Governance Practices for Open Source Foundations in the Healthcare Sector

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Abstract. Open source (OS) foundations are non-profit organizations that support open-source software development projects. OS foundations can be categorized based on their membership and governance structures. This study focuses on vendor-led and user-led OS foundations operating in the healthcare sector. The study has two objectives. The first objective is to explore the similarities and differences of vendor-led and user-led OS foundations. The second objective is to explore and define governance practices applied in these foundations to achieve success. To address these objectives, we performed multiple-case study research, with the openEHR Foundation and the RACOON consortium as our cases. We performed interviews with key stakeholders and applied thematic analysis to derive the results. We present differences and similarities of these foundations with respect to membership and organizational structure. We also present members' motivation to engage with these foundations. Furthermore, we identify and explain 32 governance practices applied in nine contexts related to OS foundations in the healthcare sector.

Keywords: open source foundation, governance practices, best practices, openEHR, RACOON

1 Introduction

The development of open-source software (OSS) is a process in which participants cooperate to produce better software with openness as a key element. OSS projects started with developer communities followed by the participation of companies and the establishment of open source (OS) foundations. OS foundations are non-profit organizations that offer neutral organizational platforms for OSS projects. They are legal entities that play a role in collecting and allocating funds to sustain these projects and protecting the rights of project contributors. They may provide assistance in governance mechanisms and technical infrastructure for their members [1, 2].

To provide an understanding of OS foundations, [3] introduced a classification which distinguish three types of OS foundations regarding the legal entity and motives of their leading members: community-led OS foundations, vendor-led OS foundations, and user-led OS foundations.

In community-led OS foundations, projects are steered by individuals, who may be both developers and users of the software they contribute to. Contributors to these community-led OS projects can be either volunteers or paid employees of companies [3]. An example of this type of foundations is the Apache Software Foundation.

In vendor-led OS foundations, the leading members are information technology (IT) companies collaborating to develop OSS components [1, 4]. Vendors' involvement in OSS projects evolved from sponsoring OSS communities to creating OSS consortia with their competitors and leading the development process collaboratively. Two examples of vendor-led OS consortia are the Linux Foundation (LF) Edge consortium, and the Open Infrastructure Foundation.

In user-led OS foundations, the leading members are end-user organizations, mostly from non-software industries. These organizations collaborate with the focus of developing software applications to use in their internal processes [3]. In these foundations, key members are organizations, not individual software developers. User-led OS foundations emerged in higher education in the early 2000s, driven by the need for tailored software and vendor independence, with the universities in the United States (US) at the forefront. Notable early projects include the Kuali Financial Systems and the Sakai Learning Management System. Some other examples are openKonsequenz from the energy industry [5], and openMDM from the automotive industry [3]. However, we did not encounter any research papers about user-led OS foundations in the healthcare sector.

In the late 1990s, healthcare providers began integrating IT systems to develop comprehensive care delivery systems. Faced with challenges in conventional software, they turned to OSS alternatives [6]. OSS has since grown in importance in healthcare, contributing to improved care quality while reducing costs—an advantage particularly valuable in low-resource settings [7].

This study focuses on the OS foundations operating in the healthcare sector steered by organizational members (corporate entities). Our goal is to investigate the similarities and differences of vendor-led and user-led OS foundations and to define the governance practices which help to achieve the success of OS foundations. Our research questions are:

- RQ1: What are the differences and similarities between vendor-led and user-led open source foundations in the healthcare sector concerning governance structures and member engagement motivations?
- RQ2: What governance practices enable foundations in the healthcare sector to achieve success?

To address these problems, we performed case study research with two cases. We selected openEHR as an example of a vendor-led OS foundation and RACOON (Radiological Cooperative Network) as an example of a user-led OS foundation. openEHR is a non-profit organization that provides technical specifications for Electronic Health Record (EHR) platforms, as well as domain-specific clinical models for defining content. RACOON is a consortium focusing on collaborative work among university clinics in Germany to provide better medical care against COVID-19 and cardiac diseases. Consortium here means a formally organized

community of organizations with a defined governance structure and processes. The specific legal form of incorporation does not matter. We therefore use the terms foundation and consortium synonymously.

The structure of this paper is as follows: In Section 2, we present the related work on OS foundations in healthcare and governance practices of organization-led open source foundations. In Section 3, we describe the methodology we employed. We present the results in Section 4, and discussion in Section 5. In Section 6, we discuss the limitations, and in Section 7 we present the conclusion.

2 Related Work

2.1 Open Source Foundations in Healthcare Sector

OS foundations in healthcare play a role in shaping a procurement strategy that maximizes resource utilization, prioritizes patient safety, increases standardization and improves healthcare services quality[8].

[9] identified the five most popular open-source Electronic Health Records (EHR) systems and compared them by focusing on their features, functionalities and performances. These systems were: OSEHRA VistA, GNU Health, Open Medical Record System (OpenMRS), Open Electronic Medical Record (OpenEMR), and OpenEHR. **VistA**(Veterans Health Information Systems and Technology Architecture) was one of the early examples of OSS projects in the healthcare sector. VistA was initiated by the US Veterans Health Administration in 1982. As a federal project, its source code was public domain. Although it was open to use by other organizations, it was not officially OSS until 2003. Applying OSS principles and building a community around the system was essential to attract talented developers to contribute to VistA [10]. [10] identified the challenges VistA faced during this transformation process. These challenges include creating a technical infrastructure for collaboration, establishing governance mechanisms to balance stakeholders' demands, acquiring domain experts beyond computer science, and deciding on intellectual property licensing. **OpenMRS** was initiated by the Regenstrief Institute and the Medical Research Council of South Africa for use by low income and developing countries [11, 12]. [11] investigated the impact, opportunities, and challenges of openMRS implementation in hospitals. **LibreHealth:RIS** is an open-source radiology information system (RIS) that began as a small module of openMRS. As of 2017, it has continued as an independent RIS project under LibreHealth [12]. [12] describes the specifications and development process of LibreHealth:RIS. **OpenEMR** is an open-source EHR and medical practice management solution. Although it started as a commercial product in 2001, in 2004 it was released as an OSS project. It is supported by the community-led openEMR Foundation and available for the use of medical practitioners [13]. [13] investigated the project's success in terms of the roles of the developers and the influence of the OSS development approach. The **openEHR** project was initiated in England and extended to other countries. [14] the technical specifications about openEHR and establishment process of openEHR Foundation. **GNU Health** is a community-led OS

health and hospital information systems project. It is supported by the GNU Solidario Foundation [15]. As of this writing, we did not encounter any research papers in English on the governance aspect of GNU Health.

Related work results show that there is a lack of literature about OS foundations in the healthcare sector focusing on the governance aspect.

2.2 Governance Practices of Organization-Led Open Source Foundations

[16] look into the **governance mechanisms** of software ecosystems in both proprietary and open-source contexts. They categorize these mechanisms into *value creation, coordination of players,* and *organizational openness and control.* Their findings highlight the most frequently cited governance mechanisms are *attracting and maintaining partners, sharing knowledge, promoting innovation, and managing licenses.* [17] explore the management of **commercial conflicts** in OS Foundations. To prevent conflicts, they emphasize establishing a screening process before accepting new members, defining governance rules, applying distributed decision making mechanisms and prevention strategies to protect culture, values and common interests. The governance rules include *separation of powers*, *tiered membership*, *limited representation from the same company*, and *having independent management entities that are not in relation with any of the member companies.* Prevention strategies include, allowing community participation, enforcing public communication, and ensuring openness and transparency. [3] analyze **the success factors within a user-led OS consortium**, emphasizing governance practices critical for its sustained effectiveness. They identify specific governance practices that bolster success, including *clearly defined rules and boundaries, collective prioritization, openness and transparency, shared resources and equality, commitment of members, inheriting established governance rules and legal structures, periodic communication, organizing events,* and *promoting hosted projects.*

3 Methodology

We conducted multiple-case case study research by following the guidelines of [18]. We chose a case study approach primarily to observe real-case dynamics in a natural setting [19].

3.1 Case Selection

We used polar sampling to select two cases [18]. Our first consideration was the type of foundation, choosing one vendor-led and one user-led OS foundation in healthcare. Additional selection criteria included the foundation's size, scope, geographical activity area, focus, and maturity level. We compiled a list of OS foundations in the healthcare sector, including the Cerner Open Source

Platform, LibreHealth, openEMR, and openMRS. After investigating the governance and membership structures of these foundations, we selected openEHR and RACOON. Detailed sampling information and background on both consortia are provided in External Appendix [23].

The **openEHR** Foundation, established in 2003, has a Governing Board consists of representatives from different membership types, including organizational members, industrial partners, individuals and professionals. openEHR is a vendor-led OS foundation, because the majority of the governing board members are representatives of vendor companies. Although founded in England, it is internationally recognized and operates in various countries, including Australia, and Canada. Its mission is to standardize Electronic Health Record (EHR) data, promoting interoperability and efficient healthcare data exchange and management.

RACOON, established in 2020, is currently active in one country (Germany). RACOON is a user-led OS consortium, because its governing board consists of representatives of user organizations (University Clinics). RACOON aims to build a national system for multicentric analysis of radiological data.

3.2 Data Collection and Data Analysis

We collected data from case websites, focusing on foundations' history, membership, and vision. Then, we conducted semi-structured interviews with key informants, using open-ended questions to allow flexibility during the discussions [20]. Before conducting interviews, we prepared an interview protocol including questions aligned with our research objectives. We performed seven online interviews in English from July to September 2023, each lasting one to two hours. Four interviews involved openEHR members, and three involved RACOON members. Following each interview, we shared transcriptions with the respective interviewees for confirmation. We assigned each interviewee and data source a unique identification number (ID) and employed these IDs in the results section to clearly attribute the sources of our findings. We share our interview questions in External Appendix [23]. Table 1 presents an overview of the interview sessions and Table 2 presents the online data sources.

Table 1. Interviewees and Identifiers

ID	Foundation	Responsibility in the Foundation	Interview Date
I1	openEHR	Former Chair of the Management Board	21.07.2023
I2	openEHR	Board Member of the CIC	25.07.2023
I3	openEHR	Chief Executive Officer of the CIC	28.07.2023
I4	openEHR	Board Member of the CIC	26.09.2023
J1	RACOON	User-Member	07.09.2023
J2	RACOON	User-Member	08.09.2023
J3	RACOON	User-Member	22.09.2023

We analyzed the interviews using thematic analysis. We followed the guidelines of [21]. First, we reviewed interview scripts to gain an overall understanding. Starting from the second step, we used a qualitative data analysis tool, QDAcity[3], and generated codes. In the third step, we refined the coding scheme by clustering initial codes into themes. Following this step, we reviewed our codes and their associations with the emerging themes. We continually revised and updated the codes and themes as necessary. After providing names and explanations for the themes, we organized themes in a logical manner and grouped different subsets within the same set to form a larger category. As the final step, we present our data analysis results in the results section of this paper.

Table 2. Online Data Sources and Identifiers

ID	Official Website and Content	Link
W1	openEHR/About openEHR	https://openehr.org/about_us
W2	openEHR/What is openEHR?	https://openehr.org/about/what_is_openehr
W3	openEHR/History 2002-2018	https://openehr.org/about/history_2002_2018
W4	openEHR/Membership	https://openehr.org/community/membership/
V1	RACOON/Project Team	https://racoon.network/?page_id=7844
V2	Charité Berlin/RACOON	https://num.charite.de/teilprojekte/laufende_projekte/racoon/
V3	Network of University Medicine /About us	https://www.netzwerk-universitaetsmedizin.de/ueber-uns/
V4	RACOON/RACOON Base	https://racoon.network/?page_id=1638

4 Results

4.1 The Differences and Similarities between Vendor-Led and User-Led OS Foundations in the Healthcare Domain

We present results in this section and a summary in External Appendix [23].

Organizational and Membership Structure. *openEHR* consists of two organizational entities: the openEHR Foundation and the openEHR International Community Interest Company (CIC). The Foundation owns and safeguards openEHR's intellectual property. The openEHR International is responsible for handling day-to-day businesses within the openEHR community (I1, W1). *openEHR* comprises four membership types; organizational partners, industry partners, professional members, and individual members (I1, W4). Organizational partners represent healthcare institutions and provide input about user expectations (I1, I3, W4). An example is the Catalan Health Service (W4).

[3] https://qdacity.com/

Industry partners are software vendors which build products or services on top of openEHR specifications (I3). They provide financial and human resources (I1, W4). An example is EY-Health (W4). Professional members are individuals who offer consultancy and training services. Individual members are individuals who contribute to and influence the community (I1, I3).

RACOON was created as part of the German Network University Medicine, which was founded by the German Government (V3). Project coordination is performed by the University Hospital Frankfurt and the Charité Universitätsmedizin Berlin (V2). *RACOON* accepts only organizations as members (J1). There are two types of members: user members which are the university clinics, and technical partners which perform development work in coordination with user members. All University Clinics in Germany are members of the consortium. Two examples of technical partners are Mint Medical and Fraunhofer Mevis (J1, V1).

Governance Structure. *openEHR* has a two-layer governance structure. The first layer is the steering board. It is the main decision organ, and consists of members from different membership categories (I4). Members vote on the allocation of resources and priorities (I1, I3). The second layer is the program boards with their independent governance mechanisms. As of 2023, there are four programs with governing boards: Specifications, Clinical Modeling, Software, and Education (I4, W1). Each program board represents different areas of expertise. For instance, the Specifications Program Board is governed by the technical experts, while the Education Program Board consists of experts in training and academia (I4, W1). Program board members collaboratively set priorities and define requirements (I2). Disagreement within the community are handled through the program boards. In the situation of unresolved disagreements, the issue is escalated to the steering board and decided by vote if necessary (I3, I4). Governing mechanisms of *RACOON* include the General Assembly, a steering committee, and coordination teams (J1). The General Assembly consists of members from all partner hospitals (J1). The steering committee consists of healthcare professionals representing different University Clinics (V1). The steering committee is the main source of decisions, including setting priorities and accepting new members (J1, J3). Conflicts and disagreements are addressed in the steering committee (J1). Coordination teams provide information flow between working groups and the steering committee (J3).

Financement. Financement of *openEHR* depends on annual membership fees. Membership fees vary by category, ranging from €150 for individuals to €17,010 for organizations (W4). The *RACOON* is funded by The Federal Ministry of Education and Research Germany for three years and as of 2023 does not collect any membership fees (J1).

Development and Output. The focus of *openEHR* is to develop data models and specifications (I1). For the development of data models, both volunteer developers and employees of partner institutions collaborate (I3). openEHR works on the data application layer, while industrial partners work on the application layer to offer projects compatible with openEHR specifications (I1, I3).

Industry partners are not required to open source application-layer projects; they may choose to release them as OSS or proprietary software (I1). On the other hand, openEHR has also an OSS development project, which, however, is not suitable for large deployments (I3). In *RACOON*, user members define the requirements and steer the development direction (J1, J2). Being in charge of the steering process allows users to be more creative in solving problems and fulfilling their functional expectations (J2). Each of the user members have an IT-specialist employed specifically for this project (J2). Technical partners perform the development work and are paid for it (J1, J2, J3). In this initial phase, the consortium only accepts contributions from its members and not from outside organizations or volunteers (J1).

Members' Engagement Reasons. A key challenge in healthcare is the variation in medical data structures, leading to unstandardized models and inconsistent data logging, which can impact patient care. The ***need for standardized data models*** has driven organizations to establish the *openEHR* community (I3). With rapid advancements in healthcare technology, traditional data models can become obsolete, highlighting the need for adaptable frameworks (I1, I2). Semantic interoperability enables information exchange across healthcare systems without altering data meaning, reducing uncertainties, improving patient care, and fostering progress. ***Addressing interoperability challenges*** is another key motivator for organizational involvement (I1, I2, I4). Since openEHR specifications are open source, organizations can continue development even if openEHR is discontinued, ensuring ***investment security*** (I2, I4). Ethically, especially for organizations using public funds, investing in open source that ***benefits the community*** is an additional incentive (I4). Industry partners can develop application layers using open specifications, ensuring ***vendor neutrality*** and reducing lock-in, which allows organizations to choose vendors based on their specific needs (I1, I2). Industry partners offer commercial services around openEHR specifications, helping them ***save costs*** by utilizing existing data models (I1). To sustain a healthy community, member companies are encouraged to support the foundation through membership fees (I2).

RACOON was initiated during the COVID-19 pandemic, while the knowledge on the disease was limited. Health practitioners needed data to gain deeper understanding about the disease. The RACOON consortium aimed to create a platform that enables data sharing and analysis among radiological departments from university hospitals, to ***enhance understanding about the disease and provide better medical care*** to patients (J1, J2). ***Expanding research opportunities*** is another motive for organizations to join in RACOON consortium. Beyond COVID-19, data sharing extended to medical imaging data on cancer and cardiac conditions. One use case of the collected data is training artificial intelligence and machine learning to improve the pattern recognition in Computed Tomography (CT) scan (J2, V4). Researchers can propose research topics, and once approved, work on the platform. Students gain access to a ***larger pool of data*** compared to what their university alone provides (J2). The platform facilitates communication and ***strengthens networking*** among university

hospitals. Its transparency policy allows any interested party to join proposed research projects (J1). The platform ***enhances collaboration opportunities*** among university clinics (J1, J2, J3).

4.2 Governance Practices for Open Source Foundations in the Healthcare Sector

We identified 32 governance practices in nine contexts which are associated with the OS foundations in the healthcare sector. In this section, we detail each context (C), with explanation (E) and practices (Pr). We present the list of these practices in External Appendix [23].

C-1. Mitigating the domination of any single member

C-1.E. The openEHR Foundation was founded as a partnership between University College London (UCL), a non-profit organization, and Ocean Informatics, a commercial entity. Some community members perceived the foundation as a front for Ocean Informatics' commercial operations, which negatively affected the community dynamic (I1).

C-1.Pr. openEHR addressed this challenge by restructuring its membership and selecting **representatives from all membership categories for the governing board**. This approach ensures that diverse viewpoints are represented within the foundation (I1, I3, I4). The revised structure emphasizes transparency and embraces a democratic approach (I1). The governing board makes decisions about **resource allocations based on votes** among its members (I3, I4). **Including representatives from competing companies on the board** helps avoid dominance by any single organization (I1). Another practice is **rotating members on the governing board**, which prevents prolonged influence by the same individuals and encourages diverse viewpoints (I4).

I1 shared the following words: *"Our structure aims to ensure that different member categories feel represented on the board without giving too much influence to national or commercial organizations."*

C-2. Focusing in-depth on specific issues

C-2.E. Collaborative work may involve diverse needs and expertise requirements, requiring insights from both clinical and technical perspectives (I3).

C-2.Pr. openEHR has four **sub-groups that focus on different areas of expertise**, addressing the needs of various stakeholders (I2). Prioritization, decision making, and disagreement resolution are expected to be managed within these groups (I2). In the case of unsolved issues, the matter is escalated to the governing board (I3). These groups are open and inclusive, welcoming organizations and individual members with diverse skills and experiences (I2, I3, I4).

RACOON follows a similar approach, organizing **working groups** to focus on specific issues, such as quality assurance (J1, J3). Each working group has its own leader, chosen by the group members (J3). These groups are open to all interested members and encourage collaborative work (J1, J3). Working groups hold weekly meetings to share updates (J3). Furthermore, each user institution in the RACOON consortium has a **dedicated IT-specialist.** These special-

ists communicate and collaborate with each other and with technical partners, positively impacting the project (J1, J2).

C-3. Facilitating mediation among diverse expert opinions

C-3.E. A common challenge in collaborative projects is that, when multiple experts with unique visions, perspectives, and experiences, come together, decision-making can become difficult. They may have different functional expectations, technical preferences, and approaches, making it challenging to reach common ground (J1, I1).

C-3.Pr. It is essential to **acknowledge and value the expertise and abilities of all individuals involved** when addressing issues (J2). The subsequent stage involves **fostering a dialogue where each person has the opportunity to express their perspectives** (J1, J2, J3). **Showing mutual respect and understanding** is crucial for finding common ground among diverse interests and viewpoints, creating a harmonious environment and an inclusive spirit aligned with the organization's goals (J1, J2, J3, I1, I3).

C-4. Safeguarding data privacy and security

C-4.E. Meeting data privacy and security regulations is a time-consuming and complex process due to varying requirements and complicated nature of the task (J1, J3). The primary challenge is to protect stored patient data against unauthorized access, while enabling multicentric scientific research using data from all member institutions (J1).

C-4.Pr. To safeguard data privacy and security, RACOON **anonymizes data stored on its cloud server and restricts access to authorized individuals** (J2). Measures such as data encryption and access controls help prevent misuse or leaks (J2). The openEHR Foundation does not store patient data (I1, I3). While cloud servers may store databases related to tools and design models, no sensitive information is kept there (I1). In both openEHR and RACOON, **the responsibility for securing patient data belongs to the data-owning organizations**, not to the foundation (I1, I3, J1, J3).

openEHR ensures that its platform and published data models comply with General Data Protection Regulation in Europe and Health Information Privacy Standards in the US (I3). Similarly, RACOON **stays in alignment with the data security and privacy regulations** (J1, J3).

C-5. Building trust and relationship among members

C-5.E. Networking and maintaining strong relationships, even with competitors, is essential for sustaining continuity of the collaboration (I1).

C-5.Pr. Face-to-face communication positively impacts trust-building and relationships among members (I1, J3). In-person gatherings also increase energy and commitment (I1). For example, RACOON organizes sessions at conventions and conferences, which foster communication and help members build personal connections (J3). Similarly, openEHR members benefit from face-to-face meetings, which aid in resolving disagreements (I1). **Regular meetings** increase information flow and facilitate direct communication between members (J3). Additionally, an **online platform** enables ongoing member interaction (J3). **Ensuring transparency** further contributes to building trust (I1, I4).

C-6. Attracting new members

C-6.E. Attracting new members who align with project objectives is essential for ensuring the continuity and financial sustainability of OSS projects (I1, I4).

I1 shared these words: *"You need to have mechanisms for generating new money. It's challenging to keep the project going, and you can't always rely on old members. New ones must come in, and they have to be convinced to put money into the project."*

C-6.Pr. In both the openEHR and RACOON communities, the primary goal is to provide better medical care and improve patient health outcomes (I4, J3). Although companies may have economic interests, it is important that they do not act with avarice (I4). For an OS foundation to succeed, it must **strike a balance** that honors OS principles—including transparency and openness—while also considering financial sustainability (I1, I4). The inclusion of commercial entities in the consortium positively impacts resource generation and enhances service provision for user organizations (I1).

Outreach and marketing efforts are essential to reach and onboard like-minded individuals by **communicating the foundation's activities** (I4). Organizations familiar with existing projects are more likely to get involved. **Encouraging interested organizations** to use the technology and engage with the community also helps attract new members (I2).

I2 shared these words: *"The process of selecting and onboarding new members into the openEHR community is often driven by the existing projects and usage of the technology. When companies start using openEHR and experience its benefits, they naturally become interested in becoming part of the community."*

C-7. Providing an inclusive and open environment

C-7.E. Besides attracting new members, it is also essential to motivate them to engage in community (I2).

C-7.Pr. This issue can be addressed by providing new members with **comprehensive information** on the governance structure and regulations through resources like onboarding protocols, the website, and consortium wiki pages (J1). **A structured onboarding protocol** that clearly defines regulations can simplify complexities for the newcomers (J1). **Transparency about projects and processes**, along with open information-sharing with new members, is essential for building trust, fostering confidence, and encouraging active participation in projects (J1). **Recognizing success, appreciating contributors**, and offering them with opportunities to speak at conferences are additional practices that motivate members to engage in projects. Additionally, **explaining the impact of projects and sharing experiences within the community** are effective ways to attract new contributors (I3). In an open environment, even competitive vendors can share experiences and knowledge as long as the shared objective of **open standards** is maintained (I2).

I3 shared the following words: *"it's about celebrating collaboration, reflecting on what works well, and explaining why we're doing what we're doing. For example, if we're talking about care planning, we don't just discuss the data items needed for care planning. We also talk about what care planning is, how it makes*

a difference to humans, why we need to tackle it. It's about being explicit with clinicians and operational people, bringing the impact to life."

C-8. Ensuring transparency

C-8.E. Transparency helps in building trust among community members. Contributions to the foundation and its projects happen in different forms, including technical, financial, and intellectual support (I4). In collaborative efforts toward a common goal, it is essential to provide openness and transparency among members (J3). Transparency ensures that decisions are not made in isolation, information is communicated effectively and every member has the information they need for contribution (I4, J2).

C-8.Pr. To ensure transparency, openEHR **documents the foundations' decisions** and **keeps the community informed** about the roadmap and resource allocation (I3, I4). For instance, openEHR organizes annual meetings to share information about foundation's progress and status (I2). **Publishing meeting minutes and sharing related information** about specific topics—such as member responsibilities, contact details, and clinical content documentation—further supports information flow (I4, J3). Additional practices include **providing an open environment** where community members can engage in dialogue with board members (I3) and allowing interested members to attend subprogram board meetings (I3, J3).

C-9. Aligning with market needs and diverse data regulations

C-9.E. Alignment with market needs is essential for an impact and success on the market (I3). In the healthcare sector, foundations must stay informed about market trends and regulations (I1). Each country has distinct regulations, making it challenging to ensure data model compliance across borders (I1, I3). Deploying openEHR in different countries requires mapping between openEHR standards and the specific standards employed in clinics (I1).

I1 highlighted this problem: *"Addressing varying regulations and requirements in different international markets is a significant challenge. There's no one-size-fits-all solution in healthcare makes it even more complex. Healthcare systems, funding models, and regulatory frameworks differ greatly between countries. [...] These differences significantly impact the mindset of vendors and clinicians."*

C-9.Pr. Policymakers' involvement in the community is beneficial, as it allows the community to stay informed about data regulations and address specific requirements (I3). Another approach is to develop open-source mapping tools to **establish mapping guidelines**. Although these tools cannot accommodate all variations due to the diversity of needs, they can serve as a foundational basis. Industry partners can customize these solutions to meet the specific institutional requirements. The main focus in addressing this challenge is to **establish interoperability** and **create uniform standards** (I1).

5 Discussion

In openEHR, the membership structure includes both individuals and organizations; however, governance is driven by organizational members. Vendors pro-

vide financial support for the community and hold the majority on the governance board. The continuity of the foundation is important for them, as they offer commercial services based on the specifications provided by the foundation. User members in openEHR provide input for the specifications. On the other hand, RACOON only accepts organizations as member. Governance is led by user organizations, meaning that development direction and priorities are steered by the users organizations. Vendors work on platform development for a fee. openEHR needs to balance commercial interests with open-source values. In contrast, RACOON does not face this challenge, as its ultimate goal is to enhance research collaboration and gain deeper insights into diseases. RACOON is funded by the German Government, so there were no financial concerns as of 2023. openEHR, however, requires resources from its members to ensure sustainability and must balance the expectations of both user organizations and vendor companies.

Organizations engage in OS foundations for various reasons. In the case of openEHR, the primary motivation is the need for standardized data models. Another motivation is vendor neutrality, which motive is observed both in vendor-led and user-led OS foundations. For instance in the openKonsequenz case, one reason for users involvement was to eliminate vendor lock-in [5]. Vendors are motivated to offer commercial services around the OS data specifications. From the vendors' perspective, having standardized data models enables cost savings. In RACOON, the primary motivation is to create a platform that facilitates collaboration and data sharing. User members participate in this project to utilize the system in their clinics.

To address this study's second objective, we identified 32 governance practices across nine contexts. Seven of these contexts were utilized by both openEHR and RACOON in developing their practices, while two contexts were specific to openEHR. The first difference is the challenge of preventing any single company from dominating the foundation's governance. openEHR was initiated by a university and a commercial organization, and the community perceived the founders' dominance in the governance process. To ensure the foundation's health and sustainability, the governance structure was revised to become more inclusive and democratic by incorporating stakeholders from different membership categories. Tiered membership structure is also a reported practice in [17] to avoid domination of one single company in OS foundations. In the RACOON consortium, governance is collaboratively led by user institutions. None of the interview partners reported concerns about any member institution dominating the governance process. The second difference relates to adapting to market conditions and data regulations. This differentiation may stem from the scope of each foundation's activities: openEHR operates internationally and must adapt to varying regulations across countries, while RACOON is active only in Germany.

Common contexts include focusing on issues in-depth, facilitating mediation among diverse expert opinions, safeguarding data privacy and data security. Additionally, building trust and relationships among members, attracting new

members, providing an inclusive and open environment, and ensuring transparency are contexts investigated in the literature [3, 16].

6 Limitations

We have employed [22]'s trustworthiness metrics to evaluate our research. **Credibility** relates to the accuracy of research findings. We applied prolonged engagement over eight-months. The first and second authors held weekly meetings to discuss progress, including interviews, qualitative analysis, and reporting. Both authors independently analyzed all interview transcripts. **Transferability** refers to generalizability of findings. To enhance transferability, we used polar sampling, considering various dimensions. We investigated similarities and differences between these two cases. Seven out of ten governance contexts were similar for both of these cases, indicating potential for broader application. However, it remains for future work to determine whether these findings apply to other industries. **Dependability** determined by the traceability and reliability of the findings. To ensure this, we transparently report our research steps in the methodology section. Due to data privacy concerns, we did not share transcripts, however, we included interview quotations to support our findings. Furthermore, we referenced results using IDs for traceability. **Confirmability** refers neutrality and involves conducting unbiased data analysis. To avoid researcher bias, we used interview protocol. Two authors analyzed the interview transcripts by following thematic analysis guidelines and reached similar results.

7 Conclusion

This study had two objectives. First one was to explore the similarities and differences between user-led and vendor-led OS foundations in the healthcare sector. The second objective was to explore and define the governance practices applied in these foundations to achieve success. To address these objectives, we focused on two cases: openEHR and RACOON. We compared these cases by focusing on their membership structure, governance structure, and members' motivation to engage. To address our second objective, we identified 32 governance practices across nine contexts. These contexts include mitigating the domination of any single member, focusing in-depth on specific issues, facilitating mediation among diverse expert opinions, safeguarding data privacy and data security, building trust and relationships among members, attracting new members, providing an inclusive and open environment, ensuring transparency, and aligning with market needs and diverse data regulations. We explained each of the contexts, and applied practices in detail.

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