



# WG Blockchain solutions for accessing health data

RDA P11 Berlin – 21 March 2018

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# Meeting agenda

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- 1) Introduction to the Working Group main objectives and WG Case statement
- 2) Guest speakers on Blockchain and Health Data
- 3) Description of the Work Plan and Internal discussion on the WG's activities and organization and next steps (with special regards to the first 6 months goals)

# A WG focusing on Blockchain in Health data

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After two successful former meetings held at P9 in Barcelona and at P10 in Montreal, the Health Data Interest Group (HDIG) has gained support within the RDA community for 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, bringing digital trust over a potentially un-trustable network.

The aim of establishing a dedicated WG is:

1. to analyse and compare usages of the blockchain in healthcare, implementations of blockchain architectures, associated legal and socio-economic impacts and perspectives
2. to assess the potential of blockchain-based self-enacting smart contracts in handling consent and data permission systems minimising transaction costs
3. 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.

# Official recognition process

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The Group has been showing an anticipated awareness of a potential game-changer in the organisation of data access and data consenting, and Blockchain is recording an extended interest from various quarters.

Therefore, the "Blockchain applications in Health WG" has started the official RDA recognition process by submitting the case statement and is undergoing the review and endorsement process. The next Plenary in Berlin will be the occasion for the first official meeting of the newly instituted WG, and to start addressing the WG objectives, activities, internal organization and deliverables, as described in the WG Case statement.

# WG Charter

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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.

# WG Charter (continuation)

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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

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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.

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# Engagement with existing work in the area

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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.

# Work plan

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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.

# TAB's evaluation of Focus and Fit

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The scope and goals outlined are reasonable within an 18-month period and appropriate and applicable to be carried out within the RDA forum. The WG proposes to carry out a review of application of blockchain technologies in handling healthcare data loads and its particular associated burden of ethical accessibility. The WG output is expected to be a working draft set of good practices, technical recommendations, and guidance to healthcare professionals interested in using blockchain solutions. Such an outcome will not only be useful to the healthcare data community, but also should stimulate and facilitate similar efforts in other domains. Additionally, the multifaceted nature of applying block chain to the sharing of healthcare data means that the multidisciplinary and wide spectrum of expertise represented at RDA is useful to such a task.

# Work Plan, Deliverables, and Outcomes

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The WG charter proposes to produce - in 6 months intervals - 3 consecutive reports at each of the RDA Plenary WG's Sessions, highlighting the analysis and activities, and ultimately leading to the comprehensive Guidelines on Blockchain Applications in Health.

To accomplish this they will divide the tasks among focused subgroups of the current members. The plan and output seems reasonable for a focused case study in an 18-month period.

# Capacity

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Initial membership represents a reasonable distribution of geographical areas. The 3 co-chairs are highly expert in this topic. Members have been involved in 3 prior BoF sessions on this topic and apply block chain technologies to their own work. However, the case statement is missing any summary of work done outside the proposed RDA WG or any mention of external groups. At least one presentation by a French expert and project in this area was made at a BoF in 2017, so the external work should be noted and an explanation of how it relates to the proposed WG should be stated. Several RDA internal groups are mentioned and welcomed to participate, however.

# Impact and engagement

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The WG is associated with the Health Data IG, which appears to be their primary target audience. The work looks especially relevant to other disciplines as well. The adoption plan is missing, however, so no specific plans are given for how the outcomming reccommendations will ultimately be used outside of the RDA.

# Recommendation

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## The Case Statement Requires Revision

We suggest:

- The intention to include "an example of basic coding for a health-data blockchain architecture" be outlined in more detail.
- A clear adoption plan should be outlined.
- Text should be provided regarding either why no other external groups or organizations are active in this area or they should be described and consulted/included.

Some of the WG members may well be representatives of such external work, but their expertise or activities are not provided.

# Additional Comment

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We note that the WG received a note on its RDA homepage on 15 February 2018 from an expert in this area who is interested in joining. This should be followed up, if it has not been already.