RDA WG - Blockchain Applications in Health Working Group

Case Statement

1. WG Charter

The Health Data IG is sponsoring the idea of establishing a WG focusing on Blockchain in Health data, as a technological advanced solution for securing data sharing among clinical institutions and individuals.

Simply stated, the blockchain is a cryptographic protocol which makes it possible to run a distributed, public and trustable ledger where transactions referring to digital objects are signed with issuer and recipient's identities, verified by a community of peers and stored as incremental "blocks" into a shared database. Beyond technicalities, the true disruption of the blockchain lies in the fact that it brings digital trust over a potentially un-trustable network. It can make Trusted Third Party-centred systems obsolete by giving decision-making powers to data subjects and clinical institutions.

The large scale deployment of a blockchain ledger can, in fact, enable health data transactions based (when needed) on the appropriate patient's consent and/or the hospital's permission and operated through self-enacting smart contracts, in combination with a catalogue of all available data, which would be browsable at anytime, anywhere and by anyone, yet containing no sensitive information.

The aim of establishing a dedicated WG is:

- to analyse and compare usages of the blockchain in healthcare, implementations of blockchain architectures, associated legal and socio-economic impacts and perspectives

- to assess the potential of blockchain-based self-enacting smart contracts in handling consent and data permission systems minimising transaction costs

- to assess whether and how the blockchain can ensure compliance with advanced data protection requirements (such as those defined by the EU General Data Protection Regulation – GDPR), yet making it happen seamlessly and efficiently, at scale.

Within 18 months of activity, starting from concrete examples, the group will draw a set of use-cases, thus feeding a working draft and concluding on good practices, technical recommendations, and guidance to healthcare professionals interested in having recourse to blockchain solutions.

2. Value Proposition

Imagine a place where individuals, research centres, pharma companies, and healthcare professionals can easily search for and mobilise on demand large volumes of data while ensuring at all times patients' clear consents and the highest standards of privacy protection and security, coping with any hurdle deriving from geographical location, data complexity, or data protection laws.

The blockchain can help to establish a solid technological backbone, supporting healthcare information systems' resilience, and acting as an operational data protection regulation-compliant infrastructure, where data transactions are informed and controlled by informational self-determination and privacy-by-design/default principles.

The guidelines produced as WG's outcome shall benefit all kind of stakeholders dealing with health data who require full traceability of data usage especially for research purposes, and who will benefit from transparency and trust, such as: biomedical researchers, clinicians, drug and device trials operators, individual patients wishing to know more about other people sharing similar medical conditions, as well as individuals/patients/citizens willing to make use of trustful blockchain-based systems for contributing to data sharing to enhance scientific research and medical knowledge.

3. Engagement with existing work in the area

The WG on Blockchain applications in Health will be directly associated with the Health Data IG, and it will seek cooperation with all groups interested in applying blockchain to other areas, such as the Ethics and Social Aspects of Data IG or the Working Group for Data Security and Trust (WGDST), as well as any group interested in the future in better understanding the blockchain potential by clustering with the Blockchain applications in the Health WG.

Two very high-level presentations were given by blockchain experts during the two BoFs on "Health Data and Blockchain" held at RDA P9 in Barcelona and RDA P10 in Montreal. The first presentation in Barcelona was by Prof. Aggelos Kiayias (chair in Cyber Security and Privacy at the University of Edinburgh and Associate Professor of Cryptography and Security at the Department of Informatics and Telecommunications, University of Athens) and focused on "Blockchain solutions and Privacy"; the second one in Montreal by David Manset (CEO of gnúbila and Head of R&I Almerys) described an example of a blockchain system (still under construction) applied to health.

Furthermore, RDA Europe promoted within the RDA Innovation Forum in Bruxelles (30th January 2018) a session on "Opportunities to shape future data research - blockchain and what is it for and

what not", focusing on the opportunities and limitations related to Blockchain Technology applied to Scientific Data and based on the suggestions coming from the paper "Blockchain and Data" by Wittenburg and Kuchinke (2017). Speakers invited to the session were: Peter Wittenburg (Max Planck Society), "Short Introduction of Blockchain and its possible role in IoT data trading"; Edwin Morley-Fletcher (Lynkeus) on "Applying blockchain in Health sector"; Monique Morrow (Humanized Internet) on "Providing Self-Verification Capabilities via Blockchain"; and Visa Vallivaara (VTT) on "Applying blockchain to increase trust in AI".

Outside the RDA, several on-going projects and initiatives confirm the rising interest for blockchain within the Health sector and the need to facilitate the establishment of a wide community of users, utilising the blockchain system for data exchange, data valorisation, data access, and product development.

Blockchain technologies can create an own ecosystem with own rules and processes when applied comprehensively; but this is still in discussion. Therefore, a WG is necessary that can discuss the disruptive potential as well as the novelty and efficiency of Blockchain solutions as potential game changers in health research.

While members of the proposed WG are already involved in some H2020 EU-funded projects dealing with blockchain and Health data (such as myhealthmydata, using blockchain technology to secure health data transactions) networking shall be pursued with already existing communities in the intersection between healthcare, health data management, and blockchain, such as the Hashed Health Collective, the Hyperledger Fabric Foundation (specifically in the healthcare domain), the Decentralised Identity Foundation, the European Institute for Innovation through Health Data, and the CONFIDENCE[1] bench pilot consortium. Further efforts will be devoted to interacting with on-going initiatives in the field, such as MedicalChain, Datum, Ocean, the EU-funded project Privacy Flag, TrustedHealth, just to mention a few, and to connect with a number of existing industrial platforms such as the Fraunhofer's Industrial Data Space, Combient and Siemens Healthineers Digital Ecosystem.

4. Work Plan

- The final deliverable of the WG will be a set of Guidelines for establishing a scalable blockchain-based data sharing system in healthcare. These guidelines will include a state-

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[1] blockChain-based cOllaborative iNtelligence on Food, bIg Data cooking rEcipe, multimedia Nutrition, and healthCare initiativE.

of-the-art report and a report on regulatory and legal issues, focussing on blockchain applications in health.

- At 6 months interval, 3 reports will be presented at each RDA Plenary WG's Session, highlighting the performed analysis and activities, following 3 steps: first, the state-of-the-art report (after 6 months) describing the current experiences in blockchain based handling of health data; second, the report on regulatory and legal issues (after 12 months); third, the comprehensive Guidelines on Blockchain applications in Health (after 18 months), inclusive also of an example of basic coding for a health-data blockchain architecture, such as allowing clinical institutions to register their datasets in the blockchain and make them available to users; for these to browse available data and apply analytics to the federated data repository; for individuals and clinical institutions to define consent, data access rights, and monitor the use of their data; for data to be accessed and downloaded by authorised data users through the blockchain.

- From the start of the WG, its members will be asked to join one or more of the proposed sub-groups

- Working documents will be made public or accessible to WG/RDA members via open tools such as Google docs.

- Over a period of one and a half year, the working group will host a general 2-hour telco on a quarterly basis and meet in person every six months at the RDA Plenary Assembly. Smaller groups, dedicated to the above-mentioned reports, will communicate on-line at least on a monthly basis.

- The WG members will work individually or in small groups depending on the activities to be performed in relation to the above-mentioned WG outcomes. Activities assigned, and draft outcomes will be discussed, monitored and reviewed during the quarterly telcos and Plenary sessions, and additional TCs will be organized when needed.

- The WG Guidelines will be reported to the Health Data IG so that HDIG members may share and disseminate them in all relevant events they will happen to attend.

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5. Adoption Plan

In view of disseminating the Guidelines outside the RDA community, the members of the WG are expected to present the outcoming recommendations in relevant events or in their work environment, or in any useful event they may occur to participate.

Additionally, RDA national nodes will be addressed to gain support for disseminating the Guidelines and other outputs or recommendations resulting from the WG.

Connections and networks established through the above-mentioned initiatives and with relevant stakeholders (see point 3) will provide the opportunity to present and discuss the Guidelines to a wider community, involving it in the revision and adoption process.

Furthermore, relevant on-going projects may benefit of the Guidelines with regard to their activities.

6. Initial Membership

Name	Membership	Region/Country
Edwin Morley-Fletcher	Co-Chair	Italy
David Manset	Co-Chair	France
Aggelos Kiayias	Co-Chair	UK
Yannis Ioannidis	Co-Chair of Health Data IG and Athena RIC	Greece
Leslie McIntosh	Co-Chair of Health Data IG and Executive Director of RDA/US	USA
Patrick Ruch	Hes-so (expert in Artificial Intelligence, Data Mining, Information Science)	Switzerland
Anne-Marie Tassé	Executive Director P3G (lawyer specialised in health law and bioethics)	Canada
Ludovica Durst	Lynkeus (legal expert on data protection and Health)	Italy
Andreas Rauber	Vienna University of Technology (expert in computer science)	Austria

Laurence Claeys	Vrije Universiteit Brussel (expert in privacy, trust, risk and end-user development in the domain of Internet-of-Things communication)	Belgium
Mirko De Maldé	Lynkeus (expert in ICT for Health) and chair of Rome's Government Blockchain Association	Italy
Aurélie Bayle	Be-Studys (legal expert on Blockchain and smart contracts, DPO)	France
Davide Zaccagnini	Lynkeus (expert in ICT for Health)	USA
Aaron Braun	Adam State University	USA
Aaron Addison	Washington University in St.Louis (Director of Data Services)	USA
Andreas Matern	Sanofi (IT Specialist in Pharmaceutical R&D)	USA
Ashish Upadhyay	CEPT University (Database management Researcher)	India
Benjamin Löhnhardt	University Medical Center Göttingen (Medical Informatics)	Germany
Fotis Karagiannis	IT Consultant	Greece
Frederic ANDRES	NII (IT architect expert in collective intelligence)	Japan
Huajin Wang	Carnegie Mellon University	USA
Joao Miranda	ESTG/IPP; CERENA/IST (Professor of Chemical Engineering)	Portugal

Joerg Geiger	University of Wuerzburg (expert in biobanks)	Germany
Marco Marsella	FAO (IT specialist and IT architect)	Italy
Mark Leggott	Research Data Canada/CANARIE (executive director)	Canada
Marta Teperek	TU Delft (expert in data research)	Netherlands
Natalie Pankova	SHIVOM (Chief Scientific Officer)	UK
Paul Uhlir	Expert in Information law and policy	USA
Timea Biro	Trust-IT Services	Italy
Wolfgang Kuchinke	Heinrich-Heine University Duesseldorf (clinical researcher)	Germany
Xuefu Zhang	Agriculture Information Institute, CAAS	China
Yin Chen	EGI.eu (IT specialist)	Netherlands
Yosef Meystel	Aperion Care (President)	USA
Yuri Demchenko	University of Amsterdam (Senior researcher in Big Data Intensive Science Technologies and Infrastructure, Cloud and Intercloud Architecture)	Netherlands