EU BLOCKCHAIN OBSERVATORY & FORUM
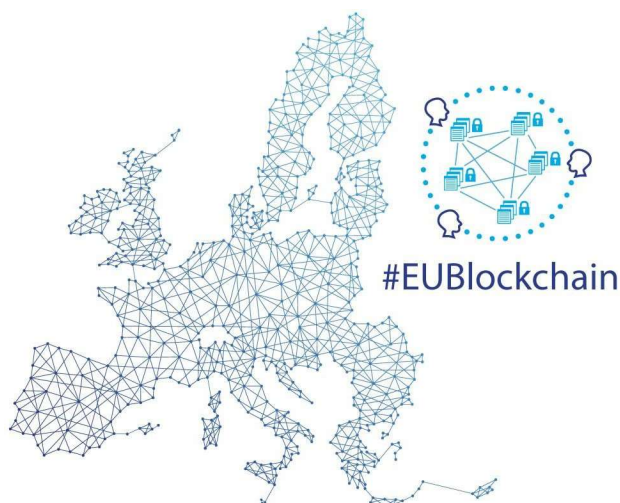
Workshop Report –
Blockchain in Healthcare
applications –
Online Video Conference, 24 September, 2020

#EUBlockchain

By the European Commission, Directorate-General of Communications Networks, Content & Technology.

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WELCOME

Peteris Zilgalvis, Head of Unit, Digital Innovation and Blockchain, DG CONNECT; Co-Chair, FinTech Task Force, EC opened the meeting. He was followed by **Kostas Votis** from CERTH, who provided a background presentation on what the discussions would be focused on.

SESSION 1 - HEALTHCARE BLOCKCHAIN APPLICATIONS & DISCUSSION ON PROBLEMS AND HURDLES FOR UPSCALING AND FURTHER DEVELOPMENT

Moderated by Gerasimos Michalitsis, New Business Ventures, Intrasoft International

Presentations and moderated discussion

- **Pharmaledger:** Blockchain Enable Healthcare, Introduction to the OpenDSU emerging standard Marco Cuomo - Novartis Pharma AG, Sînică Alboaie – Romsoft
- **BurstIQ** Blockchain for Surgical Costs and Outcomes, Dr. Wendy Charles, PhD, CIP, CCRP, CBP, Chief Scientific Officer, BurstIQ
- **Opportunities and challenges in deploying Blockchain solutions globally**, IngridVasiliu Feltes, MD MBA GBA Ethics Officer & Senator WBAF

Objectives of the session:

- To present actual blockchain applications in the healthcare sector
- To identify and discuss the problems faced by the companies implementing them in their effort to further develop and upscale.
- To provide insights on how blockchain is just a technology and it does not create value by itself

Main outtakes from the session:

- For the healthcare sector, it would be essential if governments would take the lead for the development of a blockchain network, to ensure harmonization between legislation, regulatory framework and policy. Still, the role of non-governmental, independent organisations should also be prominent in supporting the process.
- There would be great value for the healthcare sector if there was a "Golden Key" of patients' data (given their consent), to be shared by hospital, healthcare organisations, regulators, etc., so that this dataset is always up to date and verified. Monetizing this data would come both with pros and cons.
- Any time healthcare information is stored, it needs to be in a private setting (private permission chain). Selecting a blockchain for storage allows the capabilities of smart contract, for automating the ingestion process as well as automating the access, plus it is cost effective. In addition, it allows to plug in features healthcare information that is also GDPR compliant and is more efficient than traditional database.
- The main blocking factors for upscaling blockchain applications in healthcare, despite all the obvious benefits have to do with the following:

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- o There is lack of interoperability
- o There is lack of understanding of the benefits.
- o Digital illiteracy is also one of the major obstacles; it takes multiple meetings to even explain what the technology is, so it is very difficult for people in the decision-making positions to understand how it can be deployed.
- o Legal aspects: issues of accountability, liability, and the difficulty with compliance that most data and compliance officers' highlight.
- Blockchain is not gaining traction in healthcare. Healthcare organizations have been late adopters of new technology, but even so, we are seeing some really promising progress in survey results of hospital organisations, and of executives. So, for example, in a survey of pharmaceutical executives, 70% stated that they plan to implement one or more blockchain projects, this year (2020). Not sure how much the COVID situation impacted that, but the goal is that the majority are going to explore blockchain projects this year. And from surveys conducted by Health Information Technology Education and Ethics advocacy group more than half of the hospitals, stated that they are evaluating blockchain technology. So, even though they are slow adopters, there is interest; they are definitely looking at the evidence that is emerging and they are determining how well it fits within their strategic goals.
- For healthcare, we should always start with the aim to decide what needs to be totally to be done on a private chain and what needs to be on a public domain. So, having a dynamic and granular assessment, and then being very careful as to what you put on the blockchain in the first place. So, yes, you can put some information in the public domain, but you have to be very careful about what that is, and then ideally, you should start with the aim to use a private one (if you can).
- Private blockchains are designed to have a governing structure that the partner or the customer determine and that best suits their needs. So, this structure determines who gets to make the decisions, how is liability shared, how is risk shared and monitored and even though we maintain a platform, all of the partners maintain the applications, and they own their own data. The platform provider doesn't access the individual data, and doesn't manage access permissions, so we created a hard-defining line to maintain the governance structure that partners have created and maintained their sense of privacy and control.

SESSION 2 - HEALTHCARE BLOCKCHAIN APPLICATIONS & DISCUSSION ON PROBLEMS AND HURDLES FOR UPSCALING AND FURTHER DEVELOPMENT

Moderated by: Bryant Joseph GILOT, MD CM DPHIL MSC, Institute for Translational Bioinformatics Universitats Klinikum Tubingen Eberhard Karls Universitat Tubingen

Presentations and moderated discussion
- **Presentation: Blockchain Uses for Dynamic Consent - Ethical Considerations for Data Management and Privacy**, Wendy Charles, PhD, CIP, CCRP, CBP, Chief Scientific Officer, BurstIQ
- **Digital Vs Physical Identity**, Ingrid Vasiliu Feltes MD MBA GBA Ethics Officer & Senator WBAF
- **Data Exchange / Safeguarding 3rd party data transacting with blockchain**, Mike Davie, Founder and CEO of Quadrant

Objectives of the session:
- *Discuss main hurdles in the upscaling process*

- *Provide definitions of main elements within the context of "third party data"*
- *Discuss how the use of "third party data" in blockchain applications can help accelerate innovation*

Main outtakes from the session:

- Even though distributed ledger technology is in distributed networks, these are functionally different than the early stage blockchains that were built for crypto-currency. We see that terminology evolved and that the term blockchain is becoming to encompass the distributed ledger technology just by virtue of much more exposure and familiarity, so distributed ledger technologies are now referred as blockchain as well. They ultimately have similar features in the way that encryption, distribution, smart contracts, tracks, ledgers, are all being used, and can be used for unique purposes that serve a need.
- ERC20 tokens are based on the Ethereum blockchain which is actually public blockchain; but you are also the solution that tried to minimize as much bulk data that could be put on blockchain, probably for privacy concerns or competitive concerns between the institutions that are participants in a network.
- For the different applications we have identity, consent and all these particular applications or needs, that need to convincingly demonstrate that this happened at this time, by who and this was the state before and this is the state after. Nothing is really perfectly immutable, but it is definitely auditable and certainly compared to the traditional methods of doing audits, post factum or post event, or certainly not real time, I think that is a unique feature that can help your delivery – particularly for healthcare – but for research institutions, it's extremely helpful. And that is the one feature that actually convinces many organisations to use it, compared to other technologies.
- For life sciences research, the subject to FDA regulations or Annex 11 regulations, of the EU, data have already been required to have an audit trail and validation since 1997. So, there has been attestation, there has been individual traceability actions for a long time. So, for life sciences research, blockchain doesn't add value in that regard, but the big sale for life science organisations is how blockchain can empower data in ways that they have not been able to do so before, with traditional database systems. For example, the power of crowdsourcing, in exponential learning, federated learning, etc. The primary value depends on which audience you are addressing and what their particular needs are.
- There is frequently confusion between digitization, and electronic records and electronic signature. Many regulatory agencies require electronic submission of records. For their pre-market approval, for their new drug application, and those must meet specific standards for data nomenclature, for the organization, and, if stored in electronic format, it must meet the regulatory requirements for electronic records or electronic signatures which includes an audit trail by default. So, it is essential to make sure that we are comparing apples to apples in what is the current state of life sciences research and regulatory issues.

- From the regulatory perspective, having unique cybersecurity features for healthcare is going to be important; deciding what we want to put on the blockchain is crucial. Not everything there is in healthcare needs to go there. In terms of potential consequences people can, like in every other industry, take your identity and use it for their own reasons. So, if you do it proactively, and have the proper consensus amongst the participants, as to what belongs actually on the chain, or not, then you can safeguard some of those potential negative consequences. But yes, people could take over your identity for financial reasons, for voting reasons, for legal reasons, not to mention discrimination or many other issues that can occur.

Moderator: we have talked about – very specifically – healthcare systems. Except for Mike that comes from a

broader, sort of different solution. So my question is, do we really need to have specific healthcare systems that use blockchain for identity and for data exchange or should we be building more universal systems that can be used as building blocks, so for example, a researcher might use an identity system at the same time that an insurance company in a privacy preserving manner might continue to use the identity system to identify which patient is coming to the hospital today, etc.

Wendy: because I worked in healthcare, regulatory compliance and blockchain for healthcare, my views are shaped by my experience. Healthcare and life sciences research is a highly regulated environment and not just to prevent bad actors but because we want to demonstrate respect for individuals and provide as many ethical protections as possible for the most sensitive information people have, which is their healthcare information. I don't know if we necessarily need separate systems for healthcare like sciences or other industries, but we do need to be mindful that systems we create must adhere to the minimum regulation that apply to that jurisdiction, typically privacy regulation. We want to design our systems to be maximally respectful of the nature of data being stored and the individuals represented in those data as such. So they are not caused harm by any of the actions we take, no matter how well-intentioned.

Mike: I wouldn't look at the main thing in healthcare as data itself as it is off chain; the way data is stored in blockchain is a lot more cumbersome, a lot more expensive, so, there really comes a cost-benefit analysis. If all data in the world was stored the same way healthcare data are stored, we would have the security of a web page.

When you look at consent, such as consent for the usage of data, that would, voters' rights. When you are looking at consent and the right to access, or the audit trails, all that could be universal. I would say those top layer things, should be across all types of personal data and identity.

- The nature of human-centric research, clinical research is about that balance between individual privacy and greater good. Committees of experts are asked to review each proposal (the Ethics review boards) in order to ensure that there is appropriate balance of individuals' rights to have their sensitive information protected versus ways of aggregating data and information for the greater good. While the blockchain has many features that can enable privacy, regulations are in place to protect individuals and allow them to make autonomous decisions about how they want their information to be used. There are some circumstances whereby information can be used for public healthcare surveillance and for certain forms of clinical research without the users' actual consent. However, that must be close to oversight by those institutes conducting the research in order to ensure that individuals' rights are still protected.

- Blockchain can enable the dynamic consent, so that we can give people choices. Some people feel comfortable sharing their information, other people may not. The more ethical solution would be to give people more choice and to create the technologies that can enable them to have a say and be able to change their mind as well, as circumstances and perspectives change.

- China used blockchain to help manage the public health surveillance information on COVID and showed that blockchain is a successful solution for data sharing and management. The whole concept developed new public health initiatives about emergency authorization as to share information is debatable, and the degree to which people might have their information to share in ways that they do not provide permission is also a matter of debate. Blockchain capabilities with dynamic consent, transparency at least allow individuals to have a voice and a view how their information is used with the hope that they can at least understand and have more trust in the underline basis.
- Dynamic consent and transparency enable that there is trust in the network and that we don't go too far and stop sharing data, so people can trust it, and can always have a say.

Appendix

Workshop slides

- [Full deck of Blockchain Applications in Healthcare workshop presentations](#)

Workshop videos

- Videos from this and all other workshops can be found on the [EU Observatory website under reports](#).
- Videos specific to this workshop: [Healthcare workshop video](#)

Official agenda

Time	Activity
12.00	**Welcome** Peteris Zilgalvis, Head of Unit, Digital Innovation and Blockchain, DG CONNECT; Co-Chair, FinTech Task Force, EC
12:05	**Introduction to the workshop** Kostas Votis, CERTH
12.20	**"Pharmaledger: Blockchain Enable Healthcare "** Sînică Alboaie– RomSoft & Marco Cuomo – Novartis
12.40	**"BurstIQ Blockchain for Surgical Costs and Outcomes"** Dr. Wendy Charles, BurstIQ
12.50	**"Opportunities and challenges in deploying Blockchain solutions globally"** Ingrid Vasiliu Feltes MD MBA, GBA Ethics Officer & Senator WBAF
13:00	**Panel discussion**
13:40	**Dynamic Consent** Dr. Wendy Charles- BurstIQ
13.55	**Digital vs Physical Identity** Ingrid Vasiliu Feltes MD MBA GBA Ethics Officer & Senator WBAF
14.10	**"Data Exchange / Safeguarding 3rd party data transacting with blockchain"** Mike Davie – Quadrant
14.25	**Panel discussion & Q&As**
15.30	**End of day**

Speakers Biographies

Sînică Alboaie – Romsoft

Sînică has over 20 years of experience as an entrepreneur, a software developer, a technical manager, and a researcher in areas as distributed systems, software integration, privacy, and blockchain technologies. Sînică is currently co-leader of the architecture work package in the ambitious Pharmaledger European research project and is also technically leading an innovative European project called PrivateSky that invented new privacy-enhancing technologies build around executable choreographies. Sînică has the hope that the digital world is going in the direction of data self-sovereignty as a guarantee for preserving and increasing our political and economic freedom.

Wendy Charles, PhD, CIP, CCRP, CBP, Chief Scientific Officer, BurstIQ

As Chief Scientific Officer for BurstIQ, I combine 28 years of experience in conducting/managing clinical research, regulatory compliance, and blockchain. This position uniquely allows me to use my PhD in Clinical Science with a specialty in Health Information Technology with my certifications from in-depth knowledge exams as a Certified Institutional Review Board Professional (CIP), Certified Clinical Research Professional (CCRP), and Certified Blockchain Professional (CBP).

My specialties include:
• Blockchain implementation and compliance
• Federal drug and device research regulations
• Clinical research operations
• Auditing and quality assurance
• Protocol/consent form development
• IRB submissions and review
• Pharmacovigilance operations

https://www.linkedin.com/in/wendycharles/

Marco Cuomo - Novartis Pharma AG

Marco is an Applied Technology Innovation Manager, responsible for exploring, engineering and implementing new technologies such as Blockchain, IoT and API Management.
He has been with Novartis since 2005. For the last four years, his focus has been on Blockchain and exploring various use cases for Pharma.
He began his career as a programmer in 1988 and has held various positions of increasing responsibilities in software development, engineering, operations, service management and solution
design.

Mike Davie, Founder and CEO of Quadrant

Mike Davie is the Founder and CEO of Quadrant. Based in Singapore, Mike has been leading the commercialization of disruptive mobile technology and Information and Communications Technology (ICT) infrastructure for over a decade with leading global technology firms in Asia, Middle East and North America.

He parlayed his vision and knowledge of the evolution of ICT into the creation of DataStreamX, a pioneering data acquisition and transaction platform, in 2014. DataStreamX ultimately
evolved into Quadrant, a blockchain-based location data platform that allows organisations to obtain authenticated data. With Quadrant, organisations and individuals can now have full
trust in their data and use it to build targeted solutions and allocate resources efficiently to meet the requirements of their customers, citizens, and colleagues.

https://www.linkedin.com/in/mdavie/?originalSubdomain=sg
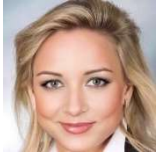
Ingrid Vasiliu Feltes MD MBA GBA Ethics Officer & Senator WBAF

Healthcare futurist who has extensive experience in the healthcare industry as a founder, executive, consultant or speaker.
She currently is serving as the Chief Quality and Innovation Officer at MEDNAX Healthcare Solutions. In this capacity she provides oversight for all quality and innovation initiatives
across the enterprise, such as Blockchain, AI, Genomics, Precision Medicine, Population Health, Telehealth, Medical Simulation, and Value Based Care. Additionally, she provides leadership
to the MEDNAX Center for Research, Education, Quality and Safety. Prior to her current role, she held several leadership positions within the academic, corporate and not-for-profit
healthcare arena, most notably serving as VP-Education, Quality and Safety, Chief Patient Safety and Quality Officer, Chief of Compliance and Quality Assurance, Medical Director of
Clinical Research Trials, and Medical Director-Managed Care. Her consulting engagements have included healthcare systems, VC funds, angel investment funds, not for profit entities and
corporations.

https://speakerhub.com/speaker/ingrid-vasiliu-feltes-md-mba-fache