**Blockchain Applications in Health WG Case Statement**

Web-Site of Health WG in RDA: <https://www.rd-alliance.org/group/blockchain-applications-health-wg/case-statement/blockchain-applications-health-wg-case>

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.

The deployment of such a ledger at large scale can 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.

1. **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.

1. **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 Health WG.

1. **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-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.
* 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.

1. **Initial Membership**

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| Name | Membership | Region/Country |
| Edwin Morley-Fletcher | Co-Chair | Italy |
| David Manset | Co-Chair | France |
| Aggelos Kiayias | Co-Chair | UK |
| Yannis Ioannidis |  | Greece |
| Leslie McIntosh |  | USA |
| Patrick Ruch |  | Switzerland |
| Anne-Marie Tassé |  | Canada |
| Ludovica Durst |  | Italy |
| Andreas Rauber |  | Austria |
| Laurence Claeys |  | Belgium |
| Mirko De Maldé |  | Italy |
| Aurélie Bayle |  | France |
| Davide Zaccagnini |  | USA |