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EXECUTIVE SUMMARY

According to the upcoming EU MDR regulation, all medical devices sold in Europe will be required to meet the MDR regulation by next year. If medical devices are not meeting the requirements, they are not allowed to be sold or used in Europe. Our mission is to use blockchain as a tool to meet the requirements for medical devices. We decided to use the MRI scanners as an example for our case study. We did this, because its manufacturing, logistical and installation process is one of the most complex in its category. Our aim is to create a tamper proof system that uses blockchain to store data and execute smart contracts that will activate automated processes with the focus to minimize delay on reshipping components and creating damage reports. In addition, we will be using IoT as a tool to avoid third party dependency and for real time tracking during logistical processes.

At Neuro Trace we are utilizing blockchain, IoT technology to tackle problems within the supply chain. Our goal is to increase transparency within the supply chain to make the process more effective and efficient. We achieve this by making an automated follow up system that excludes human interaction and decision making. The headquarters of the company is located in Amsterdam and the ownership is divided between 5 founders.

We will build our concept on the blockchain of Vechain, because they are using a hybrid blockchain, which creates an adaptive blockchain in which you can decide what part of the business should be transparent and which private. In addition, their expertise in the field of blockchain, supply chain and the patents they hold will be beneficial for us in the long term. After we are done with building on the Vechain blockchain, we will launch our own. While many projects prefer Ethereum as their to go to blockchain to build their project on, we decided to go for Vechain, because its supply chain focused.

At this moment, we cannot measure what financial impact our concept can have. If by next year, medical devices sold in Europe are not meeting the EU MDR regulations, they are not allowed to be sold. Therefore the financial stakes are high and the additional values that our concept solves, will bring even more financial benefits. With our concept we can make the logistical process more efficient and transparent to all parties involved. In addition, with our approach we can improve the customer satisfaction, by adding the additional features to the system as explained.

1. PROBLEM

The problem that we are solving is a combination of the need to meet regulations and spotting precisely when and where the damage has occurred or threshold for the specific requirements has been passed. When dealing with medical devices and their components that are of high value, not being able to find out who is responsible for a failure along the supply chain, can create the following problems : unwanted documentation work. inadmissible delivery delays, conflict between parties within the supply chain and unexpected high legal costs. Any delay in the supply chain of medical devices is not only about the costs created by the components that are not arriving at the correct time and in the right circumstances. Probably the most important aspect is the fact that it can also be a matter of life or death for the end user.

EU MDR

The European Medical Device Regulations (EU MDR) are changing May 26th, 2021. The EU MDR ensures high standards of quality and safety for medical devices being produced in or supplied into Europe. Therefore, components distributed in or shipped to the European Union must comply with the new EU MDR. The quality and safety of components need to meet all requirements from the moment components are manufactured until they are successfully delivered and assembled.

Unusable components

Medical devices are made out of a wide variety of materials, which all have different levels of endurance. During manufacturing, storage, transportation and assembling the values of components are being affected by changing circumstances in the environment of the product, such as temperature, humidity, air pressure and unexpected movements. Due to these changing circumstances, components might become unusable. When a component becomes unusable, they will create a snowball effect of delays, additional costs and impacts the customer satisfaction.

Third party tracking dependency

In the current logistical process components that are being shipped are fully relying on third party tracking & tracing. While this may be a cheaper approach in the present, this can cause the real time tracking flow to be interrupted, since there are multiple logistical parties shipping the medical device during its logistical process. Whenever a logistical company delivers a medical device to another logistical company there might be a chance that there will be moments in which the components are not tracked. This will lead to untraceability, interruption periods and a difficult way to track and trace when so many responsibilities are being shifted during the logistical process. In case of damages, if they occur in the period where there is no traceability, it is hard for companies to file a claim since there is no factual evidence that can prove that a specific party was responsible for the damage.

Delay of delivery

When components are damaged during their logistical process, it is not always possible to detect it, until after installation. Once a damaged medical device or one of its components is detected to be damaged, the followup process will start. Once everything is clear, a damaged medical device will be shipped back and a new device will be reshipped. In some cases, this will mean that a medical device that consists of multiple components will have to be disassembled. This will lead to more labor, costs, time and all the effort it takes to fix the occurring issue. Eventually this might impact the customers

satisfaction, since they are affected by the delay. In the case of MRI-Scanners a delay could be a matter of life and death.

Insurance claims

When there is no constant real time data flow generated during the logistical process, it is hard to hold a company responsible for the damages that have been made. Because of this there is no factual data which can prove who is responsible for the damage, which then will lead to insurance claims to be invalid and eventually this will lead to additional costs and lost time.

2. SOLUTION

All the previous mentioned problems are included in the Neuro Trace solution, that is what makes this solution so unique. The essence here is automation, validation and real time data flow. Blockchain technology is what enables this automation and validation. Together with smart contracts, our digital transmitter plug and a neural network, Neuro Trace can make these technologies work together. This to automate the reshipment of crucial components.

Blockchain

For our solution we need a reliable and trustworthy system that does not require the involved participants to know or trust each other or a third party for the system to function. For our solution we are relying on a system that can record certain behaviors on which smart contracts are executed to automate the follow up process. Since the blockchain is in its current form expensive and still in full development, we will use the blockchain only for necessary data collections that are needed to actually execute smart contracts.

Smart Contracts

A smart contract is a self-executing agreement embedded in computer code. This is managed by a blockchain that contains a set of rules under which the parties of the specific smart contract agreed upon. The agreement automatically gets enforced and cannot be stopped. With this type of automated regulation, we can increase the process flow and eliminate human interaction or decision making.

Reshipment Protocol

The reshipment protocol is an automated process that excludes human interaction. The reshipment protocol is initiated once a specific value is exceeding its threshold. These requirements could be based on the EU MDR regulations as an example. The authentication of the data is the key in this case, and that is where the use of blockchain comes in. The data is recorded on the blockchain once our digital transmitter plug senses a certain threshold that has been passed. Once the data is recorded, the reshipment protocol can be initiated due to tamperproof data and authentication. The protocol is designed in such a manner that the logistics data in a company's logistics chain is available in our system. To replace the damaged or invalid components the fastest and most efficient way, the protocol will have an internal search engine to match suppliers with the carrier and automatically reorder the components.

Automated Damage Reports

When the blockchain registers that a component has been damaged and became unusable, the digital key transmitter will create an automated damage report that is based on registered and collected data. Once the damage report is made and registered on the blockchain, all relevant parties will receive the report. The reports will be shared on our application, which will notify the parties of interest by e-mail or SMS.

Neural Network

To make our solution functional, we need to create a network that is connected to all relevant parts within a medical device. For example, to avoid wireless data flow around a MRI scanner, we have come up with the solution of a wired neural network within each component. Every part within the component with value, will be connected to the neural network and their parameters will be collected and distributed to one end point. Every component that gets attached or detached from the network will be recorded. During storage, transportation and assembling, there will be a digital transmitter plug that collects the data from the neural network and sends it to the blockchain.

Digital Key Plug

Since a transmitter is an electronic device used in telecommunications to produce radio waves in order to transmit or send data with the aid of an antenna, we are going to create a digital key plug with an integrated GPS that is portable and has a universal fit for all relevant components. With this device we will collect real time data during storage, transportation and share it on the blockchain to allow smart contracts to be executed. The digital key plug will be locked during the whole process until it arrives at the end destination. Before installation, a smart contract will be executed and the digital key plug will be unlocked. For example, right before a component will be installed on the main component of an MRI-Scanner, the digital key will be unplugged and the neural network of the component will fusion with the main components network. Within the digital key there is a blackbox that will record all data collected during the logistical process until it is assembled. If the medical device gets damaged, the blackbox will collect factual data and use it to create the damage report. This means that within the digital key plug, there will be a system which can make the damage report and send it to the blockchain and involved parties.

3. PROCESS

Application

For our process we will be using an application that will showcase in depth product information to the authorized parties. All parties that are within the manufacturing process will automatically add information on the application about a certain medical device. In addition, during the logistical process all important information will also be shown on the application to authorized parties. At the point of arrival of a product or during the installation of a component, authorized parties will be approved to remove the digital key plug, which will be done true to application that the party can open on any device.

Digital Key Plug

The digital key plug is a reusable plug that has a universal fit that can connect to all component that uses our system. Within the digital key there will be a GPS that will track the medical device during its logistical process based on its location. The plug will also contain an internet connection that can be used to send encrypted data when necessary. To avoid an overflow of data on the blockchain and to exclude unnecessary information, the digital key will contain a black box that will store data. Whenever a value exceeds its threshold, the data from the black box will be sent to the blockchain and an automated damage report will be made.

Neural Network

All important parts of a component will be wired to the neural network and will only measure values that are important for that specific part. With this approach we avoid overflow of data, with the aim to make the system as efficient as possible. The neural network will lead to one end, where a digital key will be placed. Once the key is removed and the component installed on the main component, the neural network will fusion with the main component and send important data to that digital key. For example, with this approach we can avoid the need of additional systems in the component and fully rely during transportation on the digital key and once installed, we can rely on the build in system of the main component of a MRI scanner.

Blockchain

Only when a certain value of a Medical device is exceeding their threshold the blockchain will be used. Based on the information the blockchain receives a smart contract will be executed that will start the automated follow-up process as like; the reshipping protocol, sharing the damage report and the reshipment of the invalid medical component.

Digital Key Lock

Once a digital key plug is placed in a medical device, the plug will be locked and can only be opened by authorized parties. The lock itself will function as a safety mechanism to avoid corruption, with the aim to create a closed loop that is tamper proof.

Smart Contracts

When the blockchain stores data of a medical device that indicates that one of the values is exceeding the threshold, a smart contract will be triggered.

- ❏ All authorized parties will receive a damage report on their application and that will automatically inform them by e-mail or SMS.
- ❏ The process of shipping back the invalid medical device will be processed.
- ❏ The reshipping protocol will be triggered, which will automatically resend a new medical device to the destination of the invalid medical device.
- ❏ For example, when a component is ready to be installed on the main component MRI, a smart contract will trigger and allow the assembly team to remove the digital key.

4. MARKET

With growth of awareness about the benefits of using blockchain within the supply chain the market is projected to witness innovative and advanced transformation that will enable access for more

participants. The market is expected to witness significant growth in the upcoming years due to increase in adoption of blockchain platforms, advent of affordable and diverse pricing offered by market players, increased need for supply chain transparency, proliferation of e-commerce industry and rise in demand for enhanced security of supply chain transactions. Various industries ex. Healthcare or food and beverage are adopting blockchain technology to trace products at various stages in the supply chain and this is expected to drive product traceability segment growth in coming years. Smart contracts application segment is projected to rise the highest CAGR in the upcoming years. Since elimination of intermediaries with blockchain, automate contract execution with smart contracts and increased automation in supply chain is expected to present strong market opportunities in coming years.

The global blockchain supply chain market size was valued at 93.16 million USD in 2017, and is projected to reach 9.852,91 million USD by 2025, growing at CAGR of 80.2% from 2018 to 2025. However, because of the Covid-19 pandemic, scarcity of skilled workforce and lack of awareness about the benefits of blockchain technology may hamper the market growth.

The market is divided into smart contracts, payment and settlement, product traceability, inventory monitoring, compliance management and others. The retail industry dominates the blockchain supply chain market share and is expected to remain dominant for the foreseeable future, due to rise in adoption by retail players to streamline their supply chain process. However, after extensive market research, the healthcare industry is to witness the highest CAGR in the coming years due to healthcare service providers implementing blockchain technology to constantly monitor and track healthcare products from production to deliver leading to decrease in illegitimate activities such as counterfeiting of drugs, improper stock control and illegal production of harmful medicine. (The deployment of track and trace solutions helps manufacturers enhance distribution channels efficiency and reduce the frequency of counterfeit products) That's why our blockchain supply chain market outlook looks positive with consistent growth annually.

5. PARTNERS

Syncronicity

Syncronicity is our incubator who will assist us during the whole process of setting up our business operation.

IBCOL

As the International Blockchain Olympiads (IBCOL) explains itself, their mission is to support sustainability and maturity in blockchain by working with academic, industry, and government partners. Primarily working with secondary and tertiary students, IBCOL provides education and training on designing complete blockchain solutions.

With the yearly International Blockchain Olympiad, IBCOL uses Top Young Talents to tackle the toughest global challenges with blockchain. IBCOL is sponsored by HSBC, organised by the City University of Hong Kong and has Hong Kong Blockchain Society as strategic partner.

In the 2020 edition of the Olympiad, Neuro Trace participated as one of the 60 teams from over 15 countries. With our concept Neuro Trace managed to win the Bronze Medal, meaning the third place

in the overall competition. After staying in close contact with IBCOL, the organisation adjudged to assist us in the making of our first working prototype.

Inholland University of Applied Sciences

Inholland University of Applied Sciences, not to be confused with a research university, offers various international bachelors, from its eight locations that are all based in the Netherlands, Inholland is leading the way on sustainability, health and creativity. Through its wide range of fields going from innovation to business and technology to media, Inholland created a network environment with the possibility to do this in consultation with businesses, not-for-profit organisations and education and research institutions.

Currently we will mainly focus on the knowledge gained out of Inhollands' Business Innovation programme, since this is the Bachelor programme where the Neuro Trace team is formed. This program is offering the expertise of multiple professionals that are currently operating in the workfield, since a high percentage of the Business Innovation lecturers and professors are only working at Inholland as part timers besides their primary business occupations . This guarantees up to date consultancy from professionals in a start-up friendly environment.

6. COMPETITION

Since it is such a fledgling industry there is not really a thing such as a competitor. As the industry is so upcoming that they are actually trying to learn from each other as much as possible. Besides that, there is still no one really taking the lead anyway, this due to the huge differences within their goals.

Maersk

Maersk is focusing on taking traditional tracking of cargo to the next level as there is an untapped potential within the market. By integrating the new tracking API, it allows their customer to have access to the granularity of tracking the contents of containers, right down to SKU or Purchase Order levels. Over processing currently represents the largest challenge within the industry. Since documentation for a single container could be exchanged over around a 100 times. The document processing accounts for 20% of the total transportation costs within the global trade.

UPS

UPS seeks to utilize their system to route and track packages globally with more efficiency. The system allows the mega delivery firm to monitor their packages across multiple carriers. This is important as customers push for quicker and cheaper shipping alternatives. UPSes Automated determination systems can track packages across international borders in real-time. This data is then combined with relevant local information in order to determine the optimal route for each package. The system will function completely on its own without the need for any human intervention

IBM

IBMs Blockchain Transparent Supply, can leverage end-to-end and real-time visibility for a more resilient, nimble, and responsive supply chain. Deepen consumer engagement, manage your inventory dynamically, and reduce inefficiencies. They focus on these three solutions:

- ❏ Ensure provenance and quality to build a trusted brand
- ❏ Improve forecasting with better demand signaling
- ❏ Reduce friction within your supply chain

Examples of other key players already setting up their operations within the Blockchain Supply chain market are: Oracle, Microsoft, Omnichain, AWS and Nodal block.

7. RISKS

The risk of fraud is minimal since every single person in the blockchain has to be in on the corruption and cooperate in order to corrupt the blockchain. Another risk is the involvement of third parties, business reputation and a variety of financial and non-financial third-party damages. We will build our project on the VeChain platform. Vechain is experienced and a well known organization that has worked with major companies, therefore risks are minimized. Also, there are risks of the plugs on devices having lack of internet access in some places. Due to that some of the problems with certain devices or their current destination can be lost and left unnoticed. However, with the upcoming 5G network, Starlink and the already in development 6G network, we believe that in the near future the risk of losing track & tracing will be eliminated. In addition, we can create a prediction route and estimate track & tracing based on timestamps that will be registered on the blackbox of the digital key plug.

Corrupted Data

Referring to errors in data that might occur during for example: storage or transition... that might lead to unintended changes to the original data. Results of this could lead from minor loss data, errors to a system crash.

Third Party Involvement

The risks that may arise from an institution's use of third parties are numerous and diverse. Failure to manage these risks can expose an institution to regulatory action, financial loss, litigation, and reputational damage, and may even impair its ability to establish new, or service existing, customer relationships. Types of risks we might face when working with a third party:

- Financial Risk
- Reputational Risk
- Regulatory/Compliance Risk
- Operational Risk
- Strategic Risk

The biggest challenge for organizations is to provide the appropriate oversight and keep these risks in check.

Damaged Digital Transmitter Plugs

Referring to the first problem with corrupted data, damage to our digital transmitters might occur during transport or storage, which could lead to either corruption of the data itself or in the worst case the complete loss of data resulting in delays and disruptions within the supply chain.

8. ARCHITECTURE

We are still researching what existing blockchain we are going to build our concept. Therefore it is still a question how the architecture will look like.

9. GOVERNANCE

We are still researching what existing blockchain we are going to build our concept. Therefore it is still a question how the governance will look like.

10. Value

Reliable Real Time Tracking System

With our proposed solution, companies moving expensive components that have to meet certain standards and regulations, such as the EU MDR regulations, exclude third party reliance. With their own real time tracking system in place, they can have a constant real time tracking and data flow along the storage, transportation and assembling process.

Responsibility

When the blockchain detects that a medical device has been damaged during storage or transportation, with the help of a smart contract we can automate the process of reshipping a new component to the end destination through a quicker route and the party responsible for making the damage will pay for the costs. This is due to the automated damage reports being sent automatically once a fault has been detected and a pre-emptive smart contract agreement between the parties involved.

Minimizing Delay

With the automated reshipping protocol, we exclude human interaction and decision making. This will increase the speed of the process in which a smart contract will play a key role.

Cost Efficient Digital Key Plug

After a component has been installed, the digital transmitter plug can be reused for another component. To make it more cost efficient, all plugs are universal and suitable for all components that are compatible within the system.

Tamper Proof Solution

With a tamper proof locking system, we can eliminate fraud and create a closed data loop. While the blockchain and smart contracts are trustworthy, physical devices might still be corrupted. To eliminate this, we came up with the solution to create a locking system that will unlock based on a smart contract execution.

Meeting the EU MDR Requirements

With our solution, companies that are involved in shipping medical components will meet the EU MDR requirements in the supply chain, in which they operate. In addition, companies tend to rely on the suppliers and the data they receive from them. This might not be tamper proof and medical device companies should consider partnering up with companies that are willing to become transparent in their operation to fully fulfil the EU MDR requirements.

11. DISTRIBUTION

The next step to take this project to market is to create a minimal viable product that showcases that our concept works. Once this has been shown, we will fully develop the IoT devices we need and test them on the Testnet of Vechain. Once our concept is fully tested and added to the blockchain, we will slowly start with real use cases. When we are fully confident that our concept is running smoothly, we will launch our own blockchain and become an independent blockchain.

12. RECOMMENDATION

In the recommendation section we will go over the advantages and disadvantages of using blockchain to track components. In order to help with the decision of whether to adapt our technology or not Neuro Trace has set up a list of pros and cons that should be taken into consideration.

Blockchain advantages

Disintermediation: Blockchain is a distributed system that eliminates the need of a middle man from your system. From all services the middlemen offer, they get a cut. In reality, a small amount of payment might not seem like much, but it does add up when your service requires a 10-15 step process. Helps prevent fraud.

Accepted by institutions as validated data: More and more institutions, governmental and private, see blockchain data as proof. This means that blockchain data can be used to meet regulations and requirements set by third parties. Companies can showcase their blockchain data system as validation of meeting certain regulations and requirements.

High quality data: Blockchain technology offers a superior level of data quality. In reality, it is a distributed ledger system where it stores data. Distributed ledger technology offers a consensus process that allows you to filter out any bad data from useful data. It means that no one can just add any kind of information on the ledger or even manipulate the existing ones. Preventing false data and human mistakes.

Durability and Security: Blockchain offers durability at its best. The overall structure of the technology makes it durable. Moreover, as it stores blocks of information around the network, it makes sure that there is no single point of failure or any single entity controlling it. So, there's little to no possibility of overpowering this network.

High level of integrity: Compared to any other network systems out there, blockchain offers the highest level of integrity so far. It means that all your data will always be the right one, and no one can alter them once it's on the ledger. Users can nott just make changes to the verification as he/she pleases. Thus, when you transact or store any other information, it would offer accurate and reliable data every single time.

Immutability and Transparency: Blockchain comes with an immutable storage system where you can't change any single form of data or let alone delete them completely. As every single block will have a Hash ID, any changes to the data of that block would change the ID drastically. And it's impossible to recreate the same Hash ID again. Thus, if anyone tries to change the data, all the other users would notice right away.

Improved Traceability: In every stage, you need to ensure that it offers the highest quality. However, if you don't know the origin of your goods, then you can't offer quality. However, blockchain ensures that you can trace these items from the very source to the endpoint.

Faster transactions: Blockchain offers faster transactions compared to traditional means. Usually, the centralized banks can take a lot of time even to process a transaction. This is more prominent when someone tries to send money overseas.

Lower transaction costs: Obviously, nothing is for free. Blockchain offers a lower transaction fee in exchange for the faster transaction process.

Simplistic Ecosystem: What blockchain does here is to shrink down the various stages of processing into a few steps. More so, as the technology can offer almost everything online, it's much easier to maintain.

Blockchain disadvantages

Complex Signature Verification Process: Basically, for every transaction in the system, you'll need a private-public cryptographic signature verification. It then uses the ECDSA (Elliptic Curve Digital Signature Algorithm) to ensure that the transaction happens between the correct nodes. Thus, every node needs to verify the authenticity of the user, which can be a tricky and complex process.

Private Keys: You need to keep your private key secured by any means if you don't want other people to abuse your assets, in this case the company's assets or data. However, if the private key is lost, access to funds on the network is as well. There's no way to recover them anymore.

Large Energy Consumption: To ensure that every transaction is valid, it needs to go through consensus processes. Obviously, the consensus process requires a huge amount of effort to form every node increases the overall power consumption.

High Cost: Blockchain is much cheaper than other infrastructures. However, it can be a costly solution, as well. Basically, the cost depends on what type of feature you want to add and what your needs are. More so, developing a solution form of starch requires a hefty amount of money. Not to mention replacing the legacy system.

Lack of In-House Capabilities: As technology is a relatively new concept, there aren't many capable developers that can work on it. So, when enterprises try to develop their very own enterprise blockchain solution, finding a capable team to handle the project becomes hard.

Conclusion

While blockchain is still in its early stage of development, we believe that by using the system in its current form is only worth it, if the registered has a meaning or purpose. This means, either the data has to execute smart contracts, that will start follow up processes, or record data that is shared with third parties as like a damage report.

We believe with our approach we created a unique system that is tamper proof, meaningful and has the potential to be used for other product categories besides medical devices that consist out of multiple components in the future. With the reshipping protocol in place and the system that will reship products based on time and cost, it makes it an automated system that excludes human interaction and quicker decision making. In addition, the automated damage report will assure that all parties involved will be notified in time and based on data that is collected on a factual basis.

Nevertheless, the digital key plug is a unique way to avoid additional costs that a manufacturer has to put in a product, but instead using a reusable plug that has no limit of reusability.

We believe that with the right set of tools, partners and the use of the blockchain we can create an automated reliable system that can act on its own. We believe that in the future logistics will be fully automated and the only human interaction there will be is when the end consumers receive its product.