

## Governance and Sustainability of an Open Source Electronic Health Record: An Interpretive Case Study of OpenDolphin in Japan

Placide Poba-Nzaou<sup>a</sup>, Naoto Kume<sup>b</sup>, Shinji Kobayashi<sup>b</sup>

<sup>a</sup> Department of Human Resource and Organization, University of Quebec in Montreal, Montreal, Quebec, Canada

<sup>b</sup> Department of EHR, Graduate School of Medicine, Kyoto University, Kyoto, Japan

### Abstract

Electronic Health Records (EHRs) are at the heart of reforms aiming for improving the efficiency and quality of citizens healthcare services. Although there is still some skepticism, open source (OS) EHR is a growing phenomenon in health informatics. Given the widespread adoption of OS software (OSS) in several domains, including operating systems, and enterprise systems, the repeated shortfalls faced by healthcare organizations with dominant proprietary EHRs create an opportunity for other alternatives, such as OSS to demonstrate their abilities in addressing these well-documented problems, including inflexibility, high costs, and low interoperability. However, scholars have expressed extensive concerns about the sustainability of OS EHR. Recognizing that OSS project sustainability relies on their governance arrangements, this case study reports on the evolution of the governance and sustainability of a Japanese OS EHR project and provides rich insights to other open source EHR initiative stakeholders, including physicians, developers, researchers, and policy-makers.

### Keywords:

Electronic Health Records, Japan, Medical Informatics

### Introduction

In order to deal with the unsustainable increasing cost of health care, aging population, and chronic diseases burdening their population, all industrialized countries are investing in Electronic Health Record (EHR)[1]. However, Health Care Organizations (HCOs) have been slow to implement EHR in most OECD countries because of their high cost. In addition, the large majority of HCOs have adopted proprietary EHRs and are facing repeated shortfalls with those tools, including dissatisfaction with costs and interoperability issue [2]. This situation creates an opportunity for Open Source Software (OSS) to demonstrate its abilities in addressing those challenges. In the context of Japan, the Japanese Medical Association (JMA) estimated that EHR implementation costs in all medical providers would amount to US \$180 billion over a 10-year period, which is not affordable for Japan without a significant reduction in costs. JMA also suggested the implementation of OSS as one of the options to overcome the obstacle [3]. However, although open source projects have been launched at a rapid pace in a growing number of medical clinics and hospitals, scholars express extensive concerns about the sustainability problem [4]. Thus, it's paramount to understand the factors that may impede wide adoption of the open-source medical informatics tools.

Recognizing that OSS projects governance affects the project sustainability [5], we report on a case study of the governance and sustainability of OpenDolphin, a Japanese open source

EHR project. The source code can be found on GitHub: <https://github.com/dolphin-dev/OpenDolphin>. A screenshot of the OpenDolphin interface is presented in Figure 1.

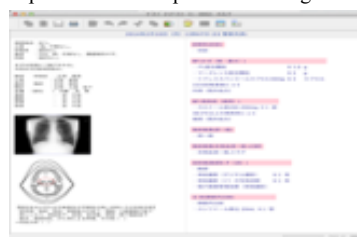


Figure 1— OpenDolphin Interface

This study was guided by the following questions: (1) how did the governance of OpenDolphin EHR evolve over time?; (2) how did the governance of the project enable or constrain OpenDolphin EHR sustainability?

### Conceptual Background

The framework is adapted from de Laat [6] three stages (see Figure 2) and Markus [7] governance dimensions ( e.g., vision and goals, ownership of the assets, etc.).

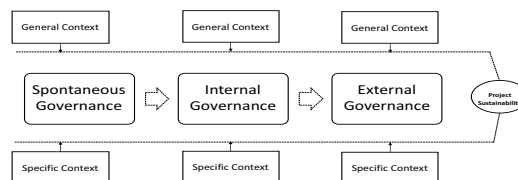


Figure 2— Research Framework

### General Context of Healthcare in Japan

Over the past decades, the Japanese healthcare system has been cost efficient and achieved significant progress in terms of life expectancy, infant mortality, and the eradication of communicable diseases [8]. Moreover, whole system reform has been undertaken in order to preserve its in the future [9], and the promotion of Medical ICT is one of the pivotal measures in the growth strategy of the Abe Government known as “Abenomics” [10].

### Specific Context of Medical Technology in Japan

In order to deal with the challenges associated with the countrywide plan of health IT diffusion, the JMA declared its intent to develop OSS as their “infostructure” in 2000. This momentum towards OSS has influenced the development of OSS projects in the medical field in Japan, including the OpenDolphin project. Overall, the adoption of EMR by medical

providers in Japan is imbalanced. Whereas the adoption rate is about 70% for large hospitals (>400 beds), it is below 14% for small hospitals (<200 beds) [11]. Thus, Japan lags behind when compared with other OECD countries. The prevalence of electronic health record in clinics in Japan is low and is estimated to be 16.5% [12] then about 30% [11]. Overall, the lack of financial resources is one of the most important barriers to EHR adoption [11].

## Methods

OpenDolphin EHR was developed within the Dolphin project. It's an open-source client system for regional health information systems as a response to the recognition of the inability of the Japanese marketplace to sustain the objective of 60% of diffusion of EHR in Japan within 5 years, as announced by the government [13]. The main contributor to the development of OpenDolphin is OS-Service Corp, a for-profit organization; and as of 2017, the system was used by over 300 clinics in Japan.

We relied on five sources of evidence: semi-structured interviews, written documents, a short questionnaire, and field notes from researchers. In addition, all research team members participated in a conference organized by the JMA and related to open health informatics in Tokyo.

In total 7 key informants from the OpenDolphin community were interviewed (see Table 1). In-depth semi-structured interviews were deemed appropriate for this study because it focuses on perceptions and meanings of informants [14]. The same interview grid was used for all interviews and covered questions related to the theoretical framework. Each interview lasted on average one and a half hour. During the interviews, the research team took notes that were later developed into detailed field notes. A short questionnaire was used to collect demographic and factual information.

Table 1—Informants Characteristics

| Name    | Role/Education       | ODolph | OSS | HIT |
|---------|----------------------|--------|-----|-----|
| Alpha   | (1), (2), (3), (4)/B | a      | a   | c   |
| Beta    | (1), (2)/B           | c      | c   | c   |
| Akyo    | (1), (2), (3), (4)/B | c      | c   | c   |
| Gama    | (5)/H                | a      | a   | c   |
| Delta   | (1), (2), (3), (4)/D | c      | c   | c   |
| Epsilon | (1), (2)/B           | a      | b   | b   |
| Zeta    | (2)/B                | a      | a   | a   |

Role: (1) project manager (2) developer (3) document creation (4) system administrator (5) sales representative

Experience (years): 0–5 (a), 6–10 (b), over 10 (c)

Education: H: high school, B: bachelor degrees, D: medical doctorate

Data analysis started as soon as data collection began and was conducted in an iterative manner, mainly based on the fundamental principle of the hermeneutic cycle [15]. Given that we aimed to understand the governance and its implication for the sustainability of OpenDolphin ‘through the meanings that informants assign to them’ [14], we read to get familiar with the collected materials. More specifically, interview transcripts were read by moving back and forth between the whole and parts of the studied phenomenon. In the same manner, interview transcripts were read between informant statements and the research framework. After several iterations, we applied data display techniques [16]. Then, a narrative approach was employed to describe the case in the form of a ‘narrative report’

[17] that helped us to develop an in-depth and global view of the OpenDolphin history, governance, and sustainability.

## Results

We draw on the conceptual framework to present the results.

### Phases 1 and 2: Spontaneous and internal governance

The development of OpenDolphin project began in 2001, following a tender launch by the Japan Ministry of Economy, Trade and Industry (METI) and targeting regional medical associations. In Japan, medical associations are built upon a three-layer model corresponding to the architecture of the country's administration [18]: the regional medical associations at the regional level, the prefectural medical associations at prefectural level, and the Japan Medical Association at the national level. All these organizations operate cooperatively, yet each and everyone has an autonomous structure.

The tender was awarded to the ‘Dolphin project’ led by a consortium formed by three universities (Miyazaki University, Kumamoto University, and Kyoto University) and one regional medical association (Tokyo Medical Association). They received a fund of 60 million yen—about \$570,000 US. One of the key reasons why the consortium won was that it proposed to adopt the Medical Markup Language (MML) for the Dolphin project, so as to facilitate the exchange of data between EHR systems within regions and beyond. In fact, MML was developed in order to generate a set of standards through which medical data, within Japan and hopefully internationally, can be stored, accessed, and exchanged among different physical locations [19]. The MML was created in Japan from research and funded by the Japanese Ministry of Health and Welfare [20].

*Vision and Goals.* From the outset, the OpenDolphin project's goal was to electronically emulate the user experience of the paper medical record at a low cost. However, instead of trying to simply achieve a high level of functional coverage, the goal was to create good user experience emphasizing simplicity, ease of use, and usability. In addition, OpenDolphin was envisioned to be compatible with different operating systems used by clinics in Japan. A statement from Akyo (a fictitious pseudonym given to the main contributor to the initial project) illustrates the vision: we wanted to have a ‘clinical user-oriented EHR with UX [user experience] resembling that of a notebook’.

*Ownership of the Assets.* The ownership of the asset was sealed by the grant awarded by the METI, which requires the research output and the software, to comply with a Bayh-Dole Act-like regulation adopted by Japan in 1999. The Bayh-Dole Act is a US federal legislation enacted in 1980 and co-sponsored by Senators Birch Bayh and Robert Dole. It allows universities, nonprofit research institutions, and small businesses to own, patent, and market any inventions resulting from federally funded research programs within their organizations [21]. Hence, the GNU General Public License (GPL) version 2 was the *de facto* choice.

*Software Development Processes.* The project started in 2000, following a requirement specification stage that took about half a year, which was followed by a software development stage with two full-time developers, including one senior (here identified as Akyo) and one junior and lasting about a year. Afterward, about six months later, the junior developer left the project and from then on, the senior developer took charge of all the software development tasks. The software was delivered to the research team in 2001 and was released to the public the same year. Another principle that guided the development of

OpenDolphin was “DIY (Do It Yourself)”. This principle stemmed from the fact that, according to Akyo, “there are various doctors with different needs, so the project needs to work as a platform on which DIY (Do It Yourself) offers solutions to the needs not answered by the project as-is when created”.

*Community Management, Leadership, and Finance.* During this first phase, Akyo was the only contributor for OpenDolphin. However, due to the newness of OpenDolphin EHR and the absence of a community of users and developers, it was adopted by 23 clinics. The revenue generated from the services related to adoption and the use was not enough to support Akyo as a professional software developer. He left and started to conduct small business activity. At that time, the fees for services related to OpenDolphin was entirely at Akyo's discretion. Meanwhile, four medical doctors from clinics that adopted OpenDolphin started to contribute to software development at a very high level of expertise, including developing new functionalities.

*Use of Information and Tools.* At this stage, the following tools were used: Repository: GitHub (dolphin-dev/OpenDolphin); Development tools: NetBeans, SourceTree, SublimeText, TeraTerms, BitBucket (only for certain parts of the software).

Given the small size of the community, only Twitter and Email were used to communicate with other actors. According to Akyo, during this stage, he was the only person who could answer the coming questions by email.

*Technologies and Translation Language.* The selection of technologies was guided by key principles, including high interoperability, freedom, and low cost. Hence, the following technologies were selected: database (PostgreSQL), development language (Java), application server platform Wildfly (JBoss), and client application (Apache MAVEN for XML). At this stage, OpenDolphin was available only in Japanese.

During this stage, the OpenDolphin project accomplished some achievements that confirmed its position as a promising open source EHR: (1) the successful connection with ORCA (Online Receipt Computer Advanced) system in 2001; (2) the release of a MacOS version in 2006; (3) the launch of an ASP service in 2007; (4) the achieved compatibility with the iPhone and the iPod Touch in 2009.

### Phase 3: External governance

As of 2009, OpenDolphin has a small community of developers, users, and support providers. The same year, OS-Service Corp, one of the support providers who have been involved with OpenDolphin for few years, suggested cooperating with Akyo for the aim of “scaling up the services related to OpenDolphin”. Thus, Akyo joined OS-Service Corp and the OpenDolphin project moved from a community-managed to a corporate-managed governance model. Since assuming responsibility for OpenDolphin formal governance, OS-Service Corp has been taking or planning to take new initiatives aimed at developing and sustaining the OpenDolphin project and products.

*Vision and Goals.* OS-Service Corp is planning to create an EHR with a combined hospital management system (HMS). According to Akyo, historically, HMS has been the foundation upon which the EHR system is installed. He indicated that they are considering the opposite, in other words, to have the EHR as the foundation system, and implement the HMS functionality on top of that.

*Ownership of the Assets.* In the meantime, the license had been moved from GNU General Public License (GPL) version 2 to GPL version 3. In order to develop its business, OS-Service

Corp created a new version of OpenDolphin named OpenDolphinPro, a more commercial version that is also distributed under GNU GPL license. OpenDolphinPro is packaged with services provided by OS-Service Corp.

*Software Development Processes.* With the arrival of OS-Service, the software development team increased to eight with four internal developers within OS-Service Corp and four medical doctor users who contribute actively at a very high level of expertise.

In order to improve the sustainability of the OpenDolphin project, OS-Service Corp is moving from JBoss AS (Application Server) 6 to server 7. In fact, the development of JBoss AS 6 has been stopped. JBoss AS 7, now known as WildFly, is a complete rewritten server that is faster and easier to configure. With the intention of reducing the risk related to this technological transition, OS-Service Corp has partnered with Red Hat Corporation in Japan in order to use their deployment methods and development environments as references. In addition, OS-Service Corp has introduced an agile development method to improve the efficiency, as stated by OS-Service Corp manager: “We are employing an agile development method where the project manager goes through the details of every request, and uses them to assign required members to do the development. Because of this, we do a much faster implementation than development, based on the waterfall model”.

OS-Service Corp has also implemented a formal process for handling requests from clients. There is now a dedicated customer support division that collects detailed requests from the users, and passes the requests on to the development division after deciding on the design through meetings. The new functionalities ensuing from these endeavors are generally implemented in OpenDolphinPro and released as minor updates. Thereafter, these functionalities are integrated into the regular OpenDolphin version.

Base on their experience, the OS-Service Corp team stated that “having the software always up to date is ideal. However, given that OpenDolphin differs from web applications (in the sense that clinics have source code updated at different levels), there is a need to consider the special circumstances from each individual clinic”. In order to properly manage this situation, the decision to update the software for a clinic is made by the customer support division based on the assessment of each clinic's environment and structure.

*Community Management, Leadership, and Finance.* At this stage, the number of resellers nationwide is increased to 27. The OpenDolphinPro sold by reseller is packaged with services provided by OS-Service Corp. Since the initial release, OpenDolphin has always been sold by salespeople who directly visit the target clinics. However, according to OS-Service Corp, from this point on, the company will put more emphasis on the cloud version of OpenDolphin. Accordingly, the company is switching to a digital strategy and expecting to sell faster than the past. In fact, between 2009–2016, with one sales executive, OS-Service Corp was selling at a rate of 30–40 clinics per year through clinic visits and sometimes 50 clinics a year. The sales target of the cloud version is set at 100 per year. It's worth mentioning that the sales executive has left the company and since then, OS-Service Corp is struggling to attract new clients.

At this stage, it important to mention that, OS-Service Corp is just above the break-even point and the management team is taking various initiatives with the expectation to depart from that. The break-even point is reached when a company's total costs equal its total revenue.

The management of OS-Service Corp has come to realize the need to create a partnership with various actors in order to

increase its community at large. One of the initiatives planned is to connect with the Medical Open Source Software (MOSS) meeting held twice a year in Japan which brings together medical informatics experts, advocates, and supporters.

*Use of Information, Communication, and Tools.* The tools in use at this stage are the same as the previous one. Repository: GitHub; Development tools: NetBeans, SourceTree, SublimeText, TeraTerms. Whereas the OpenDolphin version is managed on GitHub, the OpenDolphinPro is managed on OS-Service Corp premises.

*Technologies and Development Language.* As stated earlier, OpenDolphin client was written with Java but the client rewritten in JavaScript. This initiative stems from the fact that JavaScript is primarily a client-side scripting language designed to run in the internet browser without having to be compiled like Java. In addition, OS-Service Corp is planning to add artificial intelligence (AI) components in OpenDolphin. Regarding to language translation, OS-Service Corp is planning to develop an English version of the software so as to move into the international market and extend its market reach.

During this stage, the OpenDolphin project made some achievements that confirmed its position as a promising open source EHR: (1) the release of a comprehensive documentation named OpenDolphin Perfect Guide in 2016; (2) the release of three iOS apps (DolphinPro, VisitTouch, Super EHRTouch); (3) the launch of authentication based on SSO (Single Sign-On); (4) the establishment of compatibility with iPads in 2010; (5) obtaining the status of certified partner solution for IBM Japan in 2011; (5) the completion of connection between ORCA and OpenDolphin cloud solution in 2013; (6) the celebration of the 10th anniversary OpenDolphin cloud ZERO (pay-as-you-go system) in 2014.

Among the most important achievements is the fact that, even if OpenDolphin EHR was at first targeting medical clinics, it has successfully expanded its market share from small hospitals.

## Discussion

Open source software is recognized as a growing phenomenon with a promising potential in the medical informatics field. Nonetheless, scholars have expressed extensive concerns about open source software sustainability [4]. Although the body of knowledge related to open source in health informatics has kept growing, there have been few empirical investigations of open source clinical information systems in the context of industrialized countries outside of the western world. Our study reports on an empirical instance of open source EHR that is developed and used in an industrial country outside the western world. It contributes to deepening our understanding of the governance evolution of OS EHRs and how it enables or constrains the sustainability of the OS projects. Our results reveal that the model provided by de Laat [6] is useful in explaining the evolution of the governance of OpenDolphin. However, we are able to match only two phases out of the three suggested by the model, as the first two phases are difficult to separate in the case of OpenDolphin.

Our data reveal that the turning point from the “spontaneous and internal” governance phase to the “external governance” was triggered by the concern about the sustainability of OpenDolphin. In fact, by the time Akyo received OS-Service Corp’s offer, he had already noticed the ineffectiveness of the governance model, even though the main concern of OpenDolphin during the first phase was related to the inefficiency of the business model.

Watson and Boudreau [22] distinguished four different business models of OSS production or distribution: open community, corporate distribution, sponsored OSS, and second-generation OSS. Open community is a model for which the development and support of the software mainly rely on volunteers with limited commercial interests, while corporate distribution is a model that takes advantage of quality products developed by open community models, “improving distribution methods for these products, and providing complementary services in order to make these OSS products more accessible to a broader market.” [22]. Examples of such models include RedHat and SpikeSource. Sponsored Open Source is models of OSS projects sponsored by corporations or foundations or both. Examples of such models include Apache Web Server with Apache Foundation and Eclipse with IBM. The second-generation model is also known as professional open source—is composed of firms that are considered hybrid because their models are between a corporate distribution and sponsored OSS. Of note is the fact that second-generation firms “typically own or tightly control the software code and can exploit their intimate knowledge of the code to provide higher-quality service that could potentially competing service providers” [22]. Examples of such open source projects include MySQL and JBoss.

The deal with OS-Service Corp had an impact that went beyond the business model and *de facto* induced new governance arrangements. The analysis also reveals a high degree of dependency between the business model and the governance model. It also suggests that, during the first phase, OpenDolphin was a technological success but not an economic success. Of note is the fact that, during the first phase of governance, the community of software developers has never really grown beyond Akyo. One possible explanation might be that there were few initiatives undertaken to attract contributors. OS-Service Corp brought the needed resources to sustain technological success and convert it to economic success. Our data reveals that the involvement of OS-Service Corp has altered the “business model” of the OpenDolphin project, moving it from “open community” to “sponsored OSS project” as explained below.

At the beginning of the third phase, OpenDolphin has experienced rapid growth by attracting a large number of clinics each year (30–40 per year through clinic visits). However, since the departure of the sales executive who was in charge of sales, OpenDolphin growth has been stagnant, despite sales activities being managed by OS-Service management. Even if the stagnation can be partially attributed to the departure of the sales executive, OS-Service management feels the need to make some changes in the way they deal with their main market segment formed by a medical clinic. In fact, OpenDolphin situation is surprising for at least five reasons: (1) the OpenDolphin EHR seems to be appreciated by medical doctors who are using it; (2) the market has a great potential for growth due to the low rate of adoption of EHR by medical clinics in Japan (about 30%); (3) the rate of adoption of EHR by newly opened clinics is high (about 80%); (4) the choice of OSS by the Japan Medical Association as their “infrastructure” in 2000 and the release of ORCA, an open-source software used by medical clinics in Japan, has created a fertile ground for OS to expand at least in primary care organizations; (5) OpenDolphin was created as part of a project led by regional medical associations, which gives it a certain level of proximity to the medical field in Japan.

Going back to the stagnation of the OpenDolphin growth, our informants identified a characteristic of the local market that may explain why OpenDolphin, a product that meets the needs of medical clinics and does so at a low cost, is struggling to

attract newly opened medical clinics, knowing that the cost is one of the main barriers to the adoption of EHR by small hospitals and clinics. In Japan, a consultant on behalf of a medical doctor usually handles the process of opening a new clinic. Since consultants' fees are calculated as a percentage of the total costs of the project, including the costs associated with the acquisition of an EHR, consultants may have the tendency not to recommend OpenDolphin because of its low cost.

In order to strengthen the sustainability of the OpenDolphin project, the management at OS-Service Corp has decided to put more emphasis on the OpenDolphin cloud and digital marketing, with the aim of attracting more medical clinics. The management team seems to recognize the limitation of both the current business and the governance models. The initiatives they are undertaking may substantially alter the governance and the business models, hence the question arises as to whether other options may exist, in terms of governance models and other business models from which OpenDolphin can choose. When contrasting OpenDolphin characteristics with the four open source business models suggested by Watson and Boudreau [21], it's illuminating to recall that OpenDolphin goes through two of them (the community model and Corporate Distribution model). Given that the Second-Generation allows the firm to own or tightly control the code source, this option does not apply to OpenDolphin because of the characteristics of the GPL license. Hence, within our theoretical background, the only remaining option is the Sponsored model. If OpenDolphin has to become a sponsored project, OS-Service Corp may become the corporate sponsor in the first case or be associated with a foundation in the second case. Each of these options will allow OS-Service Corp to share the costs of developing new functionalities.

Overall, the governance of the OpenDolphin project has evolved as a consequence of the alteration of its business model so as to strengthen its sustainability. However, the results appear to be mixed. It does not seem easy for OS-Service Corp to handle, by itself, all the challenges faced by OpenDolphin. Our study reveals that it is not only the management of OS-Service feeling the needs, but also some of the elements are already in place waiting to be highlighted and combined in order to create an OpenDolphin ecosystem that will help strengthen its sustainability. This ecosystem may include OSS experts, advocates, and supporters among both health IT decision makers and Health IT policymakers.

## Conclusions

Our results indicate that governance does enable or constrain the sustainability of OpenDolphin but, considering the business model also provides a broader understanding of the sustainability of the OSS project. One of the main limitations of this study is related to the methods, this is an interpretive single case study. Thus, caution should be exercised in interpreting these results in other contexts.

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## Address for correspondence

Placide Poba-Nzaou

email: [poba-nzaou.placide@uqam.ca](mailto:poba-nzaou.placide@uqam.ca)