



BEYOND THE HYPE OF
BLOCKCHAIN
IN HEALTHCARE **DECEMBER 2017**

COCIR
SUSTAINABLE COMPETENCE IN ADVANCING HEALTHCARE

European Coordination Committee of the Radiological, Electromedical and Healthcare IT Industry



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EXECUTIVE SUMMARY

Blockchain¹ technology may have considerable potential in healthcare, although opinion leaders concede that identifying a genuine ‘killer app’ in healthcare is currently difficult. However, COCIR believes that there is a number of interesting use cases where blockchain represents a potential advance or opportunity, including reimbursement of healthcare services, exchange of health data, clinical trials and supply chains. Yet a number of challenges are preventing the large-scale deployment of this technology in healthcare, such as distributed governance of blockchain ecosystems, interoperability and data privacy. In addition, the use of public blockchains in healthcare remains a challenge.

COCIR RECOMMENDATIONS

Blockchain technology is still in relative infancy, particularly in healthcare; therefore, it is still difficult at this stage to formulate specific recommendations. Today, probably the principal recommendation for all stakeholders is **to keep an open mind and explicitly foster experimentation.**

Additionally, COCIR would like to advance the following preliminary recommendations:

ACTIONS BY POLICYMAKERS, PAYERS AND HEALTHCARE PROVIDERS:

Foster the assessment of blockchain use in real-world healthcare environment by:

1. funding proof-of-concept development;
2. offering financial incentives to adopt blockchain solutions at healthcare settings and
3. supporting start-ups in this area of application, for example through innovation hubs or hackathons.

This assessment should cover all relevant dimensions, including regulatory matters, standards, organisational and operational aspects and financing models. Special consideration should be given to scenarios where the benefits of blockchain technology, such as immutability of transactions and transparency, could be adequately applied in healthcare.

Adopt a sandbox approach, by lowering regulatory thresholds under controlled conditions. This will stimulate the assessment and deployment of blockchain technologies in selected healthcare settings.

ACTIONS BY POLICYMAKERS:

Raise awareness on this technology and educate key stakeholders on the opportunities and challenges it presents through best-practice workshops and educational sessions.

Build better skills and expertise in this technology and its applications in healthcare by increasing funding for academic research and expanding the educational offer available on this topic.

ACTIONS BY PUBLIC AND PRIVATE ORGANISATIONS, SETTING UP BLOCKCHAIN ECOSYSTEMS IN THE HEALTHCARE DOMAIN ONCE THE TECHNOLOGY IS MORE MATURE:

Adopt a three-step approach: First, deploy the technology to optimise the processes and gain more experience with it. The next step will see more experience being gained with real use cases. Finally, once partners feel confident, they may deploy the technology on a larger scale across healthcare use cases and reap its full benefits.

Engage change management and academic experts to ease the governance and operational management challenges of the ecosystems.

Rely on public-private financing mechanisms for these first ecosystems.

1. Blockchain technology is a distributed and immutable (write once and read only) record of digital events, which is shared peer to peer between different parties in a network. Currently, the most known application of blockchain is Bitcoin, a so-called cryptocurrency. However, this is only one of the several applications using the blockchain system.



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1 INTRODUCTION

The future effectiveness and sustainability of health and care systems will inevitably require greater operational efficiencies. The key to this will be the ability to use the increasing amounts of available health data from traditional sources, electronic health records and other digital health applications as well as non-traditional sources.

Large-scale data processing will provide new insights into the effectiveness of interventions and disease progression, allowing existing resources to be targeted more effectively. Ultimately, this will play a role in driving the much-needed shift to integrated care.

However, there are a number of obstacles to the full adoption of these technologies. There are concerns over the consistency and quality of data, compatibility, security and privacy and lack of standards.

One technology mooted as potentially addressing some of the challenges facing data use in healthcare is blockchain. This is a type of shared distributed digital ledger, which allows every event that a piece of data undergoes - whether it is viewed, used or changed - to be recorded indelibly. As each event occurs, information on the event is added as a **'block' connected - in sequence - to the one recording the previous event. As the data in the blockchain is recorded on a distributed, peer-to-peer basis, it creates an ever-growing, permanent record that cannot be altered retroactively; nor can the sequence of blocks be changed without it affecting all subsequent blocks. This means that it can provide a robust method of confirming data integrity as well as a permanent log of all events undergone. It could also allow the use of distributed health databases that need to be rapidly synchronised each time there is a transaction².**

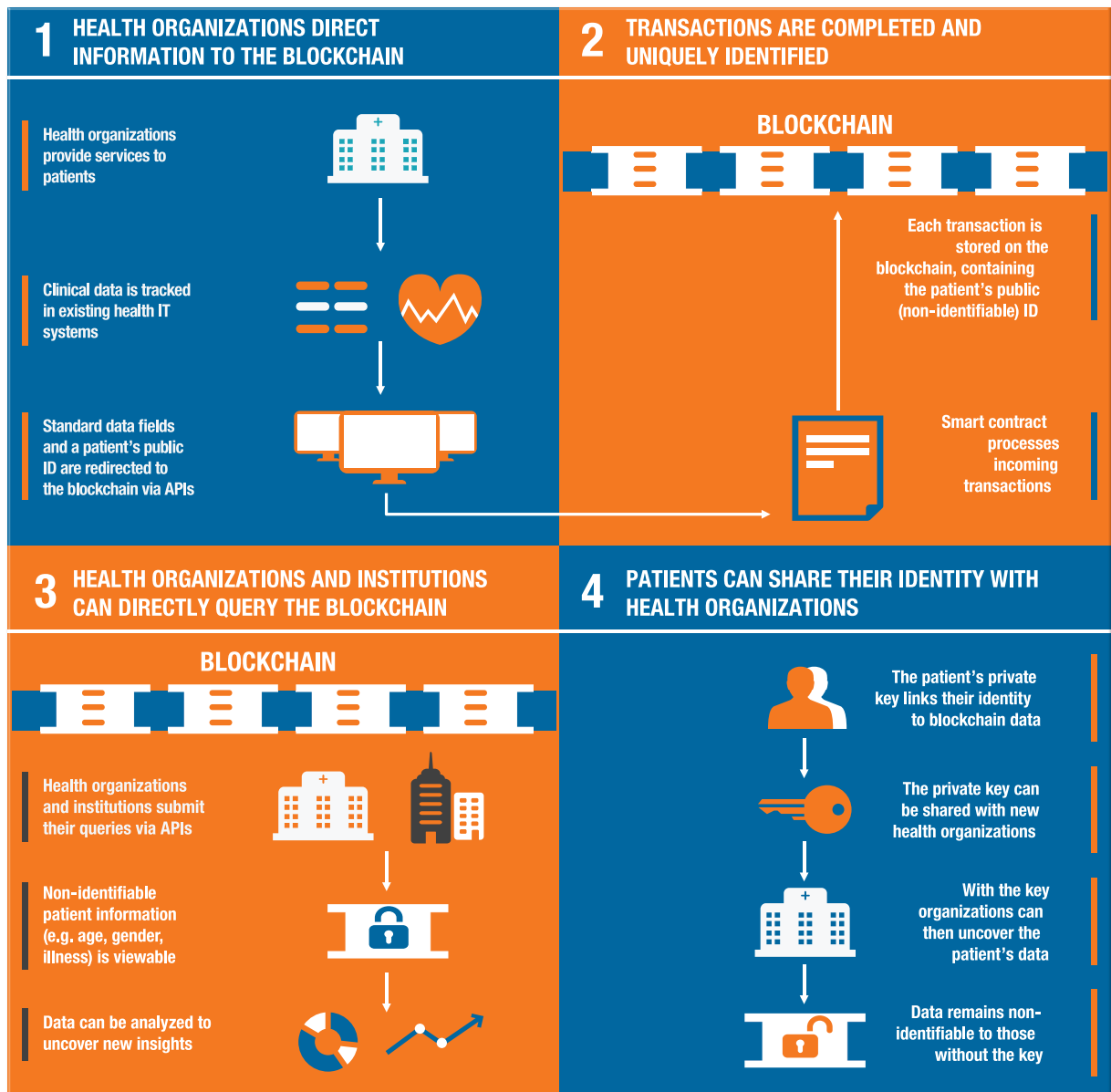
These features mean that blockchain is a potentially valuable technology for the healthcare and life science sectors, where a number of stakeholders interact on a regular basis. There is a lot of manual data entry and a high risk of disagreement over liability, particularly in 'who did what and when' information. According to Andreas Kind, Blockchain expert at IBM[1], "it basically all boils down to trust distribution". This is arguably the main reason behind the understandable excitement around blockchain's potential for the health and care sector.

Blockchain has transformative potential for our health and care systems. Adoption will be gradual, but it offers the potential to create new business models in the healthcare sector: trusted exchange of health data may lead not only to doing things differently, but also to doing new things. Potentially, one of the most influential effects will be to provide patients with control over their own health data. Blockchain will effectively allow them to manage consent and access to their health data where they see fit.



² Importantly, Blockchain will not store health data, but only the references and means to ensure the integrity of the data

Figure 1. Illustrative Healthcare Blockchain Ecosystem



Source: Deloitte 2016 [2]

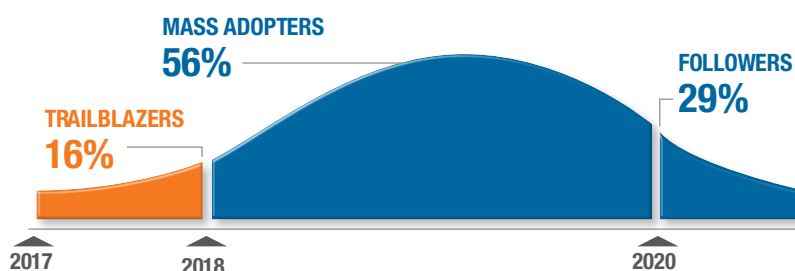
2 OPPORTUNITIES

Potential applications of blockchain in the healthcare sector have been extensively described in a number of reports and articles [3]–[7]. Opinion leaders agree that identifying a genuine **‘killer app’ in healthcare** at this stage is difficult. As previously discussed, due to this lack of clear applications, adoption will be gradual; **should a distinct role for blockchain in healthcare emerge, uptake will certainly accelerate.**

However, we believe that there are existing use cases where blockchain potentially offers an advance or opportunity:

1. **SUPPLY CHAINS:** Different industrial sectors are already exploring the potential of blockchain in enhancing integrity and traceability in the supply chains [8]. With modern medicines commanding premium prices, pharmaceuticals are an attractive prospect for counterfeiters. Although an anti-counterfeiting system based on QR codes already exists in Europe, it has some fallibilities; blockchain could add a further layer of integrity for guaranteeing product integrity.
2. **DRUG VERIFICATION:** The ability to verify the authenticity of drugs at the point of dispensing, (e.g. community or hospital pharmacy) is an example of cross-sectoral use of blockchains with the pharmaceutical industry. While there are already many examples of blockchain use for secure supply chain within the industry and its suppliers, there are only few at the caregiver level. Yet, information such as a medication’s authenticity, its expiry date and special requirements such as handling conditions or the ability to organise product recalls, is vital and would enhance patient safety.
3. **REIMBURSEMENT:** Payers, patients and healthcare providers could use and exchange data more easily to verify insurance coverage. By creating trusted relationships between all participants and by storing transactions and contracts on a shared ledger, blockchains would allow a consistent, automatic contract execution environment. This could sharply reduce the level – and cost – of administration.
4. **CONTROL THE ACCESS** to shared Electronic Health Records. Blockchain will contain references to the EHR data, while Smart Contracts³ will define and enforce access rules to EHR content. This will ensure that only authorised persons access the EHR data. In addition, the blockchain provides an irrevocable record of all events that the data has undergone. All these will enable population health management and research.
5. **CLINICAL TRIALS:** Clinical trials offer particular potential. Using blockchain could help make clinical trials reliable at each step by keeping track and time-stamping at each phase of the trial (trial protocol, patient enrolment, data collection, trial monitoring and data management and analysis). This could reduce waste - a great deal of trial data is not captured - minimising reporting errors and avoiding accusations of data manipulation or selective reporting.

Figure 2. Healthcare respondents’ expectations of when they will have blockchains in production and at scale



Source: IBM. Healthcare rallies for blockchains: Keeping patients at the centre [10].

3. A smart contract is a piece of code (the smart contract), deployed to the shared, replicated ledger, which can maintain its own state, control its own assets and which responds to the arrival of external information or the receipt of assets” [9]. It is important to highlight that, when looking at the details, today smart contracts still create as many questions as answers.

3 CHALLENGES

1. CHANGE MANAGEMENT AND GOVERNANCE TERMS OF BLOCKCHAIN ECOSYSTEMS

Blockchain technology in healthcare is most likely to develop through the ecosystems created by partners that need to share and exchange health data, interacting regularly and facing a risk of potential disputes. With blockchain-based solutions, it is possible to build confidence; however, how these consortia of typically five to ten partners will be funded and governed efficiently remains unclear. All members of blockchain ecosystems will need to agree, at a minimum, on the governance structure for their collaboration at two levels:

1. ON AN IMPLEMENTATION LEVEL, this includes agreeing on how to integrate the different systems to the blockchain and encoding the business processes via smart contracts.
2. ON AN OPERATIONAL LEVEL, this will include:
 - a) agreeing on where the blockchain system will be hosted;
 - b) who runs the different components;
 - c) what data needs to be shared;
 - d) how and who has permission to do what; and
 - e) agreeing on how to govern any potential changes to the lifecycle of existing processes.

Reaching an agreement on the implementation aspects should not offer major obstacles. There would be some migration and integration costs in connecting the systems of the different partners to the distributed ledger; however, this should not incur any great capital expenditure. Ultimately, costs would be distributed among all participants in the ecosystem and would be rapidly offset by the savings generated.

The real obstacles for blockchain to establish itself in healthcare probably lie in both agreeing on the ecosystems' operational governance and in managing the changes that this technology will bring to roles and processes.

2. BLOCKCHAIN CANNOT ADDRESS ALL THE BARRIERS TO HEALTH DATA SHARING

As this paper has emphasised, blockchain technology can help address some of the challenges currently facing health data access and sharing. However, there are also a number of challenges that this technology is not able to solve. Barriers such as unjustified health data localisation requirements, lack of technical and semantic interoperability, low data quality and reliability must be overcome. Otherwise, it is unrealistic to believe that blockchain technology can achieve its full potential for healthcare.

Any comprehensive solution - or solutions - to the challenges posed by data management and sharing remains some way off. These are interrelated but distinct challenges, which need to be solved through a combination of policy and regulatory measures [11] and need to include a genuine shift to outcomes-based reimbursement models. Only then will healthcare providers and care professionals have sufficient incentives to capture health data in reusable formats and share it to improve patient outcomes and care delivery.

3. LACK OF INTEROPERABILITY

Many blockchain implementations are proprietary, which jeopardises exchanging blockchain data and establishing an open blockchain infrastructure and partner ecosystem. In addition, the position of blockchain within the healthcare interoperability stack needs to be more clearly defined. Standardisation of blockchain APIs will typically occur when technology becomes more mature.

4. UNCERTAINTIES AROUND THE USE OF PUBLIC BLOCKCHAINS IN HEALTHCARE

Public blockchains are completely decentralised, with the permissions to read and write data onto the blockchain shared equally by all connected users that come to a consensus before any data is stored. No user has special privileges on any decision and there are no controls over the users running the blockchain.

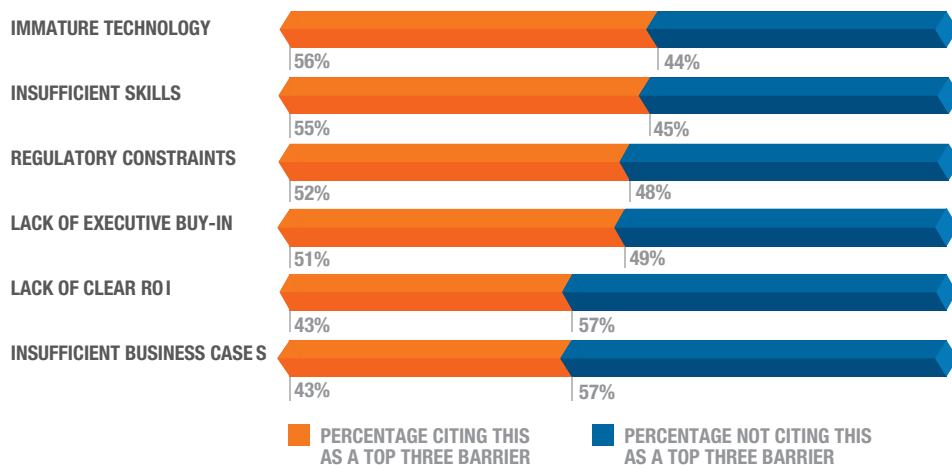
The role of public blockchains in the healthcare sector in supporting transactions taking place between unknown parties remains unclear. As previously highlighted, “permissionless [public] blockchains are much more disruptive and difficult to fit into existing legal and business frameworks” [12]. European health systems are highly regulated, and a number of existing regulations could prevent public blockchains from being used in this sector. However, a public blockchain may be the only possible alternative where there is no ecosystem of actors eager to co-operate in finding a solution.

An alternative to public blockchains are the so-called consortium (or ‘permissioned’) blockchains⁴. Anyone can be a user or a node of a public blockchain, while consortium blockchains are operated by a wider, but clearly defined, group. Similar to public blockchains there is no single actor trusted for operating the solution; this responsibility is shared among the consortium members. These are authorised to interact with the solution. In this case, trust relies on the ecosystem of actors (i.e. the consortium) operating the solution. Consortium blockchains are lighter on anonymity and transparency than public blockchains, but can provide higher efficiency and greater privacy. The use cases for healthcare described in this paper rely on this kind of consortium blockchains; only partners will be able to access the blockchain and the transactions registered therein.

5. COMPLIANCE OF BLOCKCHAINS WITH PRIVACY REGULATIONS

Compliance of blockchain implementations with privacy regulations need to be further analysed and evaluated. For example, it is unclear which organisation will be considered as the data controller when blockchains are typically characterised by distributed governance and the lack of a central authority. Another challenge how to implement the GDPR principle of “the right to be forgotten” in blockchain, where all transactions are immutable. This, and other privacy implications, requires further analysis.

Figure 3. Barriers to healthcare adoption of blockchains



Source: IBM. ‘Healthcare rallies for blockchains: Keeping patients at the center’ [10].

Data: IBM Survey, 200 respondents. What are the top three barriers your company would need to overcome in order to implement blockchain in your organization today? Select your top 3.

4. For the sake of completeness, it should be mentioned that in literature there is a third type of blockchains, namely **private blockchains**. Here, the permissions to write data to the blockchain are controlled by a **single organisation**, which is trusted by the other users. The organisation in control has the power to change the rules of a private blockchain and may also decline transactions based on their established rules and regulations [13].

4 COCIR RECOMMENDATIONS

Blockchain technology remains in its infancy, particularly in healthcare. Therefore, it remains difficult to formulate specific recommendations. Today, perhaps the main recommendation for all stakeholders is that it **is important to keep an open mind and explicitly foster experimentation**.

Additionally, COCIR advances the following preliminary recommendations:

1. ACTIONS BY POLICYMAKERS, PAYERS AND HEALTHCARE PROVIDERS:

Foster the assessment of blockchain use in real-world healthcare environment by:

1. funding proof-of-concept development;
2. offering financial incentives to adopt blockchain solutions at healthcare settings and
3. supporting start-ups in this area of application, for example through innovation hubs or hackathons.

This assessment should cover all relevant dimensions, including regulatory matters, standards, organisational and operational aspects and financing models. Special consideration should be given to scenarios where the benefits of blockchain technology, such as immutability of transactions and transparency, could be adequately applied in healthcare.

Adopt a sandbox approach, by lowering regulatory thresholds under controlled conditions. This will stimulate the assessment and deployment of blockchain technologies in selected healthcare settings.

2. ACTIONS BY POLICYMAKERS:

Raise awareness: The blockchain concept remains relatively unknown in the healthcare sector. Policy makers should raise awareness of this technology and educate key stakeholders on the opportunities and challenges it presents.

Build better skills and expertise in this technology and its application in healthcare by:

1. increasing funding for academic research and expanding the educational offer on this topic, and
2. supporting start-ups, for example through innovation hubs (in collaboration with universities/engineering) or hackathons.

3. ACTIONS BY PUBLIC AND PRIVATE ORGANISATIONS SETTING UP BLOCKCHAIN ECOSYSTEMS IN THE HEALTHCARE DOMAIN, ONCE BLOCKCHAIN IS MORE MATURE:

Follow a three-step approach: First, they can deploy the technology to optimise the processes and gain more experience with it. Second, gain greater experience with real-use cases. Finally, once partners feel confident, they can implement it on a larger scale across healthcare use cases, reaping fuller benefits.

Engage change management and academic experts to ease the challenges linked to governance and operational management of the ecosystems.

Rely on public-private financing mechanisms: At this early stage, where processes are immature and concepts relatively insecure, it could be an advantage to rely on public-private partnerships for the funding of these first ecosystems.

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GENERAL INFORMATION ABOUT COCIR

COCIR is the European Trade Association representing the medical imaging, radiotherapy, health ICT and electromedical industries.

Founded in 1959, COCIR is a non-profit association headquartered in Brussels (Belgium) with a China Desk based in Beijing since 2007. COCIR is unique as it brings together the healthcare, IT and telecommunications industries.

Our focus is to open markets for COCIR members in Europe and beyond. We provide a range of services in the areas of regulatory, technical, market intelligence, environmental, standardisation, international and legal affairs.

COCIR is also a founding member of DITTA, the Global Diagnostic Imaging, Healthcare IT and Radiation Therapy Trade Association (www.globalditta.org).

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