BioRegio STERN | Blockstart Interreg NWE Project

Blockchain Technology in Life Sciences & Health

Report

December 2022

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Preface

With the goal of supporting small and medium-sized enterprises (SMEs) from the healthcare, logistics, and agri-food sectors to explore the benefits of blockchain technology and develop proof-of-concepts for new business models, the Interred NWE Blockstart project was launched in 2018. During the course of the project, it became apparent that healthcare companies that distribute certified medical devices were less interested in participating in the training program. Therefore, BioRegio STERN Management GmbH commissioned the present study as part of the Interreg NWE Blockstart project to analyze the prerequisites for the adoption of blockchain technology in SMEs from the healthcare sector. With this study, the Blockstart consortium aims to first explore why healthcare companies are less interested than companies in the other two sectors and to identify ways in which healthcare companies can benefit from blockchain technology. Based on the results of the study, recommendations to decision-makers have also been developed on how to specifically boost the implementation of blockchain technology in companies. The Blockstart consortium hopes that this will result in better opportunities for SMEs to benefit from support programs designed to promote the use of blockchain technology in the future.

Introduction and Report Outline

Since the first implementation of the blockchain for Bitcoin in 2009 countless ideas for further applications have been discussed for various business areas. The hyped technology forces whole industries to think about potential blockchain applications for their own business models, causing either excitement or concerns about its development. The blockchain technology offers continuously new concepts, proof-of-concepts and well-developed businesses, having the potential to become a disruptive technology that changes whole industries.

Due to its immutable functioning of chronological and distributed data storing, blockchain technology has the capability to change industries such as Life Sciences and its business models drastically. At present, the new distributed ledger technology changes rapidly. Despite the difficulty of implementing industry wide standards concerning its use in the short term, it is prudent to avoid disruptive surprises or missed opportunities.

In Life Sciences & Health, those opportunities will include the improvement of data transparency to increase documentation efficiency and trust among parties. Blockchain technology will enhance the access to and the integrity of patient data. Furthermore, it will provide mechanisms to safeguard intellectual property and offer interoperability methods to create uniform standards among stakeholders.

This report explores what blockchain technology entails, which benefits and challenges it might bring for the Life Sciences & Health industry and which use cases can be envisioned. It is the result of a survey with ten participants *(8 small- and mid-sized enterprises (SMEs), 1 big company, 1 university)* and a one-day brainstorming workshop in which challenges and possible solutions were discussed.

What is Blockchain Technology?

Originally developed for the cryptocurrency "Bitcoin" and differing from a classic database by its functioning of data storing, the blockchain offers opportunities for new applications. The blockchain is based on a network of participants verifying and time-stamping new transactions before adding them to the chain of previous blocks. This process guarantees cryptographic sealing, making the distributed ledger immutable. The risk of manipulated information distributed on the network can be ruled out, resulting in a continuous mechanism of control. Further, the decentralized storage in the blockchain is known to be very failure-resistant due to its network-based verification process. In contrast to other systems including intermediaries, the blockchain enables the settlement of transactions without a trusted, central authority by replacing it with the network's consensus mechanism. Consequently, the costs and speed of transactions can be reduced significantly.

Blockchains can be deployed either publicly available like the Bitcoin blockchain or within a closed network as a permissioned blockchain. Permissionless blockchains are open concerning the access and visibility of transaction information. They are often based on a consensus mechanism requiring a reimbursement for occurred costs (Proof of Work). To achieve the network's integrity and a continually growing chain of blocks, specialized nodes need to solve mathematical problems. The new block is then validated by the rest of the network, resulting in immutable and time-stamped transaction data. Disadvantages of this approach are limited transaction capacity, high electricity consumption and public availability of transaction information. These limitations have led to the exploration of permissioned blockchains restricting the network participation. Advantages of a closed network are the possibility to use other methods of consensus (for example Proof of Authority) as well as increased data privacy. However, the approach lacks some of the benefits of a permissionless blockchain. The unnecessary trust between participants is endangered by the rather small number of members in a permissioned network. Neither immutability based on the verification process nor compatibility with other private blockchains can be guaranteed.

Benefits of Using Blockchain Technology

There is a multitude of potential benefits when using blockchain technology, independently in which industry and for which use case the blockchain is used. Key benefits are:

- Reliability: Distributed ledger technologies allow an always-online functionality and due to their decentralization, there are no single points of failure. As a direct communication among nodes and stakeholders is established, no third party is required. Blockchains enable data sharing without control overhead.
- Connectivity: As all transactions are distributed among participating stakeholders, anyone in the network can submit transactions, deploy smart contracts and innovate. Networks are usually globally accessible.
- Security: All transactions are digitally signed and the record of events is immutable, mitigating malicious behavior. In permissioned blockchains, authority parties can manage ownership and set clear rules and guidelines on which transactions are allowed and which are not, increasing data security.

Relevance of Blockchain Technology in Life Sciences & Health

Even before the advent of COVID-19, the health and life sciences industries faced significant challenges, including trusted network issues, data privacy, intellectual property thefts or interoperability. Blockchain technology can help solve these problems.

The Life Sciences & Health industry is, among others, facing the following issues:

- Lack of trusted network: There is no established network for a trustworthy exchange of data. A point-to-point connection among participants is required, especially to increase the availability and efficiency of accounting measures to document which data has been exchanged.
- Stealing of intellectual property: The increase of collaborative research, but also the digitalization, lead to intellectual property theft, making it critical to establish IP ownership.
- Data privacy: Data breaches regularly expose millions of patient record as unencrypted and centralized patient data lead to significant privacy issues.
- Interoperability: There is a lack of interoperability among stakeholders in the health ecosystem (doctors, researchers, pharmacies, etc.) due to different data standards.
- Data access: Stakeholders only have limited access to population health data and participants in networks focus only on a limited number of providers (e.g. hospitals).

Blockchain technology can solve or mitigate these issues: The decentralized characteristics of a distributed database with cryptographic functions ensure the secure data exchange. Intellectual property records are established through the permanent ledger of data (i.e. immutability). Furthermore, using private and public keys, a more secure method of protection patient data can be established. As every stakeholder interacts with preferably one blockchain, standardization among data providers and users is ensured.

Considering those unique blockchain traits, the following benefits for the Life Sciences & Health industry can be drawn:

- User anonymity: Cryptography is used to keep the identities of blockchain users hidden and the only person to know their data is the user itself or whoever the person shares the data with.
- Improved transparency: All blockchain participants are able to view the data added to the blockchain. The data integrity is improved by being the single source of truth.
- Traceability: Transparency of the immutable data on blockchains enables the permeation of information throughout the value chain, thereby decreasing counterfeits.
- Auditability: Transaction data (e.g. clinical trials data, supply chain tracing, and claims management) is stored on the blockchain is immutable and everlasting.
- Interoperability: Blockchain established consistent and rule-based methods (e.g. smart contracts) which makes it easier for health organizations to communicate with each other and automates the access to stored patient data.
- Data security: As validation within blockchains requires transactions to be confirmed by sender and recipient of the data, rules can be enabled on which every participating stakeholder has abide to.

Blockchain Market Potential and Outlook

Investors and enterprises across multiple industries and functions have taken notice of blockchain's potential. The global blockchain market is projected to reach $67.4 billion by 2026. Until now, investment and spending on blockchain-based technology have topped more than $1 billion. Current projections for the blockchain services market alone estimates a CAGR of more than 60 percent, hitting close to $7 billion by 2021.[1]

The current global market size of blockchain in healthcare was valued at $1.19 Billion in 2021. The market size is expected to grow at a CAGR of 61.3% from 2022 to 2028. An interesting fact is that Europe held 35.2% market share in 2021, due to various initiatives taken by regional governments to avoid data breach. The projected market volume for blockchain in Life Sciences is expected to reach $3 Billion by 2025.[2]

Drivers for the market growth in Life Sciences & Health include the growing need for transparency and security due to increasing incidences of information leaks and data breaches in the LSHC industry. Furthermore, digitalization of healthcare systems and related industries seems necessary as it enhances patient engagement and enables better analyses, predictions, and processes.

Blockchain Use Cases in Life Sciences & Health

The LSHC sector stand to benefit from blockchain technologies in several ways. There is a multitude of use cases at the disposal of relevant stakeholders.[3] Those use cases can be clustered into the following areas:

- Data Management, e.g. tamper-proof data recording (for clinical trials and drug development), proof of intellectual property and the secure and transparent transfer of proof of ownership.
- Digital Identity, e.g. the identity verification of patients, machines, sensors, healthcare providers and medicines.
- Payments & Financial Instruments, e.g. a decentralized transaction system and trading platform, direct payment for healthcare services, documentation of payment processes and new billing models (pay-per-use).
- Logistics & Supply Chain, e.g. traceability of all activities along a value chain, quality assurance, history tracing of medical use and recording of origin and transport routes of products.
- Patient-Centric Blockchain Usage, e.g. the individualization of medical devices, electronic patient record and patient incentivization methods (direct payment for trial participation).

Along those areas, the following use cases are especially relevant for the Life Sciences & Health industry:

Medical records and interoperability: The access to patient's medical history that is spread across providers, payers, etc., could be decentralized in a blockchain, where only the patient has visibility and control over their medical record.

Supply chain tracking: Blockchain supply chain recording could begin at the manufacturer, undergo updates by intermediaries, and be authenticated by the buyer (track and trace[4]).

Study protocol management: The complete history of changes could be immutably tracked through blockchain to enforce controls and streamline adherence.

Clinical trials: The tracking and reporting of results could be directed to a blockchain to improve the efficiency of drug development.

Medical credentialing: Credentialing organizations could accrue data to the blockchain ledger and make it available to other organizations, potentially expediting the provider credentialing process.

Consent management: A blockchain solution could manage and track informed consent across multiple sites, systems, and protocols. The consent and use could be tracked forward in research.[5]

Prescription sharing: A patient could provide consent to have personal prescriptions tracked and operated on the blockchain to improve transparency and data validation.

Patient wearables: A connected device that broadcasts patient information could offer a real-time, trustful solution for monitoring and tracking patient outcomes.

Adverse events: A blockchain solution could enable an incubation group of companies to securely share adverse events data, permissioned such that only contributing members could view other's data.

In summary, figure 1 shows that a shared blockchain network that links MedTech and pharma, patients and providers and plans and payers on the same standard could touch every part of the industry from clinical trials to claims to clinical outcomes.

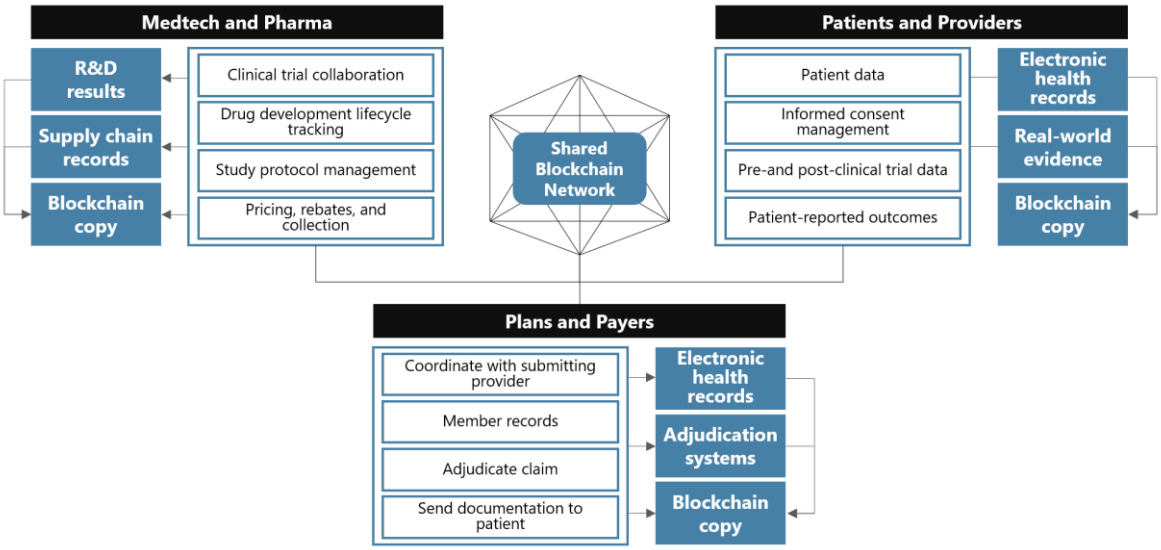


Figure 1: Shared Blockchain Network

Use Case Highlight: Clinical Trials

The tracking and reporting of (intermediate) results and the decentralized communication with clinical trial stakeholders could streamline processes, increase transparency, and optimize payments. As it stands, clinical trials produce large amounts of data and involve many stakeholders, e.g. sponsors, study subjects, manufacturers and doctors. Using a blockchain allows monitoring of the entire clinical trial ecosystem from patient health data to milestones reached. For example, a patient's cloud-based "health passport" can use blockchain to search for relevant clinical trials,

registration, patient consent and the actual participation. The blockchain can also track patient sample collection, usage and analysis throughout the trial.[6]

Relevant opportunities of this use case include the high transparency among clinical trial participants to verify protocol compliance as well as the establishment of incentive mechanisms that reward sharing information through transparency into clinical study results, crypto tokens and immediate payments. The challenges that need to be overcome include patient privacy issues and intellectual property concerns. Each make is feasibly to use permissioned blockchains with dedicated data permission levels for each member. Also, the approval processes of governing bodies need to be taken into consideration.

Noteworthy examples include Boehringer Ingelheim that cooperated with IBM to implement a blockchain bookkeeping solution for clinical trials[7], and Triall that applies blockchain and Self Sovereign Identity (SSI) to offer end-to-end trial solutions. In addition, Bloqcube tests blockchain-based solutions that might allow clinical trial participants to receive payments, for example central bank digital currencies, to speed up the payment process within trials.

Use Case Highlight: Patient-Centric Blockchain

In the digitization of health records, patients and doctors find difficulty in accessing their health records, especially when the records are fragmented with different health service providers. Patient-centric blockchains provide solutions to the requirements of patients, doctors, and health service providers by setting up a decentralized patient medical record management system.

Patient-centric blockchain activities might include: (1) Smart contracts for patient consent and ownership management of health data, (2) Patient record management across siloed healthcare data landscapes, (3) Prescription medicine management, (4) Patient claims and billings management, (5) Data security for medical and wearable technology, (6) Deployment in personalized medicine.[8]

One key example is **prescription sharing**: The Prescrypt project, spearheaded by Deloitte in the Netherlands, is an example of using blockchains for a patient's drug prescriptions. It is especially designed for patients with chronical illnesses to track a patient's prescription usage by the patient, healthcare professionals, pharmacies, and insurance providers. The underlying blockchain makes it easy for patients to decide for themselves which healthcare provider to share their information with and which supplier to send their prescription to. With the help of the patient electronic health data, the entire history of a patient could be tracked. This would allow valuing a specific treatment by tracking an individual's health over years. This transparency might improve future treatments.

Another applicable use case is **patient medical record management**: Electronic health records can be securely harbored on a blockchain and overcome siloed and fragmented medical data held by various health systems, pharmacies, and others. While patients are unable to change or delete medical information input by doctors on to their profiles, they can control access by granting full or partial visibility to different stakeholders. A company pioneering in this area is Guardtime, which collaborates with Estonian Health authorities and the National Health Service in the UK for tracking and managing patient consent to use of their health data. The cooperation has taken necessary steps to move 30 million patient records in its national medical registry onto a blockchain (the so-called MyPCR platform). MyPCR makes patient records accessible to 30 million patients from their

smartphones and to patient-approved parties.[9] The platform will help improve medication adherence in the UK, with potential savings of over $1 billion.

Excursus: Self Sovereign Identity (SSI)

As Self Sovereign Identity (SSI) is crucial for use cases such as medical records, prescription sharing and consent management, this report will provide a brief explanation. SSI stands for event-driven management of digital credentials, such as identity, driver's license, or diplomas, by the user himself. In industrialized nations, the total market potential of digital ID solutions is estimated at three to four percent of gross domestic product. SSI is conceptually and technically based on the triangle of trust (see figure 2). The user as holder has corresponding proofs (credentials) received from issuing entities (issuers). These credentials are stored in a wallet app and can be used for authentication against service providers (verifiers). The procedure thus represents the digital sovereignty of the individual, reduces data protection risks of service providers, and is considered tamper-proof due to the use of decentralized networks. In Life Sciences & Health, insurance companies could act as issuer of patient-owned record IDs that can be used by hospitals and doctors to verify the patient's data and, if allowed by the SSI holder, complement and edit their records.[10] See figure 3 below for an exemplary use case in which the use of SSI is crucial.

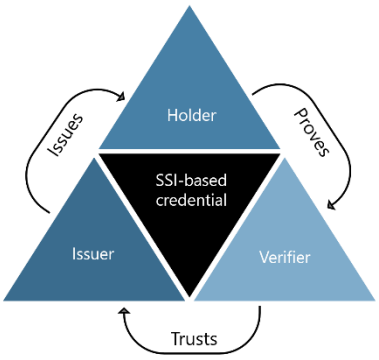


Figure 2: SSI stakeholders[10]

Until 2021, the German government has been working in close cooperation with business partners to implement an ecosystem of digital identities based on the SSI approach. This should enable citizens to digitally manage the sharing of all types of government and privately issued credentials. With the election of a new government and ongoing criticism, especially on the feasibility of SSI and its overlapping features with the smart-eID function of the German identity card, the efforts around SSI have slowed down.[11]

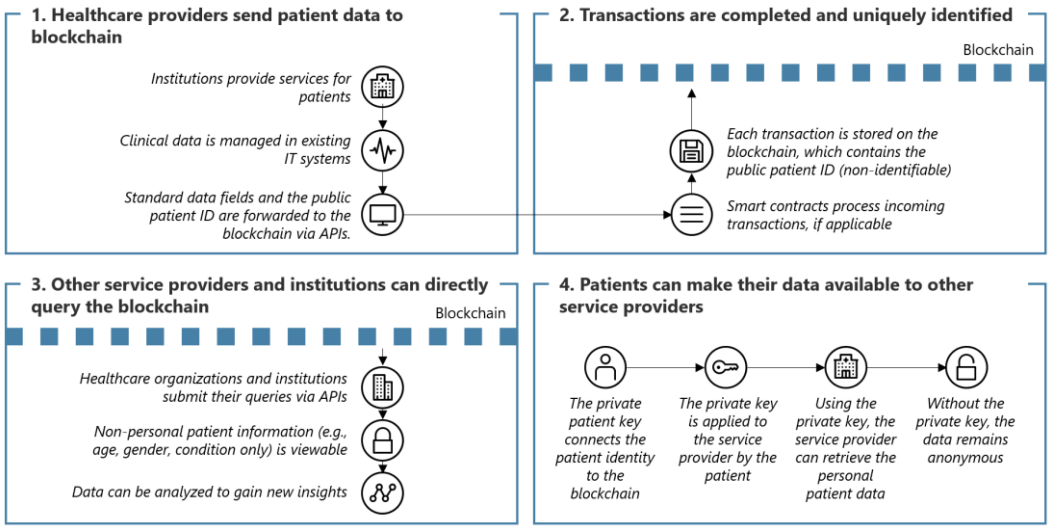


Figure 3: Exemplary use case with SSI.[15]

SSI relies on no central or third party storing or managing the identity. It establishes a one identity proof that can be used in the digital world as well as in the analogue world. Furthermore, it can increase counterfeit protection by validating against the immutable blockchain ledger. There is no more need for additional plastic cards or certificates.

Exemplary Life Sciences & Health Companies Using Blockchain Technologies

Hereafter, this report presents a selection of companies in LSHC that use blockchain technologies to either leverage their own operations or to support other enterprises in optimizing their processes.

PharmaTrace is a German startup offering a blockchain-based ecosystem to secure data and deploy smart contracts in the pharmaceutical industry. It provides a secure system for sharing crucial and sensitive information between stakeholders in the pharmaceutical marketplace. It makes use of smart contracts that are built in Hyperledger Fabric. The network allows precise control and security over the information being shared. Its core product is a Blockchain as a Service (BaaS) with easy access blockchain solutions, customizable templates (plug and play) and scalable solutions. Building up on that, for example, it caters to pharmaceutical supply chain use cases such as verifying authenticity and tracking the origin of pharmaceutical products.[12]

Molecule is a Swiss start-up that accelerates the discovery and funding of early-stage therapeutics. It connects leading researchers to funding by turning IP and its development into a liquid and easily investable asset. This makes it possible for participants to tokenize early-stage intellectual property into IP-NFTs. Molecule provides a marketplace to buy and sell intellectual property through a decentralized blockchain. It interacts with DAOs (decentralized autonomous organizations) for funding. For example, VitaDAO, as a DAO funding early-stage longevity research, used molecule's marketplace to invest $300,000 into the discovery of novel mitophagy activators for Alzheimer's disease proposed by a researcher of the University of Oslo. The transaction was executed with USDC, a USD-stablecoin on the public blockchain Ethereum, and the legal IP rights and data access control was transferred via a non-fungible token (NFT) to VitaDAO.[13]

EZ Lab is an Italian company providing a blockchain-based solution to improve the traceability and certification of agricultural products. Its initial area of focus was on digitalizing crop documentation which was often done in paper with inaccurate data and friction among participants due to missing standards. Now, the company uses blockchain to build an agri-food system through traceability, transparency & certification. Its platform, AgriOpenData, supports farmers in the traceability and certification of agricultural products through blockchain technology and smart contracts. AgriOpenData integrates blockchain to the agri-food sector through a security code that records and tracks the history of agricultural products step by step. Data is gathered both manually and automatically with Internet-of-Things sensors. Types of data collected include use of chemical treatment and weather conditions. The platform provides an efficient way for both industrial buyers and consumers to understand the product's quality.[14]

BurstIQ is a US-based company providing blockchain-based platforms to store and share personal health information. The GDPR-compliant platform uses blockchain technology and other innovations (such as big data) to give healthcare institutions and patients access and control to their data. The firm allows individuals and businesses to connect directly with each other through a shared blockchain. Through this network, personalized products and services can be traded

seamlessly and without intermediaries. B2B contacts can also be facilitated by the BurstIQ network. The aim of the platform is to increase the security of patient data, to increase the autonomy and control of patients over their data, to ease the access to data and to reduce costs for all stakeholders involved.

This is but a glimpse into a quickly growing number of Life Science & Health companies that work with blockchains. Further companies include Veratrak (blockchain-based document collaboration), Chronicled (automation of transactions through blockchains), Blockpharma (drug traceability), FarmaTrust (pharmaceutical tracking) and Patientory (patient-centric access to health data).

Challenges and Solutions of Blockchain in Life Sciences & Health

Even though there are lots of benefits and applicable use cases for blockchain technologies in Life Sciences and Health, there are still some challenges that need to be considered and overcome when integrating blockchain solutions into business operations.[15] Those challenges are:

- **Scalability**: Blockchain scalability is still unsatisfactory, albeit technological progress in the last 3-5 years. User interfaces are quite rudimentary, which limits deploying blockchain-enabled ledgers at scale.
- **Regulation**: While blockchain solutions can separate and encrypt health or personal data, regulation on blockchain eligibility must be further explored.
- **Costs and capacity constraints**: Blockchains are ill-suited to storing high-volume data due to computational and capacity constraints. Storing full electronic medical or genetic data records would be inefficient and costly.
- **Incentivization**: Blockchain participants need to be incentivized to take part in the technological blockchain consensus protocol process and lend their computing power.
- **Standardization**: For efficiency and performance reasons, organizations must consider implementing governance to control what type of data is written on the blockchain and which APIs to existing tools are used.
- **Security and data privacy**: On both permissionless and permissioned blockchains, mechanisms must be put in place to secure the network & smart contracts and ensure the privacy of sensible data.
- **Rapidity of the market**: Internal long approval and capital cycles often do not account for the rapid speed technological advancements are made in blockchain technology.

Our **survey** highlighted the missing of resilient use cases, the lack of knowledge and expertise in blockchain tech, legal uncertainties and the lack of interoperability/standardization as key challenges.

The **one-day collaborative brainstorming** workshop exposed further challenges: SMEs find it difficult to find partners to launch

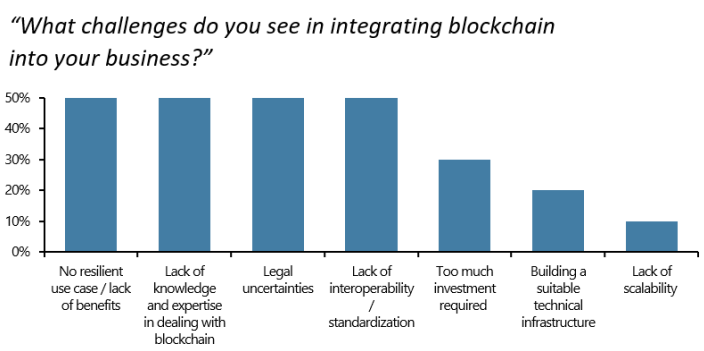


Figure 4: Challenges identified by survey participants (see survey details in appendix)

joint blockchain initiatives. Furthermore, it is difficult to gather buy-in from key decision makers as the topic blockchain is often regarded as over-hyped. Crafting compelling business cases that justify high implementation costs with often difficult-to-estimate benefits is another big challenge. There are very high entry barriers in Life Sciences & Health, due to the highly regulated environment and the overall reliance/trust of the industry in legacy systems.

Although progress has been made in Germany in recent years in the implementation of interoperability in Life Sciences & Health, an international comparison shows that Germany has still great potential for optimization in interoperability and in digitization itself. In a European and global comparison, Scandinavian countries such as Denmark, Sweden or Finland have a major head start thanks to already-established, interoperable national LSHC platforms. Neighboring countries, such as Switzerland or Austria, also made significant progress in implementing their electronic health records.[16]

Blockchain Immutability and Patient Data Privacy

Many potential use cases of blockchain in Life Sciences & Health relate to the recording, tracking and management of medical data. Applying requirements of data protection laws to blockchain-based applications can be challenging because of blockchains' characteristics.[17] The General Data Protection Regulation (GDPR, 679/2016/EU) gives individuals the rights to be forgotten, erase data and correct data - features that, in part, contradict blockchain immutability.[18] The same is true for the obligation to hold personal data no longer than it is necessary. Many people therefore conclude that it is impossible to store any kind of personal data on a blockchain.

There are methods to bypass and even remove the blockchain's immutability[19]:

Off-chain storage: A common workaround for aligning blockchains with the GDPR and the right to be forgotten is the use of off-chain storages. Here, blockchains are only used for storing a timestamp and a hash that point to the actual information held off-chain. Therefore, when new information needs to be edited or deleted, only the fact that the specific content version existed at a given point in time will remain on the blockchain. The benefits of this method include reduced blockchain data storage requirements, fewer scalability issues and GDPR compliance. The drawbacks are decreased security due to attack vectors and an overall centralized storage system.

Encrypted data on blockchain: Another alternative solution is to have the data stored in the blockchain in an encrypted form. When the user asks to delete personal information, the encryption key is deleted, which will make the data inaccessible. Although some argue that making this data inaccessible means deleting it, data protection authorities are not so sure and argue that, strictly speaking, this process is not an actual erasure. After all, the data will be still on the blockchain. The drawbacks here include the difficulty to manage decryption key among many blockchain participants, the possibility to hack/steal keys the uncertainty whether new technologies (such as quantum computing) might make today's encryption methods redundant.

Pruning: In blockchain pruning, old transactions and blocks are deleted after a predefined amount of time. The advantage here is the overall smaller blockchain size and increased privacy (as old transactions might not be locatable). However, frequent pruning adds an expensive overhead that may result in inconsistencies in data. Also, the enforceability is questionable as there is no guarantee that nodes do not save the full chain. Yet, pruning is an appropriate solution in

environments that are controlled and adjusted by an authority (for example permissioned blockchains, consortia).

Besides these methods, more technical mechanisms such as the use of chameleon hashes, consensus-based voting, meta transactions, self-destruct functions and block matrices can be used to remove or circumvent blockchain immutability.

Overcoming Challenges and Launching Blockchain Initiatives

Through a structured framework, companies can evaluate whether the use of blockchain technology is feasible for them and their networks or not.

In an initial evaluation phase, companies must ask themselves whether blockchains are suitable for their respective challenges. Usually, a distributed ledger is feasible if several stakeholders with contradicting interests generate transactions which, with shared responsibility, modify data. In such networks the involved parties must have trust that transactions are correct. If individual actors are not efficient together and they do not trust each other, there might be a reason to integrate blockchains. In a follow-up design phase, companies should explore which use cases and applications are suitable to be put on the shared ledger and how responsibilities are distributed.

If the use case is set, operational and technical aspects need to be conceptualized and tested. This includes the business model, the smart contract creation, deployment and audit, the creation and orchestration of a permissioned blockchain (if required) or the use of a public blockchain (with all the drawbacks this might entail). Further aspects such as oracles (the trustful transfer of off-chain data to on-chain smart contracts), crypto custody and data storage should be considered.

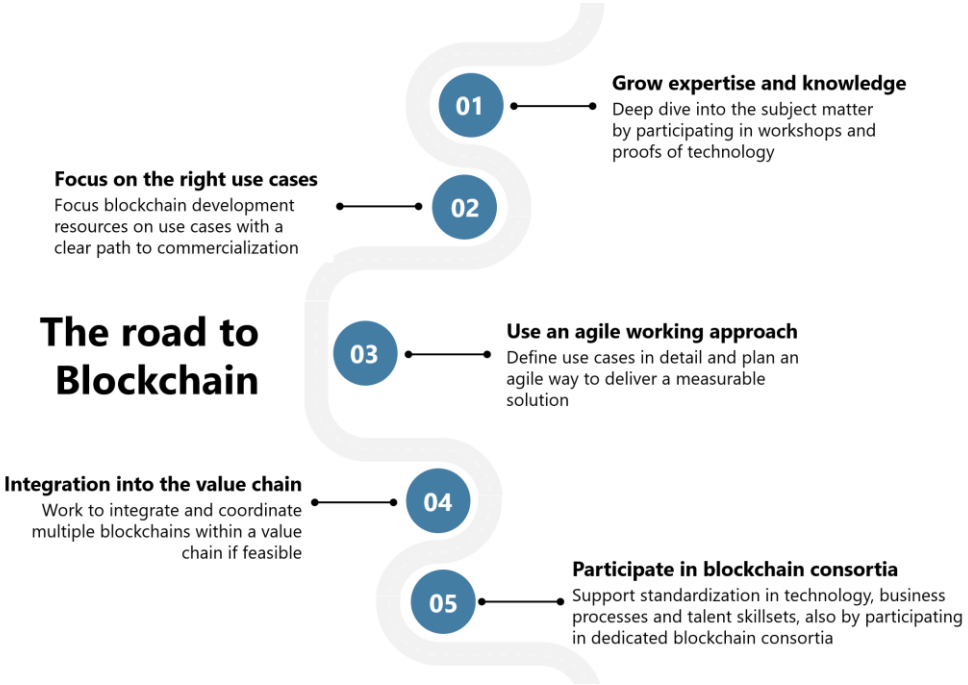


Figure 5: The road to Blockchain

Until now, there are no technical, regulatory or process standards in place. Furthermore, operational silos keep companies from collaborating with ecosystem partners on blockchain tech for mass adoption. It takes time and dedication to get to largescale adoption. In the meantime, companies can approach blockchain aspects through the following measures:

- Grow knowledge and expertise by participating in collaborative workshops.
- Focus blockchain development resources on use cases with a clear path to commercialization.
- Use an agile working approach to deliver measurable solutions quickly.
- Drive standardization in technology, business processes and talent skillset, also by participating in dedicated blockchain consortia or groups.

Our workshop participants added further valuable measures to drive blockchain initiatives:

- Involve decision makers early in the design process to improve participation and ownership.
- Explore on- and off-chain solutions and recognize that often a combination of both is the best solution.
- Do not be intimidated by regulatory hurdles, for example GDPR and the right to be forgotten, but consider technical and operational solutions (e.g. by storing sensitive data off-chain).
- Simplify the solution and make the value of using blockchains more understandable for all, for example by user experience (UX) mock-ups.
- Connect to already proven standards to mitigate concerns about long and costly changes of legacy systems.
- When crafting a business case, focus on the value for the whole ecosystem and not only for one individual company.

Moving forward: Recommendations and next steps

Based on the survey results (appendix) and the outcome of the interactive working sessions, this report recommends Interreg NWE Blockstart consortium, BioRegio STERN (German partner in the Interreg NWE Blockstart project responsible for supporting health SMEs in adopting blockchain technology) and political decision-makers to draw attention to the following fields of action:

1 Education & skills management

The survey results showed that many SMEs are not fully aware of the blockchain concept and its potential use cases in the Life Sciences & Health industry. In addition, lack of knowledge and expertise in dealing with blockchains was stated as one of the major barriers for implementing blockchain technology in SMEs. Hence, this report recommends creating further awareness of blockchain technology and support SMEs in educating their employees on this topic. This could include subsidized tailored workshops, informational events, as well as providing material with applicable use cases for SMEs in Life Sciences & Health. For doing this, political decision-makers could partner with organizations that are already working to promote blockchain technology.

In general, BioRegio STERN and political decision-makers should continuously stay in close contact with SMEs in the Life Sciences & Health industry. The recommended support measures and activities are based on a relatively small number of survey (10) and workshop participants (4).

Therefore, further research is needed to identify and focus on the right initiatives for driving the usage of blockchains in SMEs operating in the Life Sciences & Health industry.

2 Network & knowledge exchange

To address the challenge of lacking knowledge on who to contact for support when discussing the use of applicable blockchain solutions, this report recommends establishing a centralized platform (for example a website) as first point of contact for SMEs. On this platform, SMEs can get in touch with blockchain experts, service providers for implementation and other companies, who already implemented blockchain solutions. The network could serve as a base for knowledge exchange and include a forum, where stakeholders of the ecosystem can interact with each other.

3 Technical infrastructures & implementation

The survey revealed that most of the SMEs are not aware of how to access and implement blockchain solutions in their organizations. Reasons for this are primarily lacking resources and the need to change the existing technical infrastructure. This report hopes to encourage political decision-makers to provide support in this particular area by cooperating with service providers that help SMEs in selecting, building, and implementing the right blockchain infrastructure. This includes creating and aligning on clear standards, that SMEs can take as an orientation.

4 Incentivizing Blockchain usage

Based on the survey results, some SMEs already discussed the use of blockchain technology. However, no survey participant has implemented blockchain solutions into their business activities yet. To further drive the use of blockchains in SMEs, political decision makers should incentivize the experimentation with and integration of blockchain technology. One possible way of doing this is to provide tax incentives or subsidies for SMEs that adopt blockchain solutions. This can help reduce the costs associated with implementing the technology and can make it more affordable for SMEs and reduce the barriers to entry. Another option is to provide funding for research and development projects. This can help companies explore the potential of blockchain technology and develop new applications and solutions in a safe environment. The impact of these support measures should be continuously monitored and evaluated by the funding program managers.

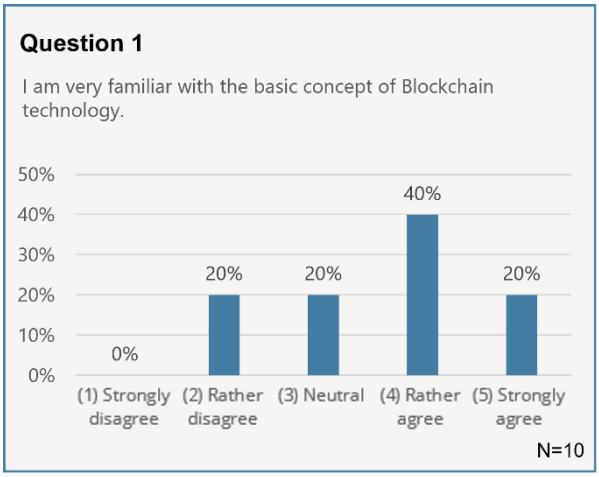
5 Regulation & standardization

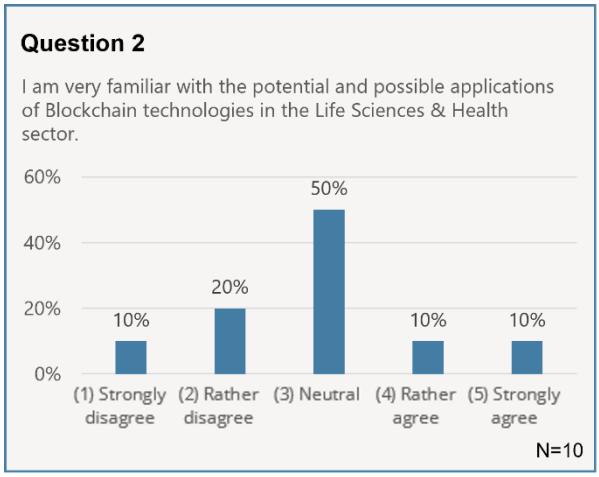
Legal uncertainties and the lack of standardization were among the top challenges in integrating blockchain solutions in SMEs according to the survey and the working sessions. To overcome this issue in the long run, this report encourages political decision-makers to focus on creating an enabling regulatory environment that provides clarity and certainty around the use of blockchain technology. For example, while this report has shown compromises how to use health data on blockchains in a GDPR-compliant way, current GDPR regulations do not provide enough clarification how to implement tangible blockchain use cases in Life Sciences & Health, e.g. accountability. Clear, targeted guidelines and rules would eliminate concerns of relevant stakeholders. EU wide standards for blockchain including financial market rules for crypto assets (such as the Markets in Crypto-assets regulation *MiCA*) should be discussed and adapted to the Life Sciences & Health industry to avoid legal and regulatory fragmentation.

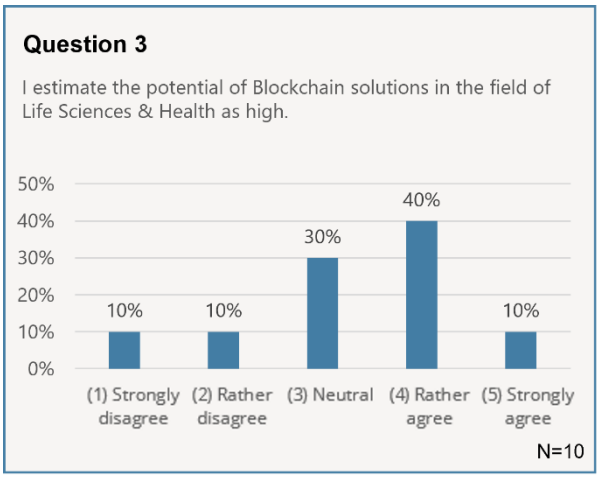
Appendix: Survey Results

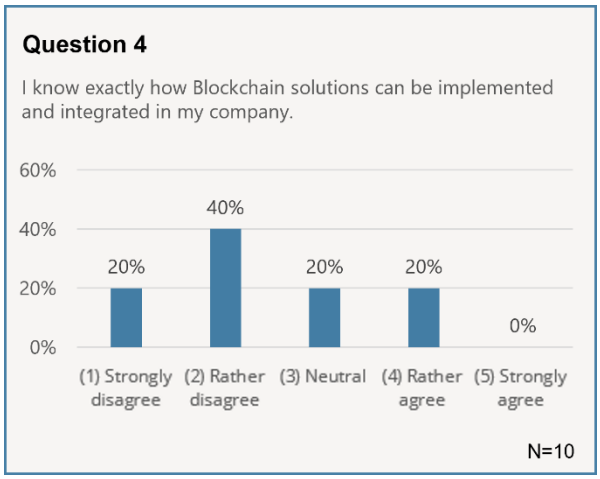
From September to October 2022, a survey was conducted among participating small- and mid-sized companies on blockchains in Life Science and Health. Hereby, results among four blocks are shown: Level of knowledge and experience, workshop topics, support measures and participant demographics.

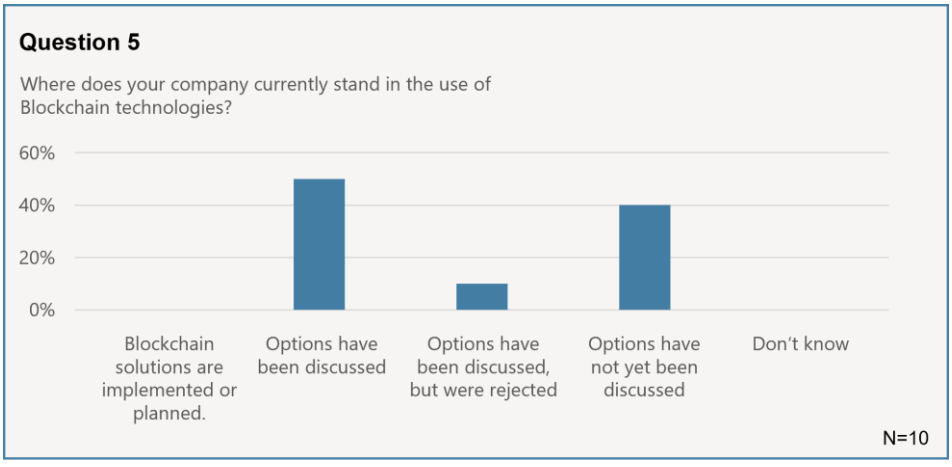
Block 1: Level of knowledge and experience







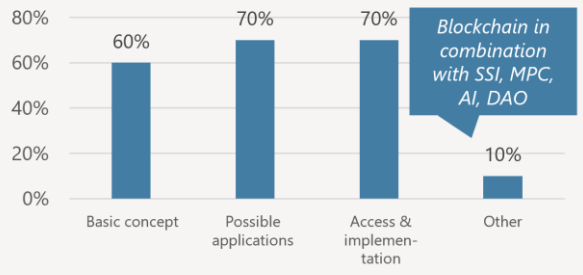




Block 2: Workshop topics

Question 1

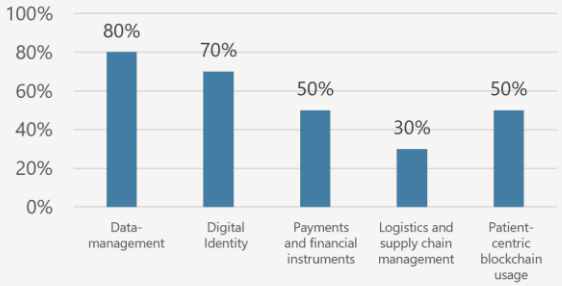
Which of the higher-level blockchain topics would you like to explore in more depth in an interactive workshop?



N=10

Question 2

Which of the following application areas of blockchain in life sciences are of interest to you?



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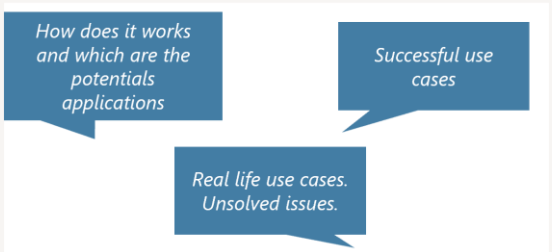
Question 3

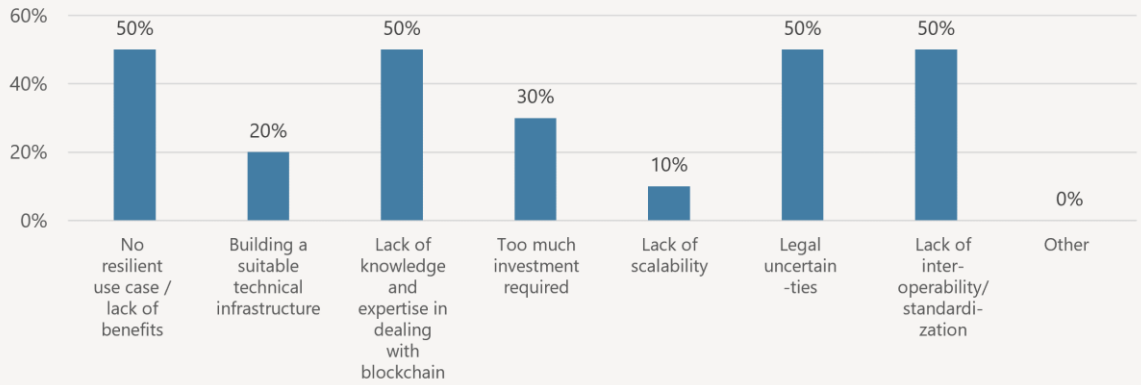
What are key topics you would like to learn more about in the workshop?



Block 3: Support measures

Question 1

What challenges do you see in integrating blockchain into your business?



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Question 2

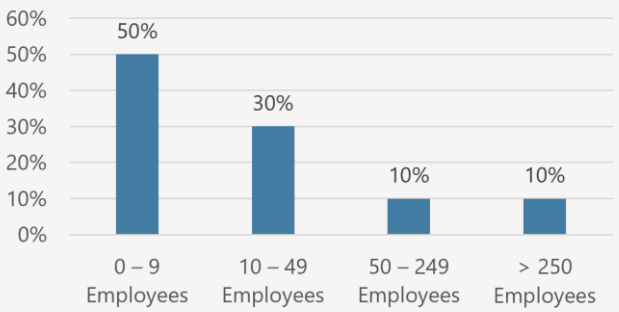
What kind of support do you need to implement blockchain solutions in your company?

I am the theme lead Health & Care of the Dutch Blockchain Coalition. I work with several companies and start-ups that provide hardware and software to deploy blockchains, SSI, MPC, DAOs, ...

Expert advice

Block 4: Demographics of participants

Firm size



N=10

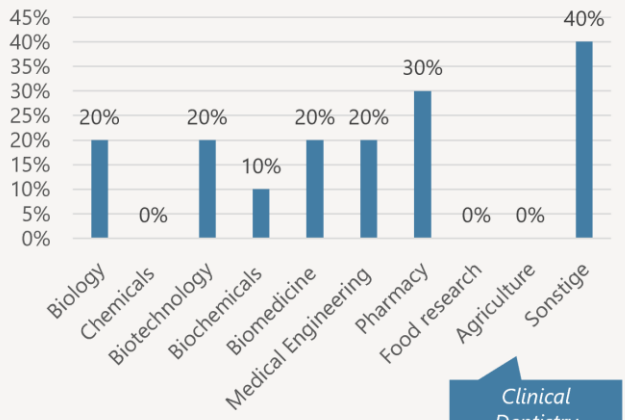
Specialization

digital healthcare for homecare services providers

Telemedizin

N=2

Sector

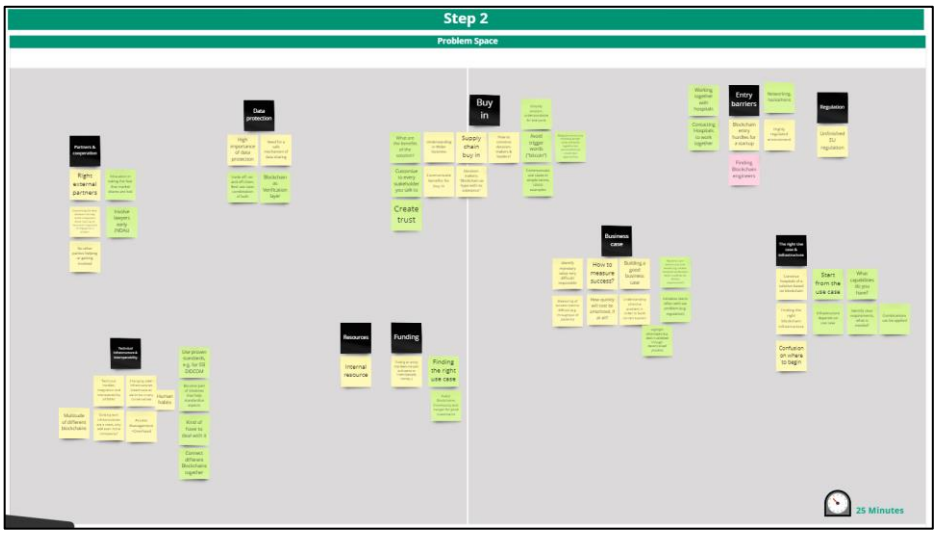


Clinical Dentistry Data Analytics Tech startup

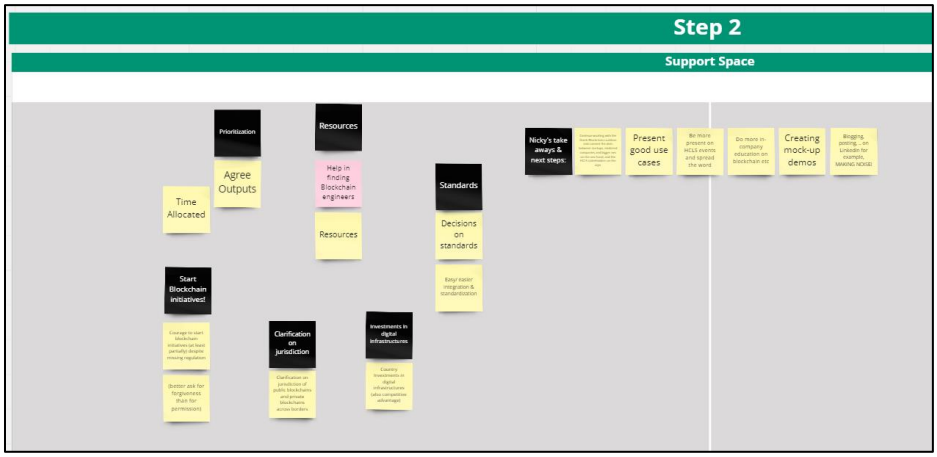
N=10

Appendix: Workshop Impressions

During our collaborative workshop, Miro was used to brainstorm and discuss current challenges and possible solutions.



Clustering of challenges



Brainstorming of solutions

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Published December 2022

Blockstart is an Interreg project supported by the North West Europe Programme of the European Regional Development Fund of the European Union.