

Success Factors of Open-Source Foundations in Healthcare Industry

MASTER THESIS

Akshat Shrivastava

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Friedrich-Alexander-Universität Erlangen-Nürnberg
Faculty of Engineering, Department Computer Science
Professorship for Open Source Software

Supervisor:

Prof. Dr. Dirk Riehle, M.B.A.
PD Dr. med. habil. Florian Putz (Medical Supervisor)
Elçin Yenişen Yavuz, MSc



Friedrich-Alexander-Universität
Faculty of Engineering

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Abstract

This extensive research study thoroughly analyzes organizations' involvement in the context of open-source foundations in the healthcare industry. The study employs a multi-case case study approach, focusing on the OpenEHR Foundation and the Racoon Project as the study samples. The motivation factors driving organizations' engagement in this domain are diverse and multifaceted. These factors encircle the necessity for standardized data models, the pursuit of vendor neutrality, the promotion of interoperability, the development of infrastructure, and the expansion of scope. However, organizations operating within the open-source environment also encounter various challenges. These challenges include organizational disputes, transitions in leadership, the establishment of trust with new partners, managing diverse expert opinions, and adapting to evolving data privacy and security regulations. Effectively addressing these challenges necessitates implementing various strategies, including transparent communication, democratic decision-making processes, information sharing, mentorship initiatives, structured discussions, and a vigilant approach to regulatory changes. Moreover, the study sheds light on significant success factors that contribute to the overall success of organizations in an open-source environment. These success factors include striking a delicate balance between open-source and commercial interests, establishing flexible governance structures, aligning with market demands, employing proficient project management techniques, maintaining precise documentation practices, and adopting an outcome-centric success evaluation framework. Overall, this comprehensive research study provides valuable insights that can serve as a foundational platform for organizations seeking to navigate the intricacies of the open-source environment.

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Acronyms

OS Open-Source

OSS Open-Source Software

OSPI Open Source Portfolio Initiative

ICT Information and Communication Technologies

FLOSS Free Libre Opens-Source Software

EHR Electronic Health Record

RQ Research Question

ARPANET Advanced Research Projects Agency Network

RIS Radiology Information System

EIS Enterprise Imaging System

CHIME Centre for Health Informatics

UCL University College London

CIC Community Interest Company

AI Artificial Intelligence

COVID Coronavirus Disease

CT Computed Tomography

KPI Key Performance Indicator

VISTA Veterans Health Information Systems and Technology Architecture

1 Introduction

The development of open-source software (OSS) exemplifies a cooperative process in which individuals cooperate to produce better software with openness as a key element. In this model, any member can freely access the source code of any given project for viewing or even distribution after they have modified it as necessary. This has produced several active communities where developers pool their time, skills, and knowledge to contribute.

Open-source has captured attention from a wide variety of people in many contexts, as discussed in Von et al., 2003. The number of developers who work on different projects in today's world is in the thousands, whereas the number of users using the software developed by open-source software development projects is in the millions. One of the best examples of widely used open source-software is the GNU/Linux operating system. OSS attracts a large user base because of its robustness.

The journey of open-source projects started with developer communities followed by the participation of companies and the establishment of open-source foundations. These foundations play a role, in providing support, structure and legal frameworks to foster and sustain open-source projects and communities. To gain an understanding of open-source foundations, Yenisen Yavuz et al., 2022 introduced a classification and hierarchy system. Various types of open-source foundations exist including community-led, vendor-led and user-led as illustrated in Figure 1.1. Community-led open-source (OS) foundations involve volunteer developers who contribute to the maintenance and growth of open-source initiatives. In user-led open-source (OS) foundations, user organizations define the functionalities of the software and manage the development process, with shared goals and needs. To accomplish these goals, they pool their resources and expertise. On the other hand, in vendor-led open-source (OS) foundations vendors define the functionalities and manage the development process. This thesis focuses on the open-source foundations which are led by organizations (user-led and vendor-led OS foundations) and work in the healthcare domain. As discussed in Shaikh et al., 2012 open-source has fostered an 'innovation culture', which further leads to a structure of innovation in the form of a process change. According to the case

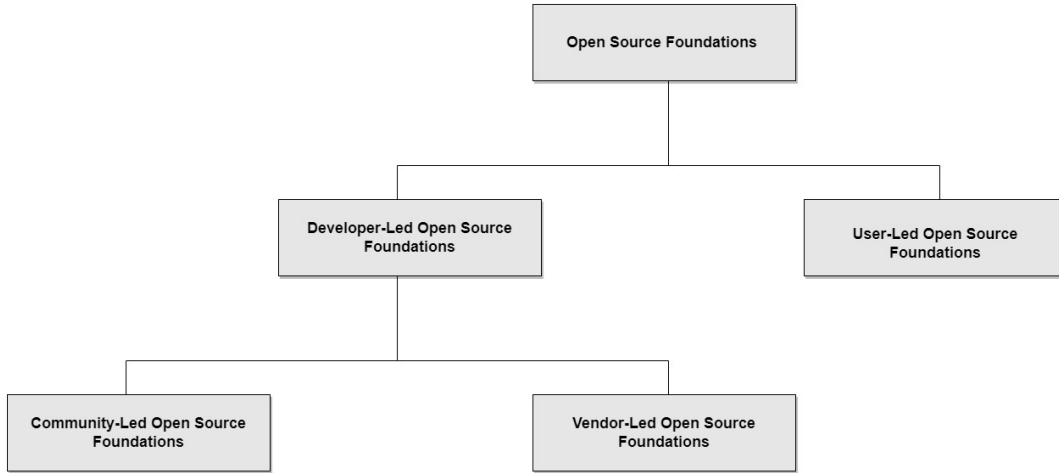


Figure 1.1: Types of Open-Source Foundations [Yav⁺22]

studies, there is a certain amount of sharing and process change that suggests an evolution in practice. The study suggests that this is due to an increase in the utilization of open-source software and internal ideas.

User-Led Open-Source Foundations

User-led consortia refers to a group of organizations or users who have common goals and needs, in order to achieve these objectives users share their resources and knowledge. These users determine the project's course and make decisions to achieve its goals. User-led open-source foundations show promise, as an approach for organizations to work together on various projects. These foundations enable companies and institutions that utilize the platform developed by the foundation to collaborate than solely relying on software development companies [Sch⁺20]. In user-led open-source foundations, besides end-users there are also software vendors which work on the software development process as described by Yenisen Yavuz et al., 2022 [Yav⁺22]. Wheeler [Whe04] noticed the instances of user-led foundations, in the field of education. These foundations were often referred to as "community source." He introduced initiatives such as the Open-Source Portfolio Initiative (OSPI), the Sakai Project, and the uPortal Project which generated interest in education. Liu et al. 2007 in their study on the Kuali case using the service-centric community approach reached a conclusion. They examined aspects of service-centric open-source development by analyzing Kuali as an example. The main focus of their research was to understand how technology adaptability relates to emerging technologies. Additionally their paper made a contribution by introducing the concept of community source within the context of large scale projects emphasizing its connection, with open-source

principles [Liu⁺07].

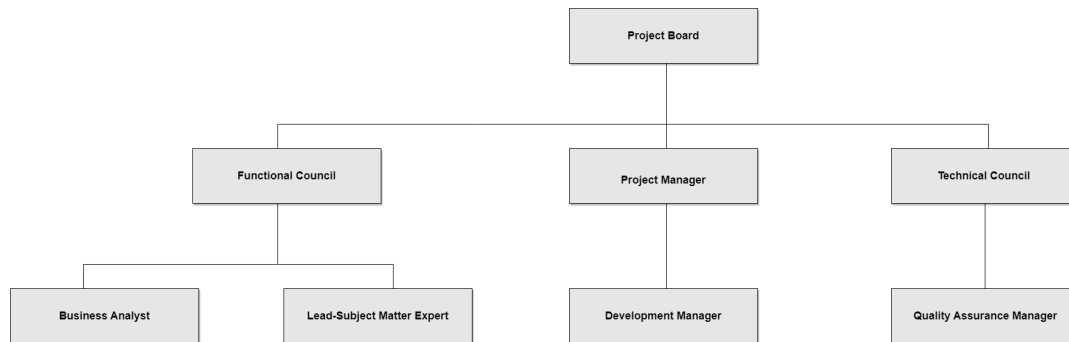


Figure 1.2: Organisational Hierarchy of Kualifoundation [Liu⁺07]

Figure 1.2 depicts the organizational hierarchy of the kualifoundation, which includes dignitaries such as the Functional Council, Project Manager and Technical Council [Liu⁺07]. However, a number of challenges were addressed in the Kualifoundation studies. Liu et al., (2014) [Liu⁺14] highlights problems with access to talent for development, coordination issues with regulations for various institutions, price evaluation mechanisms, and it also mentions the difficulties in striking a balance between innovation and control. The challenges mentioned above reflect the issues that can occur when coordinating various institutions and attempting to address multiple goals simultaneously.

Vendor-Led Open-Source Foundations

As we saw in the case of user-led open-source consortia, the development of the project is led by the user organizations. On the other hand, in the case of vendor-led open-source consortia, the development of the project is led by the vendors. Vendors strive to capitalize on this open-source model in terms of resource and software allocation. This model can be further categorised into two distinct sub-categories: Schaarschmidt et al., 2011 explains the core difference between single vendor and multi vendor open-source projects. If a single company is involved in the software development process, it is referred to as a single vendor open-source project. On the other hand, multi vendor open-source projects involve multiple companies collaborating and working together to develop a software. In 2011, Schaarschmidt et al. [Sch⁺11] conducted a study that examined the contrasting governance approaches between single-vendor open-source and multi-vendor open-source models. To analyze this, they selected the Eclipse Foundation as a case study due to its model and the availability of diverse governance mechanisms. The research sheds insights on crucial aspects across various projects, such as paid contributors, unpaid volunteers, and leadership. Additionally, it acknow-

ledges limitations, like the challenge of defining project scope and replicating findings, in foundation projects.

Open-Source Foundation in Healthcare

Karopka et al., 2014 share insights regarding the open-source foundations in the healthcare system. The paper aims to analyze the current trends and the contributions of Free Libre Opens Source Software (FLOSS) in healthcare. Many developed countries currently face issues as there is a surge in age-related diseases. Information and communication technologies (ICTs) have always been essential in radically transforming various IT domains, such as the telecommunications industry. However, the healthcare industry has faced difficulty utilizing ICT tools and infrastructure to keep up with contemporary trends. The paper concludes by proposing that the use of FLOSS has been relatively low in Europe, which could be due to the fact that healthcare is highly fragmented, making it difficult to get a clear picture of it. The paper also suggests that different stakeholders, including governmental organizations, decision-makers, regulators, healthcare IT suppliers, and NGOs, should establish an open ecosystem to cultivate innovation and address the current issues in the healthcare industry.

The existing literature on open-source foundations in the healthcare domain is limited. To address this gap, this thesis aims to investigate the factors contributing to the success of open-source foundations in healthcare. A multi-case case study with two samples was conducted to achieve this objective. The prime focus of this study is to explore aspects of an open-source foundation within the healthcare sector, including motivation factors for organizations to participate in a open-source foundations, the challenges they encounter, and the strategies they employ to overcome those challenges. Additionally, we aimed to identify the elements that contribute to a foundations' success. To better understand and analyze the problem statements outlined in this study, we selected OpenEHR and Racoon as sample cases. OpenEHR is an organization that provides technical specifications for an Electronic Health Record (EHR) platform, as well as domain-specific clinical models for defining content. The fundamental architectural principles revolve around maintaining a patient-focused shared health record using future-oriented data approaches and facilitating clinical process management. On the other hand, Racoon is a recently established platform focusing on sharing patient image data pertaining to COVID-19 and other cardiac diseases. Open-source foundations are crucial in advancing the development of streamlined healthcare information systems. They play a role in shaping a procurement strategy that maximizes resource utilization, prioritizes patient safety, and improves healthcare services quality [Rey⁺11]. The following questions served as the basis for our research:

RQ1. What are the organizations motivations to engage in open-source foundations?

RQ2. What problems are encountered in the open-source foundations (solved and/or still going on)?

RQ3. What solutions are applied to solve these problems?

RQ4. What are the success factors or key best practices for open-source foundations?

1. Introduction

2 Related Work

History of Open-Source Foundation

As mentioned in Von et al., 2003 open-source software has a history that traces back to the development of computer programming techniques and the emergence of the "hacker culture." In the days of ARPANET, the computer network provided opportunities for hackers to access and exchange software code repositories. However, challenges arose in the 1980s when MIT started licensing its hacker employees code to companies. Expert programmer Richard Stallman strongly opposed this practice. Consequently, Stallman founded the Free Software Foundation in 1985 with the aim of granting access to software created by hackers. Stallman's vision was to leverage copyright law to issue licenses that ensured rights for all users. The creation of the Generic Public License, also known as copyleft, enabled users of software to enjoy rights and have unrestricted access to study its source code without any cost. Today, open-source software extensively utilizes this type of license. Despite facing resistance, the concept of software has evolved over time, and now "open-source" is a widely used term in business circles when referring to platforms that offer free software.

Schaarschmidt et al. 2011 [Sch⁺11] investigate governance approach in open-source software (OSS) projects. Authors assess different types of projects which includes single vendor and multi vendor projects. The study also differentiates community-based and firm-based initiated projects. Eclipse foundation was investigated in this case study, and 83 project samples were selected and multiple factors such as the number of commits, voluntary, paid contributors, and project leadership were examined for this purpose. The study shows many notable findings, and six out of eight major hypotheses were justified. In comparison with single vendor projects, multi vendor projects have higher percentage of paid committers and acquire more commits. Firm-initiated projects have a higher percentage of paid committers, on the other hand community-initiated projects engage more commits by volunteers. The paper illustrates the significance of various attributes likes paid contributors, volunteers and leadership in various projects. The paper address certain constraints like incapacity to determine the project size and standardize the findings in other foundation projects.

Shaikh et al., 2009 [Sha⁺09] examine the possible association between corporate management and open-source (OS) communities and the schemes employed to manage risks and control costs. It assesses the limitations and issues dealt by the companies in lining up their objectives, governance structures, and software practices with the OS communities. The findings highlight the development in the process as companies steer around their grasp of working with the open-source communities, resulting in a culture of development and process change. Corporate companies look for multiple factors when choosing a community to work with, such as viable technology, compatible license and a healthy community. The study also suggests that healthy community in the course of time having collaboration with multiple companies is vital for the organizations to grow. Usually, contractual agreements are absent in open-source relationships, as corporations are inspired by factors like: problem-solving, control, customization, and learning. The paper concludes by highlighting the fact that firms and companies benefit by making an alliance with open-source communities through creative ideas and innovations. On the other hand, communities benefit from the alliance in terms of sustainability and contributions.

Zhang et al., 2020 [Zha⁺20] present qualitative findings revealing the motivation behind company's integration with open-source software ecosystems while taking OpenStack as the sample for their case study. In order to investigate the company's collaboration structure and to analyze the patterns, this study implements network analysis and clustering techniques. The results present various engagement strategies and resemblances in the strategies amongst various companies across the open source platform. The author develops a relation between company's collaboration and the productivity factor, which indicates the advantages of active collaboration. The study uses number of commits as a factor to determine company contributions, which is a challenging measure, the author suggests looking for other factors to measure the contribution and productivity. In conclusion, this investigation establishes baseline results in understanding the methods of company's collaboration in the open-source system, catering the results that can aid other organizations in developing their own techniques and strategies.

De et al., 2012 [dAba⁺12] discusses the use of software for managing Electronic Health Records (EHR). In developing nations, this software presents opportunities for advancing healthcare through the utilization of open-source platforms. The author focuses on three free software programs, OpenMRS, OpenVistA and OpenEMR. A comprehensive comparison is made regarding their advancements and effective implementation. These programs are compatible with operating systems such as Linux, Ubuntu, and Windows. Their performance is subsequently evaluated across web browsers. The paper recommends employing modular, configurable, versatile, and secure EHR-integrated systems. According to the study findings, OpenMRS emerges as the option that fulfills all EHR management requirements. Despite being newer compared to OpenEMR and VistA, OpenMRS

has demonstrated promising outcomes in EHR management.

The study conducted by West et al., 2005 [Wes⁺05] provides insights into the significant obstacles encountered when establishing spinout open-source projects within the VistA healthcare information system. This research emphasizes the notable distinctions between community-driven and sponsored open-source initiatives. The study also highlights the challenges in cultivating a community once the code has been developed. The spinout open-source projects also encounter issues such as leadership transition, trust establishment, managing diverse opinions, governance, and adapting to regulatory changes.

Gichoya et al., 2018 [Gic⁺18] highlight the use of open-source development in radiology which can be leveraged to create a channel for innovation, by soliciting feedback from community members and providing tools and a platform for testing standards. Open-source systems have been widely embraced in the healthcare industry within middle-income countries. This can be used as a motivating factor to bridge the field of radiology. OpenMRS and LibreHealth are the two communities that have achieved some success in the development of open-source Radiology Information System (RIS). RIS is intended to accomplish the fundamental radiology processes, and can then be further tested for novel radiology protocols. The objective of this paper is to encourage participation and enthusiasm in order to progress the evolution of LibreHealth to an Enterprise Imaging System (EIS) that can also be used in other imaging fields.

2. Related Work

3 Methodology

This chapter presents the methodology of my thesis. The research approach is derived from the study conducted by Eisenhardt (1989) [Eis89]. We performed multi-case case study research. The primary reason for choosing a case study approach is that it enables the researcher to maintain the comprehensive nature of real-life occurrences while examining empirical events as explained by Schell et al., 1992. In order to refine our findings, we utilized a variety of sources, including meeting minutes, the consortia’s website, publicly available information from videos and blogs, and interviews with various stakeholders. Our study consisted of a single multi-case study with two samples, thus constituting a multi-case case study research. Our first sample for this research is OpenEHR which is an open, collaborative project that aims to standardize and organize Electronic Health Record (EHR) data to enable interoperability, exchange, and manage healthcare information. The project was initiated in 2003 in response to the difficulties associated with the development of standardized health data models and the realization that a more flexible and clinically relevant approach was needed as opposed to the traditional, top-down standardization approach. Our second sample is Racoon Consortium, which is an open-source project that aims to build a national system for the systematic accumulation of radiological information from COVID-19 pandemic cases. This information will be instrumental in the development of future services such as epidemiological early warning systems and artificial intelligence-based medical support.

3.1 Research Questions

The main objective of this thesis is to learn about success factors. Each organization has its own set of criteria that determine the success factors. Thus, to develop a general framework about success factors of open-source foundations in the healthcare domain, we researched the reasons for their involvement in the open-source foundations, problems they encountered, solutions they applied and best practices they followed. The research questions (RQs) serve as the foundation for our research, and are as follows:

RQ1 : What are the organizations motivations to engage in open-source foundations?

Open-source foundations bring together a variety of organizations. It is crucial to comprehend the factors that drive organizations to participate in open-source projects within the healthcare sector. This understanding enables us to gain insights into the objectives and expectations of organizations actively involved in open-source initiatives.

RQ2 : What are the problems encountered in open-source foundations in the health care domain?

When organizations engage in open-source communities they encounter various challenges. The reasons behind these challenges can differ significantly. Understanding these difficulties is essential, in order to overcome them and provide assistance to organizations venturing into the open-source world. In this research we investigate both solved and ongoing problems.

RQ3 : What solutions are applied to solve encountered problems in open-source foundations in the health care domain?

Once organizations recognize the difficulties they encounter, the crucial factor lies in understanding how these organizations employ methods, techniques, and plans to overcome these challenges. These discoveries will not just benefit organizations engaged in OSS communities but also establish a universal framework for tackling similar problems in the future. Moreover, it will serve as a learning opportunity for all community members involved.

RQ4 : What are the key best practices for open-source foundations in the healthcare domain?

The last question explores key best practices that organizations adopt within open-source foundations. These valuable best practices can guide organizations and assist them in achieving success in the future.

3.2 Sample Selection

The first step was to speculate various factors that should be taken into account in the selection of our samples. We aimed to include samples from both user-led and vendor-led open-source foundations in the healthcare domain in our research. Furthermore, we considered both established samples, as well as recently established samples, to ensure that we provided a comprehensive sample selection. We selected OpenEHR and Racoon as our samples. The main factors behind choosing OpenEHR and Racoon are as follows: OpenEHR is an established foundation driven by both user and vendor organizations with a membership from different countries. Conversely, Racoon is a new user-led OS foundation, with members from a single country. Our objective is to explore aspects of problems, solutions

and factors contributing to success.

3.3 Data Collection

To gather the data, we used a variety of sources. The workflow we followed for data acquisition is depicted in Figure 3.1. Initially, we collected information from our sample website, including details about the foundation’s history, membership structure, industry partners, organizational partners, and foundation’s vision. Next, we utilized the consortium website discussion forum to reach out to foundation members and establish connections with them. This resulted in contacts from stakeholders. The crucial stage involved conducting interviews, where we asked questions outlined in the interview protocol to gain a comprehensive understanding of the subject matter. Interview protocol is presented in Appendix B. One beneficial technique employed during these interviews was snowballing, which was discussed by Wohlin in 2014 [Woh14]. Snowballing refers to analyzing literature by examining references and using that information to enhance our study. Similarly, we applied this technique to acquire information from stakeholders and expand our case study while also establishing connections. The interview process was conducted using online Zoom calls in which interviewees were asked to confirm their availability prior. Interviews typically lasted between one and two hours and were conducted in English. The interview period ran from July 21st 2023 to September 26th, 2023, with a total of seven interviews conducted from both samples. Four interviews were conducted with OpenEHR members, and three interviews were conducted with Racoon Project members. Once the interviews were completed, we transcribed the interviews and sent them to the interviewees for confirmation.

3. Methodology

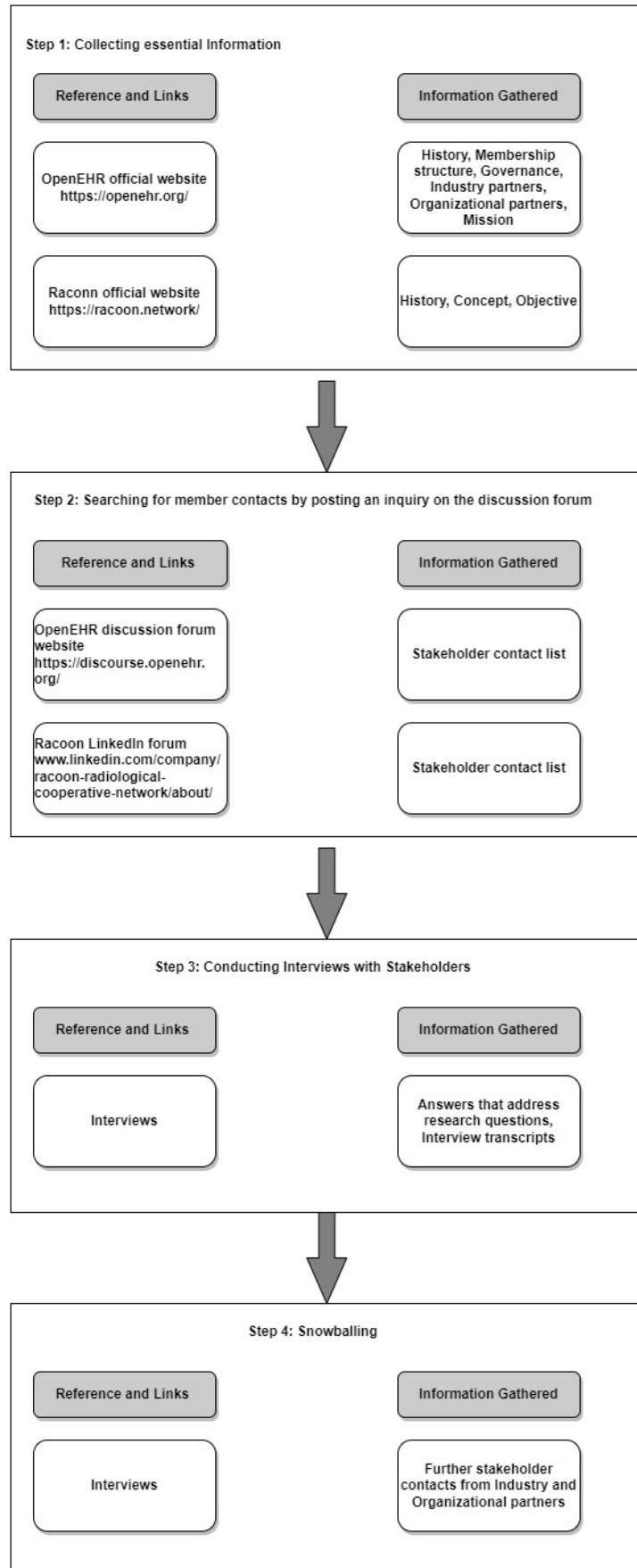


Figure 3.1: Acquisition of Information: Data Collection Workflow

3.4 Qualitative Data Analysis

In order to protect the Interviewee’s anonymity, each interviewee has been assigned a unique identification number.

Serial No.	Organization Name	Designation / Source	Identification Number
1	OpenEHR	Former Co-chair	I1
2	OpenEHR	Chief Executive Officer	I2
3	OpenEHR	Vice President Partner Management	I3
4	OpenEHR	Director, Catalan Health Service	I4
5	OpenEHR	Official website: https://openehr.org/	M1
6	Racoon	Radiologist, University Hospital of Tübingen	J1
7	Racoon	Assistant Doctor, University Hospital Erlangen	J2
8	Racoon	Senior Radiologist, University Hospital Erlangen	J3

Figure 3.2: Identifier Table

We used thematic analysis to perform the qualitative data analysis. This data analysis methodology is well-suited for data collection and analysis, as demonstrated by Javadi et al., 2016 [Jav⁺16]. Initially, the data was collected in the form of an audio file, which is later transcribed. As shown in the Figure 3.3, familiarization with the data is the first step of thematic analysis, which includes a comprehensive reading of the entirety of the interview transcript, including the correction of spelling errors. This is by far the most time-consuming stage. In the second stage, the 'Codes' are created. A code is a collection of text that is assigned a label to recognize and summarize the text. The portion of the conversation to which the same label applies is color-coded using the same color. Therefore, different colors indicate different labels. The next step is to search for a theme. It is important to be aware of the codes associated with this step. Sub-sets of similar codes are gradually grouped together to form a larger set. Additionally, a brief explanation for each theme can be provided for further use. After providing names and explanations for the themes, it is necessary to organize them in a logical manner and group different sub-sets within the same set to form a larger category. This is an iterative process, which allows themes to be rewritten and new subsets to be grouped to the primary set.

3. Methodology

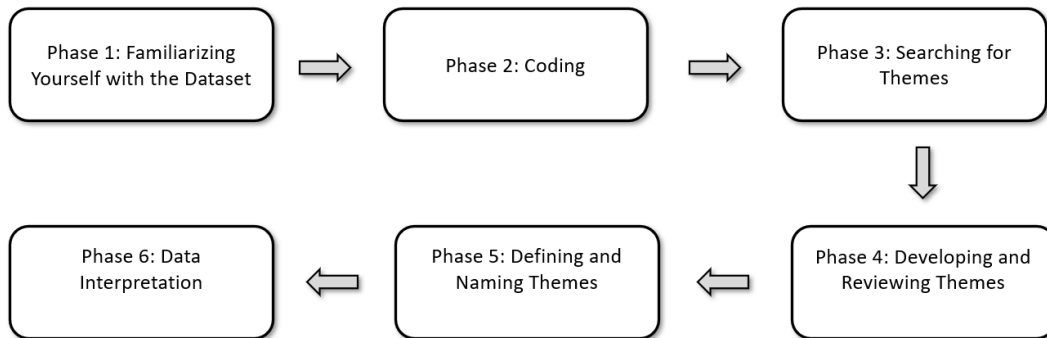


Figure 3.3: Thematic Analysis Workflow

3.5 Tool

We performed qualitative data analysis by using MAXQDA. We imported the audio file of the recorded session from the interviews to MAXQDA for transcription purposes. As shown in Figure 3.4, we can import the audio file in MAXQDA. After the file is imported we can then do the transcription process. The most prominent feature of the tool is enabling the user to click on a specific portion of the conversation to play, which will then be displayed in the accompanying audio file (as indicated on the top), while simultaneously highlighting the portion of the conversation in the text.

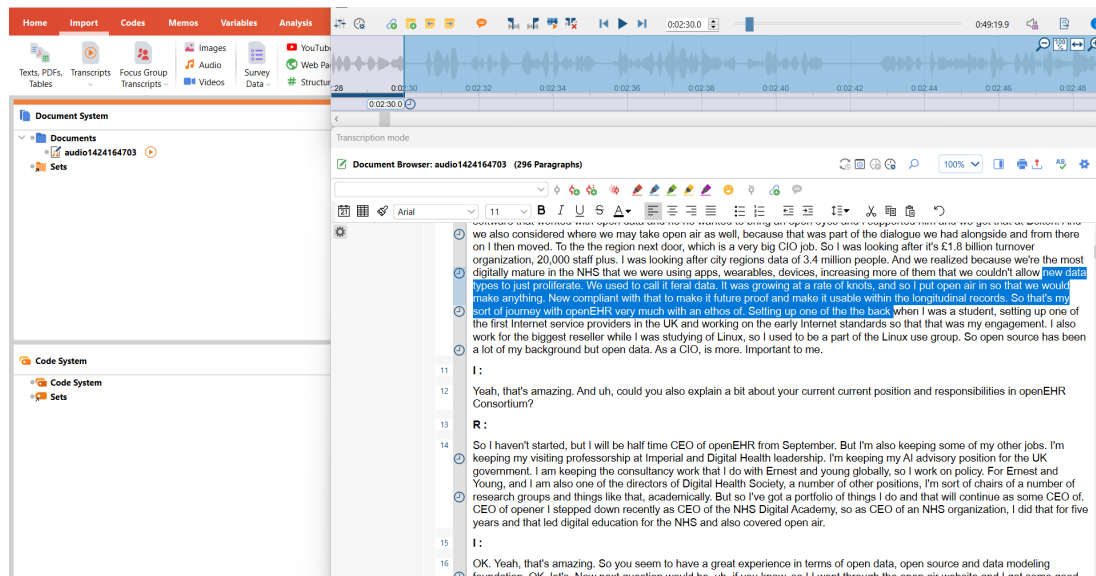


Figure 3.4: Data Transcription using MAXQDA

3.6 Background and History of OpenEHR

After exploring the details provided on OpenEHR’s official website (M1), we gathered insights into their background membership structure, member organizations and governance system. OpenEHR, founded in 2003, is an open-source organization dedicated to advancing healthcare through open-source technology. It plays a crucial role in overseeing the creation of open specifications, clinical models, and software tools that set standards and facilitate the development of interoperable solutions in the healthcare industry. OpenEHR’s primary vision is to cultivate patient-centric Electronic Health Records (EHRs). With a mission to create an open and vendor-neutral platform, OpenEHR strives to enable the management of electronic health records and computable clinical and research data (M1).

The membership structure comprises four entities; organizational partners, industry partners, professional members, and individual members. Organizational partners represent national or academic institutions. Some examples of organizational partners are: Apperta Foundation and Catalan Health Service. Industry partners encompass corporations that follow regulations to ensure a fair decision making process without any entity dominating it. Industry partners play a role in maintaining the governance of OpenEHR. Some examples of Industry partners are: EY Health and CISTEC AG. Professional members are individuals who offer consultancy and training services for OpenEHR. Individual membership include members who wants to participate in the governance structure. The organizational structure of OpenEHR consists of two primary entities: OpenEHR International (CIC) and the OpenEHR Foundation. OpenEHR International (CIC) is responsible for all business-related matters within OpenEHR. The CIC (Community Interest Company) Board oversees everything and comprises directors. The OpenEHR Foundation selects two directors for this board, and an additional six directors are elected every two years by subscribing members from various groups (Individual, Industry, or Organizational). The CIC Board appoints a Chair or multiple Co-Chairs to provide leadership. Currently, there are three Co-Chairs in place. The second entity, the OpenEHR Foundation, consists of three founding members from the original Foundation and three directors from the CIC. The Foundation Board plays a crucial role in safeguarding OpenEHR’s intellectual property. Together, these entities ensure the effective functioning and protection of OpenEHR (M1).

OpenEHR implements two mechanisms to govern its operations—one dedicated to technical specifications and the other focused on clinical aspects. Regarding technical specifications, OpenEHR follows established industry practices and utilizes JIRA for change management. For clinical aspects, OpenEHR acknowledges the limitations of resources and adopts a flexible approach through open-source

3. Methodology

methodologies. This encourages collaboration among healthcare providers and clinicians to align their efforts based on requirements—highlighting the importance of processes for achieving success.

As depicted in Figure 3.1 the development of OpenEHR can be divided into three phases. The initial phase, from 1992-2003, focused on research conducted by the CHIME Health informatics group at the University of College London (UCL). Subsequently, in 2003, the OpenEHR Foundation was established as a non-profit organization. The second phase, between 2003 and 2014 involved refining the structure and establishing governance systems. During this time, international recognition was gained alongside the development of models. As a result of the adoption of OpenEHR in 2013, plans for community self-regulation emerged. The third phase commenced in 2014, implementing various membership structures. Financial support was also secured through the establishment of the UK Community Interest Company (CIC). This transition is considered as the defining moment in the evolution of the foundation.

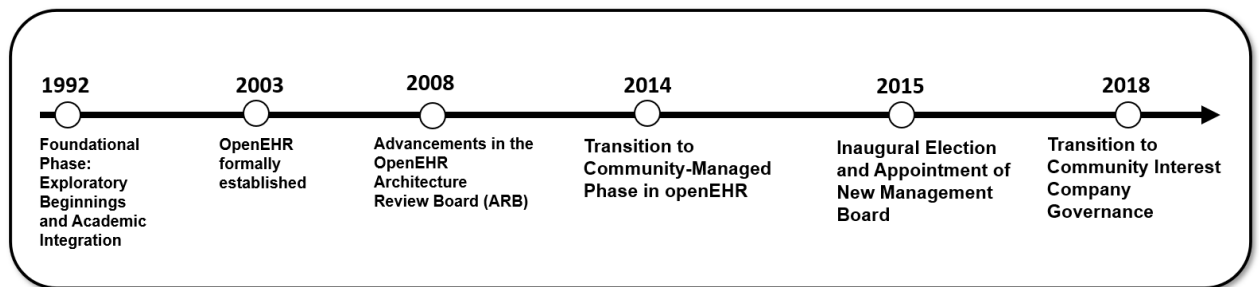


Figure 3.5: Key milestones in the evolution of OpenEHR

3.7 Background and History of Racoon

As shown in Figure 3.2, Racoon project was initiated at the start of the COVID-19 pandemic in 2020 to create a nationwide platform for systematically collecting COVID-19 radiological data. The collaborative work of 38 radiological departments of German Universities and medical imaging organizations creates the foundation. Flexibility and inclusivity characterize the membership structure of Racoon. A steering committee is in place to make all the significant decisions. Steering committee consists of the individuals who work in the member university hospitals. This committee effectively manages the organization’s governance, as it possesses the authority to oversee the decision-making process, including project direction and membership onboarding (J1). The founding of Racoon was motivated by the fact that radiological data was essential for diagnosing and evaluating disease progression. In cases of severe lung disease, radiological findings offer comprehensive information on the progression of the disease. In cases of severe lung

disease, radiological findings offer comprehensive information on the progression of the disease (J1, J2). Radiology plays an essential role in crisis management as it can detect, evaluate, measure, monitor, and identify risk factors associated with lung infections, thus playing a critical role in healthcare decision-making and monitoring. The Racoon (RECO) project aims to harness the power of artificial intelligence (AI) and image analysis to improve understanding of COVID-19 and improve diagnosis and treatment decisions. Racoon-COMBINE aims to develop a pipeline for extracting COVID-19 related imaging biomarkers to gain a comprehensive understanding of the disease and patient condition (J1, J3).

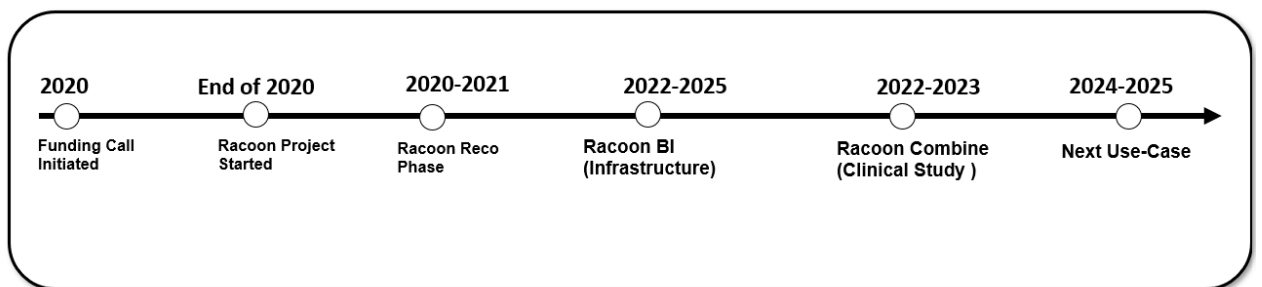


Figure 3.6: Key milestones in the evolution of Racoon

3. Methodology

4 Results

This section addresses our research questions, we present our findings which focus on three key areas: motivation, problems and their solutions, and success factors in open-source foundation in healthcare domain.

4.1 What are the organizations motivations to engage in open-source foundations?

Based on qualitative analysis we applied to interviews, we identified five motivations that lead organizations to engage in open-source software development in the healthcare domain. These motivations are need for standardized data models and continuous innovation, vendor neutrality, semantic interoperability, infrastructure development, network establishment, and improving research collaboration.

Need for Standardized Data Models and Continuous Innovation

The variation in medical data structure caused by an unstandardized data model is one of the challenges faced by the healthcare industry. As a result, the data logging procedure may become inconsistent, negatively impacting the standard of care given to patients. Organizations are aware of the potential harm that inconsistent data can cause, and open-source foundations like OpenEHR have emerged as a community to address this problem. Standardized data models has increased the number of organizations engaging in this community as they recognize the value of being part of the open-source community. As healthcare technology evolves and advances rapidly, the conventional data model can become obsolete. Consequently, it is essential to develop a framework that can be relied upon to adjust to the advancement in practices (I1 and I2).

Vendor Neutrality

Vendor neutrality is a principle in the open-source environment emphasizing the importance of impartiality and transparency in decision-making. It ensures competition among vendors and prevents any biases towards specific vendors. This

approach promotes flexibility, discourages vendor lock-in, and encourages vendors to provide innovative solutions. Conversely, if an organization shows favoritism towards one vendor, it risks becoming overly reliant on them in the future. Therefore, maintaining vendor neutrality allows for flexibility when transitioning to vendors (I3).

Semantic Interoperability

Semantic interoperability refers to the process of exchange of information between healthcare applications, systems, and devices without changing the core meaning of the data. This eliminates any uncertainties in the data, enhances patient care, and encourages advancements by establishing standardized healthcare data. They need standardization which is a motivation for the organizations to involve in the open-source foundation. Solving interoperability challenges requires an approach from all parties involved, considering the range of stakeholders within a healthcare system. It fosters greater cooperation among the stakeholders (I3 and I4).

Infrastructure Development and Collaborative Network Establishment

One of the primary reasons organizations choose to participate in an open-source foundation is to share resources and work together towards an objective. In the case of Racoon, they aimed to create a platform that allows radiological teams from all university hospitals in Germany to collaborate effectively. During a pandemic like COVID-19, where the knowledge on the disease was limited and health practitioners needed to act quickly. Access to data is crucial in gaining deeper insights into the disease (J1 and J2).

Improving Research Collaboration

The broadening of the scope of collaboration serves as another motivating factor for organizations to engage in open-source foundations. Racoon aims to utilize this platform to facilitate the exchange of medical imaging data related to cancer and cardiac conditions, and to implement Computed Tomography (CT) imaging biomarkers, expanding it for a wide range of medical conditions.. The expansion ensures utilization of the platform to its fullest potential covering a wider range of medical conditions (J2).

4.2 What problems are encountered in an open-source foundations and the solutions applied to solve these problems?

We identified five problems that organizations face and solutions they apply in the open-source foundation in health care domain. These problems are conflict

of interest between founders, transitioning away from the founder's influence, building trust and confidence with new partners, diverse expert opinions and mediation, data privacy, and data security regulations.

Conflict of Interest between Founders

Problems

The OpenEHR project came into existence as a result of a partnership, between a commercial enterprise and an institution at University College London. However, some of the community members expressed apprehensions regarding bias within the foundation towards commercial interests leading to doubts about its motives. Additionally, when individuals from different backgrounds collaborate, conflicts and differences of opinion commonly arise, which can impact the foundations operations and overall group dynamics. It is crucial to acknowledge these concerns and work towards finding resolutions (I1 and I2).

Solutions

OpenEHR addressed this challenge by adopting a new framework. The updated structure emphasized transparency and embraced a democratic approach. The organization ensured to include and treat all members equally, eradicating any concerns of favoritism or bias. The foundation aims to resolve conflicts and encourage the reconciliation of different viewpoints by fostering an environment of harmony and productivity (I1 and I2).

Transitioning Away from Founder's Influence

Problems

Another difficulty arises when the project founders dominate the community's or other members' decision-making. This can cause problems and potentially deviate from the projected growth, creating an imbalance in power among member organizations. Although the founders have played a part in the project's success, it is important to recognize that progress might be hindered if decision-making is overly influenced by the founders than being driven by the community (I2).

Solutions

This issue needs to be addressed with a careful approach. The leadership transition must be smooth and well-balanced to enable the community to adapt and evolve. The founder's crucial role in laying the groundwork and nurturing the foundation should be considered. Transparency is vital to this procedure. The founders and the entire community must engage in an open and honest conversation in which the need for the transition is clearly stated (I2).

Building Trust and Confidence with New Partners

Problems

One of the challenges that arise in the open-source community is retaining new partners. It cannot be easy to convince and attract new industry partners to the open-source foundation. These newcomers may be concerned about the foundation's governance and decision-making processes. If they do not understand how the organization functions, it can negatively impact their trust and confidence in the foundation. Additionally, organizations often compete to win over customers by proving that their problem-solving approach is most effective. This competition also have a negative impact on building trust among new partners. (I2).

Solutions

This issue can be addressed by sharing comprehensive information regarding governance structures to the new partners through various channels, such as documentation, on-boarding sessions, and various media platforms. Experienced community members can assist the new members by acting as mentors and guiding them to assist them in comprehending their respective roles and the foundation's objectives. This can be essential to build trust and confidence in new members and encourage them to actively participate in the foundation's success (J1). Competition among customers is justifiable as long as the shared objective of open standards is maintained (I2).

Diverse Expert Opinions and Mediation

Problems

One of the problems that often arises is when several experts collaborate on a project, each with their unique vision, perspective, and set of experiences. This can sometimes make decision-making challenging because they might have different feature needs, technical preferences, and approaches. Finding ground can be difficult when different viewpoints are involved, but it is crucial to acknowledge and navigate these differences to create a collaborative and harmonious working environment (J1).

Solutions

It is essential to acknowledge and value the expertise and abilities of all individuals involved when addressing this issue. This approach ensures that everyone feels valued and included throughout the process. The subsequent stage involves fostering a dialogue where each person has an opportunity to express their perspectives. The committee aims to discover ground between interests and viewpoints fostering a harmonious environment and an inclusive spirit to accomplish the organizations goals (J1).

Data Privacy and Data Security Regulations

Problems

Racoon's central server encountered an issue regarding adhering to data privacy and security regulations. Meeting these regulations proved to be a time-consuming and complex process due to the varying requirements and intricate nature of the task. The primary challenge was to ensure that the stored data remained protected against unauthorized access, thus preventing any misuse of the information. It took two years to address this issue. However, it is worth noting that as data privacy and security regulations are subject to change, keeping abreast with these evolving rules and regularly monitoring them can pose challenges in the future. (J1, J2 and J3).

Solutions

Racoon members knew the importance of data privacy and security regulations, which encouraged them to dedicate much time and resources to adhere to them. To safeguard data privacy and security, Racoon ensured that the data stored on their servers was not publicly available and that only authorized individuals had access to it. This was achieved by implementing measures like encrypting the data and controlling access, which prevented any misuse or leakage of information. Furthermore, Racoon is fully committed to staying up-to-date with the evolving regulations and adapting accordingly (J1, J2 and J3).

4.3 What are the success factors or key best practices for an open-source foundations?

Based on qualitative analysis applied to interviews, we identified six success factors for open-source foundations in the healthcare domain. These success factors are balancing open-source and commercial interests, building relationships and face-to-face interactions, flexible governance structures, alignment with market needs, documentation and project management, and outcome-centric success evaluation.

Balancing Open-Source and Commercial Interests

One of the factors that open-source foundations' growth and sustainability rely on is finding the equilibrium between open-source values and commercial interests. Open-source projects are built on principles like transparency, collaboration, and openness, making code and data freely accessible to the public. However, it is also crucial to allow for engagement from commercial entities as they often play a role in the growth and sustainability of open-source foundations. To ensure success, an open-source foundation must strike a balance that honors these principles while considering commercial interests. This approach allows the project to remain community-driven and build trust among its members, ultimately leading to success in the future (I1 and I4).

Building Relationships and Face-to-Face Interaction

Another key aspect that plays a role in the success of an open-source foundation is the element of networking, specifically building relationships and engaging in face-to-face interactions. Besides networking, it is equally essential to establish connections. These personal bonds are formed through shared beliefs and interests, creating a sense of trust and mutual respect that significantly contributes to the foundation's success. Face-to-face interactions have an impact compared to communications since they provide a personal touch and a deeper level of understanding, ultimately strengthening relationships among members. In light of COVID-19 pandemic experience, in-person communication offers an environment that fosters effective interaction. The cultivation of relationships and active engagement in face-to-face interactions are factors for ensuring long-term growth and sustainability for any open-source foundation (I1).

Flexible Governance Structures

An efficient governance structure plays a role in determining the success of an open-source foundation. The key lies in understanding the differences between international and national regulation, which helps identifying the areas that can be governed at a level and those that should be regulated nationally. It is essential to acknowledge the need for adaptability throughout this process (I3).

As healthcare regulations continue to evolve, foundations must establish provisions to modify policies and governance structures. This allows them to meet requirements while still adhering to policies effectively. Moreover, fostering an inclusive approach when making decisions involving stakeholders from hospitals, universities, IT, and other relevant sectors is essential. This inclusive participation helps reaching decisions and establishing standards beneficial for all parties involved. Striking a balance between international and regional standards is necessary to create a governance structure that promotes trust and long-term commitment within the foundation (I2, I3 and J1).

Alignment with Market Needs

For an open-source foundation to succeed, it must be able to anticipate and adapt to the market's changing demands. In the healthcare sector, where things constantly evolve, foundations must stay updated about market trends, regulations, and change. It is equally essential for them to prioritize value-based care and patient-reported outcomes. Since market needs can vary and change unpredictably, foundations must be proactive and flexible to meet these demands and stay up-to-date with the evolving trends. By aligning themselves with market needs, foundations can ensure their relevance and effectiveness in achieving their goals. This will also attract volunteers who share their vision, leading to overall success in the long term (I2 and J1).

Documentation and Project Management

Maintaining organized documentation and reaching efficiency in project management is crucial to ensure success in an open-source project. This process involves creating information, managing data repositories, and centralizing all data in an accessible hub to all participants. These practices help participants to understand aspects of the project, such as goals, challenges, and procedures, and foster transparency, trust, and inclusivity among members. Effective project management plays a role in the success of foundations by defining project objectives and establishing a roadmap with milestones to keep the project on track. It also ensures the allocation of resources like budget, technical infrastructure, and time. By following these steps, it is possible to ensure the quality of a project while minimizing risks during its development phase. Having structured documentation and effective project management is especially important for complex projects (J1).

Outcome-Centric Success Evaluation

Key performance indicators (KPIs) are commonly used to measure the effectiveness of projects. However, when evaluating the success of a project within an open-source foundation, it is essential to consider outcome-based evaluation. Instead of relying on KPIs like the number of participating organizations, it is crucial to assess the impact on real-world problems when determining the success of an open-source foundation. This involves examining how the project improves patient healthcare and quality of care. To accurately assess success factors, measuring the project's ability to address medical challenges and its overall value in the field is essential rather than solely relying on numerical data. By adopting this approach and focusing on outcomes rather than quantitative metrics, we can understand how impactful the project is in the healthcare domain (J2).

Table 4.1 represents the motivation factors for organizations to engage in open-source foundations.

Table 4.1: Motivation for Open-Source Foundations

Category	Sub-Category	Explanation	Data Source
Motivation	Improving Research Collaboration	The initial concept involved developing a platform that facilitates communication and information sharing among clinics. The primary focus was on COVID-19 patients aiming to identify risk factors and predictive indicators. Later, the platform's scope broadened to incorporate information related to cancer and cardiac diseases.	J2
Motivation	Infrastructure Development and Establishing Network	One of the primary motivations for organizations to engage in an open-source foundation is sharing resources to achieve the same goal. The goal of Racoon was to establish a single platform that would enable radiological teams to collaborate across all university hospitals in germany.	J1, J2
Motivation	Interoperability	Interoperability refers to the exchange of data, between applications, systems and healthcare devices without altering the nature of the data. It serves as another motivating factor in the healthcare domain.	I3, I4
Motivation	Standardized Data Models	The healthcare sector encounters a challenge of having medical data structures due, to the absence of a standardized data model. Therefore, it is essential to establish a framework that can adjust to evolving healthcare practices as technology advances in the industry.	I1, I2
Motivation	Vendor Neutrality	Vendor neutrality refers to maintaining impartiality and openness, in their decision making process without favoring any vendors. This principle ensures fair competition, promotes adaptability and motivates vendors to provide more creative solutions.	I3

Table 4.2 represents the problems and their solutions organizations face in open-source foundations.

Table 4.2: Problems and their Solutions for Open-Source Foundations

Category	Sub-Category	Explanation	Data Source
Problem	Conflict of Interest between Founders	When a team consists of people, from different backgrounds it is common, for conflicts and differences of opinion to arise. However, it is crucial to acknowledge that these issues can adversely affect the groups functioning and overall productivity. Therefore it is vital to address and resolve them.	I1, I2
Solution	Conflict of Interest between Founders	By embracing a democratic approach and promoting transparency, this issue can be effectively resolved. The organization aims to include and treat all members equally, eradicating any concerns of favoritism or bias.	I1, I2
Problem	Transitioning Away from Founder's Influence	The participation of the project's founders in the decision-making process poses a challenge that can result in several problems. It may hinder the project's progress and create an uneven distribution of power among member organizations.	I2
Solution	Transitioning Away from Founder's Influence	Transparency plays a vital role in this process. A smooth and harmonious leadership transition is imperative. Both the founders and the entire community should actively participate in an open and honest conversation, clearly articulating the necessity for the transition.	I2
Problem	Building Trust and Confidence with New Partners	Attracting and keeping new industry partners who are unfamiliar with the open-source foundation can be a challenge. The governance structures and decision-making processes within the OSS foundation may raise concerns for these new partners.	I2
Solution	Building Trust and Confidence with New Partners	Comprehensive information about governance structures can be shared with new partners through different platforms to address this issue. Experienced community members can provide guidance and mentorship to assist new partners in understanding their roles and the objectives of the foundation.	I2
Problem	Diverse Expert Opinions and Mediation	Another challenge identified is the existence of several professionals collaborating on the identical project, each possessing their own unique perspective and viewpoint, along with diverse backgrounds. This can result in challenges when making decisions, as they may have varying feature needs, technical preferences, and approaches.	J1
Solution	Diverse Expert Opinions and Mediation	It is imperative to recognize and respect the knowledge and skills of every individual involved. This methodology ensures that each person feels valued throughout the process. Next phase entails promoting an open discussion where each individual is given a chance to articulate their viewpoints.	J1
Problem	Data Privacy and Data Security Regulations	The process of complying with the diverse regulations and intricate requirements is a time-consuming and complex task. The main obstacle lies in guaranteeing the protection of stored data against unauthorized access to prevent any misuse. Resolving this issue required a significant amount of time.	J1,J2,J3
Solution	Data Privacy and Data Security Regulations	It is crucial to ensure that the data stored on the servers remains confidential and accessible only to authorized individuals. This objective is accomplished through the implementation of various security measures, such as data encryption and access control.	J1,J2,J3

Table 4.3 represents the success factors for organizations to grow and sustain in open-source foundations.

Table 4.3: Success Factors for Open-Source Foundations

Category	Sub-Category	Explanation	Data Source
Success factors	Balancing Open-Source and Commercial Interests	The foundation's growth and sustainability hinge on maintaining an equilibrium between open-source principles and commercial interests. Additionally, fostering commercial engagement is crucial, as numerous open-source foundations rely on commercial entities to thrive and endure.	I1, I4
Success factors	Building Relationships and Face-to-Face Interaction	The social aspect of networking plays a significant role in the success of an open-source foundation. Building relationships and having face-to-face interactions are crucial factors. Apart from professional networking, the development of personal connections is equally important.	I1
Success factors	Flexible Governance Structures	As the healthcare regulations undergo constant evolution and transformation, it becomes imperative for foundations to establish provisions for adapting policies and governance structures. Achieving a harmonious balance between international and regional standards is crucial in developing a flexible governance structure.	I2, I3, J1
Success factors	Alignment with Market Needs	To achieve success, an open-source foundation must possess the ability to anticipate and adapt to the constantly evolving market demands. By aligning itself with the needs of the market, the foundation can ensure its relevance and effectiveness in achieving its goals.	I2, J1
Success factors	Documentation and Project Management	Maintaining a clean documentation and project management is crucial for the success of open-source foundations. This practice not only aids participants in comprehending different project aspects like objectives, challenges, and procedures, but it also fosters transparency, trust, and a sense of inclusion among members.	J1
Success factors	Outcome-Centric Success Evaluation	When assessing the effectiveness of a project within an open-source foundation, it is crucial to take into account the evaluation of success based on outcomes. The evaluation of an open-source foundation's success should involve analyzing its influence on real-world problems.	J2

5 Discussion & Limitations

This research provides insights into motivations, challenges, and success factors within the context of organizations involved in an open-source foundation. A multiple-case case study was conducted to gain a comprehensive understanding, focusing on OpenEHR and Racoon Project as the selected samples. The findings of this study reveal that organizations engage in open-source foundations for various reasons. One primary motivation is the need for standardized data models and continuous innovation. This is crucial as inconsistent data can have a negative impact on patient care. Another significant motivation is vendor neutrality, which ensures fair competition and flexibility in vendor relationships. Interoperability is also identified as pivotal, as it helps to standardize healthcare data, improve patient care, and maintain the integrity of the fundamental meaning of the data. Additionally, infrastructure development and the potential for expanding the scope are identified as motivation factors among the organizations examined in this research study. The second aspect of the study aimed to identify the challenges encountered by organizations operating in an open-source environment. Common challenges include organizational controversies and personal conflicts, which can be mitigated through transparency and a democratic approach. Additionally, transitioning away from the founder's influence presents another obstacle that can be overcome by fostering open and effective communication, ensuring a smooth transition, and maintaining a democratic governance model. Establishing trust and confidence is also a challenge faced by new foundation members, often due to a lack of thorough understanding of the governance structures and functioning of the foundation. This challenge can be addressed through comprehensive information-sharing and mentorship programs. Furthermore, diverse expert opinions can lead to problems, which can be resolved through structured discussions and acknowledging the expertise of all involved members. Lastly, the ever-evolving nature of data privacy and security regulations poses the most difficult challenge, necessitating adaptation and staying updated to address these changes effectively. The final and crucial objective of the study was to identify the factors contributing to the success of open-source foundations. Maintaining a balance between the open-source principle and commercial interests is essential to ensure the foundation's sustainability. There is a need for financial stability. The

achievement of flexible governance structures is another crucial factor that can be achieved by striking a balance between international and regional regulations, thereby ensuring adaptability. The foundation's alignment with market needs is crucial to remain relevant and attract more participants. Effective project management and clean documentation are significant in maintaining transparency and proactively mitigating risks. Additionally, an outcome-centric success evaluation is another critical factor that focuses on the impact on real-world problems to assess the project's effectiveness. It is worth mentioning that the two samples encounter distinct challenges due to different phases in their life-cycle, yet they share common factors contributing to their success.

Our approach to this study involved a multiple-case case study comprising two samples. We have employed Guba's (1981) [Gub81] trustworthiness metrics to evaluate our research, considering credibility, transferability, dependability, and confirmability.

Credibility pertains to the accuracy of the research findings. During the course of the eight-month case study, we ensured the credibility of our findings by conducting a series of activities, which included weekly meetings, reaching out to potential interview partners, conducting interviews with the OpenEHR foundation and Racoon project, transcribing the interviews, and presenting a comprehensive qualitative analysis of the interviews in the end. Our diligent approach allowed us to present accurate outcomes aligned with the study objectives.

The concept of transferability refers to the utilization and implementation of the study's findings in a different context and being able to generalize it to other open-source foundations from different industries. Our research findings align with the results demonstrated by West et al. 2005 [Wes⁺05], illustrating the critical challenges faced in creating spinout open-source projects in the VistA health care information system. A few common challenges observed were leadership transition, trust establishment, managing diverse opinions, governance, and adaptation to regulatory changes. This substantiates our findings in the context of open-source foundations in the healthcare industry. It remains for future work to determine whether the findings of this case study can be applied to other industries.

The dependability of the research findings is determined by their traceability and reliability. To ensure the dependability of the work, it is essential to document the research method transparently. Our study has documented the data utilized, ensuring our findings' traceability.

Confirmability refers to conducting an impartial and unbiased data analysis while accurately representing the narrative. This can be achieved by granting the participants access to the data, comprising transcripts and other qualitative in-

formation. In order to ensure confirmability, we shared the transcripts with the respective interview partners.

6 Conclusion

This study provides a comprehensive overview of the motivations, challenges, and success factors of the organization's involvement in open-source foundations in the healthcare industry. By centering its focus on the OpenEHR foundation and Racoon project as sample cases, this study sheds light on various crucial factors pertaining to the dynamics of these two foundations. The critical motivations for organizations to participate in the open-source foundations encircle a variety of essential elements, such as the need for standardized data models, vendor neutrality, interoperability, infrastructure development, and scope expansion. These motivations are essential for enhancing the quality of patient healthcare data and ensuring fairness and adaptability in vendor relationships. Additionally, the study highlights the common challenges that organizations face in the open-source environment. These challenges include organizational controversies, change in leadership, trust-building with new partners, managing diverse expert opinions, and adaptation to data privacy. The solutions mentioned are as follows: transparent communication, a democratic approach, information sharing, mentorship, structured discussions, and staying vigilant about regulatory changes. This study's findings shed light on the critical factors contributing to success in open-source environments. These include maintaining a balance between open-source community and commercial interests, achieving flexible governance structures, aligning with market needs, effective project management, clean documentation, and an outcome-centric success evaluation that focuses on real-world problems. This research plays a crucial role in comprehending the intricacies of an open-source ecosystem. It offers a strategic guide for organizations to engage and enhance their involvement in an open-source foundation effectively. The study emphasizes the value of balance, transparency, and adaptability in the constantly evolving realm of open-source initiatives.

6. Conclusion

Appendices

Appendix A: Codebook

Level 1 Code	Level 2 Code	Explanation	Example Quotation
Background of OpenEHR	History	This code is used to highlight history that are related to OpenEHR's background	The development of OpenEHR has been divided into three phases. The first phase, which ran from 1992-2003, was research-focused and related to the CHIME Health informatics group at the University of College London (UCL). This was followed by the formation of the openEHR Foundation in 2003, which was a non-profit organization. During the second phase, which lasted from 2003-2014, the OpenEHR structure was refined, and governance structures were established.
Motivation factors	Improving Research Collaboration	This code is used to highlight motivations that are related to research collaboration	The idea was to develop a platform where those clinics could communicate and share data primarily for COVID patients to find out risk factors or good and bad predictive factors. From this, it developed into cancerous and maybe cardiac diseases. What imaging biomarkers can we find, mainly in CT thorax scans, that we can use to find information for future patients involved in their clinical treatment, for example.
Motivation factors	Infrastructure Development and Establishing Network	This code is used to highlight motivations that are related to establishing network and increasing knowledge	It's actually very simple. Within the crisis, we noticed that we needed something in common to make research between hospitals and departments easier. So we started thinking about how to build an infrastructure that can be used easily for research. The government's grant came, and we applied to get our idea funded. The main coordinator for Raccoon infrastructure is in Berlin and Frankfurt. We submitted a joint grant application, and it got funded. Now it's established in this network university medicine.
Motivation factors	Interoperability	This code is used to highlight motivations that are related to interoperability of the medical data	Our goal was to reposition the company and introduce a platform strategy that would bring all the companies together. This platform strategy was meant to create a common foundation for development and focus on semantic interoperability, including data modeling. This is when we started to get involved with OpenEHR because we believed it was the best technology to achieve our goals.
Motivation factors	Standardized data model	This code is used to highlight motivations that are related to standardizing data model	It was an attempt to standardize the data models used in healthcare from a top-down approach, creating data models using traditional methods like UML and XML. At that time, XML was just emerging. There
Motivation factors	Vendor Neutrality	This code is used to highlight motivations that are related to vendor neutrality.	We are an industrial company, a manufacturer, and we share the belief that vendor neutrality is essential in the healthcare industry. Neutrality starts with eliminating data silos in individual industry players.
Problems	Build trust with new partners	This code is used to highlight problems that are related to building trust with new partners	We need to support what I'd call 'trapped potential,' individuals who are great leaders but do not fit the typical demographic.
Solutions	Build trust with new partners	This code is used to highlight solutions that are related to building trust with new partners	We need to expedite their journey, providing training, mentoring, and education to build their confidence."
Problems	Data Privacy and Regulations	This code is used to highlight problems that are related to data privacy and regulations	Oh yeah, this is a very painful question. Yeah, it is, actually our central raccoon central server has been 2 years till we got the regulations done for this, for data privacy and data security. Raccoon will never have an open source data bank
Solutions	Data Privacy and Regulations	This code is used to highlight solutions that are related to data privacy and regulations	So you will be needing some kind of access to the data bank, so you will not be putting things online, downloadable, not downloadable like many open-source banks. But we want to
Problems	Diverse expert opinions	This code is used to highlight problems that are related to diverse expert opinions	So this is a conflict like you need to mediate between this and respect both opinions, and they are both experts, and what we did this for example a minor conflict.
Solutions	Diverse expert opinions	This code is used to highlight solutions that are related to diverse expert opinions	So we didn't take it to the steering committee what we did. We had a group of experts like OK guys like. Let's let's take this in. In, in, in our group discussion and we had a group discussion with the expert group where everybody was sitting there, and we went through all the lab results and and why we need
Problems	Conflict of Interest between Founders	This code is used to highlight problems that are related to conflict of interest between founders	We've faced conflicts and disagreements, particularly a few years ago, which led to personal relationships breaking down. It was sad because these were colleagues and friends.

Solutions	Conflict of Interest between Founders	This code is used to highlight solutions that are related to conflict of interest between founders	Such conflicts often arise from individuals investing their time and resources far beyond what they were compensated for, sometimes resulting in financial losses due to their belief in Open Air. However, a new generation of leaders is emerging within Open Air, taking the foundation in a slightly different direction, reflecting changing priorities and attitudes.
Problems	Transitioning Away from Founder's Influence	This code is used to highlight problems that are related to involvement of the founder in the decision-making process	In my case, I had already planned to step down as Co-chair and not renew my tenure as a director, as I felt it was time to move on. I believe this change was needed to address the situation and move forward. The current leadership is working to resolve these issues.
Solutions	Transitioning Away from Founder's Influence	This code is used to highlight solutions that are related to involvement of the founder in the decision-making process	OpenEHR addresses this challenge by adhering to a new structure. The new entity was more focused on transparency and adhered to a democratic process. The foundation dispelled the notion of commercial bias by ensuring inclusion and equality of members within the organization. This approach eliminates any doubts and criticisms regarding the foundation's true purpose. The foundation seeks to resolve personal conflicts by promoting a harmonious and productive atmosphere
Success factors	Alignment with Market Needs	This code is used to highlight success factors that are related to alignment with the market needs	"I believe product-market fit is critical, aligning with system needs, showing impact, and avoiding purely academic exercises. Success lies in aligning with market needs and demonstrating utility."
Success factors	Balancing Open-Source and Commercial Interests	This code is used to highlight success factors that are related to balancing the open-source and commercial interests	It helps us maintain the balance between representation and financial support. Industry members have been used by big companies, but they don't have much influence compared to industry partners. The rules are clear, and nobody is allowed to dominate. It's about maintaining the balance and inclusivity. [...] It's a necessity to maintain the balance, and we want to avoid dominance by any single category. It's a challenge, but it's worked out well.
Success factors	Building Relationships and Face-to-Face Interaction	This code is used to highlight success factors that are related to building relationships and face-to-face interaction	Networking and personal relationships play a huge role. While there are occasional breakdowns in communication, the community is generally friendly. Personal relationships, often with business competitors, have been built over the years. Face-to-face interactions, now that COVID is less of an issue, are becoming increasingly important.
Success factors	Documentation and Project Management	This code is used to highlight success factors that are related to documentation and project management	And what I think it's also very important the more the projects get more complicated and the more you are on the on the way you need to have a very clean documentation also so. Clear workflows. Clear, clear assignments. Who is responsible for what? And a clear project management at the end. I think it is, uh like basics, I think uh, basics, project management skills. You will be needing in managing these huge projects and it depending on how big. Also if it's something which can be done by two people, of course it will be easier to manage than something. Where you have 40 people.
Success factors	Flexible Governance Structures	This code is used to highlight success factors that are related to flexible governance structures	Those aspects are now gaining more attention as the organization grows. There is a need for governance structures and guidelines to ensure that technology is properly managed. OpenEHR is moving toward having international and affiliate structures to support this governance. It's about striking the right balance to ensure that members and users can take full advantage of the work that others have done while maintaining proper governance. The focus is on guiding
Success factors	Outcome-Centric Success Evaluation	This code is used to highlight success factors that are related to outcome-centric success evaluation	So I think the clinical outcome in the end or can we gain information that is helpful for treating patients in the future, no matter what disease. That's kind of I think what would be the best measurement of success?

Appendix B: Interview Questions for the Case Study				
Question Type	Topic	Question	OpenEHR	Racoon
Intro. Q		How long have you been working in the foundation?	✓	✓
Intro Q.		How did you get involved with the foundation?	✓	✓
Intro Q.		Could you explain your position and responsibilities in the foundation?	✓	✓
Transition Q.	Experience with collaborative working		✓	✓
Transition Q.	Reasons for choosing open source approach	<ul style="list-style-type: none"> • How did the foundation start? • What was the reason of open sourcing the project? 	✓	✓
Transition Q.	Onboarding and Project Requirements	Who defines the requirements?	✓	✓
Transition Q.		How do you decide about the priorities?	✓	✓
Transition Q.		How do you do the software/system developments? Are individual volunteers working on software development, or paid developers who are working in member companies?	✓	✓
Transition Q.	Top-management support	What is the importance of this project for the member/ organizations ? <ul style="list-style-type: none"> • Do they all show the same interest in the consortium? • Do they get support from the top-management of their organizations? 	✓	✓
Key Q.	Member selection*	What are the criteria and processes followed by foundation to select and onboard new members into the community?	✓	✓
Key Q.	Measures for success	How do you determine the success of the collaboration? <ul style="list-style-type: none"> • If not mentioned: is the number of organizations using the software a measure of success? • If not mentioned: is the number of organizations a measure of success? 	✓	✓
Key Q.	Success factors	According to you, what are the success factors for an user-led open source collaboration?	✓	✓
Key Q.	Success Factors: Governance	According to the white paper, the membership structure of OpenEHR consists of: Professional members, Industry members, Industry partners, Organizational Partners. <ul style="list-style-type: none"> • Could you elaborate what these categorization mean? • How does this form of structure influence success or failure of the project? 	✓	
		What type of members does the foundation have? Do you accept individual members or organizations, or both?	✓	✓
Key Q.	Success Factors: Transparency	How does the foundation ensure and promote transparency within the community?	✓	✓
		How has this commitment to transparency contributed to the foundation's success?	✓	✓
Key Q.	Success Factors: Collaboration and Community Engagement:	<ul style="list-style-type: none"> • What strategies does the foundation use to foster collaboration among its community members and stakeholders? • How do you encourage participation and contributions from a diverse group of individuals and organizations? 	✓	✓
Key Q.	Success Factors: Affiliate	What are the success factors that determine an openEHR Affiliate's effectiveness in implementing the vision and mission of openEHR	✓	
Key Q.	Success Factors: Technical aspect	How is the technical infrastructure of the foundation managed to support its growth and sustainability?	✓	✓
Key Q.	Technical aspect	How do you handle issues related to security, data privacy, and compliance within the open-source ecosystem?	✓	✓
Key Q.	Technical aspect	What measures are in place to maintain the quality and reliability of software and related components?	✓	✓
Key Q.	Success factors: Governance	What governance mechanisms does the foundation have in place to facilitate effective collaboration, decision-making, and conflict resolution within the community, and how have these mechanisms contributed to the overall success of the foundation?	✓	✓

Key Q.	Success factors: Conflict management	How does the foundation handle conflicts or disagreements within the community? How effective conflict resolution strategies contributed to the stability and success of the foundation?	✓	✓
Key Q.	Conflict management	Could you provide examples of the types of conflicts that have arisen within the community during its development, and how were these conflicts effectively addressed and resolved?	✓	✓
Key Q.	Problem	As OpenEHR gained popularity in developed markets like the UK, Nordics, and Spain, what specific strategies did you adopt to address the varying regulations and requirements of different international markets?	✓	
Key Q.	Problem	The integration of openEHR with FHIR APIs provided the best of both worlds in terms of data exchange and health data persistence. What technical complexities did you encounter during this integration process, and how did you overcome them?	✓	
Closing Q		This is the end of my questions. Would you like to add something?	✓	✓
Closing		Thank you for your time. It has been a pleasure to meet you.	✓	✓



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