,” “blood,” and “plasma.” Academic literature in this context is scarce and many of our examples draw from commercial sources. This, however, suits the design approach, as real-life examples and blueprints represent tested and proven artifacts, which are adopted already in the industry. Whereas there is plenty of research in the areas of blockchain and cryptocurrency, it has not been extensively studied in the context of health care. We struggled to find any previous blockchain studies in the context of plasma supply chain, which suggests this is an opening in a novel research area.

In the second phase of the research, we evaluated existing blockchain models in areas relating to plasma (i.e., pharmaceutical and blood donation supply chains). We adapted these models to the plasma supply chain, building use cases and proposing technical models to solve them. In the further phases potentially following this study, these models need to be refined and documented, and evaluated further—our intention is to open up a discussion and outline further research topics in this important area.

Paradigmatically, we move somewhere between interpretative and functionalist approaches.¹⁷ The objective of DSR, to create solutions for business, makes it essentially a vessel to solve managerial problems rather than generating radical change. However, we feel that we address important ethical questions, such as those relating to human dignity. Creating new designs for an information systems (IS) artifact is, on the other hand, a subjective task. As complete objectivity cannot be maintained, the researcher's background, and in this case also interpretation of previous literature and concepts, inevitably affects the design.

EXISTING LITERATURE

Plasma Derivative and Pharmaceutical Supply Chains

Pharmaceutical supply chain is a global structure consisting of upstream excipient suppliers, pharmaceutical manufacturers, logistics providers, wholesalers, and downstream distribution channels (i.e., pharmacies and hospitals).¹⁸ Plasma providers are essentially upstream suppliers in the supply chain. In summary, the plasma supply chain has three particular attributes: (1) whereas the demand is stable or increasing, the supply is irregular, (2) a certain pause is required between donations, and (3) plasma is perishable.³

Plasma is often collected as a part of blood donation process, however not always—it is possible to collect only some blood components in the donation process, rather than the full blood.⁴ In Europe, there are more than 1,350 donation centers, and annually 20 million donations are collected.⁴ Whereas national plasma markets are often led by one leading public or private manufacturer, there are a few global plasma pharmaceutical manufacturers feeding into these markets.⁴ While the plasma collection sites are often provided by a

pharmaceutical manufacturer, a significant portion of plasma is collected by independent organizations specializing in whole blood collection, apheresis plasma collection or both. These organizations deliver their plasma to pharmaceutical manufacturers by agreements in which financial terms as well as traceability and other quality parameters are specified.

Currently, plasma is tracked according to regulatory requirements defining the information on collection sites, as well as the processing and transportation steps. These are documented (e.g., in the plasma master file [PMF]), which is a template specified by the European Medicines Agency (EMA).¹⁹ The PMF is a compilation of all the required scientific data on the quality and safety of human plasma relevant to the medicines, medical devices, and investigational products that use human plasma in their manufacture.¹⁹ All individual donations leading to a specific plasma batch have to be identifiable in the PMF. Other jurisdictions have corresponding legislations (e.g., the related code of federal regulations [CFR] in the United States). Whereas today the majority of the source plasma is being collected in the United States, the largest industrial capacity for plasma fractionation resides in Europe, implicating a significant logistics of labile materials across the Atlantic.

Because of infection risks, a quarantine period (typically 60 days) is required before the plasma may enter the fractionation process. During this period, certain specified units may have to be removed from the raw plasma batch if the related donor presents signs of infection or other non-compliant characteristics during follow-up. This interim storage with strict requirements for traceability and temperature control significantly complicates the logistic chain of plasma.

BLOCKCHAIN IN PHARMACEUTICAL SUPPLY CHAIN AND HEALTH CARE

For the purpose of this article, we introduce blockchain only briefly; myriad texts are available for a more extensive introduction, including Nakamoto²⁰ seminal study. A more extensive introduction to blockchain is also published.²¹ Broadly speaking, blockchain is a de-centralized database with cryptographic protocols, which maintains a shared ledger, and which is hosted in a network of computers.²² The blockchain consists of immutable blocks that contain information (e.g., on transactions in the ledger). These blocks are then chained together creating the ledger. An important part of the blockchain processing is the verification of a transaction (i.e., the validation of a new block). In this process, the blockchain network validates the transaction based on previous transactions, and once the network reaches consensus, the new block is linked to the chain.²³

Blockchain is typically conceived as the underlying technology for Bitcoin and Ethereum, and other cryptocurrencies.²³ Bitcoin is an example of cryptographic economic system, which is an autonomous and distributed economic system without any centralized governing organization or institution. The use cases for distributed ledgers and blockchain are numerous outside of cryptocurrencies. A blockchain can be private or public.²⁴ An example of a public blockchain is that underlying Bitcoin—accessible for everyone through the public Internet. A particular user's coins are protected with private key technique, which is used to prove the ownership.²⁵ Private blockchains are, in turn, closed networks restricting the access to only chosen authorized parties.

Blockchain has also been suggested to the health care arena to bring interoperability to the patient record area,²⁶ and a related example is MedRec,²⁷

which is based on smart contracts, a concept introduced by Ethereum.²⁸ Smart contracts allow creating logic for state transitions associated with blocks.²⁷ In the patient record arena, this is useful when authorizing different parties to view and update patient records. Smart contract is one of the key features of blockchain, as self-enforcing rules enable creating autonomous organizations.²⁹ In logistics, this could mean, for example, how a container manages its way to the destination and negotiates optimal routes with shipping service providers.

It should be noted that MedRec's blockchain is not used to store health information but rather link together service providers in a secure way.²⁷ The immutable nature of blockchain may expose privacy issues such as data retention. Even if the data are in an encrypted form, there is no certainty that the encryption would not be cracked in the future.²⁴

In addition, blockchain has been suggested for the pharmaceutical supply chain area. Tseng et al.,¹⁵ for example, suggest using Gcoin blockchain to verify transaction data on sellers, buyers, and medicine deliveries. The counterfeit drugs would be identified in the supply chain through invalid data and fake drug identifiers. It is specifically the counterfeiting problem blockchain has been suggested to solve, and regulations such as DSCSA has spawned various initiatives.¹⁰ These include initiatives from supply-chain-oriented organizations, such as the Center for Supply Chain Studies, whose DSCSCA and Blockchain VirtualPilot aim at exploring how blockchain can be used to share trustworthy transaction information between the participants in a supply chain, and, therefore, meet the DSCSCA requirements.³⁰

MediLedger is a commercial project aiming at the same. MediLedger utilizes blockchain to

prove the authenticity of transactions.³¹ The idea is that supply chain trading partners can authenticate the source of the delivery through secure and private means. Instead of having a centralized database to track the medicinal product delivery, the data remain distributed across the supply chain participants. MediLedger's role is to provide a "lookup" function to securely verify product identifiers between supply chain partners. MediLedger utilizes a private blockchain—the blockchain nodes are hosted across the supply chain and are accessible only to authorized parties. Another noteworthy point is that blockchain is not used to store any sensitive product or logistics information but rather to ensure authenticity of the products with minimum data exposed on trading partners. MediLedger deploys the so-called zero-knowledge proof, exposing only the proof-of-transaction rather than any related commercial transaction data.³²

Within EU, the regulatory pressure has generated commercial blockchain initiatives in the pharmaceutical supply chain arena. One example is Modum, which tackles EU's GDP regulation. GDP requires supply chain parties to prove that medicinal products have been shipped in compliance to requirements (e.g., given the product requires a certain storage temperature). It must be proved that this condition holds for the duration of the delivery.¹³ Modum's solution is based on Internet of Things (IoT) technology and blockchain, whereby the medicinal product delivery is monitored with sensors, with the sensor data collected during the logistics validated with blockchain.³³ Modum's solution utilizes smart contracts to model required conditions and test for compliance. For example, if the temperature rises above the limit, a smart contract is triggered, and relevant parties are alerted. Blockchain ensures that logs are immutable and tamper-free.

According to Scott et al.,¹⁸ one of the problems with pharmaceutical supply chain is the lack of standardized data models. Therefore, a solution such as Modum, or MediLedger, which addresses a limited area of the supply chain process, could be a viable way to harness blockchain and seek for efficiency gains within the supply chain. A wider solution may be harder to develop because the supply chain participants exchange data in proprietary formats, and a wider, shared solution would require standardized formats. Scott et al.¹⁸ conclude that none of the solutions has as yet proven that blockchain can scale up to meet the requirements of track-and-track regulations, although the signs are promising.

Blood donation is also considered a potential arena for blockchain. An example is BloodChain, an "open social blood bank" concept developed by Blodon.³⁴ This concept is intended to form an extensive solution, a new kind of market mechanism for blood donation, incorporating BLOOD cryptocurrency. Donors are remunerated with BLOOD tokens, which can be used to acquire services in the network—the services have not been elaborated upon. Another key element is the donor registry, which holds information about donors and their blood types. The network is based on public and private blockchains and an interfacing back-end system. In concept, public blockchain hosts BLOOD tokens, and the private blockchain is used as a secure indexing mechanism for donors. The donor data are held on a back-end system, and none of the personal sensitive data are exposed in blockchain.

Figure 1 depicts a blockchain structure providing verification and validation within the pharmaceutical supply chain. Blockchain mediates communication between various supply chain parties and enables operating trust-free within an inherently trustless network—this is

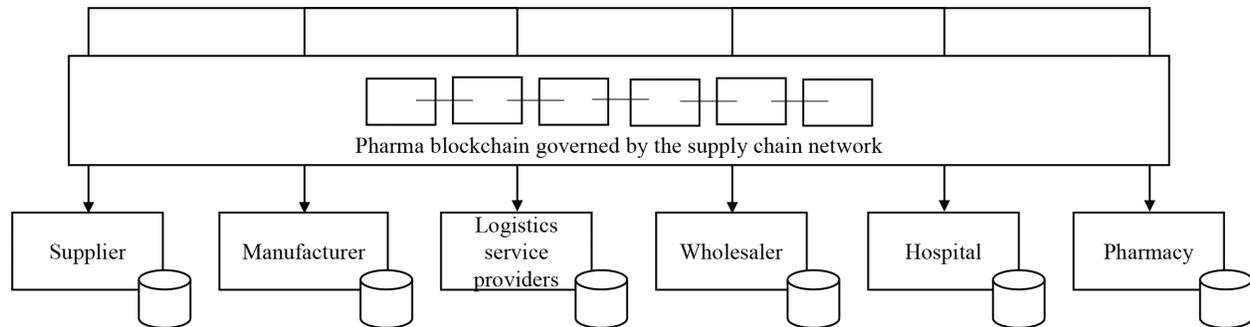


Figure 1—Blockchain in the pharmaceutical supply chain.

because it removes the need for a central middleman and decreases the need to create and maintain trust between individual parties in the supply chain.²⁹ Blockchain's role is to guarantee a valid transaction and bring transparency to the process; the status of the transaction is visible to all participants in the blockchain network. Blockchain essentially removes the requirement for a trusted middleman, an organization mediating transaction, and acts as a "trust machine."³⁵ This removes transaction costs drastically. At the same time, only minimum knowledge is needed of different parties, hence a high level of privacy can be maintained. In a market such as plasma and blood donation, a lot of sensitive data are on stake, and privacy is of high importance.

BLOCKCHAIN RISKS

It is clear that blockchain is one of the current "hype" technologies, and we should be critical when evaluating where to use it. Considering risks, we can identify organizational and technology-related issues. From organizational point of view, risks identified by Lindman, Rossi and Tuunainen³⁶ in association with blockchain payment technologies apply here as well: legal, institutional and adoption related. From a legal point of view, contractual positions must be clarified and there can be completely new legal issues relating to this novel setup. Institutionally, a key question is how

the decentralized organization will work as there is no central authority. Also, as we are discussing a platform, users, developers, and other stakeholders need to be attracted to it—it is crucial, however unclear, as to how to succeed in this.

From a technology perspective, we need to deal with issues such as maintainability, performance and security.³⁷ Given the decentralized nature, change management is more complex than in a centralized, single vendor model. This can lead to chaos with multiple development branches and turf wars. It is also theoretically possible that software, such as smart contracts, is altered without other parties' consent, which deteriorates the trust in the system.³⁷ Performance-wise, public blockchains typically suffer from high latencies, which may undermine some of the use cases.³⁷

Finally, security and privacy are highly important in the plasma supply chain field, and we need to ensure that no sensitive donor data or any sensitive business-related data are jeopardized. Whereas the plasma blockchain would be a private blockchain, storing transaction-related information to the blockchain would potentially expose it to competitors. It has also been suggested that the so-called tamper-proof monitoring mechanisms during the shipping could actually be intercepted with moderate efforts.³⁸

PLASMA DERIVATIVES BLOCKCHAIN

In this section, we will discuss some use cases for blockchain in plasma supply chain. We intend not to outline a finalized specification but rather raise ideas for further research and prototyping. It is straightforward to infer that blockchain can be utilized across the plasma supply chain in a similar way it is used with pharmaceutical supply chain. Two self-evident use cases are those relating to preventing the falsification of plasma products and the logistics of plasma.

First, blockchain could be utilized in the same way MediLedger is used to counter falsified medicines. The main components here would be a private blockchain, hosted by plasma supply chain actors, and nodes representing supply chain actors. A plasma delivery would be assigned an identity, stored in blockchain along with the certificate of origin. When the delivery progresses in the supply chain, each step is recorded in the blockchain complemented with other relevant information. Supply chain parties can access the blockchain through their nodes and enquire the origin of the delivery and individual donations, while maintaining a high level of privacy.

Blockchain's main role here would be to verify logistics transactions and provide immutable ledger, which prevents attempts to tamper any origin information or inject falsified plasma to the supply chain. The benefits would also include the enhanced traceability of plasma: for example, in the case a delivery has to be withdrawn due to a contaminated donation, it would be easy to follow the blockchain trail from the single donation to the batch and its current location.

Second, as plasma logistics is a major transatlantic industry, whereby the product is highly sensitive in terms of storing conditions, a solution monitoring these conditions, and raising

alerts where applicable, is another area blockchain could be utilized in. The benefits would include that blockchain would verify plasma batch's shipping conditions and provide information if there are any suboptimal conditions across the shipping chain that may cause defects in the plasma. Again, this solution would be based on a private blockchain, which is accessed by nodes representing the supply chain parties. Logistics transactions would be stored in the blockchain and the solution would incorporate IoT sensors monitoring the batch.

In addition to these two use cases, we introduce a third one, which is based on the donor's perspective. The idea here is to provide mechanisms for incentivizing donors and allowing them to take better control of their data and donations. From a governance point of view, this would also allow monitoring individual donations and prevent too frequent donations. Generally, this would entail a distributed, decentralized donor registry, whereby a donor's data, such as health screening, would be located in one authorized donation center and donation events would be recorded in the blockchain. Each of the donors would have a single identity, which would work in each of the centers.

From an ethics perspective, the end customer of plasma could monitor donations and exercise corporate responsibility: for example, it could be monitored that a donor does not donate too frequently (e.g., by going to different centers). The health effects of too frequent donations are not clear, but there may be an adverse effect. The controlling could be conducted with a smart contract. For example, if a donor's previous donation is within a certain time period, a new donation is forbidden.

Another key factor in this model is an incentive model, which could be tied to the system.

For example, rather than remunerating with cash, donors could be granted tokens they could use in public health services, public transportation or other public services. This would follow the example of BLOOD tokens described above. In a more far-reaching manner, blockchain could contribute to a diminishing role of the middleman (i.e., the global plasma collection firms, which currently collect plasma and remunerate donors). A completely new kind of plasma supply chain networks could be built whereby donors could obtain an increased control to their donations economically.

This is depicted in Figure 2, which illustrates how donors donate the plasma across the network of trusted collection centers. The donor is registered in one of the collection centers and identified through blockchain. The donation transaction is

verified with blockchain and recorded with the user's data in a secure data source.

A comparison here could be drawn to MyData—a concept that has recently gained traction. It aims at increasing individual's control of his or her data and transforming it to an economic resource.³⁹ MyData is based on a network of MyData operators, which host functionality for users to consent the use of their data for different parties; in our model, plasma blockchain is essentially carrying out this task. The philosophy is still the same: give more control to donors. The remuneration could be in the form of cash transfer or a crypto currency transfer to the donor's crypto wallet.

Based on these solutions, we are now revisiting the plasma supply chain risks in Table 2 and evaluating how blockchain could be used to mitigate them.

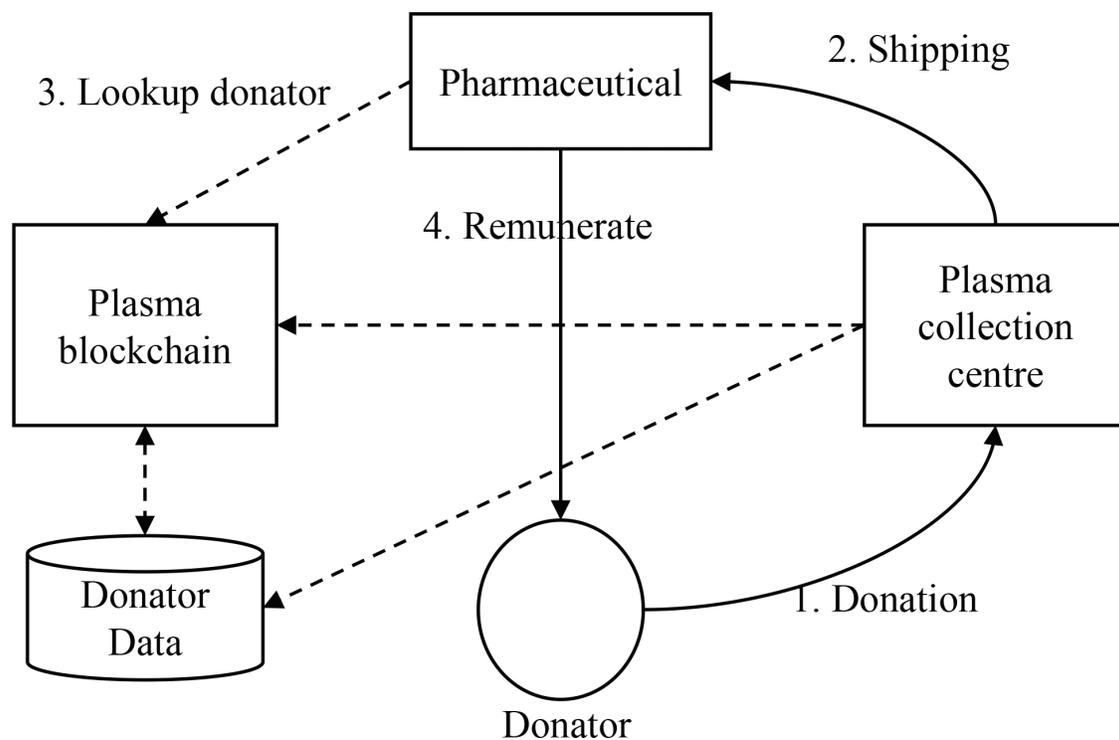


Figure 2—Plasma derivatives blockchain. In the figure, dashed arrows depict connections to data sources, whereas solid arrows depict concrete material or remuneration flows.

Table 2. Blockchain solutions for plasma supply chain risks.

Risk	Blockchain Solution
Ethical	Blockchain could be used to implement a decentralized donor registry, which would enable monitoring of donations and prevent too frequent donations. This would discourage unethical patterns, whereby addicts or otherwise distressed individuals would be exploited through frequent donations that would jeopardize their health. Furthermore, blockchain could be utilized to enable donors take control of their data and donations and related economic benefits through incentive models and diminished role of the middleman in the market.
Contamination	Whereas blockchain-based solutions cannot prevent contaminated blood being donated, they can be used to verify the origin of the plasma and ensure that it comes from a trusted source, with adequate testing and disinfection processes. This solution aims at preventing falsified plasma products being injected for delivery across the supply chain.
Falsification	As with the contamination risk noted above, blockchain can be used to verify the origin of the plasma and ensure it is coming from a trusted source.
Supply chain	New plasma market mechanisms and incentive models could contribute to an increased supply of plasma in regions that are currently heavy importers of plasma.
Regulatory	Blockchain-based solutions can be utilized to control and monitor the supply chain, in terms of verifying origin as well as the shipping conditions, which would contribute to the compliance to regulations.
Reputational	Improved risk management overall will mitigate the reputational risk, as increased control, monitoring, and ethicalness prevent incidents, which could have reputational impact.

CONCLUSIONS

In this study, we have examined how blockchain is used within health and pharmaceutical arenas. We have adapted these learnings in the plasma supply chain through suggesting various use cases. The intention of the paper is to provoke thoughts and outline areas for further research.

The plasma supply chain in its current form imposes various risks, and it seems that blockchain-based solutions could be utilized to mitigate these risks.

First, current blockchain solutions, which are designed for pharmaceutical supply chain to prevent medicine counterfeiting and monitor

logistics chains, could be aligned to the plasma supply chain. This would contribute to preventing falsification of plasma and managing the risk that poor quality or contaminated plasma with uncertain origin is transmitted to the supply chain. Maintaining the quality is important from reputational perspectives. Furthermore, regulatory risks are increasing as regulations are becoming stricter—having a solid mechanism to confirm the origin will mitigate this risk.

Second, blockchain and MyData can be utilized to increase donors' control on their data, donations, and economic benefits. This could entail new incentive models for donations, which, for example, could increase donations and therefore mitigate the supply chain risks.

Utilizing blockchain or a similar solution to build a decentralized donor registry would also enable controlling the frequency of donations. From an ethical perspective, this would allow plasma industry to exercise corporate responsibility and discourage too frequent donations from addicts and other distressed individuals.

These, however, are only initial findings and require further study. This study is limited to review of some of the recent developments in the field. The academic research in the arena of plasma blockchain is virtually non-existent and even in the pharmaceutical arena it is scarce, which undermines any attempt to conduct a systematic literature review. Our solution is top-level, and an initial attempt to outline how blockchain could be used in the plasma supply chain. We want to initiate the discussion and understand how blockchain technology can mitigate various risks associated with the plasma industry, and the solution outlined here is to be evaluated and taken into a more detailed level.

We consider outlining a top-level solution and pointing out multiple areas of further study contribute both theoretically and practically. For the former, we especially welcome research on blockchain and MyData and the related economic system as a novel area in terms of plasma blockchain. The follow-up research can be conducted from multiple perspectives, such as those of design science and technical designs, as well as considering organizational and economic impacts of such a system. For practical contribution, we consider the adaptation of the current blockchain solutions used in the pharmaceutical supply chain to the plasma industry a straightforward next step.

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Contributors

Both authors made substantial contributions in terms of literature review, market risk evaluation, solution design, and the writing of the manuscript.

Conflicts of Interest

Jarkko Ihalainen serves as the Medical Director at Finnish Red Cross Blood Service, which supplies plasma to the pharmaceutical industry. Teijo Peltoniemi declares no potential conflicts of interest.

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