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Digital service innovation enabled by the blockchain use in healthcare: the case of the allergic patients ledger

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**Abstract.** By combining the institutional approach and the rational model of digital innovation, there is increasingly a great interest in the implementation of blockchain solutions in healthcare but, until then concrete evidence for this type of project is missing. At the same time the healthcare sector, allergology in particular seems to face security (confidentiality, availability and integrity) issues and information audit trail weaknesses. For these reasons, our study focuses on the co-construction of a distributed ledger for patients allergies with healthcare professionals. The aim is to design and implement a reliable tool to deal with the availability, integrity and confidentiality of information about new allergies and distinguish between validated allergies and declarative allergies for the purpose of mitigating negative effects of unavailability of reliable information about patients allergies. This article defers the first step of our methodological cycle by explaining how collaboration is organized between Pikcio (blockchain technology provider) and allergists. As a result, we have first versions of some deliverables such as formal specifications, risk matrix document and a UML design (class diagram, use case diagram and sequence diagram) as the research project is iterative.

**Keywords:** Allergology, pikciochain, blockchain, digital innovation, co-construction, social innovation
1. Introduction

In recent years, digital innovation has attracted great interest from the information system community with the rapid expansion of digital technologies in business and society in general. As a definition, digital innovation is the use or production of digital technologies in the innovation process (Nambisan, Lyytinen et al. 2017). The digital innovation has two main approaches: institutional and rational model (Hinings, Gegenhuber et al. 2018). The institutional approach of digital innovation emphasizes the belonging of organizations to a society that imposes on them behaviours that must be adopted in order to comply with the law or socially acceptable rules (Hinings, Gegenhuber et al. 2018). From this point of view, the fashion phenomenon has a lot to do with the adoption of new tools in companies and organizations. The most striking example is that of blockchain technology, which is originally use in the field of cryptocurrency and is found to attract great interest in other sectors, one of which is healthcare (Hölbl, Kompara et al. 2018). However, in spite of the multiplication of studies on the application of this technology in healthcare, it is far from visible and concrete applications of blockchain potentialities in this sector (Hölbl, Kompara et al. 2018). Far from contradicting the potential of the blockchain technology, this last remark aims to put things in context by finally recalling the rational purpose of the digital innovation that is to bring solutions to specific problems encountered by users (Tolbert and Zucker 1999).

Nevertheless, beyond the hype, the blockchain has strong promises in the healthcare sector, where existing systems have failed (Rabah 2017); especially in terms of security (Manaouil 2009) and compliance with health data regulations (Lucas 2017). Since security is made up of the availability, integrity and confidentiality of data (2013), it also involves looking at the audit trail in the system for the purposes of control and audit (Cruz-Correia, Boldt et al. 2013), mainly related to the question of forensic responsibility or accountability of healthcare professionals.

The security issue is particularly visible in healthcare with a great negative effect on patient safety especially in the field of allergology where reliable information concerning the patients allergies are often not available nor accessible, which causes a lot of medical incidents (Demoly, Hillaire-Buys et al. 2003). On the other hand, the few information available are of dubious quality especially for penicillin allergy with approximately 10% of patients who report a penicillin allergy while up to 90% of these patients do not have a true allergy what causes anaphylactic reactions or antibiotic resistance after administration of inappropriate treatments (Sullivan, Wedner et al. 1981). The low quality of these data is often related to the fact that the validations are not made or are made by non-expert professionals who do not finally establish the correct diagnosis (Demoly, Hillaire-Buys et al. 2003) which leads to questioning the source of the data by keeping in mind that the data will be more reliable if the validator is legitimate.

This lack of reliable and traceable information causes the increasement of morbidity and mortality rate as well as a significant socio-economic cost (Bousquet and Demoly 2005), hence the importance to deal with the construction of solutions that enable the permanent availability of such healthcare information in a secure way. In this sense, our research question is about how to use blockchain technology to design and implement a reliable
and secure healthcare information system in the allergology field in order to improve the safety of patients during the treatment?

Before answering the question "how?" we must return our attention to the primordial question of "what?" since it is demonstrated that the success of a solution is based on the value it has in relation to the problems that arise (Pozzi, Pigni et al. 2013). Hence the importance of clarifying the state of needs to bring out relevant solutions, especially since the literature describes needs as being generally unknown and technologies as unintelligible (Cohen, March et al. 1972). Meanwhile, the literature of social innovation advocates, for studies focused on the social interest of users to integrate them in the construction of the solution because they ultimately better know what they need (Mulgan 2006). This last remark brings us back to the problems of misunderstanding that can occur during the collaboration between technology experts and users, given the heterogeneous knowledge they hold and which must be combined for the success of the project (Ratcheva 2009). For these reasons, we believe that the co-construction approach (Oudshoorn and Pinch 2003) is relevant to complement the concept of boundary objects (Mark, Lyytinen et al. 2007) in order to design the best suited solution for users’ needs.

This research project focuses on the involvement of healthcare professionals and patients in the co-construction of a digital and social innovation of a distributed ledger for allergies that allows the reliable identification of each patient and healthcare professionals, the distinction between validated allergies and declarative ones, as well as patient consent access management for the purpose of improved patient safety during the treatment.

The remainder of this paper concerns successively a background on the blockchain concept follow up by the theoretical framework, methodology, preliminary results and expectations as well as implications of this research project.

2. Background : blockchain technology

Blockchain technology has a lot of definition either holistic or specific (Fosso Wamba, Kamdjoug et al. 2018) but can easily be described by four main technical characteristics (Dinh, Liu et al. 2018): distributed ledger as all participants in the chain has the same version of data records, block and cryptography as data are organized in block and each block is cryptographically linked to his predecessor and many cryptographic techniques are used to avoid data alteration or redundant records, consensus protocol as the achievement of a transaction depends on the validation of participants, finally Smart contracts as the system verifies conditions and apply automatically changes (Watanabe, Fujimura et al. 2015). Overall, we can say that the blockchain ensures the secure transfer of data in a secured environment without the intervention of any third party that would validate operations (Yli-Huumo, Ko et al. 2016). This technology was first used for financial transactions with bitcoin cryptocurrency before being gradually adapted for other purposes with several other technologies such as Hyperledger and Ethereum among others (Dinh, Liu et al. 2018).

However, whatever the field of application or the implemented tool, the blockchain technology faces several challenges that can be summarized in three main terms (Swan 2015) namely: correctness that describes the capability for a blockchain system to distinguish fraudulent transactions, agreement that describes the mechanism set up to ensure that all or
almost all participants in the network accept a transaction and finally the utility that describes the necessity for a blockchain system to be useful. These challenges are more and more taken into account in the different developments of blockchain and according to the domains, we can have public or private blockchain (Dinh, Liu et al. 2018) whose comparison can be summarized in the following table:

Table 1 Public VS private blockchain

<table>
<thead>
<tr>
<th>Key proprieties</th>
<th>Data model</th>
<th>Consensus</th>
<th>Frequent applications</th>
<th>Examples</th>
</tr>
</thead>
<tbody>
<tr>
<td>Public Blockchain</td>
<td>Free access</td>
<td>Coins or account</td>
<td>All nodes are involved, the consensus process is time and energy consuming</td>
<td>Crypto currencies, general applications</td>
</tr>
<tr>
<td>Private blockchain</td>
<td>Access control</td>
<td>Accounts, assets</td>
<td>It could have master nodes for the consensus process</td>
<td>Finance, healthcare (Linn and Koo 2016) and closed organizations networks in general</td>
</tr>
</tbody>
</table>

The first adaptation of blockchain in healthcare was reported in 2014 (Ashoor and Sandhu 2014) after what many other papers and white papers had been written to describe the potentialities or a particular tool made for an application in healthcare (Hölbl, Kompara et al. 2018). Rabah Kefa (2017) presents a list of possible usage of blockchain in healthcare sector and we can summarize them in few terms: audit trail, access grant, data integrity or electronic health record. In the literature, the identified challenges for blockchain in healthcare and the proposed solutions can be summarised in the following table.

Table 2. Challenges of blockchain in healthcare

<table>
<thead>
<tr>
<th>Challenges</th>
<th>Solution</th>
<th>References</th>
</tr>
</thead>
<tbody>
<tr>
<td>Anonymity</td>
<td>Patients grant access to identified persons or institution</td>
<td>(Hölbl, Kompara et al. 2018)</td>
</tr>
<tr>
<td>Security / confidentiality</td>
<td>Access control, right granted by patients</td>
<td>(Hölbl, Kompara et al. 2018)</td>
</tr>
<tr>
<td>Data management</td>
<td>- Data lake (Data repository enabling the storage of diverse data type) with only</td>
<td>(Yue, Wang et al. 2016) (Kuo, Kim et al. 2017)</td>
</tr>
</tbody>
</table>
indexes saved on the chain
- Data stored locally by users and exchanged peer-to-peer when it is necessary

The new legal requirements General data protection regulation (GDPR) and good practices regarding health data in Europe are related to the security, integrity, the right for patients to give their consent for the visibility of their data and to change their mind as whenever they want (De Hert, Papakonstantinou et al. 2018). In addition to this requirements, healthcare information system needs to be improved in the way of audit trail (Cruz-Correia, Boldt et al. 2013) for the purpose of data integrity and accountability of healthcare professionals of all transaction for the purpose of audit and forensic responsibility. All these requirements seem to match with the potentialities of blockchain technology which answer all these requirements with the following’s characteristics: transparency, data immutability and traceability, hence the great interest of healthcare in this technology.

3. Epistemological and theoretical framework

Tolbert and Zucker (1999) distinguish two models of innovation adoption process by explaining the fact that while the institutional approach of digital innovation focuses on the over socialised nature of organisations in the process of adopting a solution, the rational actor model remain very important in that it is the best way to have a successful innovation because it involves taking into account the value of a solution for a given need. In this perspective, the issue involved in a research project must address a real problem in practice, in our case the information traceability issues and security of data encountered by health facilities for the purpose of improving patients safety. This idea is supported by Wainwright, Oates et al. (Wainwright, Oates et al. 2018) who developed the evidence based practice in information system from the model found in medicine called evidence-based medicine which is the basis of the decision support system (Stavrou, Challoumas et al. 2013). In addition to deal with the idea of involving real information system problematic, the evidence-based practice emphasizes on the importance of evidences during the conclusion phases and research results diffusion.

In the same way, Greeno (Greeno 1994) points out the notion of affordances in its original sense that defines the explicit or implicit existence of needs, leaving thus to show the importance for a researcher to be able to synchronize with practitioners without being influenced by fashion effects (Baskerville and Myers 2009) but more by the possible value of an artefact for users and their needs. In the same vein, Gregor and Jones (2007) propose the design theory to show its definite impact both in research and in practice with the influences it has had, among other things, in the analysis of structured systems. Nunamaker Jr, Chen et al. (1990) and Gregor and Hevner (2011) argue in this sense the usefulness of "design science research" for research and practice in information systems. This concept highlights three
aspects: proof of concept, proof of value and proof of usefulness which are important and make it possible to describe the need for information system researchers to find solutions to practical problems but also to ensure that these solutions are used to promote the benefits they imply. Moreover, these notions can be crossed with those found in "evidence-based" where a particular emphasis is placed on the definition of the problems to be solved, the sources of information necessary for the resolution of those problems, the resolution of those problems and the dissemination of the solution (Goeken and Patas 2010; Wainwright, Oates et al. 2018) since in both cases, it is a question of broadcasting an innovation that is useful and used by the target audience. However, to deal with the need of the organizational relevance of a solution, the design science research has been improved to the action design research by emphasizing on the importance of continuous evaluation along the process rather than conduct evaluations ex-post (Sein, Henfridsson et al. 2011). This last approach deal with the challenge of clarifying the needs with users in order to design the best suited solution.

The importance of the clarity of needs and the usefulness of solutions lead therefore to be more interested in the theory of affordances which is defined as the value of a solution for a user (Pozzi, Pigni et al. 2013). Transposed into an information system, the notion of affordances describes the fact that the possibilities of a tool may not be systematically perceived by the user. This view leads to the conclusion that users would not always be aware of their need or that the values of a solution would not always be easily perceptible as argued by Cohen, March and Al (1972) and Lomi and Harrison (2012) through the notion of organized anarchy (garbage can theory) which highlights the fact that in the organizational reality the solution can pre-exist the problem, and that it can be in adequacy or no with a pre-existing solution. This idea runs counter to the basic premise of design science which is that we design and develop a solution to answer a problem or a need. It should also be noted that problems in organizations are almost poorly defined, especially in professional organizations such as schools / universities (Glaser 2017) which have the same organizational structure as hospitals (Romelaer and Mintzberg 1982).

We propose to complete the approach of action design research by considering organized anarchy in a process of co-construction of digital innovation. Our research approach is inspired by the new theory of digital innovation (Nambisan, Lyytinen et al. 2017) that puts forward a strong link between the innovation process and outcomes by describing a collaborative work environment that needs to be orchestrated in order to match solutions to existing problems. This collaborative environment is made up of future users who are likely to know their needs better and therefore help the designers of the solution to build a better tool with a real social contribution (Mulgan 2006). In doing so, we wish to base ourselves on the recommendations of Haki et al (2018) to move from an approach emphasizing the technological originality brought to an approach that takes into account the multitude of actors at stake in a collaborative approach of co-construction (Oudshoorn and Pinch 2003) with the concept of boundary objects to facilitate the communication between project team members.

4. Methodology

Based on the principles of action design research (Sein, Henfridsson et al. 2011), we propose to carry out action research for the co-construction of a distributed and secure allergy ledger. It consists of several iterative loops for refining needs and solutions involving the designer
and the users, as well as the design of the innovation, materialized through an application allowing the registration and the management of allergies with patients and healthcare professionals. The design process of this application can be drawn as follow:

The three main steps involved in the circle (specification of needs, conception, and evaluation) can be summarized in two stages since we deal with the action design research: intervention and evaluation.

The **intervention stage** is made up of two steps:

- The iterative refinement of problem through a co-construction process between allergists and pikcio. In this step, data gathering will take place during meetings, speed trainings and online discussions with the use of boundary objects such as Business Process Model Notation (BPMN), Unified Modelling Language diagram to facilitate the communication between interdisciplinary team project members.

A particular case of co-construction at this stage of the project is shown in **Erreur ! Source du renvoi introuvable.** below. It is related to the definition of the global purpose of the project
Figure 2. A co-construction case: definition of the general purpose for the project

- The iterative refinement of the prototype is conducted with the use of interactive mockups as a boundary object to facilitate the understanding and the visualization. For this purpose, we use the software Balsamiq mockup 3.

Concerning the evaluation stage, we distinguish in this research level of evaluation:

- Functional evaluation to assess user benefits (e.g. before / after comparisons to evaluate the decrease in the input time). It will include both data from the monitoring of tests (e.g. time for the identification, numbers of bugs) and directive interviews with the users to evaluate their perceived ease of use and usefulness about the solution. For the last purpose, we will use some constructs of adoption theories such as Theory of Acceptance Model (TAM) or Unified Theory for Adoption and Usage of Technology (UTAUT) in order to analyse the acceptability of the solution in view of patients.

- Technical tests will be processed with digital libraries such as JavaScript library or any other units test library available depending on the technology involved during the development.

- Usability evaluation consisting in ergonomics evaluations with real life scenarios

- Clinical trials organized by allergists in order to ensure that the safety of patients is met with the solution.

During all the process, data collection will be done in several levels using a qualitative methodology with interviews and observations. This will occur during the following activities:

- Analysis of the state of art, mainly related to the actual process of the management of allergies and dispositions to make information on allergies available.
- Observation of meetings allowing the co-construction of innovation. The so called co-construction will be enabled by the discussion on each other ideas and the enrichment of the solution with each other knowledge
- Prototype design and technical tests involving UML modelling, development and unit tests
- The construction of scenarios and functional tests with users

5. Preliminary results and expectations

Our methodological cycle was initiated by the need’s specification stage, which was done through meetings, modelling and discussions in which allergists and the solution provider Pikcio were better able to identify needs and the possibilities of the pikciochain technology to match with these needs.

As a result we were able through to better understand the actual processes with the description made by allergists either textual and schematic. This exercise allows to highlight the followings specifications:

- There are three user groups: patients, healthcare professionals and allergists
- The patient, his doctor or his allergist can declare an allergy concerning him, but only the allergist after conclusive tests can validate an allergy.

Through meetings and online discussion on the implications of blockchain for traceability and data regulations both about healthcare data and consent management, those specifications had been added:

- Each user must be reliably identified
- The patient has total control of his data and has the right to authorize or not access to other users
- The patient chooses his trusted third parties to manage his access rights in case of his unavailability
- The healthcare professional can urgently access a patient's file if he / she cannot grant him the rights and he / she has not been able to reach any trusted third party

Then, a document referencing the different risks - risk matrix, was assembled from the clinical point of view by allergists and from the technological point of view by Pikcio. The purpose of this matrix is to identify all or almost all the elements that can undermine the effectiveness of the solution in order to improve specifications in a way of mitigating some risks.
Table 3. List of some risks and the proposed solutions

<table>
<thead>
<tr>
<th>Identified risk</th>
<th>Description</th>
<th>Proposed solution</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Technological risks</strong></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
| Data loss | Since data are saved by users and exchanges are made application to application the risk of data is too high | - Users may choose some trusted third parties to help them save their data in case of loss  
- A healthcare data host (HDS) may be requested to serve as a warehouse for all data |
| Misalignment of system with local practices and processes | The tool could impose a particular new behavior to users | A user-centric approach will be processed with a circle methodology involving needs and solutions refinement |
| Choice of support hardware suitable for any type of users | The mobile version is a suitable choice but, in some situation, users may want to access their data with their personal computer | Both mobile application and desktop version may be developed to encompass all scenarios |
| **Clinical risks** | | |
| False information | Tests ill processed or processed by a non-specialist | The validation of allergies functionalities in the application will be right granted and available only for allergists.  
A criteria of trust capital index will be involved for the evaluation and filtration of bad validators |

These specifications have been formalized and signed by both parties. All the previous elements were used by pikcio to build the UML (Unified Modeling Language) analysis document which describes the technical specifications of the solution. This document was explained, discussed and improved during a meeting with allergists.

Here is the general class diagram of the application in its first version drawn in UML.
Let’s us take the specific example of patient identification process involved in the solution. The following figures represent successively the sequence diagram of the identification process and the screenshots of interactive mockups done with Balsamiq mockup 3.

Figure 3. Class diagram
This sequence diagram describes the identification process that begins with the form that the user completes, then he loads his vouchers and from the hash done by the system of all these elements, the duplicate check is performed. If the hash already exists in the chain, the user will have to reconsider his existing account by resetting his code. If the duplicate does not exist, a more detailed risk analysis is performed on the vouchers to verify compliance with the information given by the user. In the best case, the user's account is created. Graphically we have materialized this process by interactive mockups some of whose screenshots are below.
6. Theoretical and practical Implications

The framework of this research project being posited by the evidence-based practice, we enrich it with the action design research as a working methodology. In doing so, we will create evidence of concrete implementation of blockchain in healthcare by highlighting details on aspects such as needs and solution refinement in the intervention stage, as well as a full evaluation even technical, functional, ergonomic and clinical. Moreover, by highlighting the collaboration between interdisciplinary actors, we enrich the literature on digital innovation, the co-construction and the orchestration of various skills in a project. In the literature, a special emphasis is placed on the role of boundary objects to facilitate understanding between actors of different skills in a project, we complement this approach with a co-construction process by seeing this beyond the improvement of communication, as a way to better understand the needs by enriching each stage of the project specifications with the skills of each other. In addition, this co-construction approach will also enrich the theory of organized anarchy, which highlights the gradual construction of solutions to meet needs that become clearer over time.

We also enrich the literature on social innovation in that beyond the technological and functional aspect generally evoked in information system, our solution will answer a social problem related to the high mortality and morbidity rate around the lack of information on patients allergies. Moreover, the social aspect comes from the fact that we have integrated users throughout the process in the idea that they know better their need and could help to build a better adapted tool in an iterative step.

Beyond the enrichment of theories, this project through the evaluation phase, will enrich the literature on the acceptability and usability of blockchain solutions by patients and healthcare professionals.

In practical terms, we propose the modelling and evaluation of the blockchain solution (pikciochain) for the case of allergology, thus producing proofs of concepts and interesting axes of deployment of a solution that seems still lacking in France. But more importantly, the solution we are building will be a social innovation in addition to being a digital innovation in that it will concretely reduce the negative effects related to the unavailability or inaccessibility of reliable information on patient allergies. In doing so, we are opening up possibilities of adaptations of this solution for other cases of interesting use in healthcare.
Références


