UNIVERSITA' DEGLI STUDI DI PADOVA

DIPARTIMENTO DI SCIENZE ECONOMICHE ED AZIENDALI "M. FANNO"

CORSO DI LAUREA MAGISTRALE IN ENTREPRENEURSHIP AND INNOVATION

TESI DI LAUREA

"BUSINESS MODELS AND ECOSYSTEMS FOR PATIENT SUPPORT PROGRAMS: A COMPARISON OF CURRENT EXPERIENCES IN ITALY"

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ANNO ACCADEMICO 2022 – 2023

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ACKNOWLEDGMENT

I would like to dedicate this space to the people who contributed to the realization of this dissertation.

To my thesis supervisor, professor Marco Ugo Paiola, as the person who not only helped me throughout this last work, from topic selection to completion, but also as the person who profoundly influenced me and my professional career thanks to his inspiring classes and extracurricular activities.

To my parents who have always been there for me, supporting my every decision, despite the ups and downs we have experienced in recent years

To all my friends, colleagues, and my partner for pushing my limits even when circumstances and time (and to be fair, sometimes also my laziness) were particularly difficult to manage.

Finally, I want to congratulate myself, my sacrifices, and my resiliency over the years for allowing me to reach this important milestone, proving that one's hard work and the time invested will never betray them.

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ABSTRACT

Identifying the correct business model and joining an ecosystem can bring several advantages for both the companies and the society likewise. This research is meant to provide in-depth information and insights on the main challenges that are currently affecting the Italian PSP market, and how an ecosystem approach based on a service platform business model could help in addressing said issues. In this dissertation two case studies, the externalized and internalized business model for patient support programs, have been conducted and confronted with each other from a value creation and value capture point of view by outlining the respective design and development process of a PSP. This enable us to highlight the root causes of the current market inefficiencies represented by the weak intercompany relationships, as well as how said weakness impacted the overall value proposition delivered to patient and healthcare professionals alike. However, the regulatory framework represents another major contributor for the current situation, suggesting that significant changes are required in this field as well.

INTRODUCTION

Over the last two decades, the pharmaceutical industry has experienced plummeting R&D productivity (New York Times in Cockburn, 2006). In fact, despite the spike in investments made in developing new drugs and therapies, the return on investment didn't experience a similar level of increase; rather, it became more and more difficult to develop new solutions that could meet regulatory obligations on the one hand, and the same level of output that the industry used to provide years before on the other (EFPIA, 2020). Moreover, with increasingly demanding customers due to the technological developments that have made it easier for patients to access health-related information, patients are advancing rising demand to be involved during the development stages of new therapies and solutions, and have their feedback seriously taken into consideration by the involved actors (Singhal and Carlton, 2019). These variables pushed companies to make a drastic change in their traditional way of doing business, towards the adoption of new business models that would embrace more transparent and patient centric approaches, and this is how Patient Support Programs (PSP) were developed (Brixner *et al.*, 2019).

With the aim of reducing one of the major public costs, that is provided by patient's non-adherence to therapies (AISM, 2021), especially those where the result and benefits comes by long and constant medication and monitoring (Wallance et al., 2020), patient support program were developed to address the root cause for these expenditure by significantly increasing therapy adherence and patient's quality of life.

However, many challenges have been raised in front of the interviewed industry related companies as no clear role and responsibility boundaries have been defined, leading to a situation where many market failures and agency costs are taking place, slowing down the diffusion of this new concept of the PSP, although its efficacy has already been proven many papers (Brixner *et al.*, 2019). Thus, the aim of this dissertation is to provide an in-depth analysis of the current challenges that companies in the PSP industry are facing by means of a qualitative analysis based on an empirical research conducted over several interviews to companies in the Italian market, and how an ecosystem approach based on service platform business model could serve as a guideline for how the numerous interactions among stakeholders should unfold. Nevertheless, significant steps need to be taken also in the regulatory framework for both PSPs themselves (Kayaalp, 2018), which as of today there are none at national level (Giambelluca,

2021), and in terms of general data protection issues, since data breaches are one of the most challenging problem that's is affecting all the industry (*The History of Data Breaches*, 2022).

This research is divided into four chapters. The first chapter provided a comprehensive description of the current market situation by highlighting existing market inefficiencies on one hand, and the main trends affecting the pharmaceutical industry on the other, such as patient centricity, value-based healthcare systems, the opportunities provided by technological development, as well as the new challenges that they brought about, and how all of these must be defined through new business models and approaches in order to truly provide and capture the value proposition that companies promised to deliver through their PSPs. Following, in chapter two the methodology being adopted for this research and the reason why it represents a good approach to this topic is outlined. Here, the analysis of the two case studies that have been conducted in order to provide empirical information and credibility to the research. Moreover, for each model the respective pain points have been listed based on the current approach for the design and development of the PSPs, as well as the opportunities provided by an ecosystem approach to address the issues being analyzed. In chapter three, the main findings from the case studies are reorganized in sequence and additional discussion about the causal effect of each topic emerged during the analysis is provided. Lastly, in chapter four a summary of the content of the research has been outlined, and it tries to offer suggestions for future research to complement the present one, and to provide more credibility on the emerged findings.

CHAPTER 1. THE PHARMACEUTICAL INDUSTRY: THE CURRENT STATE AND FUTURE PROSPECTS

1.1 Overview of the pharmaceutical industry

The driving forces of technology development are opening up opportunities for companies to develop and experiment with new business models and value propositions for their customers. This change of pace has also influenced the pharmaceutical industry, which is entering an era of medicines development driven by the possibilities offered by personalized medicines, and the potential offered by harnessing the power of big data (EFPIA, 2020). However, the pharmaceutical industry is facing additional regulatory hurdles compared to other sectors in terms of the range of information and promotional actions that can be conducted on their products and services, and the collection and usage of patient data (Farmindustria, 2022). On top of that, there's also an issue about the lengthy (on average 12-13 years) and costly (estimated to be around €1,9 mln in 2014) R&D process that medicinal products have to go through until they become marketable while considering also the 20 to 25 years of patent expiry term (EFPIA, 2020). The combination of these elements leads the pharmaceutical companies to develop a need to differentiate the value proposition for their customers, which, in combination with the emerging technologies, translates into reshaping the healthcare industry under different aspects such as the way consumers can access it, how and which provider delivers it, and what health outcomes it achieves (Singhal and Carlton, 2019).

According to a research conducted by Singhal *et al.* (2020), one of the main industry-level changes that could disrupt healthcare value proposition is the creation of an intuitive and personalized ecosystem centered around patients, where healthcare professionals would be then integrated. The importance of creating a thoughtful ecosystem for the healthcare industry rises from the need to effectively integrate the contribution coming from a multiplicity of actors which, according to the WHO (*Health Systems Governance*, n.d.), can be classified into three main categories, namely: the State, referring to governmental institutions and agencies; the Health service providers, who are both public and private clinical, non-clinical and para-medical service providers; and lastly, the Citizens, representing the general population that are in need of any type of medical care from providers. However, as the industry experienced a significant expansion over the years, new actors (mainly IT related players) are joining the network by adding from on hand undeniable value and room for improvement to the healthcare industry, but at the same time, it increases the difficulty to reach a better coordination among parties to answer people's need for a faster and more personalized way of care (Hoffman and

Cole, 2018). Therefore, the importance of establishing a well-functioning healthcare ecosystem, which should begin by identifying a comprehensive set of actors, and giving them clear roles and expectation, so that it will be possible to deliver the right type and amount of care, in the right place, at the right moment (Singhal and Carlton, 2019).

1.1.1 Current market inefficiencies in the pharmaceutical sector

The current pharmaceutical sector is characterized by several market inefficiencies which are increasing the toll on this industry productivity crisis. The first indicator of said recession can be discerned from the ratio between output over input, which in this case can be defined as the number of drugs approved over the R&D expenditure. In fact, according to New York Times in Cockburn (2006), while R&D investment in the pharmaceutical industry have more than doubled, the number of new treatments that the Food and Drug Administration (FDA) has approved decreased by more than half between 1996 and 2005 (Figure 1).

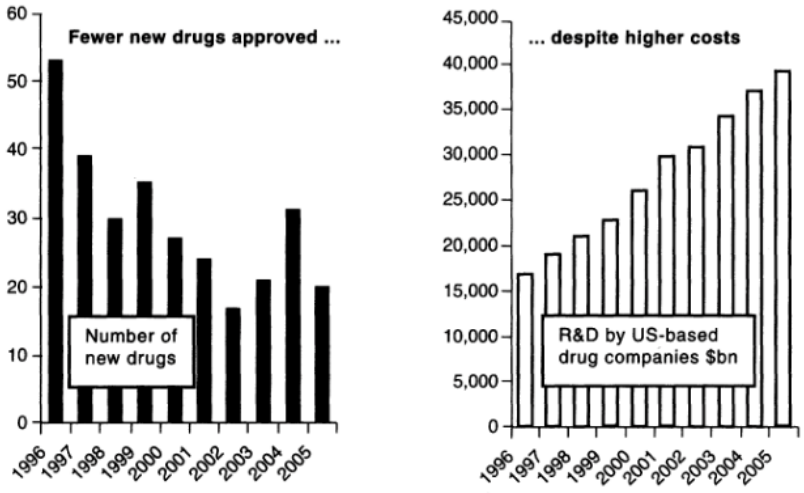

Figure 1 The productivity crisis (New York Times' graphical display of data in Cockburn)

Similar results are shown in a survey from The Economist in Cockburn (2006), where the global industry R&D spending increased from $30 billion per year in 1994 to $54 billion in 2004, while drug launches have decreased from 40 to 26 per year during the same time span.

However, this index for measuring the productivity of the pharmaceutical industry is very approximate, thus it's not a good representation of the real industry productivity. For instance, it doesn't take into consideration: the "quality-adjusted output", to measure the potential rise of the value of new drugs to consumers in terms of their impact on human health or by consumers' willingness to pay; nor the inflation over the years, reflecting the fact that the real R&D expenditure has not risen as fast as its nominal counterpart; or even the fact that an increase in R&D might be a good sign as it shows that business has responded favorably to the rapid

advancement of technology; or simply it may represent the increasing focus on more challenging diseases (Cockburn, 2006).

Nevertheless, many empirical researches show actual evidence of a long-term decline in R&D output from innovative activities in many industries, including the pharmaceutical sector (Pammolli, Magazzini and Riccaboni, 2011), which, in addition to the rising cost of each newly approved drug, is a severe cause for concern, particularly when it is due to agency costs, and the late-stage cancellation of drug development projects (Cockburn, 2006). For instance, in accordance with the industry's standard operating procedure, consumers only pay for a drug or treatment if its development is successful, while the pharmaceutical companies assume all of the risk of a failed development (Levy and Rizansky Nir, 2008). According to this approach, pharmaceutical companies would incur losses if they invested in the development of medications for diseases with a tiny patient population. As a result, these drugs are not produced despite the fact that they could represent a lifesaver for those smaller populations of patients (Levy and Rizansky Nir, 2008).

According to Cockburn (2006), there seems to be some agreement among the scientific community in industry about why the failure rates of new drugs development are so high and how they might be reduced. The main reasons for those high failure rate can be linked, among others, to poor communication and lack of interaction with regulators, lack of cooperation in precompetitive and preclinical research, excessive secrecy, data hoarding, and attempts to obtain exclusive rights to basic research tools and data. Whereas, the possible solutions to those problems could be identified by simply overcoming the before mentioned critical factors, like developing better mechanisms to incentivize collaboration between industry, government and academia through a "profit divide" approach, or through the deployment of advanced information technologies which creates the opportunities to generate and collect greater amount of data that can be then leveraged on by developing better predictive analytics (Cockburn, 2006). Moreover, according to Cockburn (2006)'s opinion, the most alarming finding was the one coming from Kola and Landis study, in which it has been reported that the main cause of drug development failure is attributable to the economic problems, consisting in "prohibitively high manufacturing costs, and unspecified 'commercial' reasons" (Cockburn, 2006, p. 19), which share of failure increased from a 5% in 1991 to 30% in 2000 (Cockburn, 2006).

Overall, a low R&D productivity would jeopardize the entire pharmaceutical industry's business model if left unattained. In fact, Paul et al. in Mahlich, Bartol and Dheban (2021)

believe that if the current business model is preserved, it would require a drop of 50% of current cost per new chemical entry (NCE) to make it a sustainable model.

1.1.2 Patient centricity: moving to a holistic approach of care

What has been made clear in the previous paragraph is that the value for the money in biological research is clearly declining (Cockburn, 2006), and if no attempts are made to change the current state of art then the traditional business model being used will become obsolete much faster than expected.

In addition to this increasing pressure coming from the larger economic factors, there is another important trend that is currently affecting the industry, that is a direct consequence of the constant technology improvements which is allowing people, and in particular the patients, to have better and easier access to the information they want to seek (Du Plessis *et al.*, 2017). As a result, the importance for the pharmaceutical companies to take into consideration patient's opinions is becoming one of the major pillars in building trust with their audience. Additional evidence to this shift in the social landscape is proved by the increasing requests by regulatory agency (such as in the Food and Drug Administration (FDA) and the European Medicines Agency (EMA)), academia and healthcare providers, to incorporate patients' inputs throughout each step of the design and developments of new drugs and the decision-making process for the development of novel patient journeys (Du Plessis *et al.*, 2017).

This denotes a change in the focus from disease-centered to patient-centered approaches. In fact, as mentioned by Du Plessis *et al.* (2017), historically the pharmaceutical industry was focused on developing science and medicines for disease prevention and/or disease medication, whereas now, the focal point shifted to projects that will increase the effect and value for patients and caregiver as a consequence of seeking out a more holistic and patient-centric solution.

This being said, to thrive and create a true patient-centric strategy, pharmaceutical companies are required to clearly define their purpose and vision in order to generate alignment both internally with its own employees and externally with the many other stakeholders involved (Du Plessis *et al.*, 2017). Then, a feasibility study needs to be performed to understand how sustainable it is in order to not aggravate the already declining R&D productivity in industry. Although, it would be fair to remind that the initial investment required from this industry-transformation will follow the cyclical pattern found by Schumpeter (1939) in his S-curve

theory, where it is expected that marginal returns will be initially modest, to increase significantly as the new paradigm takes off, and eventually become flatter again as it approaches maturity stage (Cockburn, 2006). This dedication will in turn help to establish credibility with external stakeholders, such as patients and regulatory agencies just to mention a few of them (Du Plessis *et al.*, 2017).

1.1.3 Four main challenges for patient centricity in the pharmaceutical industry

Additionally, according to Du Plessis *et al.* (2017) to properly integrate patient centricity, four primary issues must be addressed, starting from a change in the industry's cultural mindset, followed by implementing practices to increase public trust. Then, the challenge would be creating the condition to incentivize openness to learn from others in addition to both vertical and horizontal collaborations, and last but not least, a standardized framework to measure success.

As previously mentioned, pharmaceutical companies are experiencing a change in the focus from disease-centered to patient-centered approaches, which in other words means to change the way this industry is creating value and capturing it. Now, the focal point shifted to projects that not only will provide more effective and efficient care, but also enhance the whole end to end customer journey experience for both patients and caregivers. But this shift in mindset refers also to a changed from a product-led to a patient-led development process, that can be achieved only if it starts from the highest levels of the organization by redefining the whole strategy and operational processes, and making it as transparent as possible to satisfy the needs from patients and other stakeholders likewise (Du Plessis *et al.*, 2017). The commitment required to the pharmaceutical industry is to actively involve, listen to and partner with the patients, instead of simply finding a way to fit the patient into their already established solutions retrospectively (Du Plessis *et al.*, 2017).

Another point that the pharmaceutical industry needs to pay special attention would be that of building trust. By establishing a clear communication regarding the trade-off between risk and benefits for each medication, and a transparent procedure for drug development which proactively involves and captures patients' needs, as well as regulators and pharmacovigilance challenges, can help to build trust between the pharmaceutical sector and the public opinion as a whole (Du Plessis *et al.*, 2017). But to improve the credibility and therefore trust with third parties, especially other organizations, a common ground and framework need to be developed,

while avoiding going astray from the main goal of maintaining a patient centric approach. And that is achieved by establishing a standard endpoint measure to facilitate and to promote a healthy and meaningful way of vertical (between patient, regulators to mention a few) and horizontal (between companies) comparison (Du Plessis *et al.*, 2017). In fact, as Du Plessis *et al.* (2017) mentioned, currently there's a consortium of representatives from pharmaceutical firms, regulatory agencies and government, who are working together by sharing data to develop standardized patient-reported outcomes (PRO) metrics. Those metrics are defined by the FDA in Du Plessis *et al.* (2017) as:

> *"any report of the status of a patient's health condition that comes directly from the patient, without interpretation of the patient's response by a clinician or anyone else".*

Finally, alongside the previous point, Du Plessis *et al.* (2017) suggest that learning from the existing best practices of other organization that have already experienced this co-creation of value for and with the patients themselves, and collaborating with said organizations is a far better strategy then working individually to gain additional insight to lead the industry through this transition towards patient centricity. In fact, as mentioned in Du Plessis *et al.* (2017)'s paper, there are already several partnerships and ongoing collaborations between public and private stakeholders in the pharmaceutical industry to guide and share best practices for better interaction between patients, pharmaceutical firms, and healthcare providers.

Overall, patient centricity can only be achieved through a coordinated effort between many different stakeholders who need to work in synergy and avoid duplication of effort, silos mentality, and excessive data hoarding (Cockburn, 2006), which could become increasingly counterproductive for the rebuilding of the industry's reputation (Du Plessis *et al.*, 2017). Thus, the importance of sharing not only best-practices among peers, but also data collected throughout the journey to develop solutions that could better address patients' needs thanks to more accurate data analytics practices. This situation, where the failure of even a single link of the chain may undermine the collective effort of all the other players (Adner, 2016), represents the precondition in establishing a meaningful and highly effective ecosystem, where it's important for each individual subject to define and find a clear role and responsibility in this new industry's environments (also discussed later).

1.1.4 Value-based healthcare system

If patient centricity denotes a shift from disease-centered to patient-centered approach, in which the value proposition of healthcare organizations revolves around the design of the "solutions" centered, for instance, around the patient and therefore the concept of a "patient journey", a value-based healthcare approach focuses specifically on the notion of "value". A value based exclusively on the health outcome relative to the cost of getting said results, which is a patient's single and foremost desire (Putera, 2017), rather than treating health as a commodity to be sold and exploited by selling the most amount of it (Catalyst, 2017).

The type of outcome desired by a patient, according to Porter in Putera (2017), reflects the point of contact of three dimensions. The first is provided by the achieved health condition, which refers to functional status. Then there's the dimension of care and recovery, which includes readmission and the time required to resume normal activities. Whereas the last dimension is about health sustainability, both in terms of economic affordability and of mental energy depleted by lengthy therapy. This means that health providers should thrive to achieve all three aspects of a "good patient outcome", and not become complacent with a single one of them.

To achieve this kind of healthcare delivery model, health providers and other stakeholders must make significant changes, such as defining the processes to ensure true health outcomes, constructing interconnected health systems, enabling health information technologies, and developing policies that incentivize this change (Putera, 2017).

1.1.5 Conceptualization of Patient Support Programs (PSP)

As the industry trend moves toward a customer-centric business model and logic, and given the increasing pressure for a more affordable healthcare system, pharmaceutical companies have to demonstrate value propositions that go beyond clinical efficacy. This is even more relevant if we consider a specific category of diseases, such as chronic conditions, degenerative diseases and rare diseases, where, from one side, patients have to go through longer periods of therapy (Wallance et al., 2020), and from the other side, companies need to meet their economic targets despite the tiny patient population, without compromising the quality of the service provided (Levy and Rizansky Nir, 2008). In addition to that, data shows that about half of patients do not take their medications as prescribed due to the typical long-term management of chronic therapies, which results in poor clinical outcomes (Brixner *et al.*, 2019). This underwhelming therapy adherence represents a significant variable bearing the risk of further disease

complications, a lower quality of life, and higher overall health care costs (Shillington, Ganjuli and Clewell, 2016).

Over the years numerous techniques have been put in place to improve patient outcome, including motivational interviews and education programs, but as any relatively new approach, they are going through deeper analysis since there are still many areas for improvement, despite the fact that they have been shown to enhance patient's quality of life (Christie and Channon, 2014). More recently, pharmaceutical companies have adopted a new solution given by the conceptualization of the Patient Support Program (PSP) (Brixner *et al.*, 2019). A PSP is defined by the Farmindustria's Code of Conduct (2022) as:

> "*an initiative that has as its purpose the provision, by the pharmaceutical company, of additional services and not substitutes to those of the institution or the NHS for the direct benefit of the patient being treated with a specific medicine already authorized for placing on the market*"

These programs aim to increase the therapy adherence of patients under treatment for specific diseases such as multiple sclerosis, Parkinson's, chronic diseases or any other highly debilitating illnesses where treatment benefits may not be immediately felt by patients (Wallance et al., 2020). Medication non-adherence is one of the main reasons for therapy failure while generating also a health and social cost, which in AISM (2021) is reported to be around €125 bln in Europe spanning through hospitalizations, emergency care, and outpatient visits. Given the recent economic downturn that this industry has experienced, by reducing those costs the pharmaceutical industry as a whole would experience a non-insignificant boost, both in terms of efficiency of therapies and in resource allocation throughout the entire network. That being said, and despite their fairly new adoption, patient support programs have been shown to significantly improve therapy adherence for enrolled patients compared to a non-PSP cohort, as well as reduce therapy discontinuation, which includes both switching to another treatment and the discontinuation of any therapy (Brixner *et al.*, 2019). Furthermore, the same study conducted by Brixner *et al.* (2019) revealed that disease-related medical costs were substantially lower for those enrolled in a PSP compared to non-PSP patients.

Overall, improving patient adherence could result in lower medical costs and significant progress toward a value-based care approach, which, when combined with another major trend that permeates current years, such as digitalization and digital transformation, will reveal better

opportunities, and the creation of more holistic patient care will no longer be a distant vision, but rather a real contingency to embrace right now. While doing so, the only adoption of the new technologies is not sufficient to create and sustain the value proposition embedded in the patient support programs. Instead, a truly efficient PSP requires a highly connected network where the major players of the pharmaceutical industry could find a trusted environment where current market inefficiencies may be avoided (Du Plessis *et al.*, 2017).

1.2 Digitalization and data strategy's impact on a value-based healthcare system

Because of continuous advancements in fields such as cloud computing, AI, and many other computer science-related disciplines, society is becoming increasingly digitalized and connected. However, people remain skeptical about this change which may be caused by the poor design and performance and lack of true scalability of early systems (Bart, 2003), making the degree of digitalization and the benefits that comes with it a slow process.

Digital technologies are based on code, which can be easily changed, updated, or fixed without physically touching the machine. This adaptability and flexibility has accelerated the process of connecting people to machines and vice versa, opening up a plethora of new opportunities for companies to exploit and disrupt existing industries (Dufva and Dufva, 2019). The transition to a computational information society can be viewed as a shift toward an era in which what is considered digital is completely integrated into people's daily lives, like the smartphones, wearable devices, and the Internet of Things in general (Dufva and Dufva, 2019).

The integration of digital technology into all areas of a business is making companies rethink their old business models in order to take full advantage of the possibilities unlocked by this new trend, such as enhanced data-collection, data-driven customer insights, better customer experience just to mention a few of them. *(Impact of Digitalization on the Business World | The Enterprise World*, 2019). Not surprisingly, the same trend is also affecting the pharmaceutical industry as the convergence of IT and health-related disciplines are sparking major changes on how pharmaceutical companies will lead their businesses in the years to come (Reinhardt, Oliveira and Ring, 2020). In particular, it has become clear that data is an asset, and as any other asset, it should become a core part of the organization strategy where a clear policy and guideline on how to capture, to store, and more importantly, how to make the most of it, are declined (Perrons and Jensen, 2015).

1.2.1 Data silos

Although nowadays the cost of storing data has been reduced significantly thanks to either proprietary or open source products such as Microsoft Azure or Amazon Web Services which are acting as disruptive catalysts (Reinhardt, Oliveira and Ring, 2020), another important aspects to be considered during the design of a data strategy is to avoid data silos. Indeed, it is not uncommon to see different solutions being adopted department by department, with each of them managing their own set of independent and disconnected data and technologies to support their business processes (Patel, 2019). Although subtle, data silos can act as an invisible catalyst that hinders information sharing and collaboration, not only internally within the company but also for other potential stakeholders. Furthermore, by having a limited visibility of data, people may end up losing the big picture of the company's main strategy and goal, therefore, losing not only the opportunity to extract the full value from the collected data, but also leading to poor decision making, and consequently to a negative impact on profitability (Patel, 2019). That being said, granting everyone the ability to access all of the information in all of the company's applications can be counterproductive. As a result, it is critical for any company to first develop clear internal policies and guidance on who is permitted to access certain types of data versus those that should be kept outside of it (Patel, 2019).

Whenever discussing data strategy and data culture, it's also critical to consider the impact on customers, not just employees, because having an all-encompassing data capture strategy may raise some concerns and questions about how much data is being captured and potentially abused by companies (Maher *et al.*, 2019). This is especially relevant in the healthcare industry as a whole, where highly personal patient information is shared between care-providers, and therefore requiring a specific and more stringent set of regulations regarding privacy and patients' consent to use and share those data in order to provide them with better health solution (Maher *et al.*, 2019). Data is no longer just an IT function (Koltay, 2016).

1.2.2 Patient Privacy and regulatory constraint to data collection and manipulation

As the pharmaceutical industry approaches a more holistic approach to patient care, multiple parameters from different domains, like clinical and physical data, as well as social and psychological information among others, start to get analyzed all together to develop more efficient and personalized solutions for patients. This trend that sees organizations collecting increasing amount of data year by year, also referred as Big Data, is even more accentuated due

to the advent of IoT devices, as they provide near to real-time monitoring and access to care, representing one of the major factor for their adoption in the health industry (Kupwade Patil and Seshadri, 2014).

Nevertheless, despite all the advantages that collecting and analyzing those data could bring to the industry and patients likewise, important steps need to be made in the policies and regulatory fields to ensure that the so called Protected Health Information (PHI) and the Personally Identifying information (PII) are properly managed in compliance to industry, local and regional standards (Kayaalp, 2018). Patient privacy and data security are one of the most debated topics nowadays especially when dealing with massive amounts of data. In fact, according to a study mentioned in Kupwade Patil and Seshadri (2014), 94% of hospitals experienced at least one security breach between 2011 and 2012, and that in most cases those attacks were carried out by insiders rather than outsiders. Therefore, companies need to put additional effort in design and developing a data governance strategy in order to have better control over who can access specific data by deploying a user permission and permission levels strategy throughout the whole set of tools used in the network.

Overall, leveraging on big data can significantly increase industry concerns about security and patient privacy, particularly due to widely dispersed data sources, which adds to the burden of storing, processing, and communicating information around the network (Kupwade Patil and Seshadri, 2014). As a result, traditional security solutions cannot be directly applied; instead, specific regulatory framework and tools must be developed in order to achieve a balance and clearly define which information is subject to legal protection from those that can be accessed for scientific purposes through a de-identification procedure, such as the practice of anonymization of data prior to any type of data manipulation, of Protected Health Information (Kayaalp, 2018). Another solution to perform some sort of data analysis while protecting the patient's identity is given by new technologies such as privacy-preserving encryption schemes. And to add an additional layer of protection, it's an industry practice to use ad-hoc decentralized data storing and processing facilities (Kupwade Patil and Seshadri, 2014).

This leads to the requirement where all stakeholders must work together to protect patient privacy, as each one of them has distinct roles and responsibilities to uphold. Local regulatory agencies must establish the boundary and responsibility for requesting and granting only the strictly necessary health information for scientific research and development, while developers of de-identification tools must provide a number of methodologies and best practices to

maximize the tools' effectiveness. Last but not least, the institution in charge of storing the PHI must strictly adhere to these rules and ensure the quality of the de-identified data before sharing them with other stakeholders (Kayaalp, 2018).

1.3 Technology driven business models and paradigms

1.3.1 Platform based business models

Overall, to support a culture where data is more accessible, understandable, and actionable, the adoption of more advanced tools is of paramount importance to support them, and here is where data platform comes into place. However, developing said platform from scratch may require significant up-front investments which not every company can afford. Given this, it's not surprising that many big tech companies have seen this market opportunity, and developed multiple ready-to-use commercial services and tools that can be implemented by companies in a relatively short amount of time without committing too much capital investment (Singhal *et al.*, 2020). But what is a platform? According to Gawer and Henderson in Smedlund (2012), a platform can be defined as such when:

> *"it is one component or subsystem of an evolving technological system, when it is strongly functionally interdependent with most of the other components of this system, and when end-user demand is for the overall system, so that there is no demand for components when they are isolated from the overall system"*

Furthermore, as mentioned in Smedlund (2012)'s research, firms are increasingly organized around platforms, which provide a more personalized experience for the end-users as a result of a collaborative effort among many actors, such as firms, suppliers, customers, and other key stakeholders. In general, platforms-based business models create an ecosystem in which a focal firm exert a certain level of influence over other actors providing complementary products and/or services (Gawer and Henderson in Smedlund, 2012). At the same time, it's also true that stand-alone strategy will no longer work since the success of this integrated network depends on the effort provided by multiple firms. Moreover, the power of these platforms lies in their ability to become an appealing place where other businesses can build on top of them, thereby increasing the platform's value as a whole (Chesbrough in Smedlund, 2012). Within this framework, what appears to be the core element around which the concept has been developed is the capability. Capability does not simply refer to a person's or company's ability to create a tangible product, but rather in its ability to design and tailor a service around the target customer based on human knowledge and skills, which is dynamic and ever changing in nature

(Smedlund, 2012). And, for all of this to happen, businesses must recognize the importance of co-creation and co-design of their value proposition, not only within their network, but also with the final user.

According to Smedlund (2012) there are four types of service platform business models, and each one of them uses a different strategy to create and capture their value proposition (Figure 2). Despite that, there are some common characteristics among platform-based firms that are worth mentioning according to Gawer and Cusumano in Smedlund (2012). Firstly, it has been emphasized the importance of the leading firm collaborating and supporting other platform contributors, as well as simplifying network interaction through standardization of certain procedures and conventions. Following that, analyzing and defining multiple scenarios to counter potential future competition from other platforms is just as important as the companies' commitment to their current strategy. Finally, the establishment of a trusting environment allows for continuous improvement and information sharing, which contributes to the enrichment of the current value proposition (Smedlund, 2012).

According to the literature and the below matrix, there are 4 main types of service platform business models identified by evaluating the higher or lower value in terms of interfirm collaboration investments (y-axis) and front-end ICT investment (x-axis). Firms that heavily invest in both direction are referred to as Open service platform (ex: Amazon) by Smedlund (2012), outlining the presence of a strong and flexible front-end interface to be leveraged by the end-user, while also representing an appealing marketplace to join in for other third-party companies to increase their own visibility while also empowering the platform itself. Despite the advantages of an open service platform, not all the companies adopt this kind of solution and prefer to choose a closed service platform (ex: Apple) in order to maintain a stronger control of the quality of service provided by rigorously selecting a smaller circle of third-party companies with which to collaborate. In the other hand, companies that don’t need to profusely invest in their front-end interfaces can be classified as Customer service or Platform complementor, based on whether they need to invest lower or higher amounts of capital respectively in improving the interfirm collaboration. In the first case, the Customer service platform business model, is meant for companies that built their differentiating characteristic on superior customer service (ex: American Express), while also covering that market segment of end-user that is not willing or physically incapacitated to use online services, like in case of more senile population. For these instances, as mentioned by Smedlund (2012), the ICT investments are made for the back-end personnel to assist them in providing better customer

service. Finally, companies that want to simply provide their services to complement an already existing platform are called Platform complementor. This strategy allows for lower front-end investments, but requires an attentive effort in integrating different systems, and coordinated collaboration among players (ex: game industry).

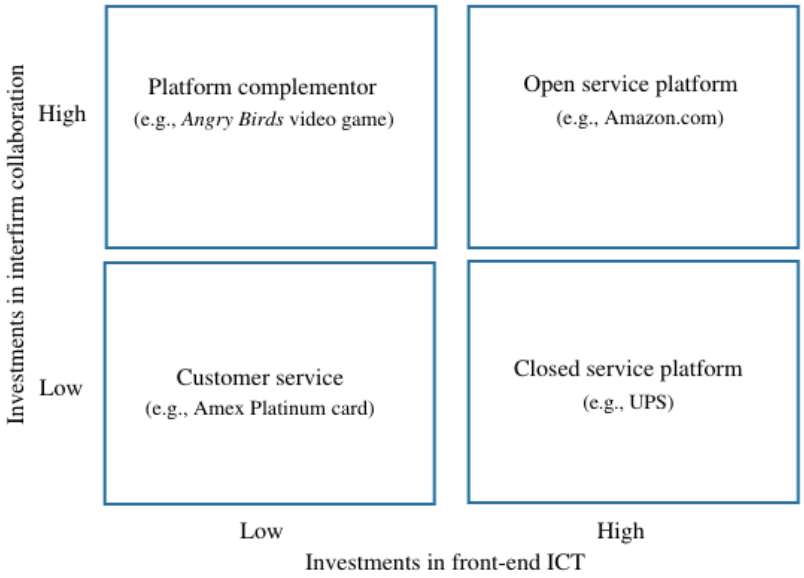

Figure 2 Four types of Service Platform Business Models (Smedlund, 2012)

Overall, it is possible to state that value creation in the service industry is a process involving multiple interconnected actors, and it should be designed in such a way that the end-users are allowed to proactively provide their feedback and contribution for the further improvement of the business model (Smedlund, 2012). This idea is reinforced by the following statement from Maglio and Spohrer in Smedlund (2012): "advances of service innovation are only possible when a service system has information about the capabilities and the needs of its clients, its competitors, and itself". But, as it has been stated in previous paragraphs, information needs to be further analyzed before they can become actionable items and insight that might bring value to the organization (Perrons and Jensen, 2015). Again, raw data are just blank statements of a fact, and without a context they don't mean anything, so it is critical for businesses to have a clear picture of their capabilities, how they capture value and to map them. For the purpose Smedlund (2012) described the capability-based service value co-creation model that he deduced from previous literature (Figure 3), which identifies the main platform service model's actors who are contributing to the creation of value based on the idea of co-creation and information sharing empowered by the front-end ICT. However, it's important to note that other factors, such as staff training, second degree or higher suppliers and the market environment, can have an impact on the overall performance of the network as well.

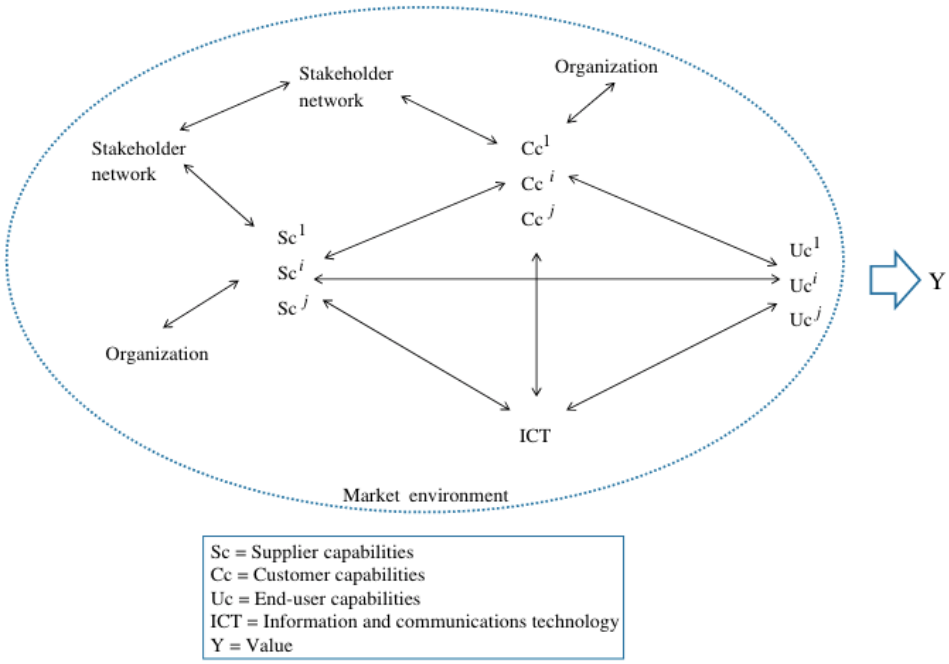

Figure 3 Capability-Based Service Value Co-creation Model (Smedlund, 2012)

This model represents a general overview of all possible interactions that can occur among the main actors; thus, multiple variants can be generated from it to better describe the situation outlined in the four types of service platform business model's matrix.

1.3.2 Ecosystem based approach

The healthcare industry has made significant progress over the years, starting with a focus on contagious diseases and workplace accidents and progressing to today's primary goal of preventing and effectively managing chronic conditions by empowering patients and healthcare professionals through better disease education and continuous support (Singhal *et al.*, 2020). This shift in trend has resulted in a situation in which an ecosystem-based model of care appears to be the direction in which the healthcare industry is moving to. To enable this change, digital technologies play a central role in broadening the possibilities for companies. Several industry forces are driving technological innovation (Singhal *et al.*, 2020):

- The current industry inefficiencies in terms of affordability, outcome, and quality, are providing the perfect condition for innovation to take place;
- Technology giants are investing billions of dollars in R&D to create new services that can be used by a broad range of customers. For instance, there have been alliances between tech companies and pharmaceutical companies that show the increased integration but also the concerns around patient privacy.

- Regulatory changes and innovations are taking place in fields such as that of technology, in order to better draw the line for data accountability, ownership, and usage.

The reason why the healthcare industry is moving towards an ecosystem-based model is that ecosystems provide several advantages such as:

- Benefit from the network effect, which reduces silos mentality among players, while also increasing the likelihood of serendipitous interactions among companies that will increase the overall value creation of the system (Adner, 2017);
- Have better access to data generated within the ecosystem and therefore provide tailored solutions for stakeholders and consumers likewise (Wallance *et al.*, 2020);
- Improve customer retention due to ease of use of the ecosystem-integrated services and structures that show their utmost potential only within the system (Singhal *et al.*, 2020).

As the barriers and therefore the inefficiencies that exist among companies that are not in an ecosystem disappear by joining one, the product and services provided by the companies will change for the better. And in the case of the healthcare industry, the traditional modalities of care will likely start to fade off, while a new more holistic approach to patients will take their places, such as home and self-care, social care, telemedicine, and so on (Singhal *et al.*, 2020). However, each of these new services can be delivered on the precondition of companies being able to collect and analyze data. Therefore, an underlying data backbone and advanced analytics technologies are required for the ecosystem to take place (Singhal *et al.*, 2020). The consumer-oriented nature of the ecosystem will provide the starting point to collect data, as the number of healthcare touchpoints increases, while striving to improve therapies outcome by modifying patient behavior. From one side, the healthcare ecosystem will address the needs of healthy patients who will experience a more digitalized experience by consuming data in a highly personalized way through wearable devices. On the other hand, the healthcare ecosystem will address the needs of the patient who have very debilitating diseases or chronic conditions that require a highly coordinated approach between the providers and the service delivered either virtually or at the patient's home. Also, in this case, digital technology plays a central role in enhancing the experience throughout the whole patient journey (Singhal *et al.*, 2020).

1.3.4 Definition of ecosystem

Overall, the notion of ecosystem has raised the attention on new models of value creation driven by technological development, as it can align actors by improving their coordination and

generating further collaboration among a different set of partners (Sklyar *et al.*, 2019). And in fact, according to Adner (2017), an ecosystem is defined by:

> *"The alignment structure of the multilateral set of partners that need to interact in order for a focal value proposition to materialize*".

This means that the starting point is given by setting a "*focal value proposition*" that acts as the general direction towards which the actors of this ecosystem should strive to. By focusing on the value proposition, it raises the requirement for companies to reach a certain threshold level of coordination, described as "*alignment structure*" while balancing different interests. That is because the actors must reach an agreement about finding and setting their positions and activities within the ecosystem. For instance, they have to decide whether they want to act as "curators" (the counterpart of "leaders" in the health industry), who has to ensure constant and meaningful improvement in patient outcomes within the ecosystem, or as "participants" (the counterpart of "follower"), who provides competitive and distinctive value proposition compatible with different ecosystems (Singhal *et al.*, 2020).

This leads us to the importance of analyzing the extent of divergence in interest, which refers to competition and value capture, and divergence in perspective, which is the notion of value creation for third parties, that a specific ecosystem can sustain. Finally, "*multilateral*" stands for the multiplicity of actors and, therefore, relationships that are not decomposable to an aggregation of bilateral interactions (Adner, 2017). The reason why an ecosystem should be established must be because there are some critical interactions among a variety of actors that are all meant for the "*materialization*" of the value proposition, and if one of them is missing, the ecosystem would experience a significant blow that must be recovered as soon as possible.

1.3.5 The component layers of an ecosystem

According to the literature, ecosystems are built on three main layers that interact with each other in order to provide a seamless workflow and value creation within it. Those foundational layers are represented by the infrastructure, the intelligence, and the engagement layers (Singhal *et al.*, 2020) (Figure 4).

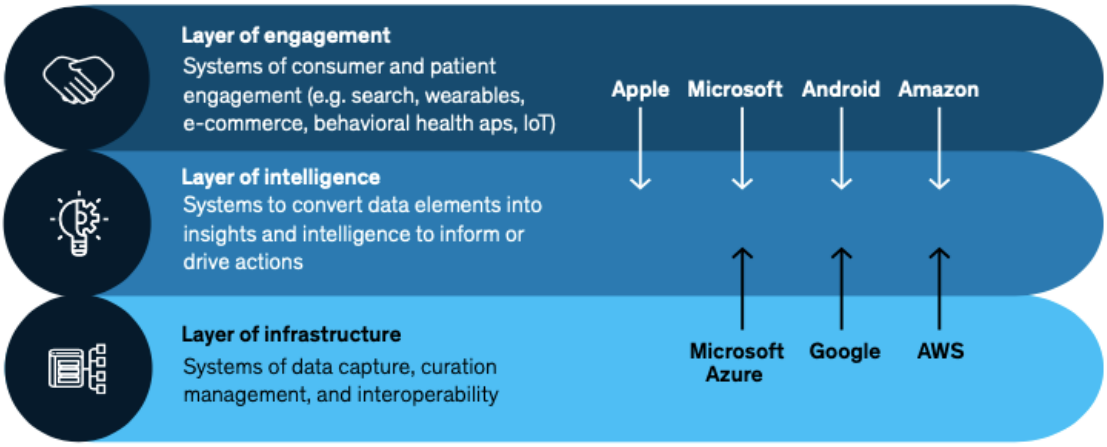

Figure 4 Component layers of an ecosystem (Singhal et al.*, 2020)*

The first layer is characterized by an effective data collection system that not only captures data but also manages it and stores it, either on-premise or in the cloud, in order to build a common database that the ecosystem can leverage. Improving data liquidity is of utmost importance for players of an ecosystem, as data represents the fuel that runs all the complex services that companies provide to meet the increasing customer expectation and demand for customization. Therefore, in the healthcare industry, it is important to collect as many longitudinal patient records as possible, like patient-generated data, provider-generated data, health and wellness data (Singhal *et al.*, 2020). However, who should be the owner of those data is still a debated topic in both literature and the real world, but for what concerns the healthcare industry, it's probably a wise choice to leave patients be the owners of those data, while stakeholders should request their permission to leverage on them. This tradeoff should be balanced by building appropriate privacy safeguards and clear value-added benefits before patients are willing to make the exchange (Singhal *et al.*, 2020). Protecting an individual's privacy is, therefore, a critical issue that has to be addressed prior to building an ecosystem, while also taking into consideration the regulatory obligation and compliance with data interoperability.

The intelligence layer is used to derive useful and consumable insights by analyzing data that have been accumulated over time in the infrastructure of the ecosystem. The conversion of raw data into insights is done through advanced analytics, which will provide increasingly customized and on-point actionable information as the data liquidity increases. In the healthcare industry, this means more reliable personalized and predictive insights for patients, and tailoring patient-journey based on each individual's needs. For example, pharmaceutical companies can leverage machine learning to improve cancer diagnoses or use AI to improve remote monitoring. According to Singhal *et al.* (2020), a great portion of innovation in this field could be facilitated by technology giants such as Google, Facebook, Microsoft, and Amazon which

have already invested billions of dollars in developing these technologies, therefore lowering the fixed costs that the incumbent would have to incur if they had to build them from scratch (Singhal *et al.*, 2020).

Finally, the engagement layer acts as a link between the infrastructure and intelligence layers with the end customers. It comprehends all the interactions and touchpoints with the customers, thus it represents the most critical point where companies can finally exploit financial benefits from their previous investments in building the ecosystem. It requires a shared digital platform where the end customers can access all the services (like appointment scheduling, transportation assistance, health monitoring, etc.) through one main portal (Singhal *et al.*, 2020). This new way of providing services requires a significant effort for patients to change their care behaviors, therefore, moving from the traditional way of care towards a more digitalized and holistic way of providing it.

Although many companies are moving toward a holistic approach to healthcare, only a few of them have established a well-functioning ecosystem among the players, which is required for the above-mentioned reasons to provide complex services with a patient-centric logic (Singhal and Carlton, 2019). The reason is that technology-driven progress can be quite expensive in the early stages of digital transformation. In fact, it has been estimated that the next five to seven years will require additional investments to unlock the potential of the newly adopted assets, for example, to fully integrate patient data infrastructures (Singhal and Carlton, 2019). But as the progress proceeds and the companies build an ever-connected system, costs could drop significantly thanks to economies of scale (Singhal and Carlton, 2019).

The healthcare ecosystem provides a tremendous opportunity to improve patient outcomes and affordability while also increasing the interaction with other health providers, therefore increasing the overall resiliency of a country. But to realize this objective, several barriers have to be overcome, like the rate of technology adoption, the current healthcare regulation, and the fragmented sources of customer data. And if addressed half-heartedly, the emerging technologies could increase the cost of care instead of making it more affordable (Singhal and Carlton, 2019).

CHAPTER 2. EMPIRICAL ANALYSIS: COMPARISON BETWEEN TWO PSP BMS IN THE ITALIAN MARKET

2.1 Methodology

A qualitative analysis based on a case study was conducted to investigate the main challenges of developing an ecosystem around PSP. Therefore, the following research question was raised:

"What are the main challenges of building ecosystems around patient support programs?"

The case study approach allows for a better understanding of the current situation in this niche and relatively new industry (Sklyar et al., 2019), where data are both limited due to the small number of players in the sector and subject to complex regulatory constraints. As mentioned by Yin (2023) "a case study is an empirical method that investigates a contemporary phenomenon (the "case") and within its real-world context, especially when the boundaries between phenomenon and context may not be clearly evident". The case study was therefore chosen to provide a comprehensive picture of the key actors involved in the discovery, development, and deployment stages of a PSP, as well as to examine the implications and interactions that occur among the different roles.

Given the aforementioned situation about the scarcity of information, data were collected through a qualitative research based on semi-structured interviews to capture opinions from managers or other similar roles with decision making power. In this type of interview, as described in Bryman (2012), the interviewer follows a "series of questions that are in the general form of an interview schedule but is able to vary the sequence of questions. […] (or even) ask further questions in response to what are seen as significant replies". Because the topic and market for PSP are still relatively new, and very few data are freely accessible as of today, the flexibility of this type of approach has been deemed ideal for leading interviews for the scope of this research.

The decision to select people covering medium-high level roles within organizations was adopted with the goal of capturing the strategic choices made behind each statement that has been provided. That is because the decision to choose one supplier over another or, more broadly speaking, the decision to form a partnership rather than another is typically made by people located at higher levels of the organizational structure. Moreover, this trend is accentuated in cases where a significant change in traditional strategy is required, such as when

an important redesign of the core business strategy and model is required as a result of the most recent trend of digital transformation.

Therefore, at least one person per company has been interviewed for each of the three different roles that characterize the network of a standard PSP, namely:

a) Pharmaceutical company: the sponsor of the program;
b) PSP-Provider: the actor who provides the resources required to needed the services included in the PSP;
c) Software-House: the tech-company that builds all the technologies required to support the services, and its subsequent maintenance.

For the purpose of this research, two different business models were identified throughout the course of the interviews:

a) The first describes a scenario in which the PSP-Provider serves as the network's orchestrator, connecting with both the pharmaceutical company and the software house.
b) In the second model, the pharmaceutical company orchestrates and coordinates the other two actors, either directly or indirectly.

With this in mind, a total of nine interviews were conducted and divided into two groups based on the type of business model referred to by the specific companies (see Table 1). A total of seven interviews can be counted under the first BM (which name was chosen and explained in a following paragraph), three with PSP-Provider, two with the Software-House, and the last two with pharmaceutical companies. In contrast, only two interviews were conducted for the second BM, one with the PSP-Provider and one with a pharmaceutical firm. It’s important to note that this research builds on the material gathered by another student in his thesis; thus, three interviews were conducted by this fellow colleague and two others by the supervisor (as shown in Table 1), and that’s why some data referring to those instances are missing from the table.

Table 1 Interviews data

Business Model	Role of company	Company name	Company size	Function	Data	Channel	Time
Externalized Model (PSP proposed by provider)	PSP-Provider (A)	Italiassistenza	Small	Head of Project Development	July 14, 2021	Phone call	0:20:42
	PSP-Provider (A)	Italiassistenza	Small	Head of Project Development	August 8, 2021	MS Teams	0:57:03
	PSP-Provider (A)	Italiassistenza	Small	Head of Project Development	March 3, 2022	Zoom call	0:50:21
	Software-House	Omnys	Small	Owner & CTO	June 28, 2021	Zoom call	0:46:22
	Software-House	Omnys	Small	Owner & CTO	March 7, 2022	Zoom call	0:47:20
	Pharmaceutical company (A)	AstraZeneca	Large	Medical Advisor Biologics	April 5, 2022	Zoom call	0:35:52
	Pharmaceutical company (B)	Biogen	Large	Medical manager	April 27, 2022	Zoom call	1:13:44
	Aggregated coding						
Internalized Model (PSP proposed by pharma)	Pharma (C)	Abbvie (Merk)	Large	Customer experience & Omnichannel Manager	November 28, 2022	Zoom call	01:10:16
	PSP-Provider (B)	Adecco	Large	PSP Manager	September 19, 2022	MS Teams	01:05:23
	Aggregated coding						

All interviews were recorded with the participants' explicit consent, despite the fact that the majority of them expressed a desire to remain anonymous (reason why each explicit indication about firms' and people's names were omitted), and that their statements were not representative of their respective companies' views and thoughts. Nevertheless, their contribution can still be considered significant for the scope of this research due to the size of the PSP market itself (a niche market), which sees companies, particularly the large ones, organized in specialized business units specifically set up to cover this market share. This means that the interviewees can be considered part of a small group of PSP subject-matter experts for their respective firms.

In order to remain as consistent as possible to the insight provided during the interviews, each recording was transcribed and carefully reviewed before proceeding with the interview coding process, which employs a data reduction method that links subsequent order objects from the detailed to the general (Sklyar et al., 2019). The structure of the codes is pyramidal: a bottom-level code (first-order categories), followed up by second-order themes and finishing with the aggregate dimension, which represents the broadest and most generic topics of analysis. Every single interview has been codified following the above-mentioned methodology, generating a number of categories and sub categories on their own. Then, an additional step has been performed in order to cluster the categories coming from different "Role of the company" (in the network) into what has been called as "aggregated coding". Finally, the same process has been repeated for the second business model that has been identified during the course of the research. By generating two different aggregated codings (which can be found in the appendix)

a cross-comparison between the two BMs could be therefore performed. Thus, generating potential insights in terms of challenges of building business models and ecosystems around PSP by having a comparison of current experiences in the Italian market.

2.2 Business models & network-based relationships around PSP: the case studies

As the pharmaceutical industry faces multiple challenges due to several market inefficiencies affecting industry productivity, and customers expecting better services in terms of accuracy, up-to-date information, simpler interactions, and, most importantly, being treated as individuals and thus creating a trustworthy environment, new approaches have been experimented with and adopted in the last two decades, with the Patient Support Program being just one of them. Pharmaceutical companies are embracing holistic and patient-centric solutions in order to provide value propositions that could meet or exceed patients' expectations while also promising them a good quality of life.

Patient support programs were created only ten years ago and they are initiatives that have as their purpose the provision of additional services on top of the already authorized medicinal pill. A PSP is an instrument that integrates itself with, but is not concurrent with, the services provided by the national health system, with the main goal of improving the therapy adherence for treatments that engage patients over a long period of time (Giambelluca, 2021). Given their recent adoption and the fact that PSPs represent a niche market, neither time nor a truly competitive environment have allowed for the development and subsequent improvement of truly effective business models and ecosystems approaches. Thus, this case study attempts to highlight the strengths and weaknesses of current business models in the Italian market with the hope of bringing a contribution for further research on the subject under analysis.

2.2.1 Overview of the two PSP business models currently adopted in the Italian market

Over the course of the research and based on the information collected through the interviews, it emerged that there are two prevalent types of interaction networks among the three main players characterizing the development and management of a PSP in the current Italian market.

As stated in a previous paragraph, a PSP is created with the joint effort and capabilities of the pharmaceutical company, the PSP-provider, and the software-house to provide a value proposition based on tailored services for the patients, where the notion of co-creation and co-design plays a central role. And because the set of services included in a PSP is built and

managed through the creation of a platform solution, it means that each service delivers its full value if and only if it is considered together with most of the other components. Having outlined these preliminary concepts, the natural consequence that can be inferred from this is the undeniable importance to establish an effective communication and a collaborative environment where the key players can focus on their expertise and contribute to the overall value proposition. In other words, a stand-alone strategy will not work in this framework because success is dependent on multiple firms that influence the creation and delivery of the service (Smedlund, 2012).

In fact, as previously stated, those basic characteristics have found evidence in the statements provided by the interviewees, although slight discrepancies have been revealed both in terms of compliance to some concepts highlighted in the literature, as well as strategy being adopted among different clusters of companies, resulting in the identification of the two business models.

The first one describes a situation where the PSP-Provider play a central role in orchestrating the relationships and communication within the network. The PSP is fully funded by the pharmaceutical company which wants to provide a free of charge value added service for the patient in addition to its standard offering, whereas the PSP-Provider proposes a set of already developed modular services to the pharmaceutical company after winning a tender. These services will then go through several cycles of fine-tuning to meet the pharmaceutical company's requirements. With those requirements, the PSP-Provider will reach out to the Software-house to develop the software required by the newly designed PSP, as well as being in charge for the future maintenance of the programs. Then, the final PSP will be managed and operated by resources provided by the PSP-Provider, although the ownership will still remain with the pharmaceutical company. Thus, the name of "Externalized Business Model", being the PSP fully developed and operated outside the pharmaceutical company.

The other model that has been identified refers to a situation in which the pharmaceutical company, that has already developed its own PSPs, covers the role of network orchestrator. In fact, the pharmaceutical company will contact the PSP-Provider to cover only a portion of the services, primarily for the operational activities (ex: home care, remote nursing services, etc), which requires a high demand of health care professionals specifically trained for the disease treated by the PSP, that can be find in the wide network of HCP offered by the PSP-Provider. In this second model, the software house can either work directly with the pharmaceutical

company to develop the latter's PSPs, or work for the PSP-Provider to develop the technologies needed to support its operational activities. Given these characteristics, this case will be called "Internalized Business Model", because the PSP is developed and managed primarily within the pharmaceutical company.

2.2.2 Service platform business model

To better analyze the aforementioned situations, Smedlund (2012) capability-based service value co-creation model comes in handy, as it describes the relationships between the multiple capabilities provided by the main actors, namely service suppliers (Sc), supplier's customers (Cc), and end-users (Uc), required for value creation, which is further enhanced by the adoption of an additional layer represented by front-end ICT. This is a theoretical framework that builds on three previous European models on service innovation which outlined the nature of interaction between different actors and end-users in the value co-creation process. The first contribution comes from Gallouj and Weinstein in Smedlund (2012) who defined service innovation as a series of incremental changes resulting from either service competencies or technological advancements, or both. Whereas the second and third contributions in Smedlund (2012) come from den Hertog and Edvarsson, and Olsson, who included the end-users in the value creation process, and the concept of supporting "service systems", which will later be explicitly linked to ICT systems by Qiu in Smedlund (2012).

Overall, this framework can be adopted to accurately describe the interaction among players in the PSP network. In particular, the value co-creation in platform complementor business model (see Figure 5) and the closed service platform business model (see Figure 6) can be considered good representations of the externalized business model and the internalized business model for PSP respectively. The below two representations are based on the diagrams presented in Smedlund (2012). However, for the purpose of this research, they have been adapted to fit the main actors involved in the two business models under analysis, while maintaining unchanged the main interactions and capabilities exchanges underneath the specific service platform business model taken into consideration.

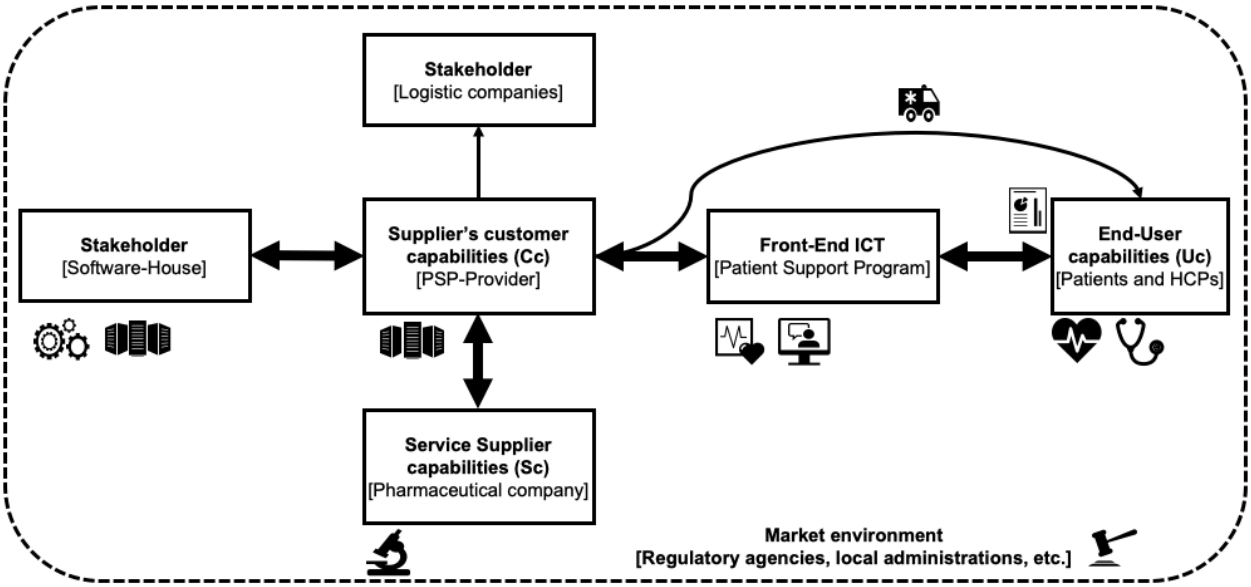

Figure 5 Value co-creation in platform complementor BM (Smedlund, 2012)

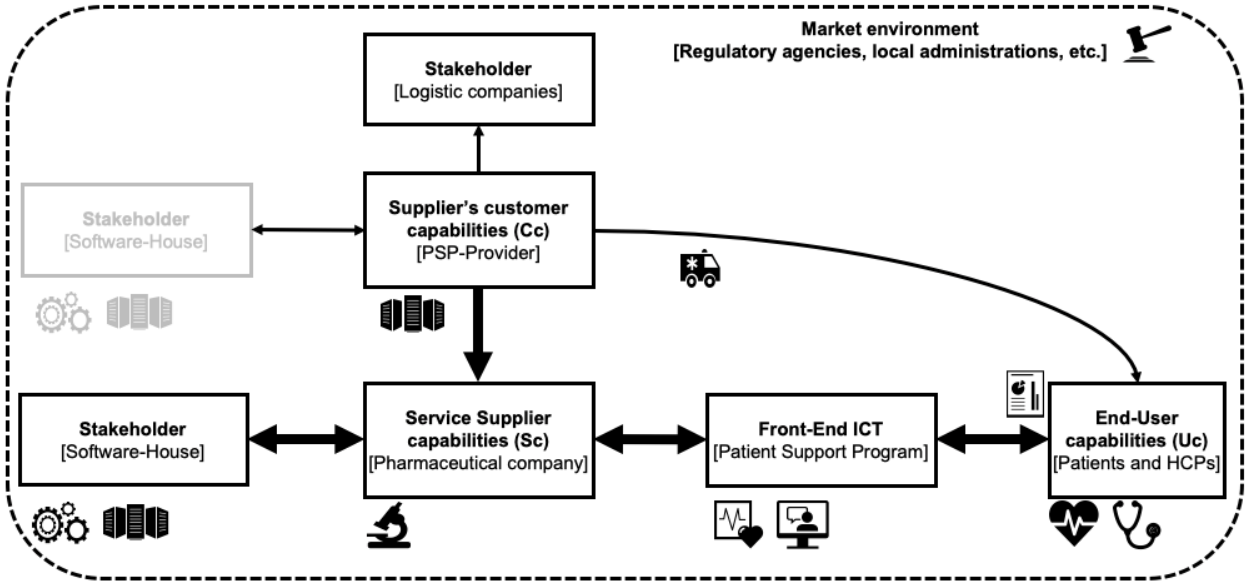

Figure 6 Value co-creation in closed service platform BM (Smedlund, 2012)

In both cases (externalized and internalized BMs):

- the service supplier (Sc) would represent the pharmaceutical company, being the one financing the PSP and owner of the services designed and developed for the specific instance;
- the supplier's customer (Cc) represent the PSP-Provider, which covers the role of orchestrator of the interaction and relationships among the main players in the externalized model, while becoming simply a trusted provider of service to complement the supplier's platform in the internalized model;

- the stakeholder, who for the purposes of this analysis will mainly represent the software house, which is in charge of providing additional support to the pharmaceutical company, either directly or indirectly, depending on the BM they are part of. To be mentioned also the role covered by the logistic companies contracted by the PSP-Provider;
- the front-end ICT, will be the PSP object of development and main medium of interaction between the end users and the HCPs;
- the end-user (Uc), as the patient utilizing the services from the front-end, such as the PSP, is thus an important asset in terms of providing valuable feedback to the other actors in order to thrive for a constantly growing network;
- Normal arrows represent the causal mechanism for the interaction;
- Double-header arrows represent a strong cooperation between the actors.

2.2.3 Analysis of the current state of the Externalized business model

Starting with the first case, the platform complementor business model (Figure 5) describes a situation in which the supplier provides services that increase the market share of an existing platform (Smedlund, 2012). In the case of the externalized business model that would represent the pharmaceutical company (supplier) taking advantage of the PSP-Provider (customer) as an intermediary to provide the service to both health care professionals and patients (end-uses) enrolled in their PSP (front-end ICT). Whereas, the PSP-Provider's role is to mediate every potential interaction between the other actors, while effectively eliminating any direct contact between the pharmaceutical company, the software-house, and the end-users.

According to Smedlund (2012), this would theoretically allow the pharmaceutical company to avoid investing huge amount of capital in its own front-end ICT , as it will be taken care off by joining the platform offered by the PSP-Provider, being the one in charge of developing, managing, and maintaining the platform. For instance, the PSP-Provider (A) stated that their strategy was to develop a wide variety of services into what they called "building-blocks" or modular platform solution, with the aim of leveraging on them so that they could, from one side, reduce the capital investments as the suite of services grew larger and capable of covering an increasing variety of needs, while still meeting the pharmaceutical company's needs for personalization and customization of the workflow of services that they have been planning to design and develop for their PSP. However, the reality of things turned out differently for the PSP-Provider (A) as it has been outlined by its direct stakeholder, the software-house, who was and still is in charge of developing and maintaining their "building-block" of services. In fact,

according to what the latter said, although the initial idea was logical and it could have worked, at least on paper, in the reality, whenever a PSP-Provider presented their suite of services already developed, they would always be met with a variety of requests for personalization from the pharmaceutical company (B) which they could not turn down according to the software-house being interviewed. This situation created several inefficiencies and unmet return on investments for both PSP-Provider and Software-house alike.

In the case of the first actor, they were unable to not only benefits from economies of scale on their initial intensive investments in developing this massive suite of predefined services, but they were also unable to avoid the ongoing additional investments required to develop customized solutions for each additional PSP, making this strategy flowed and unsustainable in the long run. In fact, the Pharmaceutical company (B) testified that, although they do start their initial interaction with the PSP-Provider (A) with a collaborative mindset aimed to foster the co-creation and co-design of a solution by providing a list of requirements from their side, and hearing out the presentation of a package of therapy targeted solutions that the provider has to propose them so to find a common ground of understanding, the pharmaceutical company usually ends up obtaining what they wanted as the PSP-Provider says that most of the things are doable. Therefore, instead of finding and simply combining a number of modular services that the PSP-provider could offer to create a new PSP, the pharmaceutical company will use them as a baseline to start and develop their own customized modules and solutions. Given those statements, it appears that there's a clear divergence between the approach that the PSP-Provider would like to take, for instance that of developing modular services where the customization part depends on how those modules will be combined with each other based on the pharmaceutical company's requirements, and the latter's approach, where they want to customize every single module that the provider presented them in order to better address patients' needs according to their opinion.

Overall, this situation resulted in an exponential increase in the number of different varieties and versions of potentially the same service being customized for different PSP to be maintained by the software-house. According to their statement, this will surely become unsustainable in the future, as they won't have a single way to either resolve potential problems that may arise during the usage of said software, or to provide updates over time in order to avoid becoming obsolete in a very short period of time, in other words, to provide software update to potentially improve the efficiency of the services as more and more data is collected

over time through their usage. In fact, this situation led the interviewed Software-house to record a loss in a financial year, highlighting the unsustainability of this business model.

Given those statements, it appears that the PSP-Provider failed to consider the relationships that had been established and are still in place today (as of the interview) between the main actors of the so-called network with which they are interacting, despite their role of coordinator of the relationships between actors expected by the business model chosen by them. The lack of a comprehensive analysis in this area resulted in a not indifferent loss and failed strategy for the PSP-Provider, as well as finding themselves in a excessively passive position, since they are confronted with pharmaceutical companies that have many more years of history behind them, and have diversified their revenue streams, making them a much more resilient company compared to the relatively newly established PSP-Provider, who started this business in the last 15 years according to their statements.

Moreover, as the Software-house contact person being interviewed stated, the exact fact that the actors have only established bilateral relationships with each other led to poor communication outcomes, especially between software-house and PSP-provider. In particular, one aspect that has been highlighted during the interview was about the unclear requirements that the PSP-provider would advance to the software-house. Those requirements often came with the form of extremely synthetic notes that the provider took in its own meetings with the pharmaceutical company. Therefore, as it would be expected by leaving out the technical personnel, many decisions being taken in those tables considered only the functional aspects, and in some cases even more high-level discussion about simply the desired services that the pharmaceutical company wished to have for their future PSP. On the other hand, in the software-house point of view, this turned out to be a very complicated situation where, for three pages of notes, they responded with over ten pages of more specific questions to clarify the actual need for certain functionalities. As a result, the software-house often had to go above and beyond the scope of the activities it was supposed to cover, such as providing additional consulting and strictly functional activities rather than purely technical services. This is a clear reference to the situation described by Adner (2017) in which actors have not efficiently defined each other's responsibilities and scope of activities that are required for the establishment of an ecosystem, as the circumstances demanded. Furthermore, during the interview with the pharmaceutical company (B), they also testified that they do not have any interaction with the software-house or any other subcontractors (e.g. logistics companies), other than the PSP-Provider.

Overall, this situation resulted in long lead time to deploy and launch new PSPs, while also increasing the costs for their development, highlighting that there is clear space for improvement for the said business model (see Table 2). Therefore, the original goal for the pharmaceutical industry as a whole to improve its offering in terms of better quality of life for the patients, while also attempting to fight back the decreasing R&D productivity through the adoption of the new digital technologies it's not being met. This is evidence that simply adopting said technology won't necessarily result in improved efficiency and outcomes, but it requires a thorough analysis on how to use these tools, as well as a realization for the companies of the importance of collaboration among them rather than viewing each other as separate entities.

Table 2 Pain points of the current Externalized Business Model in the Italian market

List of pain points	Consequences	Potential causes
Lack of cross interaction	Only bilateral relatinships were established. Poor communication. Unrealistic and/or unclear requirerments to be found at later stages of the project. Long lead time for to deploy and launch a new PSP.	No real collaboration mindset has been established
Divergence of interest	Pharma wants to pin-point the patients need according to their specific circumstance, thus the hyper customization required. PSP-Provider wants to address to single needs through standardized modular solution to reduce their costs over time.	Main players don't see each other as part of the same ecosystem.
Modular platform solution	High initial investments for PSP-Provider. Not enough personalization to satisfy pharma's needs.	Lack of stanrdard measurments of patients needs that prove the efficiency of the currently developed solutions.
Hyper personalization	Leads to unsustainable cost for both PSP-Provider and Software-House. Inability to leverage on past experience and solutions. Challenges on maintianing and updating all the services for the Software-House.	Lack of a standardized framework and best practices to follow.
PSP-Provider's passive position	Aceptance of most of the requirements from the pharma. Inability to leverage on the already built suite of modular services.	Players still see each other in a market to market fashion, without collaborating with each other.
Lack of clearly defined scope of activities and responsibility	Software-House to cover also consultancy service insteat o purely technical services. Both PSP-Provider and Pharma believe in their leading position in the network.	Not enough attention has been put on analyzing the real relationships among actors, and the consequences that this could bring.

2.2.3.1 Current externalized business model and patient centricity approach

Despite the fact the PSP were intended to improve patient's therapy adherence and quality of life by developing a patient journey that could address their needs in a holistic way thanks to the adoption of the digital technologies as well, there's an important element that almost didn't come out, or at least that was not voluntarily addressed more deeply from the interviewees, and that is patient centricity.

The only point that the interviewees emphasized was that the goal of a PSP is to solve a specific set of patient's needs identified by the main actors involved during the design and development stage of said tool (see Table 3), which for instance can't be too many per single PSP as the PSP-

Provider (A) stated. However, except for the testimony from the Pharmaceutical company (A), none of the other people interviewed mentioned an active involvement of the actual patient, target of the disease being treated, during the design and development process of the PSP. In fact, the only evidence that has been collected during this research of such direct feedback coming from the patients comes from what the pharmaceutical company (A) mentioned as "focus group", where clinicians, doctors, and patients were actively involved in the definition of the most impacting patient needs. Therefore, it is questionable whether the other companies are actually putting in place any means of collecting patient feedback for the creations of the PSP as they advocate, unless such activities have "simply" been forgotten to be mentioned during the interviews causing this research to fail in collecting all the relevant data. Despite the potential inability of this research to asked in a more direct way said question to the interviewees, the fact that it has not been mentioned directly by the involved stakeholders it may represent an evidence that the active involvement of patient during the design and development stage of a PSP is not a top of the mind aspect to be considered by said actors as of today.

Table 3 List of main actors involved pre and post PSP launching based on interviews outcome

	Pharma side	**PSP-Provider**	**Software-House**	**Others**
Design and development stage	Product and project manager, procurement, market research team, focus group (cliniciants, doctors and patients), medical directors, scientific supervisors, regulatory compliance function, legal function.	Organizational referent, project manager, business analyst, medical advisor, CFO	Engineers	Administrations that manage public tenders, patients, doctors.
Post-Lauching stage	Medical, medical scientific liason, agents to inform doctors of the existance of a PSP	Health-care professional (ex: nurses, nutritionist, physical therapist, psychologist)	Engineers	Telecom providers, patient associations, patients, doctors, local spacialized disease centers.

However, as previously mentioned in the literature review paragraph, incorporating patient inputs throughout each step of the design and development of a new product or service in the pharmaceutical industry is not only required by regulatory agencies such as FDA in the US market or the EMA in Europe, but it also aids in building trust with all stakeholders, patient or non-patient alike.

Trust, alongside with a change in industry cultural mindset, the importance of fostering collaboration, and last but not least, the establishment of a standardized framework to measure success are the four major challenges to be addressed by companies in adopting a patient centric approach as mentioned by Du Plessis *et al.* (2017). And the fact that the concept of patient

centricity has only been talked about but not been supported with real actions by the analyzed actors stays at the foundation of the previously listed pain points, or at least it had some sort of influence on the challenges being recorded.

To transition from the traditional business model driven by product-led strategy to a more patient-centric and holistic approach, a shift in mindset is required, which can only be achieved if it begins at the top levels of the organization, which must redefine the strategy and operational processes that actively involve, listen to, and partner with the patients, in order to make the entire process more transparent and demonstrate to the patients, partners, and other stakeholders that their goal is indeed that of achieving better therapy outcomes. By doing so, the actors in this externalized business model would have a clear and transparent goal to help them align their mission and vision, rather than establishing a simple market to market bilateral relationship where the divergence of interest would create inefficiency for everyone, particularly between the pharmaceutical company, which wants to customize every single proposition from the provider, and the latter, which wants to futilely build a suite of modular services to solve specific patient needs in a standardized way in order to take advantage of potential economies of scale in the long-run.

Building trust, as previously mentioned, is an especially important aspect to consider if companies want to take a patient-centric approach. Indeed, the next step after goal alignment among stakeholders is to establish clear communication regarding the trade-off between stakeholders on one side, so to not fall back into a situation where one tries to take advantage of the other's weaker contractual position, and with patients, so that the latter are willing to accept the collection of a certain amount of data in exchange for receiving better therapy outcomes and higher quality of life, thanks to the implementation of improved data analytics tools, while respecting also the local regulations and constraints about data and privacy (ex: GDPR).

With trust comes real collaboration, allowing each actor to focus on their specific field of expertise without worrying of being taken advantage of. Moreover, collaborations will also foster positive behaviors such as the sharing of existing best-practices from other organizations that may have already experience practices of value co-creation with and for the patients, while also gaining additional insights thanks to a larger pool of data to be exploited among the companies from the same network and platform (Du Plessis *et al.,* 2017). However, based on the statements coming from the interviews, this is a critical point that is missing from the actors

of the externalized business model, who have shown no signs of collaboration at all between them, while, on the contrary, only bilateral relationships have been contractually established, and all the communication being mediated by the PSP-Provider (A). This, in fact, led to poor communication outcomes, as well as unclear and sometimes unrealistic requirements to be found only later on the development stage of the PSP, because of the nonexistent direct communication between pharmaceutical company and software-house. On top of that, the lack of collaboration in combination of the lack of trust among players, resulted in a situation where concurrent roles and duplication of efforts were a real problem, as outlined by the Software-house, which mentioned how they found themselves providing functional consultancy services instead of only developing the technical solutions they were meant to do, while at the same time not being recognized and paid for this additional effort.

It should come as no surprise that without collaboration, those companies were unable to create a standardized framework and platform to be leveraged on as the PSP-Providers desired and envisioned about. On the contrary, by taking advantage of their stronger contractual position, both of the interviewed pharmaceutical companies have opted for a hyper customization approach both in terms of type of modular services they wanted to include into their PSP, but also personalization within every single service module already developed by the PSP-Provider (A) in collaboration of the Software-house. As a result of the inability of the PSP-Provider to leverage past resources and experience, as well as an ever-increasing cost of development for each additional PSP rather than decreasing cost through economies of scale and experience curve over time, the PSP-Provider (A) shifted its strategy and market position from being solely focused on the PSP market to expand their business into assistance, social welfare and social health services on the one hand, and funds related audiences, bilateral entities and mutual societies from the other, while also looking at the international market rather than just the Italian market alone. However, for what concerns the PSP industry, the establishment of a common ground and framework based on the platform business model is still required by the nature of its value proposition, being services offered partially through web services or at least enabled by digital technologies as mentioned by Smedlund (2012). Moreover, based on the contribution from Du Plessis *et al.* (2017), it is suggested that to establish credibility with external stakeholders such as patients and regulatory agencies, a standard endpoint measure and framework to facilitate the comparison of therapies outcomes and companies adherence to local regulation parameters is required such as the patient reported outcome metrics defined by the FDA.

Overall, true patient centricity and a holistic approach that faithfully covers a patient's needs can only be achieved through a coordinated effort and collaboration between the stakeholders, who should on the contrary avoid stepping on each other's shoes as it can result in counterproductive scenarios such as the one described in this case study.

2.2.3.2 Current process for the design and development of the PSP in the externalized BM

According to the statements recorded during the interviews, the current design and development process of a PSP in the externalized business models is represented by the following flow chart (Figure 7).

A PSP project starts at the convergence of a set of unmet patient needs (step 1), and the necessity for the pharmaceutical company to differentiate their value proposition while also improving therapy efficiency and patient outcomes (step 2). In order to do that, the pharmaceutical company approaches a PSP-Provider, and together they lay down a temporary PSP blueprint with the services to be included in it, aimed at solving the unmet patient needs (step 3). Following this, the PSP-Provider will reach out to a software-house in order to develop a workflow engine to support the specific patient's and healthcare professional's journeys that have been defined by the pharmaceutical company with the help of the PSP-Provider (step 4). Although this process may seem very logical as it follows the traditional waterfall workflow, what emerged from the interviews is that this linear model doesn't seem to be as efficient as the PSP-Provider expected it to be. In fact, not only the linearity has been disrupted several times due to many follow ups for further refinements of the model, but the establishment of bilateral relationships represents also a hindrance for an effective communication among them. In fact, any changes to the blueprint must be mediated by the PSP-Provider (steps 5-6). The final result of the PSP represents the combination of the pharmaceutical company's requirements, the underlying technical infrastructure developed by the software-house, and the PSP-Provider's own network of healthcare professionals to support the specific services applied for that PSP, such as telemedicine and homecare services just to mention a few (step 7). At that point the PSP can be officially launched and patients, alongside the HCPs, will be enrolled within the program. In the meanwhile two activities could occur: from one side, the PSP-Provider, as the owner and the actor contractually entitled to collect anonymized and aggregated patients data, will send monthly reports with the KPIs required by the pharmaceutical company during the definition of the contractual agreements (step 8a); from the other side, the software-house provides continuous software maintenance to keep the infrastructure running and to solve

potential technical issues that may arise (step 8b). Lastly, depending on the PSP performance (in terms of number of enrolments, for example), the pharmaceutical company, as the actor concretely subsidizing the whole program, will decide whether to close the PSP, in case of low performances (step 9b), leading therefore to the initiation of the exit strategy for the patients, for instance by helping them finding alternative therapies or solutions in general (step 10b). While, if the so called "virtuous cycle" has been established, when there is high number of patient enrolments relative to the specific disease being cured (step 9a), it allows the pharmaceutical company to sell a stable if not an increasing amount of medicines of the same disease, making a successful and sustainable PSP, which will be kept running (step 10a) unless these conditions are violated.

During the interviews, the pharmaceutical companies testified that they have no interaction with other stakeholders, other than the PSP-Provider. However, as mentioned before, this situation resulted in a lengthy lead time to deploy and launch new PSPs, as well as increased development costs. This last point is especially a sore point for the following reasons:

- Both of the pharmaceutical companies interviewed (A-B) testified that they do not use break-even logic for their PSP projects, but rather that each project has a predefined budget to work with, and if the expenses were not sustainable over time, they would simply close the program.
- Although precise information about the actual costs to develop a PSP has not been leaked, other interviewees have suggested that the pharmaceutical company does not have significant economic problems that would limit their requests for customization.
- As a result of this contingency, the PSP-Provider, who was in a weaker contractual and economic position, was forced to accept the majority of the requirements, undermining their effort to build a standardized modular platform.

Finally, because the single PSP are disconnected from one another, it was not possible to create a shared platform, resulting in severely fragmented data repositories, complicating their overall accessibility, and impeding further PSP improvement to increase therapy efficiency. Furthermore, the pharmaceutical companies stated that they developed several stand-alone services such as mobile applications, and static websites meant to improve the disease awareness for patients. However, by having all those disconnected services it didn't help patients to easily access important information, while showing also how these solutions were not thought of and designed with a patient centric strategy in mind.

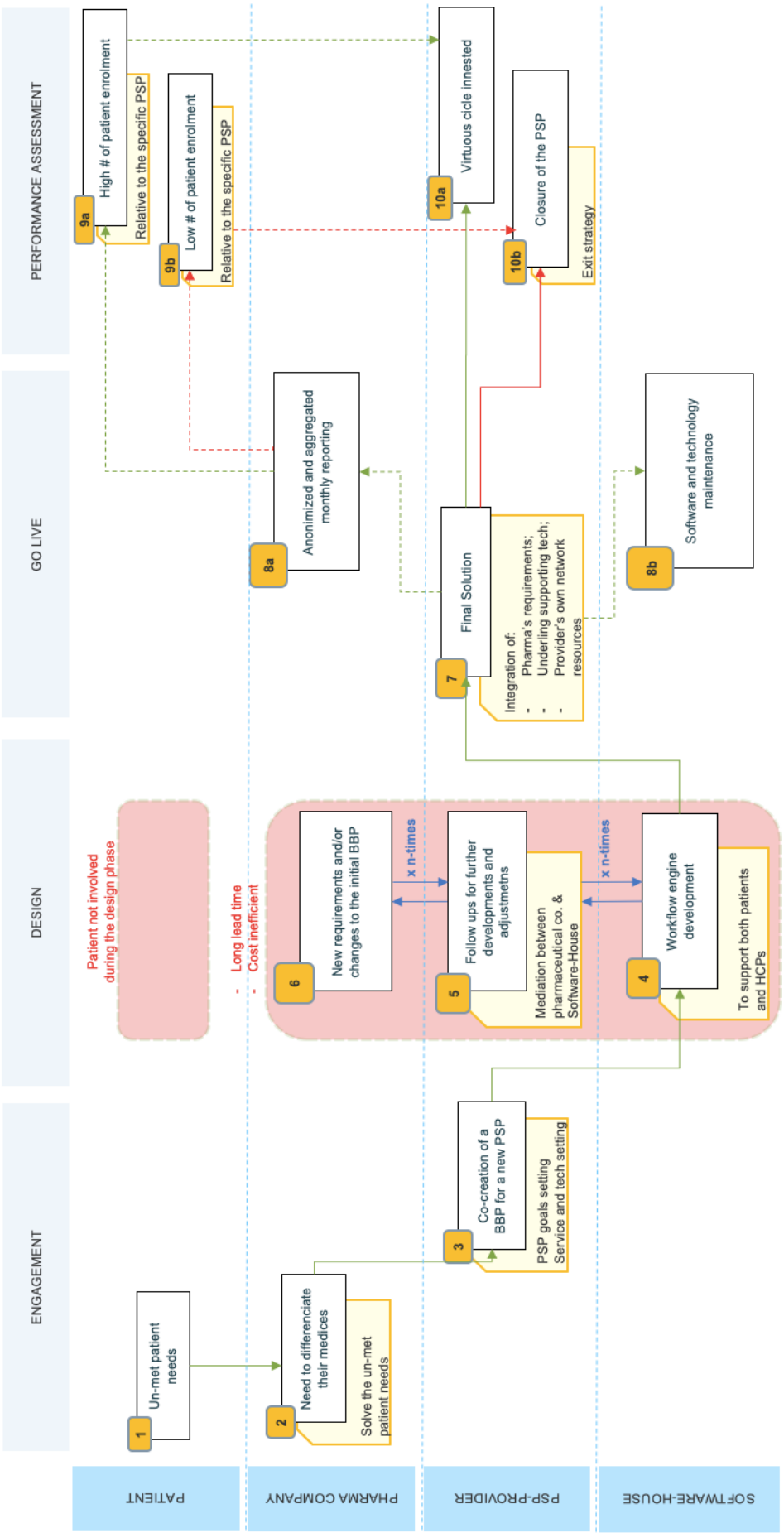

Figure 7 Design and development of a PSP in the Externalized Business Model

2.2.4 Analysis of the current state of the Internalized business model

The second case under consideration is a closed service platform business model (Figure 6), which according to Smedlund (2012), describes a situation where the supplier of the platforms does heavily invest to create a flexible front-end ICT, so that the end-user can have access to a set of comprehensive services, but at the same time chooses to not cooperate with just any third party customer of the platforms. In other words, the supplier decides to choose only a few selected partners which are essential to properly and effectively run the platform. In the case of the internalized business model, that would represent the pharmaceutical company (supplier), incorporating specific services provided by the PSP-Provider (customer) to complement its own service offerings, which are designed to address the needs of the end-users (patients) enrolled in the PSP (front-end ICT).

Compared to the previous case, here the coordinator of the relationships within the network is represented by the pharmaceutical company instead of the PSP-Provider, which become, for instance, a simple customer of said platform in order to complement the pharmaceutical company's PSP offering. Another difference is given by the fact that in this model, the front-end ICT is controlled by the supplier, whereas in the previous case, it was managed by the customer. Lastly, for the purpose of this case study, if in the platform complementor BM the stakeholder (Software-house) was in direct contact with the customer (PSP-Provider), eliminating any direct communication between the pharmaceutical company and said stakeholder, in this second BM, the pharmaceutical company would be managing a direct relationship with the software-house, thus developing its own set of services for the PSP without the mediation of the PSP-Provider. Therefore, the name of "Internalized business model".

According to Smedlund (2012), this would allow the pharmaceutical company to reduce its investments in creating and managing inter firm collaborations, because the whole purpose of the closed service platform business model is to integrate only a limited number of firms, eliminating the need to manage new integrations on a continuous basis. In contrast, it necessitates a high level of investment in front-end ICT, since that falls under the supplier's scope of activities, as opposed to the previous model. For instance, the pharmaceutical company (C) stated that the decision to develop and to provide a PSP resides in the core strategy of the company, as the purpose for creating a PSP is largely not driven by economic reasons. In fact, as in the previous case as well, a PSP in most of the cases is subsidized and provided for free to the patients currently under treatment with one of the medicines developed by the specific pharmaceutical company. Moreover, by regulation (Farmindustria, 2022) those services can't

be used as a marketing tool to influence patient's decision to choose one medicinal products over another, but instead, a PSP can be proposed only by the doctor currently tending the patient, after the latter has already chosen a specific medicine, unknowingly of the existence of those additional services on top of it. Here, according to the person being interviewed from pharmaceutical company (C), the very end-purpose of the PSP remains that of providing additional support and higher quality of life for chronic disease or rare disease patients, whereas the returns for the company is not measure in terms of direct economic returns, rather it comes from different transversal means such as to shows the company's commitment towards a specific disease, for the historic positioning of the company, as well as for the firms' overall positioning in the market. In fact, the way a PSP is managed within the pharmaceutical company doesn't come from reaching a threshold of the break-even point, but instead it depends on a carefully managed budget that has been assigned for the specific PSP of the company over the performance of the program itself. However, this doesn't mean that there are no issues at all from a purely economic standpoint. According to the PSP-Provide (B), the most critical part of a PSP development process is not its design, which is much appreciated by the pharmaceutical company, but rather where the design and economic phases meet, where most projects failure or downsizing come from. That's because, for the PSP-Provider, the economic aspect is an unavoidable element to be considered for each one of their PSP projects, and their economic profile depends on the overall status of all their active PSP. Unlike the pharmaceutical company, the provider's minimum requirement is to achieve at least the break-even between costs and revenues, according to the interviewee, while the sheer amount of marginal return varies greatly depending on the size of the projects, ranging from tens of thousands to a million of euros.

Another important recipient of the services provided by the PSP, according to the statement from the pharmaceutical company (C), are the specialized doctors for the specific rare or chronic disease. That's because a PSP can support the patient by providing information, instruction on how to use specific devices or how to take medicines, as well as issuing homecare services directly from the app and so on, that are all activities that can relieve the physician from personally tending to them, which can quickly become unmanageable with a larger number of patients. Instead, the doctors may have a better overview of the patient's therapy status thanks to real-time or near real-time information displayed in the dashboard provided with the PSP. The same concept has been outlined by the PSP-Provider (B) who added also a comment on how obtaining those benefits, can help in reducing the number of hospitalizations, which in turns improve the national health care systems' resiliency, that became one of the main

topics of discussion following the experience of the COVID-19 pandemic in recent years (2020-2022).

Overall, it's extremely important for the pharmaceutical company to build a trusted relationship with the doctors, as they are ultimately the ones who decide whether or not to enroll a patient into one of the pharmaceutical company's PSP. Doctors represent also the main source of reputable feedback for the improvement of the PSP, as well as a medium for the patient's feedback regarding what needs are not covered yet, which services may be underperforming or are just irrelevant based on the expertise of the physician and the empirical evidence coming from the usage of the PSP itself. This on-field feedback is an important factor to consider when determining which are the true drivers for this industry's future improvements, which are substantially different from the traditional technology driven upgrades.

2.2.4.1 Current relationships between actors in the internalized business model

The core strategy adopted by the pharmaceutical company (C), is based on the development of their own platform to support all the services that should be provided through a PSP, however the operative activities such as homecare, nurse-based call center, injections and so on, are delivered by the PSP-Provider, because that would require additional human resources that the pharmaceutical company couldn't afford to provide, thus the activity being outsourced to a third-party. The same is true for technical partners hired by the pharmaceutical company to assist them in the development of the IT infrastructure required by the PSP platform and the platform itself. And here come two main differences compared to the previous case.

The first major difference is given by the fact that the pharmaceutical company (C) stated that, although they outsourced the above mentioned technical and IT part of a PSP project, they did that by differentiating the software-houses they came in contact with. In fact, the interviewee mentioned four different companies they've been working together with since they started developing PSP one and a half decade ago. This is a clear strategic choice made to avoid the problem that affected the PSP-Provider (A) in the previous model, who on the contrary developed their whole suite of modular PSP services with the same software-house, falling into what is widely known as the lock-in effect, as they became largely dependent from said partner.

The second difference is a direct consequence of the fact the pharmaceutical company (C) is developing its own platform. This created the need to outsource the data collection and management part of the PSP usage, which was previously handled by the PSP-Provider as they

were in charge of the front-end ICT, but now it must be outsourced to a third-party, represented by the software-houses, in order to avoid infringing on the strict regulations governing topics such as patient privacy and the ethical usage of big data by the companies.

According to the PSP-Provider (B), on the other hand, they don't seem to share the same idea of the pharmaceutical company being the orchestrator in their network, as they strongly declared themselves being the one managing the relationships around the network. However, it's not clear whether they can be considered concurrent orchestrators of the network because, if the pharmaceutical company manages mainly the relationships required for the design, development, and launching of the PSP, the PSP-Provider (B) statements appears to indicate more the relationships and partners required from a more operational standpoint. As a matter of fact, the latter also mentioned that "for sure are the (pharmaceutical) companies the ones contacting us, and then we will activate our services in terms of gathering the (pharmaceutical company's) requirements, but it is equally true that we also have a specific role (within the organization) in charge of scouting existing local needs". Therefore, what can be inferred from this statement is that, in both cases, new PSP requirements in terms of services to be included into the program depend mostly, if not entirely on the pharmaceutical company's decisions, leaving the PSP-Provider as an actor who at this stage can just identify those needs, and then provide feedback and suggestions for the pharma. In other words, in the early stages of PSP design and development, it is indeed the pharmaceutical company that connects the dots within the network to complement its own offering. However, if the analyzed stage of the PSP life cycle is closer to the second half, the PSP-Provider's claim to be the orchestrator is not entirely false, because all the operational activities were outsourced for them to be managed on behalf of the pharmaceutical company. As a result, the relationship management mentioned by the PSP-Provider (B) spokesperson most likely refers to other stakeholders who may be involved during operational activities, such as logistic partners in charge of supplying patients with consumable parts of a specific treatment, or another software-house to develop their own set of tool and CRM portals which would then be integrated into the pharmaceutical company's platform as mentioned by the interviewees.

In fact, as stated by the PSP-Provider (B), they have strict requirements (commercial, financial, technical and informatic standards) that must be met in order for other stakeholders to become their partners, and this eligibility is further tested through an annual auditing review in which partners are compared against the KPI determined by the contractual phase. Lastly, if some

KPIs are not met, there's a “remediation” process in which the partner is required to solve the problems before deciding to end the partnership.

Overall, it appears that in the internalized business model, the actors have better defined roles and scope of responsibility (Table 4) compared to the externalized business model. In fact, in this case the pharmaceutical company’s requirement can be directly addressed to the partners entitled to cover the specific part of the PSP design and development process. This helped in avoiding the risk of falling into the previous case's two-step mediation of the same information managed by the PSP-Provider, which not only had severe consequences in terms of poor communication among actors, but also increased the lead time to design and deploy the new PSP, causing a surge of the overall development costs.

Table 4 Roles and Responsibilities in the Internalized business model

	Pharma side	**PSP-Provider**	**Software-House**	**Disease specialized doctors**
Design and development stage	Is the main orchestrator of the networks as the one reaching out the PSP-Provider to outsource the operative activities, and many different Software-House for the technical developments to avoid lock-in effect. Data collection and data management are also being outsourced to third party for regulatory constraints. Can be considered as orchestrator for the relationships management of this stage of the PSP.	Is not involved in the strategic decision for the design and development of the PSP, which remains entirely in the pharmaceutical company's scope. Is called to cover the operative services required by a PSP. It enriches the pharmaceutical company's PSP platform with only small piece of sotware for the operative services.	Is involved for the design and development of the pharmaceutical company's PSP platform for a purely techcnical stand point.	Are actively involeved during the design and developmen phases of the PSP.
Post-Lauching stage	Assessing the PSP performance based on the monthly reported received by other partners. Careful managment of the allocated budget as PSP doesn't generate direct revenues.	Is required to send monthly reports of the aggregated and ananonymized data collected from the enrolled patients. Can connect with other stakeholders, whose performance are assessed periodically to meet specific KPIs, else, there's a remediation procedure, and finally the termination of the relationship. Can be considered as orchestrator for the relationships management of the purely operative stage of the PSP.	Can either sell or sign a new contract for the PSP platforms maintainance. Is required to send monthly reports of the aggregated and ananonymized data collected from the enrolled patients.	Are the only ones who can actively propose the PSP services to patients that are already taking said pharmaceutical company's medical products. Are considered the true drivers for the PSP improvements, instead of technology driven drivers for other industries.

2.2.4.2 Current process for the design and development of the PSP in the internalized BM

In the internalized business model, the design and development process of a PSP follows a different sequence and type of interaction among the main actors of the network. The flowchart below (Figure 8) has been designed according to the statements recorded during the interviews of the pharmaceutical company (C), PSP-Provider (B), and partially, the same Software-House from the previous model, since that specific company had interaction with companies from both networks (see the aggregated coding for the externalized business model), therefore its statements on this specific business model can be considered as part of the meaningful contributions being recorded for the internalized business model.

The reason behind the creation of a PSP remains the same regardless of the business model being analyzed, however the main differences between the previous design and development process of said programs resides in the type of interaction that has been created, and the purpose behind each of them.

According to what the pharmaceutical company (C) reported, in the internalized business model, the active role in initiating a PSP project comes from within the pharmaceutical company itself, where there could be either single business units divided by the macro category of medical specialist branches which decide to open their own PSP, or a cross business unit team specialized in patient support programs, depending on the size of the pharmaceutical company itself (big and small respectively). Within those organizational units, there is a specific role called the "medical function" that is in charge of managing the entire PSP life cycle, from design to launch and further monitoring activities. This role is supported by a specialized physician of the analyzed disease to list and design the potential patient's needs that must be addressed and solved through the to-be developed PSP. Another crucial role is that of the internal person in charge of the legal department, who must coordinate the internal team to ensure that the PSP complies with local regulations and privacy rules, as well as the external administration in charge of the public tender (which is mandatory whenever a project exceed a certain threshold in terms of value).

The first problematic point that is shared with the externalized business model as well, is the fact that the patient is not actively involved during the design process of a PSP. In fact, as the PSP-Provider (B) mentioned, the identification of the patient's needs comes from the assumption and therefore, the inferences deduced from the analysis of what they called "real patient needs" that could be an element that makes a difference for the patient, followed by a pathology, therapeutic area, and drug posology analysis. And that is how the patient's needs are identified by adopting a patient centric approach. However, it could be argued that the above-mentioned approach is truly adopting a patient centric mindset (Giambelluca, 2021); after all, according to the literature review, patient centricity comes from considering patient's opinion during each phase of the design and development process of a product or service (Du Plessis *et al.*, 2017), whereas in this case, not a single input from the patient was included during the analysis.

That being said, there are certainly differences compared to the previous business model, and that is represented by the fact that in the internalized business model, the larger share of the

PSP design comes from the pharmaceutical company, while previously it was a result of a collaboration with the PSP-Provider. Which approach shows a better result can't be inferred from just a qualitative analysis of the interviews, however from this perspective it's at least possible to make some assumption on which elements provided some benefits and which did not. For instance, in this second case study, by avoiding the mediation of the PSP-Provider with other stakeholders and without coming into conflict on the core services to be included in the PSP desired by the pharmaceutical company, the latter could quickly proceed with the development stage of said tool by directly reaching out the software-house, who is only in charge of the technical development of the underneath infrastructure and platform to support the PSP.

Following the realization of their own PSP, the pharmaceutical company will then outsource the operative activities and services that require an intensive amount of human resources to the PSP-Provider. At this stage, the provider can propose some minor tool from their side to be incorporated into the pharmaceutical company's platform (e.g.: CRM, telemedicine tool, etc), while the main services and strategic decision of the PSP have already been decided by the pharmaceutical company as mentioned before.

Finally, the activities regarding data collection and data management must be outsourced even if the pharmaceutical company is the one actively managing the front-end ICT. That's because the latter can't come across patient data unless they are aggregated and anonymized. In the internalized business model, the ownership of the patient data and their managements are decided during contract negotiation with both software-house and PSP-Provider, who have their own central repository of data that are independently segregated project by project, while in the externalized business model, data were mostly collected and provided in the form of monthly reports by the PSP-Provider.

Overall, PSP platforms are designed and developed for and under the name of the pharmaceutical company, who has direct ownership and management over them, being the one initiating and subsidizing the whole project. However, these projects require an important investment from the pharmaceutical company as mentioned in the previous paragraphs, where a limited budget is allocated PSP by PSP, therefore requiring a careful and transparent management of the resources (Table 5). In fact, as mentioned by the pharmaceutical company (C), the decision to develop a specific PSP, or even a single piece of service for these programs, is usually dependent on permission from the Global team of the company, who would allow the

investment for a local service if the same solution can benefit the global network as well. The main strategy is to reduce the capital expenditure required for the development of each additional PSP as much as possible by leveraging on a proprietary modular platform solution, which was attempted by the PSP-Provider in the externalized business model, but with poor results. In this case, according to the interviewed software-house, the same strategy worked because of the fact that it's the pharmaceutical company itself who wants to exploit already developed solutions whenever possible. However, as mentioned by the pharmaceutical company (C), even when adopting existing solutions, the cost reduction does not completely exempt the company from the additional cost of a new project, as the same module must be declined for the specific pathology and within the local regulatory framework, which requires, for example, additional changes and customization, even when the desired outcome is fundamentally the same.

Table 5 Pain points of the current Internalized Business Model in the Italian market

List of pain points	**Consequences**	**Potential causes**
Not truly patient centric approach	Patient-Journeys are not designed to provide the patients with the most seamless process flow (ex: daily lenghy patient diary).	Patients are not actively involved during the design and development phases of the PSP, which goes against what the patient centricity definition provided by literature.
Lack of cross interaction	Only bilateral relatinships were established. Two separate stages of PSP development: one with the software-house and one with the local PSP-Provider.	No real collaboration mindset has been adopted by the pharmaceutical company and being the orchestrator of the network.
Modular platform solution orveseen by Global Team	High front-end ICT investments from the pharmaceutical company. Every single serive or PSP to be developed need to receive the approval from the Global team and have to bring benefits for the whole network, instead of the single local needs.	Although some logic of re-utilization are being adopted by the pharmaceutical company, the cost saving are still minimal as the "standard PSP" needs to be tailor and fit for the local regulatory framework and needs.
Lack of collaboration between direct and indirect stakeholders	Silos mentality, excessive secrecy or attempts to obtain exclusive rights to basic research tool and data.	Unfavorable environment that doens't incentivize collaboration among actors.
Strict regulatory framework	Pharmaceutical companies must outsource the data collection and data management activities to third parties, and receive only aggregated and anonimized reports. The most cutting-edge technologies using big data, like ML and AI, cannot be used, thus slowing down the PSP improvements.	Lack of a standardized framework and best practices to follow and the uneven development speed at which regulatory and technology words are evolving at.

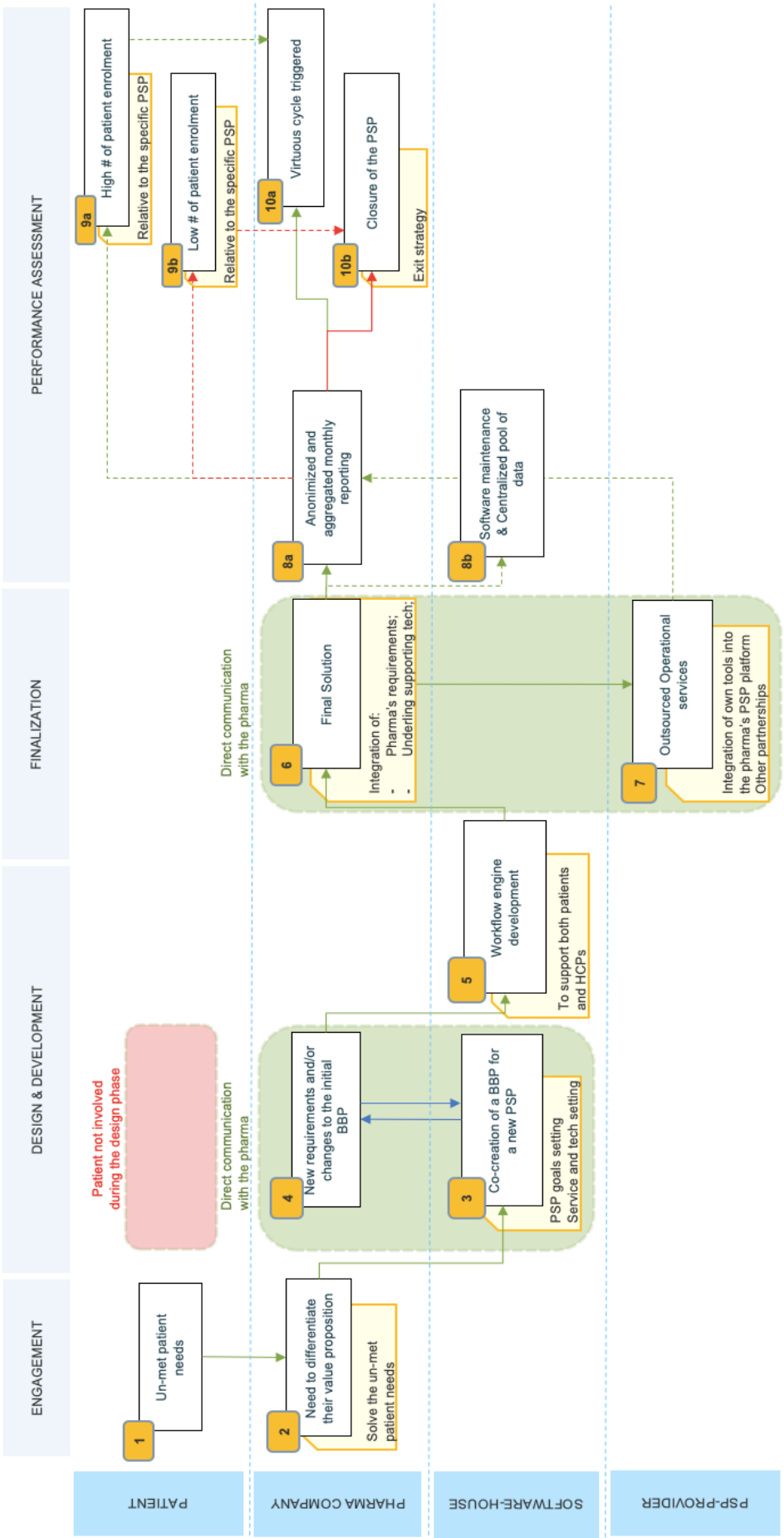

Figure 8 Design and development of a PSP in the Internalized Business Model

2.3 Current regulatory obligations and constraints on data exploitation

Each model has advantages and disadvantages that are directly related to how the regulatory framework and policies are today and how they will evolve in the near future, as there is currently no definitive legal definition or specific regulation for PSPs, leaving many questions unanswered. This is especially true when digital technologies are involved as they provide the means to collect large amounts of data, bringing out the ethical aspect about how much data firms are allowed to collect (Giambelluca, 2021). In fact, the only existing source that provides an outline of the PSP for the Italian market is given by Farmindustria's Code of Conduct, which has a binding effect only for member firms as the PSP-Provider (A) stated. This emphasizes the importance of defining a national regulatory framework and guidelines so that public institutions can provide a standard procedure for those who want to open a new PSP, rather than having procedures made in the local-for-local logic (Giambelluca, 2021).

According to the experience of the pharmaceutical company (C), which is a multinational company, one of the most challenging aspects of deploying a PSP is addressing each country's unique set of regulations and policies, which differ from one another. Indeed, according to the statements, regulations vary greatly depending on the "continent" under consideration, as the interviewee made a clear distinction between the United States, Europe, Asia, and Oceania. Nevertheless, additional layers of regulations governing local privacy issues must also be considered, as they usually overrule the more general norms. Therefore, by focusing on the Italian market specifically, the patient privacy topic is further detailed by the policies provided by institutions such as Farmindustria[1] and AIFA [2]. Finally, there's a whole series of little policies internal to the pharmaceutical company (C) itself that are even more restrictive than what is legally required for additional self-protection, outlining how sensitive the topic of data management and data governance alongside patient privacy is today.

Overall, it has been stated that an increasing complexity of industry regulations may lead to the closure of a PSP. An example being reported was when the GDPR was first introduced in 2016 since the data being regulated there are exactly the one being collected and analyzed throughout the usage of the patient support programs. Because the data being circulated concerns a patient's pathology, information such as the patient's name and surname, phone number, home address,

[1] Farmindustria is the association of drug companies that is a member of Confindustria and, in international arena, to the European Federation (EFPIA) and the World Federation (IFPMA), bringing together about 200 companies, both with national and international capital ('Protocollo_Intesa_AIFA_Farmindustria.pdf', no date).
[2] AIFA (Agenzia Italiana del Farmaco) is the national authority responsible for drug regulatory activity in Italy, and is the public body that, among other things, ensures access to the drug and its safe and appropriate use as an instrument of health defense ('Protocollo_Intesa_AIFA_Farmindustria.pdf', no date).

and any other piece of information that could help in identifying the specific person were strongly regulated from that moment onward, while also limiting their accessibility to the strictly necessary people. According to the pharmaceutical company (C) testimony, this led to a sort of "lock-in" of the platform, meaning that the accessibility of the data was much more restricted. Moreover, following other statements gathered during the interviews, pharmaceutical companies were prohibited from having access to patients' personal information, which made them necessarily outsource the data collection and data management activities to other stakeholders, such as PSP-Provider and software-house for instance, whereas the data ownership topic is typically agreed upon contractual phase. On the contrary, the pharmaceutical firms would only receive aggregated and anonymized data from said partners through what has been reported as monthly reports, from which the only type of analysis allowed were limited to having a high-level overview of the PSP performance in terms of number of patients enrolled, call handling, and the on-field operator response time, for example. These KPIs were typically decided during the contractual confrontation between the actors, in accordance with the requirements of the specific PSP.

Table 6 Current regulatory framework

Current state	**Consequence**
The only regulation for PSPs is provided by Farmindustria's Code of Conduct, which has a bidding effect only for member firms.	It represent the only reference point for companies, public institutions, etc. which bring a certain level of confusion.
Importance of defining a national regulatory framework and guidelines.	Procedures to open PSPs are made in the local-for-local logic.
The ethical aspect about how much data firms are allowed to collect, and the role of the GDPR.	Companies, and especially pharmaceutical companies are met with stringent rules over patient data collection and explotation.
Pharmaceutical companies are prohibited from having access to patients' personal information.	Outsourcing of the data collection and data management activities to other stakeholders.
Data are not supported by as developed regulations and policies.	Gap between what could be done (improved therapy efficiencies), how it should be done (ex: ML and AI), and how it is currently done (ex: lenghy questionnaires)
One of the most challenging aspect of deploying a PSP is addressing: - Each country's unique set of regulations and policies; - Local regulation and privacy policies; - Pharmaceutical companys own set of policies.	It represente one of the main reason behind the steady costs of PSPs.

Overall, it has been stated that whenever the regulations and policies governing the applicability of a PSP become too complex, pharmaceutical companies would typically argue whether it is still worthwhile to invest resources into developing and launching new PSPs, as they cannot always find a favorable environment, or simply being in a position where they are not allowed to further leverage on the collected data, as previously described. In fact, as the software-house stated, although they have already collected huge amounts of data through the years, a limitation that they found themselves confronting was due to the unequal speed at which the technological and regulatory worlds are traveling at. For instance, while technological advancement has already provided us with access to powerful tools such as machine learning and artificial intelligence that can generate valuable insights to be turned into value-added propositions for both end-users and companies, those tools can only function by being fed a large amount of data. However, these same data are not supported by as developed regulations and policies, resulting in a gap between what could be done, how it should be done, and how it is currently done. Therefore, the proliferation of customer's privacy violation news[3]. For instance, according to the software-house, ML and AI could be leveraged to automatically cluster patients and assign them a patient risk profile as they get enrolled into a PSP, since they are required to provide some personal information in any case. Today, the same procedure is managed by analyzing patients' data collected through questionnaires, which are typically internationally validated questionnaires like the Morisky as mentioned by the PSP-Provider (B). However, whether the requirement for patients to complete these typically lengthy questionnaires can be considered an approach that places the patients at the center of their strategy has been debated. In fact, according to Kruger in Giambelluca (2021), some PSPs provide "patient diaries" in which patients record information about their own health status, but there is currently no incentive system in place to encourage patients to continue filling out, which could be for instance a consequence for not actively involving patients during the design of the PSP's patient journey.

2.4 Ecosystem enable solutions and opportunities for PSPs

By analyzing two different business models for the patient support programs being adopted in the current Italian market, several industry inefficiencies have been identified (Table 2 for the externalized business model, Table 5 for the internalized business model), and in addition to the highly restrictive regulatory framework for data protection from one side, and the undefined

[3] It is reported that the major data breach incidents occurred in 2005 onwards. In 2005, 157 cases of data breach with 66.9 million records exposed were reported only in the US, which increased to 783 breaches by 2014, and more than doubled in just three years, reaching the 1579 reported cases in 2017 (*The History of Data Breaches*, 2022).

laws to regulate PSPs from the other, it all sum up to an adverse environment for the main actors involved in the PSP market to:

- Create lasting connection and nurture them over time for both partners and patients;
- Leverage on the most cutting-edge technologies like machine learning and artificial intelligence enable tools;
- Develop truly dynamic PSPs for patients that could evolve and be tailored for each patient as more information is being captured over their therapy journeys.

In fact, despite the fact that the patient support programs are intended to address patient's needs holistically and with a patient-centered approach, evidence shows that the various services included in them can hardly be considered accessible in a seamless manner because many of them are managed separately from one another. For example, the pharmaceutical companies interviewed mentioned a static website used to improve the disease awareness for patients that was not part of the PSP, which contradicts the objective of simplifying the therapy process for patients as it was supposed to be while developing the patient journey. Moreover, the current approach to patient support programs of the pharmaceutical companies is one in which actors interact in a bilateral way and the programs are designed and delivered in a market-to-market approach (Wallance et al., 2020).

2.4.1 The state of art of the PSP network VS an Ecosystem approach

Therefore, given the aforementioned situation, if Adner (2017)'s definition of ecosystem is considered, neither the externalized nor the internalized business model for PSP can be regarded as a real ecosystem. In his definition Adner outlined several key pre-conditions that have to be met in order to establish said system, namely: a focal value proposition; an alignment structure; multilateral relationships; materialization of the value proposition.

It can be recognized that the first condition, identifying a focal value proposition, has been met, since the overall purpose for the patient support programs is to increase patient's therapy adherence while also offering better quality of life through the adoption of a patient centric approach that covers the both patient and HCP needs in a holistic way. However, it's important to note that there is a significant difference between identifying an objective and actually accomplishing it, not to mention how it is accomplished. In fact, technically speaking patients enrolled in these programs have been proved to increase their therapy adherence compared to who did not go through the same solution (Brixner *et al.*, 2019), whereas whether patient's quality of life has truly improved is still difficult to assess because of the lack of a widely used standard key metrics, such as patient reported outcome (PRO) used in the US, and whether the

existing solutions are the most efficient ones, since the collected data can only be used for the operational improvement of the PSP and not for the purely scientific improved of the therapy and medication due to the unclear regulation in place, as mentioned by the PSP-Provider (A). However, to Adner's point, the important aspect of the establishment of an ecosystem at this stage is to just find said focal value proposition that serves as the general direction in which the ecosystem's actors should strive, as it provides the starting point to build on the remaining aspects of a more interconnected network. This leads us to the next key condition represented by the alignment structure.

According to Adner (2017), as companies commit to achieving the above mentioned focal value proposition, they will be required to satisfy a certain level of coordination and balancing each other's interests, in other words, to create an alignment structure where roles and responsibilities are clearly defined. Provided that there may not be a single best solution, the evidence shows that roles and scope of activities are far from well defined; in fact, in the externalized business model the network orchestrator role is represented by the PSP-Provider, whereas in the internalized business model, the pharmaceutical company covers the same role. This situation is most likely the result of a failure to achieve a balance between the respective interests, which resulted in the development of one or the other business model depending on which company prevailed over the others in their respective network. However, for the establishment of an ecosystem, balancing each company's requirements and expectations is of paramount importance, as, based on Adner (2017)'s considerations, ecosystems have a certain level of acceptance for said discrepancy to still being able to bring the promised value proposition. In fact, every company being interviewed mentioned the importance of the co-creation and co-design during the development of PSPs, although not much has been done to encourage this behavior, because the deciding factor was always a purely economic driven evaluation, as the interviewees stated that many projects failed due to the fact of not finding an economic agreement, despite the value that the envisioned PSP could bring to the patients, and conversely to the society.

Generally speaking, the problem of weak collaboration among the actors of the network represents one of the main reasons for the PSP market failure and its shallow grip on the current industry. In fact, the lack of collaboration contributed in the declining R&D productivity for the pharmaceutical industry, as it led to poor communication with regulators, rare cooperation during the precompetitive and preclinical research, excessive secrecy or attempts to obtain exclusive rights to basic research tool and data (Cockburn, 2006). This industry level

framework didn't encourage a transparent communication between pharmaceutical companies, patients, regulators, and other stakeholders, which could for instance help in building trust, which is a requirement for the establishment of meaningful collaborations among parties (Du Plessis *et al.*, 2017). Without collaboration, or with a low level of collaboration a standard framework to regulate the industry, or platform to share best practices can't be built. Instead, as it emerged from the case study analysis, various independent and at moments even overlapping solutions have been developed over the last 15 years that PSP industry reached the Italian market. Moreover, since each PSP development is contracted individually, they are also owned and operated independently as mentioned during the interviews. This situation leads to the fact that there will be little to no opportunities to compare different PSPs, analyze their data, and therefore find useful insights, like identifying the best practices to replicate in future developments, optimize patient outcomes and cost related efficiencies (Wallance et al., 2020). In fact, as the PSP-Provider (B) stated the costs tend to scale almost linearly with each additional PSP due to the various fixed costs involved, like human resources related costs, and the fact that regardless of the proposal from the provider, additional customizations were always expected from the pharmaceutical companies. This plethora of patient support programs not only makes it difficult for healthcare professionals to manage them, but it also makes it difficult for patients to access the various services, when the goal should be to place the patient at the center of the strategy by developing a solution that is more user friendly and convenient for them (Wallance et al., 2020). Overall, this brought the consequence, as complained by the software-house being interviewed, of an overly scattered repositories of data which increased the difficulties for companies to comply to the current general data protection regulation that is in place in the European regulatory framework, which in cycle doesn't encourage a collaborative behavior as required by the industry and for the creation of an ecosystem.

According to Adner (2017), another condition required for the development of an ecosystem is the establishment of multilateral relationships among actors. However, the multilateral relationship that is important to the creation of the new construct is not one in which there are simply direct and indirect interactions, but rather one in which there is a critical connection among players such that if one relationship is undermined, another one will fail. But the evidence from the case study shows that only bilateral relationships have been established. There are instances where the pharmaceutical companies never need to be in contact with the software-house or other logistic partners required to deliver the services like in the externalized business model, or other cases in which software-house and PSP-Provider directly in contact with the pharmaceutical company do not interact with each other since the platforms being used

are distinct from one another by nature and by construction as in the internalized business model case, for instance.

However, Adner (2017) stated that multilateral relationships and the aforementioned conditions must be met for the materialization of the agreed common value proposition as intended in the definition of ecosystem. This would lay down the environment in which each actor could focus on its own role and activities without fear of being exploited by other network firms, since it would only harm the ecosystem as a whole. Therefore, resolving the current problem about trust, and the not aligned structure as previously described. Transitioning toward an ecosystem-based approach will likely bring significant improvements in patient outcomes (Singhal et al., 2020) while also reducing and/or eliminating some of the common causes of inefficiency seen in the current approaches.

Based on the analysis, it can be stated that none of the reviewed business models can be considered as an ecosystem, however the advantages and solutions that adopting an ecosystem approach could bring to the existing network are significant, and companies should take this opportunity into consideration.

2.4.2 Technical requirements for an Ecosystem approach

Thus far, only the type of interaction that must be established among ecosystem companies has been examined; however due to the influence of digital technologies, the technical aspect required for the establishment of an ecosystem, especially if a holistic approach is to be achieved, as in the pharmaceutical industry case, cannot be overlooked.

According to Singhal *et al.* (2020), ecosystems are the result of three main layers that are interconnected to provide the means and the infrastructure to build a seamless exchange of data and information, not only within the same company but also between different entities, in order to tend to the common value proposition. Those foundational layers, as mentioned in previous paragraphs, are represented by the infrastructure, the intelligence and the engagement layers.

However, the logical inference the can be made based on the information recorded during the interviews conducted for this research is that: while the engagement layer was undoubtedly the most debated aspect of the PSP, being the platform to be developed to sustain the services required by a specific use case, it also represented the weakest part of the three because the best approach to developing and maintaining the many different PSP solutions has yet to be discovered. Indeed, challenges have been encountered in both externalized and internalized

business models, with the former presenting more visible issues than the latter due to the common requirement for customizing every single PSP according to the local needs. However, in the second case, said PSPs are developed and owned by the pharmaceutical company itself, so some logic of re-utilization of already developed modules is implemented as mentioned by the software-house, whereas in the other case, the same logic is completely disregarded because said modules are developed and owned by the PSP-Providers, leaving them with no opportunities to leverage their suite of already developed services, and to be part of an unsustainable business. Another aspect of the engagement layer mentioned by Singhal et al. (2020) is how it should require a shared digital platform so to provide to the end-users with an easier access to all services through one main portal, which not only is not satisfied as many services can only be found and reached from different portals, but it also required a significant effort for patients and healthcare providers to feel accustom with the new technologies. In fact, one of the main challenges for the PSP-Provider (B) was to provide remote communication channels to patients and physicians that greatly differed from the traditional face-to-face communication to which they were accustomed to.

With regard to the infrastructure and intelligence layers not much information has been shared, although it was mentioned that the software-house developed their services based on Amazon web services (AWS) as the infrastructure to collect data from both patients and HCPs usage of the PSPs (see Figure 4). This is in line with the modern days trend to consider data as an asset, since it is from the collected data that additional insights and actionable information can be extracted from. However, as both PSP-Provider (A) and software-house being interviewed stated, although the amount of data being collected in the last few years are enough to be leveraged by the advanced analytics tool to improve current processes and to provide patients with better services, most of these opportunities are being obstructed by the regulatory framework and constraints which greatly limit companies' ability to exploit the collected data. However, according to Singhal *et al.* (2020), this situation can partially be attributed to the lack of trust and transparency between the value-added benefits that companies promise to offer in exchange for the exploitation of patient data before the latter is willing to make this trade. As a result, protecting an individual's privacy is a critical topic that must be addressed before new digitally enabled approaches and paradigms can be developed and adopted by companies, allowing them to serve patients in a holistic way.

CHAPTER 3. DISCUSSION AND FINAL REMARKS

Patient support programs are one of the new ways for patients to access additional services that are not concurrent with the national healthcare system to enhance their therapies while receiving holistic care from certified HCPs both in person and at home, thanks to the adoption of new technologies and ICT in general. These programs have been demonstrated to improve the patient therapy adherence and quality of life if properly designed and developed with the patients and for the patients. However, several issues characterize the current approach to patient support programs, both in terms of how companies could better provide and capture the value added to the society, and the several institutional and national challenges, such as defining a common regulatory framework for the PSPs, and the topic about the general data protection.

Thus, the significance of this paper, which attempts to outline the main challenges that exist today in the PSP industry, and how an ecosystem approach based on a service platform business model could represent a solution to them is highlighted.

Overall, an in-depth analysis of the current market situation in the pharmaceutical industry, in addition to the main trends characterizing current day's paradigm shift from a product-centered to a customer-centered approach driven by technological development, was described to provide a general idea of the existing situation in which the PSP industry is confronted with. The analysis of the two PSP business models reveals that companies have yet to reach the stage where their relationships and connections can be considered as part of an ecosystem, as Adner (2017) intended.

3.1 The inherited past challenges

From the analysis it was evident that companies have yet to find or even define the boundary of responsibilities that each role should follow. In fact, there isn't a common understanding and agreement about the extent to which one can exert their influence and requirements, while actually obtaining them, which, for instance, led to the unsuccessful strategy adopted by the PSP-Provider (A). The only adoption of the service platform business model in its variations adjusted for the two case studies under consideration are insufficient to address neither the current market needs and expectations from the end-users, nor the industry inefficiencies, with the declining R&D productivity serving as the root cause and driving force of said challenges. This shows us how a thorough analysis and definition of the relationships to be created with

other stakeholders should represent a main part of a company strategy, instead of addressing it retrospectively.

What emerged from the analysis is that regardless of which business model is being taken into consideration, there is clear divergence of interest among players. Although a certain degree of misalignment between the notion of competition and value capture and the expectation of value creation and value distribution among parties can coexist within the same network, there is a certain threshold that each ecosystem is able to sustain while still being able to deliver the promised value proposition (Adner, 2017). This represented the starting point for the several issues that has been identified during the analysis, as well as the variable that gave birth to the two business models from the case study, depending on which company's interest prevailed over the other, thus marking the firm who will play the role of orchestrator.

However, as mentioned in the analysis, the high degree of divergence of interest among parties in the same networks is a consequence of the inherent lack of trust, despite the fact that they all share the same focal value proposition of improving patient therapy adherence and quality of life through the development of the PSPs. This hindered any proactive behavior to initiate meaningful collaborations, while only bilateral relationships were established among companies in both the externalized and internalized business models. Many of these challenges come as a direct result of the overall industry environment where companies used to heavily compete with each other even in the preclinical research, which led to the development of excessive secrecy, data hoarding and silos behaviors in the attempt of obtaining exclusive rights over the new discoveries. And if this practice is common and incentivized in the consumer industrial market as higher competitions foster innovation and better value proposition, it can be argued whether the same behavior should be as marked in the healthcare industry as well, where patients' health should be put at the center of attention by companies as it is reported in their mission and vision.

In the case of the externalized business model, poor communication and unclear roles and responsibilities are just some of the weaknesses touched during the previous analysis, and all those issues coupled together resulted in long lead time for the PSPs deployment, increase overall costs, and occasionally, it also led to project downsizing or failure despite the clear advantages that the PSP could bring to the end-users. The same issues could be found in the internalized business model, although with a smaller impact than the previous case, since the pharmaceutical company owns the products/services in question. However, the lack of cross

interaction remains a persistent issue as it led to two separated stages for PSP development: the first with the software-house for the development of the pharmaceutical company's own PSP, and the second with the PSP-Provider, for the integration of the latter's piece of services into the pharmaceutical company's already developed platform.

3.2 The arising new issues

On the other hand, if digital transformation and the fast-paced technological development opened new opportunities for the pharmaceutical industry to exploit and to face the current market challenges, this new frontier also raised additional questions and hurdles to be addressed, such as the ethical data usage and data collection by companies, as well as the issues arising from data breaches and patient privacy safeguard mentioned in previous chapters.

Therefore, the regulatory framework must be considered to complete the overall industry picture, starting from the local regulations and policies. This is especially true in the pharmaceutical industry and the healthcare industry in general, which require tighter and more regulated practices compared to other industries, since sensitive patient data are regularly collected for therapy-related procedures. However, as emerged by the interviewees' collected statements, there is a clear gap in the current national and international data regulations, which is even more accentuated when the focus is on patient support programs. In fact, the code of conduct elaborated by Farmindustria, which is not a public institution, is the only point of reference for PSPs in the Italian market. However, due to its role and reputation in the related industry, it still provides a reliable general indication about the best practices that other companies must follow, though it should be noted that the clauses contained in said code have a binding effect only for the member firms. Therefore, as suggested by Giambelluca (2021), a public regulation must be developed as soon as possible in order to provide a standard procedure that both private and public institutions could follow, while also reducing uncertainty on many questions that remain unanswered today. As a result, the earlier the PSP issues are addressed and framed, the more efficient and smooth the process will be for everyone (Giambelluca, 2021).

Finally, both models showed significant restrictions regarding their ability to improve the existing PSPs further and provide better-tailored solutions and processes due to the local regulatory constraints regarding data collection and management. In fact, it has been mentioned how the collected data can only be used for the improvement of the operational aspects of the developed solutions, while any purely scientific analysis made on the collected data cannot be

performed, since the pharmaceutical companies are only allowed to access to aggregated (depending on the disease not even regional data may be allowed) and anonymized patient data. This is the reason why, although digital technologies made significant progresses over the last few years, many new tools for data analytics, such as machine learning and artificial intelligence that companies like software-house in primis would like to implement in the PSPs, are faced with a hard wall that can't be overcome unless some changes happen within the regulatory framework first.

This last aspect outline how the starting point for further improvement in the PSP market should begin with a definition of clearer rules that not only provide a standardized process for companies to follow instead of finding solutions at local levels, but it should also encourage companies to provide more transparent value proposition in terms of the exact amount of benefits that patients can expect to receive in return for personal data being collected and analyzed before they are willing to make this exchange. As a result, this commitment will help to establish credibility with external stakeholders such as patients and regulatory agencies (Du Plessis *et al.*, 2017), but it will also contribute in improving the lack of trust among companies of the same network, thus fostering the creations of a true ecosystem around patient support program.

Overall, clearer roles and responsibilities, improved communication among players, reduced agency costs, and the establishment of multilateral relationships among stakeholders are all aspects that must be addressed in order to meet both past and current challenges of the PSP industry. This emphasize the importance of adopting an ecosystem approach as guideline for the creation of meaningful interaction between all actors of the network, and ultimately fully exploiting the opportunities provided by new technologies to push scientific research towards new heights.

Understanding the root causes of the current PSPs problems is the starting point for further analysis on this topic. Therefore, additional research is suggested to provide more quantitative data about the real impact that the opportunities of an ecosystem approach based on service platform business model could offer to companies, and serving as evidence for its efficacy and credibility not only for the directly involved firms but also for the public institutions, who would then have a reason to develop better policies and regulations to foster industry's development.

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APPENDIX

Table of Figure

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Aggregated codings

Externalized Business Model

First order concepts	Second order themes	Aggregate dimensions
L'azienda farmaceutca, che ha sviluppato un nuovo farmaco, si rivolge ad un PSP provider per migliorare l'aderenza terapeutica al farmaco.	Modello di sviluppo del PSP	Design e sviluppo di un PSP
Idetificazione degli un-met needs dei pazienti e sviluppo di servizi di supporto ad hoc		
Processo di co-creation con il PSP-provider parte da una base standard da customizzare		
I needs da risolvere non possono essere troppo numerosi.		
Co-design tra software-house e provider di un workflow engine per supportare un patient journey specifico		
Key activities necessarie allo sviluppo del PSP: project management, project design, ricerca di mercato, focus group con clinici, medici e pazienti, coinvolgimento di funzioni aziendali come la direzione medica, supervisione sientifica, funzione regolatoria di compliance, funzione legale.	Attori coinvolti per il design del PSP (lato pharma)	
Soggetti per la parte dei PSP provider sono: head of project development, team di referenti, medical advisor, CFO	Attori coinvolti per il design del PSP (lato provider)	
Arruolamente del paziente al PSP tramite forma cartacea, QR code o altre modalità in un centro aderente ai PSP	Patient-journey	
Gamma di servsi e posibili touchpoint in base alle esigenze del paziente: call-center, messaggistica, video esplicativi, coaching-programs, supporto psicologico.		
Informativa sul PSP da parte del medico avviene mediante la direzione scientifica o la direzione medica di territorio oltre che dall'agente dell'azienda pharma	HCP-journey	
Coaching per il personale sanitario		
Criteri di scelta del PSP per il medico e per il paziente		
Check up regolare degli infermieri sui pazienti tramite servizi di messaggstica e call-center		
L'ecosistema del PSP è composto da: software house, PSP provider, aziende farmaceutiche, professionisti sanitari, sub-contractors e pazienti.	L'ecosistema del PSP	Ruoli, Attori ed Ecosistema nel PSP
Nel modello esternalizzano non c'è alcuna interazione tra l'azienda pharma e le software-house e/o altri subcontractors.		
La software-house non può essere propositiva nel proporre un PSP ad una azienda pharma, se non in parternship con un provider.		
Tipo di interazioni medico-paziente dipende dalla complessità della malattia, ma comunque preponderante per il rapporto tradizionale piuttosto che quello telematico		
Sviluppo di un know-how specifico da parte della software-house in relazione ai processi del PSP-provider che porta allora formazione di un lock-in effect		
PSP provider si occupa di fornire gli operatori sanitari, che sono contruattualizzati a progetto.	Attori di un sistema PSP	
Tutti i servizi sono rivolti ai pazienti cronici.		
Le aziende pharma sponsorizzano la creazione dei PSP, tramite i PSP-providers o contattando direttamente le software house.		
Rete di professionisti composto da 250-300 individui (in ITA)		
PSP non sono una leva prescrizionela per il farmaco, ma sono una leva sana in ottica dell'aderenza terapeutica del paziente	Compliance	Obblighi e restrizioni normative
Normative dettate da Farmindustria rendono molto difficile per le aziende pharma crearsi il PSP autonomamente		
L'azienda farmaceutica non può avere accesso ai dai dei pazienti, se non che solo a livello macroscopico di dati aggregati e anonimizzati forniti dal PSP provider.	Vincoli sulla raccolta e utilizzo dei dati dei pazienti	
PSP-provider ha il maggior potere di accesso ai dati dei pazienti		
Tipologia di dati spendibili sono solo quelli anonimizzati e aggregati ai fini di reportistiche		
Vincoli legali sull'uso dei dati del paziente (no profilazione pazienti)		
Vincoli sull'uso dei dati del paziende imposti dalle pharma ai providers (solo per miglioramento dei servizi)		
Misurazione indiretta dei KPI per: aderenza terapeutica, efficacia dei PSP	Utilizzo dei dati	
Uso di dati per migliorare i processi logistici		
Dati aggregati utilizzati dalle aziende pharma per monitorare l'andamento del PSP soltanto per la fase post-lancio fino al raggiungimento di una fase di stabilità		
L'estrema granularità dei ruoli rende molto complessa la visualizzazione dei dati dei pazienti ai prestatori di servizio		
Ristretto uso di ML e AI		
Applicazioni mobile a supporto del PSP per la Sclerosi Multipla collegato ad un sistema CRM	Tecnologie digitali interconnesse	Tecnologie digitali
Applicazioni mobile indipendenti dal PSP con l'unica finalità della diseas-awareness	Teconologie digitali statiche e non connesse	
Mancanza delle aziende pharma di APP / Piattaforme / devices / tecnologie aggiuntive da sfruttare per raccogliere ulteriori dati dai pazienti		
Esistenza di un web-site statico dell'azienda pharma a servizio dei pazienti da cui reperire informazioni sulla patologia, ma non prevede interazioni tra le due parti.		

3 Tipi di pagamenti: una tantum, ricorrenti mensili, ricorrenti variabili	Revenue streams	Business model del PSP-Provider
I programmi dei PSP sono dei contratti d'appalto a tempo (nuova gara ogni 2-3 anni), con strategia di exit		
Rete di professionisti sono tutti freelance in partita IVA; dipendenti interni (tra cui, centrale operativa e i PM) ricevono uno stipendio e basta	Cost structure	
il PSP è un prodotto/servizio fatto su misura, basato sul concetto di modularizzazione e customizzazione	Value proposition	
Vantaggio competitivo dei loro PSP è dato da: la trasparenza, la chiarezza, il co-design		
Offrire al cliente dati di resa porta più svantaggi che vantaggi, poichè l'AIFA non paga i PSP		
Mercato di nicchia e l'importanza di ogni singolo cliente	Customer relationships	
In un modello esternalizzato i costi per l'erogazione dei servizi di un PSP sono sostenuti dalla farmaceutica	Cost structure	Business Model dell'azienda pharma
Non si fa uso di logiche di break-even point, bensì di budget allocati per specifici progetti		
In ambito PSP, i ricavi delle farmaceutiche derivano esclusivamente dalla vendita dei loro farmaci	Revenue streams	
Brevetti sui nuovi farmaci	Key resources	
Attività informativa, non publiccitaria, degli "agenti" delle farmaceutiche presso i medici prescrittori dei	Key activities	
Numero di servizi e tipologie di professionisti sanitari di un PSP dipende dalle richieste e dalle disponibilità economiche della farmaceutica	Value proposition	Business Model della Software-house
Contenere tutti i dati all'interno di un sistema chiuso e protetto mediante i cloud di AWS		
A seconda del modello di business creatosi con gli altri soggetti, i ricavi possono arrivare o dal PSP-provider o direttamente dalla farmaceutica	Revenue streams	
Due tipi di contratti: a team dedicato; a time-material.		
Alti costi di interazioni con la casa madre dell'azienda farmaceutica per questioni di compliance	Cost structure	
Network costruito sulla base di relazioni passate e per referenze	Channels	
Capitale umano di ingegneri informatici	Key resources	
L'efficacia solo parziale della logica dei building-blocks del PSP-provide nel modello di business esternalizzato	Difficoltà per il PSP-provider nell'assecondare le richieste dell'azienda farmaceutica	Caratteristiche del modello di business esternalizzato
Personalizzazioni difficili da manutenere anche per la software house		
Richieste del PSP-provider poco chiare portano ad un numero eccesivo di iterazioni nella fase di progettazione del PSP	Difficoltà per la software house nell'assecondare le richieste del PSP-provider	
I servizi apportati dalla software house non sono puramente tecnici ma anche di consulenza		
Alto tournover nel team dal lato del PSP-provider causa un ripetitivo dispendio di risorse e di tempo per la software house		
PSP gestito internamente da una BU dell'azienda farmaceutica stessa	Facilità per la software house nell'assecondare le richieste dell'azienda farmaceutica	Caratteristiche del modello di business internalizzato
Maggiore libertà d'azione per la software house nel soddisfare le richieste dell'azienda farmaceutica		
Possibilità di riutilizzo dei building-blocks all'interno di PSP diversi della stessa azienda farmaceutica		
Presenza di un team dedicato con cui interagire		

Internalized Business Model

First order concepts	Second order themes	Aggregate dimensions
Un progetto PSP parte da una proposta dell'azienda pharma (mediante bando), accolta e negoziata dal PSP-Provider a seconda delle necessità da soddisfare e del budget a disposizione. In alternativa, il provider può avvalersi di figure di scouting di necessità sul territorio.	Modello di sviluppo del PSP	Design e sviluppo di un PSP
L'obiettivo del PSP è quello di migliorare l'aderenza terapeutica.		
Approccio paziente centrico ed olistico derivante da un'analisi della patologia, dell'area terapeutica, dall'inclusione di stakeholder specializzati nella patologia, e della posologia/formulazione del farmaco.		
Valore etico del PSP che va incontro alle esigenze del paziente.		
Servizi inclusi nel PSP variano a seconda della patologia curata tra cui: call center di infermieri per servizi a domicilio, piattaforme digitale per l'e-commerce (di consumabili della cura), supporto psicologico.		
L'azienda pharma tende a sviluppare piattaforme standard e modulari con la totalità dei servizi a livello global, che verranno successivamente declinati a seconda delle necessità delle singole "regioni" (localizzazione).		
Eventuali personalizzazioni vengono implementate solo se va a vantaggio di più paesi. altrimenti è difficile che l'HQ dell'azienda pharma proceda con l'investimento.		
Il PSP "finale" è l'unione dei moduli specifici sviluppati dal PSP-Provider per conto della pharma e dei moduli/tool generali di proprietà della pharma stessa.		
PSP dinamici al fine di migliorare l'efficacia mediante la raccolta di feedback sia dei pazienti che dei medici.		
Difficoltà inorgono tra la fase progettuale e la fase di contrattazione economica.		
Amministrazioni per la gestione delle gare pubbliche.	Attori coinvolti per il design del PSP (lato pharma)	
Referente interno all'azienda pharma con esperienza scientifica e medica dell'area patologica, per la gestione della parrte legislativa, privacy, coordinamento tra dipartimenti.		
La Medica è la funzione interna alla pharma che si occupa della gestione del PSP e di tutta l'attività non promozionale.		
Ruoli del personale coinvolto sono: - Lato psp-provider: project managr, business analyst, varie figure speiclistiche quali il biologo nutrizionista, fisioterapista, psicologo, e altri partnes come software-house, provider di telefonia, e l'associazione pazienti. - Lato non sanitario: project manager, medical scientific liason (MSL), procurement della medica.	Attori coinvolti per il design del PSP (lato provider)	
La piattaforma di un PSP è caratterizzata da un front-end sia per il paziente, dove sono presenti i servizi da questo utilizzati (es: calendario iniezioni), sia per il medico (es: dashboard con dati aderenza del paziente).	Patient&HCP-journey	
L'intervento del PSP-Provider avviene solo nel momento in cui il medico prescrive un farmaco dotato di PSP.		
Fiducia tra medico e forza vendita dell'azienda pharma o il case-manager sono alla base del successo di un PSP.		
Sviluppo di piattaforme multi-channel per soddisfare le esigenze degli stakeholders (software , app mobile, etc).		
L'exit strategy porta a diverse conseguenze anche reputazionali all'azienda pharma, oltre che a guidare il paziente verso una soluzione alternativa della gestione della propria patologia.		
Sviluppo del PSP a nome dell'azienda pharma da parte della software-house senza l'intermediazione del PSP-Provider. Quest'ultimo, si limita ad eseguire la parte operative che l'azienda pharma gli delega.	Rapporti tra gli attori del network di un PSP	Ruoli, Attori ed Ecosistema nel PSP
Il PSP-Provider è libero di gestire più piattaforme di aziende pharma differenti.		
Il PSP-Provider crea e gestisce il proprio network aggiungendo o rimuovendo partners.	Gestione del network	
Collaborazioni con partner qualificati, seguendo policy global del PSP-Provider.		
I criteri per individuare un partner qualificato comprendono l'aspetto commerciale, finanziario, tecnico informatico.		
Processi di auditing da parte del PSP-Provider a cadenza annuale per verificare il rispetto dei KPI stabiliti in fase di contrattualizzazione.		
Processo di "remediation" del PSP-Provider, che, se fallita, fa interrompere la collaborazione.		

La legislazione dei paesi ha un forte impatto sulla gestione dei PSP. Gli USA hanno una regolamentazione distinta da quella che è quella europea basata sul GDPR, che è a sua volta diversa da quella dell'Asia e dell'Oceania. Inoltre, esistono anche regolamentazioni locali e policy aziendali più restrittive.	Compliance	Obblighi e restrizioni normative
Normative stringenti in materia di privacy detttate dall'AIFA.		
L'aumento della complessità delle normative di settore può portare alla chiusura dei PSP.		
Il paziente non è mai oggetto di attività promozionali, né dai psp-provider, né dalle aziende pharma o dalle aziende produttrici di medical device.		
L'azienda pharma ha accesso solo ai dati anonimizzati dei pazienti.	Raccolta dati e loro accessibilità	
Sussiste un obbligo di anonimizzare ed aggregare i dati raccolti (ad un massimo di dati regionali) prima di poterli utilizzare/condividere mediante reportistiche.		
Tipologie di dati grezzi che si possono raccogliere sono: dati anagrafici del paziende, l'operatore assegnato al paziente, l'ora in cui il paziente viene contattato.		
La definizione del ruolo del PSP-Provider a titolare dei dati raccolti avviene durante la fase contrattuale.		
La raccolta dati può avvenire mendiante l'utilizzo di questionari validati a livello internazionale (es: Morisky).		
Principale feedback di riferimento è dato dai medici e dai pazienti sull'uso dei servizi attuali, che vengono recepiti dal team di gestione del PSP.	Utilizzo dei dati	
I KPI dipendono e variano a seconda della patologia e dalle esigenze del cliente.		
KPI principali sono: - Performance nella gestione delle chiamate e i tempi di risposta dell'operatore territoriale; - Percentuale di utilizzo del PSP rispetto alla popolazione dei pazienti; - Livello di aderenza terapeutica; - Dati aggregati e statistici sulla qualità di vita del paziente, necessari per individuare aree di miglioramento.		
L'evoluzione da un approccio face-to-face ad un approccio più digitale.	Evoluzione dell'approccio strategico	Platform-based solution
Difficolta nel far accettare agli users le nuove tecnologie.		
Nuove partnerships con aziende terze (Siebel CRM su Oracle Cloud infrastructure) hanno agevolato l'adozione delle nuove technologie da parte degli utenti finali.		
Utilizzo di piattaforme e app facilita la comunicazione sia con il paziente sia con il medico.	Vantaggi	
E' possibile sfruttare conoscenze pregresse per sviluppare nuove soluzione ad esigenze passate.		
Utilizzazione di un database univoco per raccogliere e analizzare i dati, ma sempre nel rispetto delle norme in materia di privacy.		
Forte tendenza alla personalizzazione delle piattaforme nonostrante l'esistenza di soluzioni trasversali già esistenti (database univoco).	Restrizioni	
Disconnessione tra le varie piattaforme dei PSP differenti.		
Aziende Pharma di grandi dimensioni si organizzano in BU, centralizzando invece tutte le funzioni necessarie allo sviluppo e gestione dei PSP, mentre quelle di medie dimensioni utilizzano l'approccio di un team cross BU.	Struttura Organizzativa delle Aziende Pharma intorno ai PSP	Business model dell'azienda pharma
Il fulcro della BU è la macrocategoria di patologia. Al suo interno ci possono essere delle suddivisioni in base alle varie specialità.		
Nelle grandi aziende pharma la BU può avere al suo interno attività quali marketing, gestione del personale operativo, legal & compliance, sicurezza. Nelle aziende più piccole, la BU fa solo attività di marketing e vendite, mediante gli informatori farmaceutici.		
I principali beneficiari dei PSP sono sia il paziente sia il medico. Lato paziente potrebbe essere anche un care-giver ad utilizzare concretamente il PSP e non il paziente stesso.	Key resources	
PSP-Provider che si occupa della parte operativa (es: gestione dei call center, invio di infermieri a domicilio). Costui è scelto in base ad una gara pubblica per contratti che superano una certa soglia di costo.	Key partners	
Software-House che si occupa della realizzazione della piattaforma e gestione dei dati, che è sempre affidata ad una figura esterna all'azienda pharma.		
La decisione di sviluppare un PSP dipende più per un posizionamento dell'azienda nel mercato che per il raggiungimento di un ritorno economico.	Cost structure	
Il farmaco deve consentire un margine di ricavo in grado di sostenere investimenti richiesti da un PSP che il normale farmaco da banco non è in grado di coprire.		
La software-house può o vendere il tool finito e concludere il progetto o firmare un nuovo contratto per supporto successivo e miglioramento.		
Mancanza di logiche di economie di scala dovuto a costi fissi del personale e di sviluppo di piattaforme.	Cost structure	Business Model del PSP-Provider
Know-how trasversale in numerose aree terapeutiche (neurologia, endocrinologia, oncologia).	Value proposition	
Logiche di economicità applicate ad ogni progetto, volte al raggiungimento di almeno il break-even, mentre il profitto dipende dalla dimensione dei progetti.	Revenue streams	
Dimensioni del progetto varia a seconda delle necessità del cliente (range da 20.000€ a +1 mln €).		
Know-how del PSP-Provider focalizzato sulla selezione e gestione delle risorse.	Key resources	
Team coposto da 20 persone e circa 35 professionisti sanitari on field.		
Il mercato di riferimento è dato dall'intero mercato nazionale italiano.	Customer segment	
I PSP nuovi vengono erogati a partire da alcune regioni pilota.		
Clientela composta da azienda farmaceutica e aziende produttrici di medical devices.		
Il target è il medico specialista che lavora nei centri ospedalieri pubblici, mentre gli studi privati solo come appendice di attività che nasce sempre dal pubblico.		