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Transposing responsible technological innovation to the healthcare field: a case study in the digitization of healthcare data within public institutions.

Transposer l'innovation technologique responsable au domaine de la santé : une étude de cas sur la numérisation des données de santé au sein des institutions publiques

Abstract: The development of strategies for implementing digitization processes in the healthcare sector is confronted with paradoxes caused by the innovative and futuristic aspect of the projects, and by unexpected and unforeseen consequences resulting from the interaction between the technical and the social factors. These challenges require actors in the e-health ecosystem to anticipate, react and adapt during and after the deployment of innovative digital services.

Our research aims to study the integration of the responsible dimensions during governance in an open innovation collaboration context. Building on an inductive case study of an E-health data transformation in France, we outline conditions and fundamental design principles for a visionary

Résumé : Le développement des stratégies pour la mise en œuvre de processus de numérisation dans le secteur des soins de santé est confronté à des paradoxes causés par l'aspect innovant et futuriste des projets, et par des conséquences inattendues et imprévues résultant de l'interaction entre les facteurs techniques et sociaux. Ces défis exigent des acteurs de l'écosystème de l'e-santé qu'ils anticipent, réagissent et s'adaptent pendant et après le déploiement de services numériques innovants.

Notre recherche vise à étudier l'intégration des dimensions responsables lors de la gouvernance dans un contexte de collaboration d'innovation ouverte. En s'appuyant sur une étude de cas inductive liée à la création et la mise en place d’une base des données de santé en France, nous décrivons des conditions et des and responsible management to create and implement social license for the development of institutional mechanisms in the case of innovation projects.

Key words: responsibility, digital healthcare, social license, governance of innovative projects, collaborative innovation principles.

principes de conception fondamentaux pour un management visionnaire et responsable afin de créer et de mettre en œuvre une licence sociale pour le développement de mécanismes institutionnels dans le cas de projets d'innovation.

Mots clés : responsabilité, santé digitale, licence sociale, gouvernance des projets innovants, principes de l'innovation collaborative.

1. INTRODUCTION

Access to affordable, high-quality medicines and healthcare services is essential to achieving Sustainable Development Goal 3 by 2030[1]. William C. Olsen and Carolyn Sargent (2022), in their study of ethnographies around the world, demonstrated the inadequate quality of services rendered to patients and delays in procedures due to shortages of doctors, supplies and funding.

In France, the healthcare ecosystem is facing complex and multiple challenges: increase in chronic diseases, aging of the population, medical under-densification, social isolation, increase in social and territorial inequalities in health, renunciation of care, increase in the cost of certain treatments, expectation of personalized approaches to care (Grenier et al., 2019).

In parallel with these challenges, the emergence of new technologies is disrupting economic sectors, affecting the entire value chain of the industries concerned. This is particularly true in the healthcare sector, where digital technology is at the heart of the revolution. It is also the driving force behind a strong ambition to invent an effective response to the sector's challenges and accelerate the shift towards so-called "5P" medicine: Personalized, Preventive, Predictive, Participative and Proof-based.

As part of France 2030, the French government is launching a "Digital Health" acceleration strategy to encourage the emergence of innovative digital health solutions, prepare for the future and make France a world leader in e-health[2]. This transformation of digital healthcare, supported by innovative multidisciplinary scientific approaches and proposals for ambitious medico-

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[1] https://www.un.org/sustainabledevelopment/health/

[2] https://www.entreprises.gouv.fr/fr/strategies-d-acceleration/strategie-d-acceleration-sante-numerique

economic models, must be carried out responsibly, securely and ethically, for the benefit of the general population and patients.

A major e-health ecosystem mobilizing mixed public-private organizations has emerged in France. This raises the question of **how to develop responsible innovation collaboration for the e-health data transformation in France.** What are the conditions and principles to be mobilized to implement the social license in digital healthcare projects?

To this end, in the remainder of this manuscript, we first present our theoretical framework (2) including the characteristics of technological innovations in the healthcare field (2.1), the social license as the aims of Big data projects (2.2), the criteria for a responsible innovation (2.3), and innovative governance by the Five Design principles to measure the project's values (2.4). Our case study relating to the construction of a digital health data warehouse in the French context will illustrate the integration process of innovation responsibility dimensions during the digitization governance (3). We will present the methodology (3.1), our findings from the case (3.2) and the conclusion of our paper (4).

2. THEORETICAL FRAMEWORK

2.1 Technological innovations in healthcare

Considered a vector of progress (Godin, 2015), innovation is not always desirable in the healthcare sector (Boukamel & Emery, 2019), which is protected by ethical rules (Jordan, 2014). Although the transparency implicit in telehealth processes offers interesting business models and promotes more efficient care scenarios, e-health alone cannot lead to complex and sustainable healthcare models.

Technological innovations, including those involving digital technology, are promoting more accurate predictive medicine and therefore a more resilient care pathway (Balagué, 2021)[3]. Nevertheless, an algorithm is not accepted if it is not explained and explicable for healthcare professionals. Moreover, the automation of data processing increases discrimination between patients, between geographical areas and therefore inequality of access to care, not to mention the lack of protection for sensitive individual data. Thus, with innovation, the past and present are no reasonable guide to the future (Adam & Groves, 2011), so such retrospective accounts of accountability are inherently limited. We face a dilemma of control (Collingridge, 1980) in that we have no evidence to govern technologies before they are implemented, dependence (David, 2001), technological lock-in (Arthur, 1989), "entrenchment" (Collingridge, 1980) and closure (Stirling, 2007). Balagué (2021)[4] recommends that innovation in the healthcare sector must be responsible, i.e. it must anticipate potential negative effects and take into account the societal and environmental impacts of technologies.

This raises the question of the definition and criteria of social license and then responsible innovation.

2.2 Social license

The notion of social licensing is one of the avenues advanced internationally to provide an ethical and socially just basis for data integration, creating pathways through which diverse publics can participate in conversations about the use of government-regulated data (Braunack-Mayer et al., 2021; National Data Guardian & Hopkins van Mil, 2021; Waind, 2020; Gulliver et al., 2018; McKelvey, 2014). Social license recognizes that datafication has social implications that go

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[3] Innovation in healthcare: responsibility takes center stage - I'MTech (imt.fr)

[4] Balagué Christine is co-holder of the *Good in Tech* Chair: *https://www.goodintech.org/?lng=en*

beyond the individual, have a differentiated impact on diverse audiences and require broad public support to progress ethically and sustainably. It is also based on the principle that civic participation in government and society should be fostered by the political environment (Warne et al., 2021).

Social licensing has been conceptualized in different ways. On one side of the spectrum, a minimal vision presents social licensing as involving a communications strategy, coupled with targeted stakeholder or community engagement and consultation with selected experts to generate information about public attitudes and, in some cases, to build relationships with selected audiences and expert groups, as well as determine the limits of acceptability of various data practices. These activities may be aimed at enhancing transparency or avoiding scandal or negative public reaction.

At the other end of the spectrum, social licensing is understood as a deliberative process of dialogue and community engagement that generates an iterative identification of socially valued futures and uses of technology and aims to elicit mutual respect and social inclusion, rather than community adherence to shared principles or values (Rooney et al., 2014). Such an approach to social license aspires to high levels of public participation, even public control of policy-making, processes informed by open engagement that allows positions to evolve over time of communication and relationship-building (Warne et al., 2021).

For Smith et al. (2023), social licensing should be approached as an institutional mechanism involving a process of open discussion and public participation and government accountability to its publics, rather than as a communications strategy to gain acceptance of data practices. Such an institutional channel would provide information to governments, data custodians and data analysts on data governance and the design of data-driven projects. Creating a social license with institutional roots means that audiences can influence data integration at a systems level, rather than an ad hoc or project level. Communication strategies, awareness-raising and trust-building are all important. But in the absence of accountability channels, efforts to develop social license could easily be reduced to a branding exercise designed to convince the public of an already established agenda, rather than an ongoing process to create avenues for civic participation and public control of datafication and its social effects (Warne et al., 2021). To achieve this, key government agencies need to put in place a visible and accessible mechanism for ongoing community consultation and feedback, periodically.

Smith et al. (2023) propose that in healthcare Big data projects, a "*social license*" with institutional roots is essential to deepen accountability to audiences and help ensure that datafication can be co-produced by and with citizens and reflect the sociotechnical futures envisioned by a wider range of actors. Practitioners have operationalized the notion of social license through an orientation of data integration towards democratic and socially responsible trajectories - sociotechnical futures to which many data integration experts aspire (Smith et al. 2023). For public healthcare projects, this means public healthcare organizations trust their citizens, users and stakeholders in the collaboration.

This leads to another question: how to develop and implement this mechanism, or in broader terms, a social license? Responsible innovation may be a good response to this question.

2.3 Responsible innovation

According to Von Schomberg (2011), responsible research and innovation is "*a transparent, interactive process by which societal actors and innovators become mutually responsive to each other with a view to the (ethical) acceptability, sustainability and societal desirability of the* *innovation process and its marketable products (in order to allow a proper embedding of scientific and technological advances in our society)*".

Stilgoe et al. (2013) define innovation responsibility as "*taking care of the future through collective stewardship of science and innovation in the present.*"

We can cite "second-order" responsibilities (Illies & Meijers, 2009) or "meta-tasks" (van den Hoven, 1998; van den Hoven et al., 2012) to ensure that responsible choices can be made in the future, by anticipating and acquiring knowledge about possible consequences and building the capacity to respond to them.

While actors are not individually irresponsible, it is the often complex and coupled systems of science and innovation that are the most irresponsible, what Ulrich Beck (2000) calls "organized irresponsibility". Von Schomberg (2013) proposes four categories of irresponsible innovation that manifest themselves mainly: technological push, neglect of ethical principles, importance of politics, and lack of precaution and foresight.

Innovation governance focuses on the different modes or institutional rules of coordination between individuals, organization, societal subsystems and states, ranging from hierarchical leadership to networks, communities, associations and forms of coordination organized by formal and informal rules (Benz et al., 2007; Treib, Bähr and Falkner, 2007 cited in Konrad and Böhle, 2019). Collaborative innovation implies collaboration across domains of expertise, and also collaborative practices that are needed. The open innovation extended to external parties may incur challenges in "messy" coordination, knowledge creation, or operational function due to the ambiguous organizational boundaries and heterogeneous and evolving actor preferences (Jelinek et al., 2008; Gassmann, Enkel, and Chesbrough, 2010; Rindova & Kotha, 2001).

There is a need to have more in-depth research in the process perspective about the organization of collaborative innovation (Ollila & Ystrom, 2016) or in methodological and empirical opportunities[5] of studying open innovation collaboration in the digital age (Enkel et al. 2020).

New forms of innovation governance have adopted a forward-looking view of responsibility, integrating the social and political choices that stabilize certain innovations (Pinch & Bijker, 1984; Williams & Edge, 1996; Winner, 1986).

The transition of socio-technical systems requires a holistic approach to managing multi-level, multi-stakeholder complexity (Pereno & Eriksson, 2020). The Five Design principles (Ollila & Ystrom, 2016) may offer a conceptual tool for collaborative innovation and value measurement.

2.4. Five Design principles for value measurement

According to Ollila & Ystrom (2016), in a design perspective, the organization is considered as a continuous change with ever-improving design through a dynamic process. Consequently, its outcomes are impermanent, while the boundary line is blur between the inside and outside organization. These authors proposed Five Design principles as follows:

(1) Presence of participants equals influence, which means the actors "felt a need to be present and take part in practice". They need to "see it happening in order to believe in it". The actions and the connection of actions are crucial for success.

(2) Diversity fosters creativity. It encourages a diverse range of partners and different competences to work together to create new alternatives.

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[5] "How to analyze open innovation collaboration in terms of their boundaries, leverage, scope, structure, and dynamics?"

(3) Multiple identities create an extended action net. Each participant is often attached with minimum two affiliations, thus possessing a mixed culture, supporting the collaboration.
(4) Higher purpose unites the participants and attracts complementary actors as each organization has such limited resources that it has to work with other partners to have enough resources to achieve a higher mission.
(5) Participants are the creators of collaborations who conceptualize and construct symbols / processes to navigate and make sense of how to organize a collaborative innovation and manage the joint responsibility. The collaboration is shaped by interaction and continuously re-designed by participants.

These Five Design principles give a foundation on how to organize open innovation collaboration in a fast-changing technological environment. They demonstrate a few of qualitative values such as embracing messiness, fostering creative solutions (1st and 2nd principle), promoting multiple identities (3rd), recognizing the needs of others (4th), being responsible for the collaboration evolution (5th).

In the case of healthcare, public organizations must consider social capital and collective intelligence as a common asset to be developed but not as a resource to be exploited and controlled. Open data provides real opportunities to appreciate horizontality: it becomes possible for data to be reused to make available to all users a surplus of knowledge, produced by the subjects of the network. The practice of transparency associated with the freeing up of data towards a given population makes it possible to observe and build a social model. The strategy based on open innovation can optimize the association of participants to create value for citizens, users and all other relevant stakeholders, therefore can combat resistance to horizontal practices, based on cultural barriers both within organizations and in the contexts in which they are (Curcio Rubertini et al. 2017).

Our objective is to study the integration of the dimensions of innovation responsibility and the governance of a digitization study project in the French healthcare sector. During this process, many quantitative and qualitative indicators are used to measure and pilot the performance of innovation collaboration by considering the social license.

3. CASE STUDY: HEALTH DATA WAREHOUSE CONSTRUCTION PROCESS

3.1 Methodology

3.1.1 Research design

To explore the research question, we are conducting a qualitative case study of an open innovation arena, digital health warehouse, from May 2023. This approach corresponds to our desire to deeply understand the institutional context and explanatory factors via actions and practices, views and expectations, and the organizational structure of partners during their collaboration. A qualitative methodology seemed appropriate as the context of the innovation process is complex, as a result of multiple and heterogeneous actors, fragmented processes and difficult anticipation of project evolution. An inductive approach allows us to confront the understanding of pre-existing theory with empirical data (Eisenhardt, 1989; Stake, 2005) and to evaluate the internal validity of results.

3.1.2 Data collection

The case study includes multiple sources to improve the validity of the finding (Eisenhardt, 1989). We consider official publications about the project, conduct semi-structured interviews with all stakeholders and follow the shadowing of the technical director, a member of the Project's consortium during the research. Up to the time of writing the paper, seven interviews were conducted with project technical participants following an interview guide, between May 2023 and January 2024. The interviews were conducted by the two authors, either online, in groups or individually. They were noted down or recorded and lasted a total of around 10 hours. Interviews guide and details are presented in appendices No.1 and No.2. In parallel, several exchanges have taken place with the Technical and Innovation Director since the beginning of the project.

3.1.3 Data analysis

The data analysis follows an inductive approach and aims at identifying responsible anticipation practices, innovation project governance, collaboration principles between partners and indicators of performance measurement. These concepts are progressively outlined from data following a grounded theory approach (Strauss & Corbin, 2008).

The qualitative analysis process focuses on the information as expressed by respondents (Gioia & Chittipeddi, 1991) in cross-referencing data on the project and the project context. We follow the three-step coding: (1) open coding to identify the key words, in crossing with secondary data (Strauss & Corbin 1998); (2) axial coding to classify the categories identified in the first step; and (3) selective coding to compare our results with other research and propose variations specific to our field. In each step, the content of interviews is analyzed separately by each author, then crosschecked by both of us before debriefing sessions with the technical director to clarify certain occurrences or explain some actions.

3.1.4 Case description

X[6] is a research project for development of a platform for data in health care including data from the last twenty years from two million French patients who have consulted general medicines in medical centers all over French territory. Many stakeholders from healthcare sectors (academic, hospital, industry), government authorities and digital start-ups participate in this inter - organizational collaboration to produce innovative knowledge jointly. Table 1 outlines the details of the case.

Table 1: Description of project X

Initiation	2018
Main activity	E-health data system
Purpose	Creation of the first innovative digital healthcare data warehouse at national level. These unique primary care data on reason, diagnosis, care actions and examination results collected from longitudinal and massive sources (data from the last twenty years of more than two million patients throughout France) will complete synergistic added value with other data. Indeed, many objectives are expected from Big Data Analytics "descriptive" and Augmented Analytics "exploratory" data processing solutions: (1) decision support through the restitution of dynamic information tailored to the user, (2) connectivity and availability as data is updated in real time and is easily accessible to the people concerned, (3) medical data security by complying with the RGPD[7] (General Data Protection Regulation) through data anonymization and application of the precautions of

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[6] The name of the case is anonymized to preserve the identity of the partner organizations and the respondents.

[7] https://www.cnil.fr/fr/reglement-europeen-protection-donnees

	the personal data security guide of the Commission Nationale de l'Informatique et des Libertés (CNIL) and the EDS reference standards[8] (Entrepôt de Données de Santé); (4) medical diagnosis aided by Artificial Intelligence (AI), which can propose disease probabilities thanks to auto *machine learning* of historical and observational data (history, biometry, motives, symptoms) and (5) creation of a medical search engine by proposing automatic seizure choices thanks to *Natural Language Processing* (NPL) analyses; in this case, the extraction of medical rules from texts) and the creation of a medical knowledge base (Health Data platform) by cross-referencing medical record data with standardized medical ontologies. The benefits will be felt by the various stakeholders in the healthcare sector: public administrations, local authorities, healthcare organizations, biomedical laboratories, healthcare software publishers, patients, doctors, teaching and research actors. The aim of these initiatives is to create an Intelligent Medical Record (IMR), thereby strengthening the digital solution and forecasting the influx of patients into healthcare organizations (ex: epidemic surveillance, diagnostic and decision support for doctors, and patient research for clinical testing of new pharmaceutical products and treatments, etc.). It will be an open database.
Organizational status	A consortium of six members, in which five from the public sector (university, university hospital center (CHU), a public interest organization, an organization representing teaching doctors, Department of Medical Informatics and Information), and one from the private sector (a start-up in Data analysis). Each actor has an equal stake in the project.
Funding	Public via French public sector investment bank (Public Bank), as part of the France 2030 future investment program. The public-sector members receive 100% of the funding, while the private-sector member receives 45%.
	This is a three-year project (2022-2025) initiated from two regional projects (2018-

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[8] https://www.cnil.fr/fr/entrepots-de-donnees-de-sante-la-cnil-publie-une-check-list-de-conformite-son-referentiel

Characterization of work	2021). The roadmap is grouped into seven packages according to a predefined timetable when responding to the call for projects in 2022. ● Package 1: Steering, coordination governance ● Package 2: Ethical governance and data efficiency, following CNIL compliance ● Package 3: Construction and technical deployment of the Health Data Warehouse at national level ● Package 4: Deployment in the field by Doctors ● Package 5: Input of medical data into the Health Data Hub ● Package 6: Case studies, definition of clinical research and epidemic surveillance tools ● Package 7: Dissemination and exploitation Each partner is responsible for one or more work packages, depending on its capacity, with the participation of other partners. The objectives are set in three waves, depending on the number of participating doctors, data quality assistants and referring doctors recruited. At each stage, public communications are carried out by the consortium.
Number of organizations involved	Six in the consortium, many external organizations; such as : software Publishers, la Caisse Nationale d'Assurance Maladie (CNAM), patients, Système National des Données de Santé (SNDS), l'Agence du Numérique en Santé, Délégation ministérielle au Numérique en Santé (DNS).
Organizational set-up	Three organizational levels are determined: - **Decisional and operational level:** by an operation committee (COPIL) composing operational contacts for each consortium member. The lead partner is a start-up in the new technology sector. - **Strategic level:** by a Strategic Committee (CS), made up of a lead from each consortium member, permanent guests and exceptional guests.

	- **Advisory and scientific level:** by external experts invited to the COPIL or CS, selected by the consortium. To receive the Public bank funding, each package must be validated by all members at all levels.
Management structure and decision making	Without a legal status, agreements are drawn up between the consortium members to determine the responsibilities and scope of each member's involvement. Committees meetings are held at regular intervals. Each consortium member (“leader”) selects its participants in Committees. All decisions are voted on by the consortium members. Sometimes at meetings, decisions are not taken by the participants. The leaders discuss off-line the next day to reach a decision. Every consortium member has an interest in seeing the project progress in order to obtain the release of funds. Decisions are obtained by negotiation, and sometimes imposed by technical constraints. When the deadline approaches, members tend to reduce their objectives in order to complete the deliverable.

From content analysis of our interviews and secondary data, in the finding section below, we reveal the complexity of an innovative project, the conditions which serve as a basis for implementing the social license and the Five Designs Principles application in the case.

3.2 Findings

3.2.1 Issues and challenges of an open collaboration context

Project X involves data of more than two million patients with general doctors working in many medical centers. The consortium reunites six key stakeholders collaborating to work and make decisions together. This organization is confronting a dynamic and messy environment, contributing to their tense relations.

The on-going changes in technology, regulations and customers' demands create confusion and frustrations to stakeholders.

> *"There are ongoing changes in regulations and technology. We are facing a Big Data technological challenge and strict security requirements for storage. For example, the location and use of data are only for intended purposes and must follow CNIL standards"* (DS4).
>
> *"The customer's demands change regularly. For instance, three doctors are constantly challenging us"* (DS2). *"The customer doesn't have a specific request, because he wants to challenge us, and then explore hypotheses with us, but we have to provide solutions"* (DS4).
>
> *"Different expectations and constraints from partners, resistance linked to different cultures and language. We have experienced many schedule delays due to unforeseen governance issues (who decides what, what is authorized by law)"* (DS1). "N*ine months to a year should have been expected to prepare the legal file before launching the warehouse"* (DS3).

Moreover, the heterogeneous data and limited data availability also increases the complexity.

> *"We often have no authorization to access data (due to skepticism of doctors and software publishers) because their data is not open data source"* (DS4). "*There are data gaps, unvalidated intermediate hypotheses"* (DS2), *"and heterogeneous, non-standardized data (because of different software and different uses), especially text fields: scalability"* (DS4).

In particular, the conflicts among members in the consortium often come from the discrepancy in terms of benefits and their alignments at individual and organizational levels.

> *"In general, the leaders in the consortium are pretty cool, but their subordinates are less cooperative. The latter are afraid of losing their power, their safety and thus their jobs, in particular, doctors in the medical information technology department. Moreover, most participants coming from the public sector have experienced a perceived 'unfair treatment" from other service private companies. For example, these companies charge unreasonable service fees for any software solution subscriptions"* (DS1).

As a result, the arbitrage in the consortium is very challenging and the project delay is inevitable.

3.2.2 Social environment supports and norms as conditions of social license

From our analyses, two conditions have emerged concerning social environment support for ecosystems and norms to obtain the social license and to implement the collaborative practices.

Social environment supports

In digital health, France has lagged behind, as a result of a lack of investment in digital infrastructure, the complexity of systems created in silos, a lack of acceptance and confidence in digital technology by both the general public and professionals, and a lack of training in healthcare issues for healthcare professionals and engineers. To catch up, a historic €2 billion plan has been released as part of the digital component of the Ségur healthcare plan launched in 2021, to enable healthcare data to be shared smoothly and securely between healthcare professionals and patients[9].

The 2023-2027 digital healthcare roadmap, spearheaded by the Délégation ministérielle au Numérique en Santé (DNS), under the impetus of the government, in conjunction with its partners (la Caisse Nationale de l'Assurance Maladie - CNAM, l'Agence du Numérique en Santé, etc.) and all the players in the ecosystem (user and citizen representatives, healthcare professionals and structures, and companies in the sector), aims to *"Put digital at the service of healthcare"*, and is made up of four main areas (prevention, care, access to healthcare and a supportive environment), 18 priorities and 65 objectives[10] .

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[9] Stratégie d'accélération « Santé numérique » | entreprises.gouv.fr

[10] https://esante.gouv.fr/sites/default/files/media_entity/documents/dns-feuille-de-route-2023-2027.pdf

Given the fragmented nature of data between city and hospital, there is a growing desire to structure healthcare databases at national level. In Europe, there have been a number of initiatives to collect and use primary care data on a national scale, such as the CPRD projects[11] (Clinical Practice Research Datalink) in Great Britain, or SGPN (The Dutch Sentinel General Practice Network) then LINH (The Netherlands Information Network of General Practice) (Schweikardt et al., 2016) in the Netherlands, or Cegedim's THIN (The Health Improvement Network) database[12]. In France, there were only some local projects. As a consequence,

> *"The ineffective Covid management demonstrates the urgent need for healthcare systems to be changed. A high-profile personnel in government who was persuaded about our potential value contribution had to send a personal endorsement about us to other stakeholders. In another word, they agreed to sponsor us. Finally, we are approved to join this project as a leading member.* (DS1)

This context offers an opportunity to develop the ecosystem of project X including stakeholders and their relations as presented below (figure 1).

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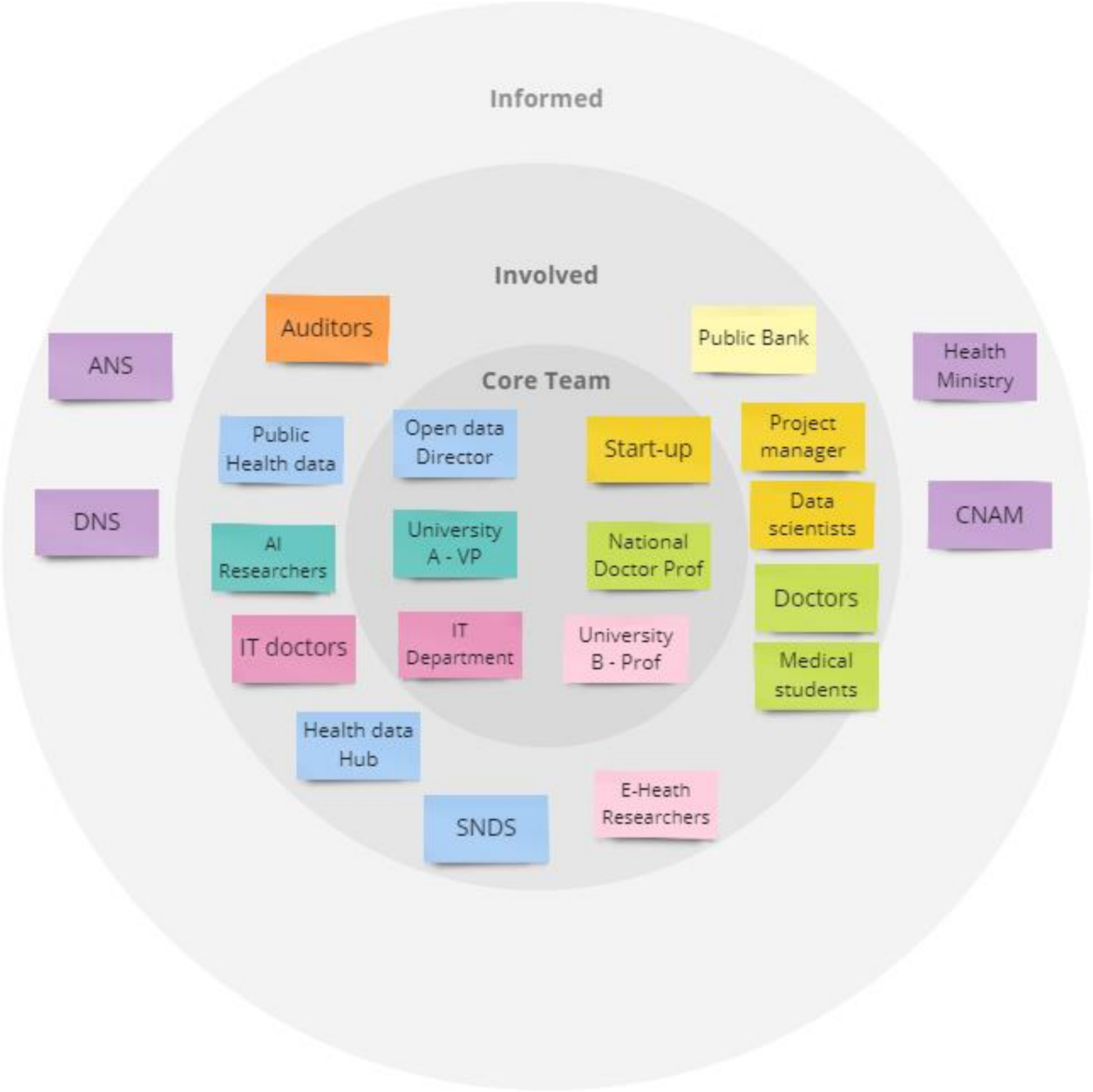
[11] https://cprd.com/

[12] THIN: The Health Improvement Network - Cegedim Health Data (cegedim-health-data.com)

Figure 1: Ecosystem of project X



This ecosystem has to follow norms to obtain the social license.

Norms

One of the rules associated with medical diagnosis is to keep the human being at the heart of the medical act, leaving the decision to the practitioner, in order to avoid the "industrialization" of healthcare.

The challenges of health data are numerous: the non-security of sensitive health data, the risks of adopting unsuitable treatments or operations due to the limitations of the algorithm, the worsening of inequalities in access to care by adding a digital divide to the social divide, or the depersonalization of the relationship between patient and doctor linked to the misuse of technology.

The data is massive, coming from a variety of sources and structures. It must respect the confidentiality of patients and doctors (the principle of parsimony), but it must also allow to re-identify the individual if specific treatment is required. The algorithm must be open sourced. The data warehouse compliance criteria include security, governance, communication, sovereignty, scalability, interoperability, availability, traceability, integrity and global architecture. Considering the purposes and uses of the data, the starting point is a scientific question that needs to be developed in the light of the data available.

Synthetic data will get popular, so the ethical standards governing the use of health data are strict, and all project partners must respond to CNIL standards, RGPD precautions and EDS references during the mobilizing and protecting data processes. Concretely,

> *"Several practices are necessary, eg. obtaining ISO standards, early sourcing of service providers (e.g. data hosting provider), monthly meetings with CNIL, regulatory updates, regular contacts with experts and medical IT departments (DIM)"* (DS3).

3.2.3 Application of Five Design Principles

In response to the research question "how to develop responsible innovation collaboration for the e-Health Data transformation in France?", the findings are presented on the basis of the Five

Design Principles framework. It provides an illustration of complexity, uncertainty and ambiguity of objectives, as well as governance dynamics during the evolution of collaboration. As analyzed above, the arbitrage in the consortium is very challenging and the project delay is inevitable.

Presence of participants equals influence

Given the scope of the projects, the involvement of stakeholders is extensive. The consortium has six core members who are also the leaders of their own organizations. They also represent their own interests and those of the consortium. Their roles were also defined at the beginning, and continually adjusted during the innovation collaboration.

> *"At the beginning, each leader wanted to introduce their products into the projects because of their self - interest. The partners will define the detailed project scope, but have to rely on the initial framework approved by the Health Ministry"* (DS1).

There are three Committees to ensure the innovation collaboration:

- **Operation Committee:** weekly meeting and focus on operational issues. This meeting is led by each leader with their team members. For example, the start-up CEO meets with his project manager and data scientists on a weekly basis, while the medical organization meets its participating doctors and medical students.
- **Strategy Committee:** every 3 - 6 months to identify the next steps of the project. Health Data Hub (HDH), a public interest grouping, sponsors the logistics and organization, while the start-up hires an independent project manager to coordinate the different stakeholders and meetings. Each member has an equal vote.
- **Scientific and Ethics Committee:** once per year. The participants involve the external national organizations to evaluate whether the Strategy Committee follows all related

regulations and ethics rules. The evaluation has gone through four steps. Each step is required to be approved by three evaluators.

- Step 1 relates to business model,
- Step 2 relates to technology model,
- Step 3 relates to innovation characteristics (in particular, newness and authenticity),
- Step 4 relates to public interests.

Every six months, the investment national bank (Public Bank) would release its public funding for project X if the team satisfies all Public Bank's audit requirements. This is a crucial factor to accelerate the project advancement and the alignment of stakeholders' interests. Among six stakeholders, five organizations, being public, receive 100% funding from the government, whereas only one stakeholder, the start-up, being a private company, receives 45% from Public Bank.

> "*Each leader is committed to make the project advance as per the requirements of Public Bank so that Public Bank can release the funding on time. Otherwise, everyone would suffer for this delay. Given the long and complicated administrative processes in public institutions, five stakeholders face more challenges to satisfy their financial commitments than the start-up. Consequently, all members are obliged to find a compromise to work together. Whenever we have a conflict, the leaders will meet offline and then find a common ground. After that the leader will give instructions to his/her team members. One of the big advantages of public organization is their respect for hierarchy. The subordinates will follow their leaders"* (DS1).

Such a presence together with the prompt actions of each stakeholder is important to ensure the innovation collaboration success.

Diversity is the source of creativity

In order to develop responsible innovation collaboration for the e-Health Data transformation, Project X extends the diversity to the next level: from diverse stakeholders (especially in different backgrounds and competences) to diverse governance processes.

Firstly, for such a project having sensitive information about healthcare and humans, the active involvement of a private actor since the beginning has been rare, especially in French administrative culture. However, the start-up has succeeded in convincing other public institutions to open the door and proved its value creation.

> *"To be accepted in such a national project, we had to prove ourselves in smaller but similar regional projects. We bring in a new perspective for our public partners. Being private, we have a better sense about the viability of a business model and its feasibility. That's why they often wait for our green light before the final decision. Moreover, our process is more flexible, thus we can make cash advances for emergencies to avoid any project delay. We also hired a project manager to lead this complicated collaboration process. We play the role of innovation facilitator to the whole project"* (DS1).

In another word, the participation of diverse stakeholders, both public and private, is considered as a key success factor for this innovation collaboration thanks to their different but complementary perspectives and approaches although the healthcare system in France is often dominated by public stakeholders. The private actor processes better business sense and flexibility, while the public ones, by having direct connection to the government and public health system, know the latter's expectation and have their support. Such complementarity is crucial for the successful innovation collaboration.

Each stakeholder brings their own competences for the team, and is ready to work together. They understand and appreciate the difference. This difference may either cause conflict, thus delay in project advancement, or facilitate it faster.

> *"We are working together and learning about our differences every day. We are complementary, but not competitive to each other"* (DS1).

Secondly, a number of governance methods have been employed to ensure cross-check control. Three Committees - Operation, Strategy, and Scientific - together with Public Bank to ensure the project advancement in the right direction. Each partner has one equal vote. Depending on the importance of the decision, they need the majority approval level of leaders.

> *"For some decisions, we need 50% approval votes. For others, more than two thirds are required"* (DS1).

In conclusion, the diverse governance method and diverse background and competences facilitate innovation collaboration processes.

Multiple identities of participants create an extended action net

Each leader has at least three affiliations: one in the Operation Committee, another in the Strategy Committee, and also their own official organizations. Meanwhile, the subordinates are attached to at least two affiliations: one in the Operation Committee and another in their institutions.

As a result, they have multiple identities and different perspectives: being both leaders and executors, being both pioneers and gatekeepers, being both businessman/woman and benefactors. These identities help them to be better involved in the innovation collaboration processes in an effective way.

The participants are creators of the collaboration

The project employs disruptive innovation with fragmented heterogenous data, thus its scope and organization have been continuously redesigned and evolved to keep up with the technology advancement and requirements from customers and regulations. However, the project framework has been designed and approved a long time before its official launch in order to obtain public funding. The public bank and its auditors need to have a basis to measure the advancement of the project, thus the funding release. This creates a dilemma between the rigid framework and ever changing nature of the project. The participants play critical roles to manage this dilemma and facilitate the collaboration.

> *"Everyone wants to have everything. How can we fulfill all doctors' needs?"* (DS4).
>
> *"Each partner has different expectations and constraints. They are also resistant due to different cultures and languages. To be able to move forward, each partner has to "compress" their demand to fit with the initial approved framework so that they can meet the deadline imposed by the public bank. However, they still push their creativity to satisfy the newness and authenticity required by the Scientific Committee. The collective penalty - no funding release - is an effective extrinsic motivator to ensure the business velocity and agile methodology* (DS1).

Nevertheless, all partners are also motivated by an intrinsic motivator. They are the real owners of this innovative tool and they can upgrade it and extend its value to specialists or private sectors.

> *"All leaders in the consortium pay particular attention to the opinion of "start-up" about whether the business model is profitable, viable or not. In the current project scope of work, we can provide an innovative solution to doctors and the government. But we also aim to provide upgrading services to them such as social label licensing, data mining results, database connection, and so on. The net margin will be equally shared to six stakeholders"* (DS1).

Despite their differences, the participants in the project share joint responsibility, apply agile methodology to ensure business velocity. Given the constraints in the public sector, the participants have to own both extrinsic and intrinsic motivations to engage in the continuous re-design of the projects and thus collaborative innovation.

A higher purpose unites the participants

The ambition to embark on open data in healthcare in democratizing data for the public good and maximizing the use value of data has attracted partners. Thinking about social capital, they are aware that to facilitate the achievement of universal perspectives, the practice of 'open innovation' is increasingly proving to be a real canvas for modeling public service offerings that meet citizens' expectations and are economically sustainable for the community.

The platform enables data available internally, to deploy data experiences in all formats according to the needs of stakeholders, to create data services and to publish open data portals.

For the Government, the database facilitates access to locally collected and structured data which constitutes tools for epidemiological surveillance and healthcare research and governances (eg. fraud detection, standardization of health softwares, logistic preparation in hospitals).

For healthcare professionals, health data pooling provides modeling tools for doctors and researchers in primary care practices, research and teaching (eg. solutions based on intelligent medical records, google medical, identifying patients with particular characteristics for clinical studies, research into the effects of drugs).

> *"Everyone needs to find their DNA (core business) in participating in the project, and we can't do such a big project on our own, because the value of health data results from a chain of multiple contributions from clinical, technical and operational expertise that increase its value in use"* (DS1).

For the start-up,

> *"It's an opportunity to collaborate with the health authorities, to gain a public image and to have a project with a longer life cycle (10 years instead of 3 to 5 years in technology). State funding and support allow the company to enter in a challenging field with fewer competitors because of the very high barrier to entry"* (DS1).

4. CONCLUSION

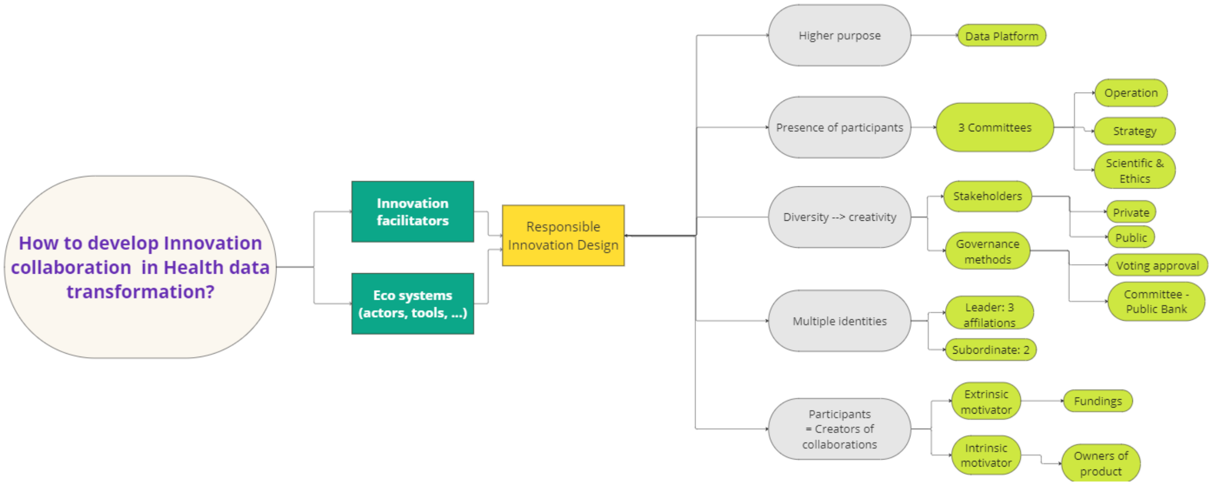
The French healthcare sector is facing the challenge of finding a consensus on how to build a sustainable future for care. Digital health offers solutions to strengthen the healthcare system by transforming and expanding service delivery. The e-health sector, which aims to ensure the responsiveness and productivity of services, has become a national strategic priority and is mobilizing all actors. This social support offers opportunities to develop open innovation collaboration, which must be responsible to take into account the possible opportunistic behaviors of organizations and communities, while remaining creative.

From a literature review on the responsibility or irresponsibility dimensions of innovation, the practices of anticipating unforeseen scenarios and principles of innovation collaboration governance, we propose a theoretical framework to achieve the social license of responsible innovation in the e-health field.

This model is tested through the case of the implementation of the project to create a digital health data warehouse to arrive at the Intelligent Digital File at a later date. We study in an exploratory way collective strategies in the construction of responsible futures. Qualitative approach by shadowing and interviews with stakeholders involved in digital projects have allowed us to identify the technical and ethical issues at stake in these projects, as well as the functioning and malfunctioning of anticipatory practices in the governance process. Our results confirm the Five Design principles proposed by Ollila & Ystrom (2016) used by key stakeholders to measure and pilot the open innovation collaboration.

The boundaries between healthcare and digital professionals are becoming increasingly blurred. For policy makers, we recommend that digital health training for doctors is essential to increase their acceptance and confidence in digital technology. Moreover, to create and implement the social license for the development of e-health data systems, it also needs social environment support and strict ethical and technical norms (figure 2 below).

Figure 2: Framework proposal to develop innovation collaboration governance in Health data transformation



To continue this exploration stage, further interviews are planned with other stakeholders to test this model.

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Appendix 1: Interview guide: Practices for governing an innovative project in the digital health sector

1- Presentation of the research project by the researcher(s).

2- Presentation of interviewee: background, position in company/organization

3- Presentation of the project(s):

    a. Origin, context (including socio-political).

    b. Factors (scientific, political and market), objectives.

    c. Governance (executive and control at three levels: macro = public policy; micro = research team/laboratory, private company, university, university hospital, regional and national authorities, hospitals, healthcare industries, patients, communities, professional and ethical bodies, meso = institutional practices and structures).

    d. Stakeholders (who, what roles/commitments, influence of each stakeholder, interaction between them).

    e. Dimensions to consider.

    f. Expected results (including budget and schedule).

    g. Your role.

4- Project development:

    a- Stages: who and how to establish each lot

    b- Coordination, communication and dialogue.

    c- Problem management, methodology => the way processes are set up and managed (the legitimacy of inputs).

    d- Anticipating the management of unforeseen / unexplored impacts.

5- Results obtained:

    a- Measurement indicators.

    b- Challenges, constraints.

6- Using the results:

    a- The users

    b- Their level of acceptance, the value they bring

    c- Impacts

d- The unexpected => the legitimacy of results / the effectiveness of governance.

7- Conclusion: other topics to discuss.

Appendix 2: Summary of interviews with participants of Project X

N°	Code	Profile	Date	Duration	Comment
1	DS1	Director of Innovation and Technology, Doctor of Computer Science	28/5/2023	80'	Several exchanges since
2	DS 2	Doctorate in mathematics, specialist in biotech	5/6/2023	120'	Group meeting
3	DS 3	Engineer, project manager			
4	DS 2	Doctorate in mathematics, specialist in biotech	23/10/2023	70'	
5	DS 3	Engineer, project manager	23/10/2023	80'	
6	DS 4	Engineer, responsible for data collection and LAB (for R&D of complex projects).	25/10/2023	90'	
7	DS1	Director of Innovation and Technology, Doctor of Computer Science	11/1/2024	135’	
	Total			**575’**	