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**Innovation Hub: a new era of Digital Innovation in Lifesciences.
Pfizer case study**

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ABSTRACT

In an era when everything is changing at high speed and when Industry 4.0 is driving all industries to embrace timeless digital transformation, the Lifesciences sector is also witnessing its own revolution and the emergence of disruptive technologies that are revolutionizing the patient experience and all organizational and decision-making processes in general.

This discussion is structured as follows:

In the introduction, the topic under consideration will be framed, its importance and why it will be studied through an overview of the state of the art of the topic, what we already know and what is proposed to be known.

Next, the first chapter will review the literature on the topic with a particular focus on two main aspects, which are then the two pillars of the discussion and on the basis of which the final conclusions will be constructed.

The first aspect is research. An overview of the current situation of pharmaceutical companies will be given, starting with what digital innovations are, what has already been implemented in the industry, and what has been discovered so far until an overview of the Lifesciences sector examined.

The second section will be devoted to the second macro-theme, that of collaboration and sharing of experience and knowledge: open innovation. In fact, it will start with a general overview of the concept of Open Innovation with a thorough analysis of the texts of the greatest scholar on the subject, Henry Chesbrough. The next step is to analyze Open Innovation in the Lifesciences sector to understand what is meant when a pharmaceutical company implements this type of strategy.

And it is from the concept of Open Innovation that we move on to analyze those who are the promoters of this strategy: the Innovation Hubs. It is through these innovation hubs that pharmaceutical companies are undertaking collaborations with universities and startups to expand their portfolio of knowledge in digital innovation.

The second chapter is devoted to describing the research methodology deemed most appropriate for analyzing the case study, which will be detailed in the next chapter. A meticulous analysis will be made of the steps that were taken from the choice of the research object to the actual qualitative interview with selected interlocutors.

The pharmaceutical company Pfizer is, however, the subject of this research. In the last chapter of the discussion, an overview of the company, its approach and goals achieved in recent years will be made. It will then go on to explicate the work that Pfizer's Innovation Hub does and how the digital technologies that spring from it impact the organization through quotes from the qualitative analysis conducted.

The ultimate goal of the discussion, then, is to answer the following research questions:

RQ1: How has the introduction of Innovation Hubs changed organizational arrangements, the way research is done, and the way pharmaceutical companies open up to the world?

RQ2: What are the perceived benefits generated by the implementation of digital technologies in pharmaceutical organizations?

to ultimately get a 360-degree perspective of the digital transformation taking place in pharmaceutical companies.

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INTRODUCTION

In the wake of the Covid-19 pandemic, companies in the Lifesciences¹ sector found themselves in need of investing in digital innovation. Not surprisingly, in just a few months most companies had to acquire skills and develop strategies on most of the major innovative digital technologies, particularly, as we will see below and in the case study analyzed, on artificial intelligence, cloud, Internet of Things (IoT), big data, and digital twins.

"Digital innovation has been accelerated by 10 years by what has happened in the last 18 months"². This quote turns out to be quite eloquent and makes us understand how change has happened at a revolutionary speed in the Lifescience sector and, along with it, digital transformation, which has been a consequence of it on a large scale, but mostly happened overnight.

Yong Chan Kim, Erdal Atukeren, Yeon Woo Lee (2022), in the paper for which they are the authors, explain how these changes turn out to be related to the development of digital technology-based pharmaceutical products, from digital therapy to patient monitoring, to telemedicine.

Lifesciences companies have been rather cautious compared to other industries in terms of revolutionary digital innovation in addition to lagging behind in terms of adapting to Industry 4.0 changes. The importance of digital initiatives lies in the possibility of accelerating digitization and solutions in the industry. One of the main obstacles is the willingness of companies not to take risks. In fact, at a time when people's lives are at stake, companies in the industry preferred to take a more conservative approach to change and paid more attention to compliance and security than to the rapid adoption of innovation.

Before the pandemic, pharma organizations lagged behind other industries in digital innovation but quickly embraced a range of technologies that enabled them to manage their operations remotely or virtually.

This is all that deserves our attention: the digitization-oriented approach to innovation in the Lifesciences sector.

Some companies have established true centers for digital innovation, Innovation Hubs, within their organizations. These come into being with the aim of reinventing the biomedical field at

¹ Companies operating in the pharmaceutical, biotechnology, medical device, and biomedical technology sectors.

² Manoj Raghunandan, president, global self-care and consumer experience, Johnson & Johnson

all levels through the development of new digital strategies and technologies that aim to introduce innovation to improve not only patient health but also processes (starting with research and development and ending with drug production and distribution).

In the discussion we will focus on the topic of digitization, how innovation created by Innovation Hubs impacts the organization. What are the positive aspects and what are the critical ones that still need to be researched.

Another aspect that is important to reserve space for is Open Innovation.

The pharmaceutical industry has always been one of the most regulated industries and also one of the most reluctant to share discoveries and research. A new perspective that as yet few companies are approaching is precisely that of openness to collaboration and a willingness to bring together experience, know-how and expertise at the digital and Lifesciences sector levels. In this regard, Innovation Hubs also play the role of being the promoters of the new reality of Open Innovation. It is through them that some pharmaceutical companies have formed collaborations with external partners (universities, startups, research centers, incubators) in order to combine expertise to bring more value to the innovation process.

In the present discussion, therefore, we will look at how the creation of Innovation Hubs in Lifescience changes the way they do research and open up to the world.

The Lifescience sector is a very complex, regulated sector and includes companies operating in the pharmaceutical, biotech and MedTech sectors. Their role is fundamental in the field of research and development and in the production and distribution of drugs; this is precisely why we aim to understand how at this moment in history digitizing in this sector is important and how the prospects are changing in the future.

There are three areas in the pharmaceutical sector that mainly promise long-term evolutions: the process of new drug development, digital initiatives, and product lifecycle management.

We will focus particularly on the second aspect, that of digital initiatives.

The connection between technology and medicine in recent times has prompted pharmaceutical companies to consider a major digital revolution that, until recently, they have been slow to recognize (Hird, Ghosh, Kitano, 2016).

Digitization in other sectors has occurred rapidly and without realizing it. In the world of healthcare, however, the pattern of innovation is diametrically opposed such that it has been limited in the speed and penetration of digital technologies within it.

Pharma companies have remained on the sidelines, leaving the first steps into the digital world to be taken by their investment sectors rather than by frontline clinical development teams.

Digital technologies with the ability to record, collect, analyze, and communicate data provide the pharma sector with an incredible opportunity, an unprecedented possibility not only for the benefit of patients but also for health care providers, physicians; in general, digital benefits all pharma operations.

The emergence of digital medicine, therefore, promises to transform and disrupt health care from now on.

At this stage we aim to take a detailed look at what digital innovations have been applied in the medical field so far.

Oleksandr Sverdlov, Joris van Dam, Kristin Hannesdottir, and Tricia Thornton Wells, in a 2018 paper, explain how digital technologies such as AI, data lakes, cloud computing, augmented/virtual reality (AR/VR), wearables, digital twins, IoT, blockchain, and quantum computing represent a new way of treating diseases; digital systems such as smartphone apps are being used as therapeutic interventions approved by regulations governing the medical field (Sverdlov et al. , 2018).

In fact, digital technologies can be successfully integrated into clinical trial design and testing, implementation, and analysis and dissemination of study data.

Deloitte in 2021³ conducted an analysis by surveying 150 leading biopharmaceutical companies that helps us understand their experience with digital technologies and the industry's approach to digital innovation in this context aimed at accelerating change.

Digital innovation can lead to benefits including the realization of ambitious goals in shorter time frames, optimal patient and partner engagement, and faster drug commercialization. Research leads us to understand that biopharmaceutical executives have an urgency to take risks, invest and innovate faster to gain an advantage that can be achieved through digital innovation.

³ A report from the Deloitte Center for Health Solutions “Biopharma digital transformation: Gain an edge with leapfrog digital innovation”. (2021)

A prime example is the following quote from Pfizer's CEO: "Our strategy is to win the digital race in pharma, recognizing that digital is going to be extremely impactful, and that it is a race. Everybody is trying to (win that race), and one day, someone will-I want it to be us."⁴

The use of digital platforms in remote data storage and collection help simplify the informed consent process, clinical operations and can enable clinical trial research. Remote monitoring of patient compliance, life signs and adverse events can provide home-based therapy without the need to travel to doctors' offices or hospitals.

With respect to clinical trials, having high-quality data is a prerequisite for drawing the right conclusions. Electronic Data Capture (EDC) technology has become a standard, and electronic systems are increasingly being used in drug development. The major benefits found from using this technology include greater accuracy and transparency of data, improved patient compliance, and better overall cost-effectiveness than old-fashioned trials.

The digital ecosystem (Ding, Baoyang, 2018) is highly fragmented and diverse, and the pharmaceutical industry should aim to build an ecosystem of partners around a horizontal platform that allows multiple solutions to coexist. A flexible ecosystem of partners would simplify processes and allow sharing the risks of innovation while simultaneously preventing the system from experiencing long-term blockages.

Recently, many companies have engaged in major strategic partnerships beginning to test the waters of Open Innovation.

Beginning to write a new era of digitization in pharma means opening up to innovation, which some companies in recent years have been doing, realizing that sharing and pooling intelligence could lead to important results.

The second point that deserves our attention.

Open Innovation is a model of innovation that consists of organizations opening up to the outside world in order to take advantage of the experience and expertise of external actors (in most cases startups, universities and research centers). To quote the one who most precisely defined this model, Henry Chesbrough, we can say that "Open Innovation is a paradigm that asserts that companies can and should make use of external ideas as well as internal ones and

⁴ Albert Bourla, CEO, Pfizer (2020)

access by internal and external routes to markets if they want to advance in their technological competencies."⁵ (Chesbrough, 2003)

In fact, the origin of Open Innovation dates back to the essay written by Chesbrough in 2003, "Open Innovation: The New Imperative for Creating and Profiting from Technology," in which the author explains his theory: innovation should no longer be synonymous with R&D. The new paradigm of open innovation allows organizations to draw on expertise, resources, technologies and ideas from outside thereby accelerating the process of prototyping and commercializing new products and market services.

In the course of the discussion, we will look at how companies in the pharmaceutical sector do Open Innovation, what strategy they adopt when implementing this type of innovation, and what type of Open Innovation they refer to.

The research questions posed are derived from a study of the literature that helped us understand how complex this topic is. There is still little reference to what types of digital innovation are actually implemented in pharmaceutical companies, how these change organizational arrangements, how they are approaching open innovation today, and what benefits digital innovations have generated.

Within this discussion, an attempt will be made to answer the research questions through a case study: Pfizer.

Pfizer is a U.S. pharmaceutical company and one of the world's largest companies involved in drug research, manufacturing and marketing.

The methodology consists of administering qualitative interviews to privileged stakeholders who hold key roles within the Innovation Hub in Thessaloniki, the innovation headquarters of Pfizer Global.

In particular, the viewpoint of Nico Gariboldi, site lead of the Innovation Hub, will be analyzed, with the intention of going deep into the topic of innovation and understanding mainly with what purpose the Center of Digital Innovation (Cdi) was created.

Lidia Fonseca Chief Digital and Technology Officer, Executive Vice President, will help us understand the importance of the strategy behind the implementation of a new digital technology and what impact it has on the organization.

⁵ Chesbrough, Henry W. "The Era of Open Innovation." MIT Sloan management review 44.3 (2003)

Jeff Hamilton SVP, Finance, Global Supply, to get an even more comprehensive view from a finance perspective as well.

Thanos Stavropoulos and Thomas Kareklas, both Senior Managers in the Technology and Innovation department, will help us get a clearer and more detailed idea of the concept of Open Innovation and what it means for Pfizer to open up to collaboration with the ecosystem.

From the analysis of the interviews, we will try to fill in the gaps left by the literature analyzed in the course of the discussion and thus understand what future prospects pharmaceutical companies aspire to and attempt to achieve through investments in digital technologies.

CHAPTER I – Digital Innovation is changing the way of doing research and opening up to the world

1.1 How research and development are changing

As mentioned in the introduction, because of the Covid-19 pandemic, every sector has been faced with an unprecedented digital revolution. In order to follow a flow that can lead to a comprehensive answer to the research question, it is necessary here to go out and frame what digital innovations are.

Recent literature (Kohli et al., 2018) shows that organizations are under increasing pressure to apply new digital technologies in order to renew and transform their business models. Indeed, many digital technologies appear to be increasingly important in order to achieve business goals, and their effects have led to the radical restructuring of many industries.

In research conducted by Daniel Nylén, and Jonny Holmström (2015) it was found that digital technologies give rise to a vast potential for product and service innovation that is clearly difficult to control and even to predict. It goes without saying that, at this moment in history, companies need to introduce dynamic tools to manage new digital innovation processes that are emerging. The nature of these processes forces companies to question their previous strategies related to their product and service range, digital environment and work organization.

1.1.1 Digital Innovations challenges

Digital innovations are defined as new technologies, applications and business models that leverage digital technologies to improve an organization's efficiency, agility and competitiveness.

Below are some of the most widely used digital technologies:

- *Artificial Intelligence (AI) and Machine Learning (ML):* Artificial intelligence (AI) is a discipline concerned with creating systems and algorithms that can emulate certain human cognitive abilities, such as reasoning, learning, perception, and problem solving. The goal of AI is to develop machines that can perform tasks that require human intelligence or otherwise appear to require it. Machine learning, on the other hand, is a subset of artificial intelligence that deals with the development of algorithms and models that enable machines to learn from data and improve performance over time

without being explicitly programmed. Instead of following specific instructions, machines learn from data, draw conclusions and make predictions.

AI and ML right now are becoming increasingly important as organizations seek to take advantage of the vast amount of data available to them. There has been a lot of research on the implementation of AI and ML in various sectors such as healthcare, finance, manufacturing and agriculture, to name a few.

- *Blockchain*: Blockchain is a distributed ledger technology that allows transactions or information to be securely and transparently recorded and shared across a computer network. It is the system used by the most popular cryptocurrency, Bitcoin, but it also has broader applications beyond financial transactions. Blockchain technology is rising rapidly because of its ability to create immutable and secure records. There are many potential applications for blockchain, such as supply chain management, data security, and financial transactions.
- *Internet of Things (IoT)*: Internet of Things (IoT), or the Internet of Things, is a concept that refers to the connection of physical devices, such as sensors, wearables, home appliances and other objects, to the Internet network. The main goal of IoT is to enable communication between physical objects and the exchange of data between them without necessarily human intervention. The IoT is creating a vast network of interconnected devices that offer many opportunities for automation and process optimization. There has been a lot of research on IoT implementation in various sectors such as logistics, energy and especially health care.
- *Cloud computing*: is a model of providing computing resources such as servers, storage, databases, software and services all via the Internet. Instead of physically owning and managing computing resources onsite, organizations can take advantage of these resources on demand from cloud service providers.
It is becoming increasingly important as it offers a flexible and scalable way to process data. There are many applications for cloud computing such as data management, payment processing, and through data sharing collaboration among work groups.

- *Virtual and Augmented Reality*: virtual reality (VR) and augmented reality (AR) are two technologies that allow users to experience and interact with virtual environments or add virtual elements to the real world.

Virtual reality (VR) creates a simulated environment in which users can interact using devices such as goggles or VR viewers. These devices provide an immersive visual and auditory experience that can also include tactile and movement sensations. VR is used in various applications such as games, training simulations, virtual travel experiences, medical therapies and more.

Augmented reality (AR), on the other hand, superimposes virtual elements on the real world, creating an experience in which digital objects coexist with the physical environment. This overlay can be viewed through devices such as smartphones, tablets or AR glasses. AR is often used to enhance understanding and interaction with the real world such as in e-commerce, education, industrial design and health care.

Both technologies, VR and AR, are finding increasingly broad applications in a variety of fields by offering new possibilities for user experience, learning, communication and entertainment.

- *Big data analytics*: big data analytics is the process of exploring, extracting and identifying patterns, trends and meaningful information within large volumes of complex and heterogeneous data, known as big data. This data can come from a variety of sources such as sensors, social media, business transactions, server logs, biometric data, and more.

The goal of big data analysis is to gain insight that can help make informed decisions, improve business operations, identify market opportunities, prevent fraud, improve efficiency, and more.

Technologies and techniques used in big data analytics include distributed storage, parallel processing, machine learning, statistical analysis, text analysis, data visualization, and artificial intelligence.

Organizations leveraging big data analytics can gain competitive advantages, improve their understanding of customers, optimize operations, customize offerings, and create new products or services. However, big data analytics also requires specialized skills, appropriate infrastructure, and attention to data privacy and security.

The main reasons for industries to use digitization are to reduce costs (Manyika et al., 2013), improve performance, (Markovitch & Willmott, 2014), promoting internal efficiency (Parviainen et al., 2017), improving the smart manufacturing process (Gerlitz, 2015), adding value to a supply chain (Tihinen & Kääriäinen, 2016), creating a new product or service (Degryse, 2016), adapting to new changes (Henriette et al., 2015), managing competition and stimulating demand (Sabbagh et al., 2012).

In this regard, Parviainen and colleagues (2017) explain that:

"The potential benefits of digitization for internal efficiency include improved efficiency, quality, and consistency of business processes by eliminating manual steps and achieving greater accuracy. Digitization can also enable a better real-time view of the operation and results by integrating structured and unstructured data, providing better views of the organization's data, and integrating data from other sources. In addition, digitization can lead to better job satisfaction for employees through automation of routine work, freeing up time to develop new skills. Digitization also improves compliance through standardization of records and improves recovery through easier backups and storage distribution."

Numerous research, particularly those by Henfridsson et al., (2014); Yoo et al., (2012), have shown that the characteristics of digital technology enable new types of innovation processes that are diametrically opposed to the analog innovation processes of the industrial era.

As market and business paradigms change, organizations are under increasing pressure to make sure that they implement digital technologies and introduce new business models.

Digital innovation has now become a key to survival for all these challenges as well as an answer to the need to evolve rapidly and conform to the dictates of Industry 4.0.

Although Industry 4.0 has been widely covered, there are only a few studies investigating the implementation of digital technologies in both developing and developed economies.

The imperative is to innovate digitally to realize new products, processes or business models with technology platforms; digital innovation contributes to the transformation of both industry and society.

Industry 4.0 refers to an industry that has begun a process of enhancing mechanization through the use of Information and Communication Technology (ICT). Digital innovation is key to shortening the time of production processes, streamlining distribution, and above all, collecting data: *simplifying and automating supply chain systems, improving logistics and warehousing*

systems, and making the way of analyzing research results ten times faster and more automated (Tvenge & Martinsen, 2018).

Organizations can use digitized robotics, Artificial Intelligence systems, remote sensing technologies, and Augmented Reality programs to ensure a better experience for their customers.

The various technologies, mentioned above, such as IoT, cloud computing, big data analytics, Machine Learning, and Artificial Intelligence, are used to improve existing and obsolete business models as well as to increase the performance of existing organizational services.

According to a recent study (Gregory et al., 2021), digital technologies help business organizations achieve both economic and operational goals. Artificial intelligence (AI) and machine learning (ML) *enable supply chains to become more resilient and flexible*.

Digital Innovation assists organizations in responding to unforeseen challenges and situations such as the COVID-19 pandemic, environmental problems, political or economic instabilities, and so on.

One very interesting aspect is that because of this growing trend of acquiring information, platform systems can collect and analyze user data, offering the opportunity for managers to make timely decisions to cope with turbulent times. Automated analyses of the collected data help predict possibilities and strategies to go beyond individual perceptions.

In fact, again referring to the Covid-19 pandemic period, digital innovations have greatly helped small and medium-sized enterprises to cope with countless difficulties also through increasing the decision-making efficiency of their managers.

In addition to artificial intelligence to machine learning, some technologies such as blockchain, cloud computing and big data analytics have helped organizations manage their activities by implementing medium- and long-term strategies.

During the pandemic, technology in health care massively deployed blockchain-based platforms to track the spread of the virus among patients by constantly monitoring them.

One of the highly leveraged digital technologies is cloud computing, which gives users access to shared resources such as networks, servers, storage, applications and online services, thus reducing the cost of deploying services. It expands knowledge, resources, and applications thereby coming to enable people to use resources for long-term development.

Big data analytics collects, stores, formats, organizes, processes, and analyzes data for its end users and customers to use in order to make thoughtful decisions.

Many studies cited below argue that new theories are needed in this era of digital transformation and innovation.

Nambisan et al. (2017) state that "there is a fundamental need for new theorizing on digital management that more adequately addresses the rapidly changing nature of the innovation process in a digital world."

For Nambisan, digital innovation is the use of technology in a wide range of innovations. We understand the term digital as the conversion from predominantly analog information into the binary language understood by computers.

As such, digital innovation is about the concerted orchestration of *new products, new processes, new services, new platforms and even new business models*.

Currently, the new technology represented by artificial intelligence, blockchain, cloud computing, Big Data and the Internet of Things is growing the economy and bringing disruptive changes to the organizational structure, business processes and business model of enterprises. Information technology (IT) has become a driver of digital transformation in enterprises. Indeed, companies see investment in IT as a way to gain a competitive advantage in the increasingly fierce and dynamic market environment. Companies in almost every industry are moving to explore the new IT and take advantage of its benefits.

It is a complex journey that must be guided by a timely transformation strategy; digitization has completely changed traditional strategic rules and redefined competitive advantage and its realization.

Some of the main impacts correspond to *improved operational efficiency*; digital technologies have enabled organizations to automate and *optimize business processes, reducing operational costs and improving overall efficiency*.

For example, the automation of business processes, the adoption of cloud solutions for data storage and access, and the use of collaboration tools (Zoom, Teams etc.) have simplified and accelerated time-consuming daily activities.

We observe from some studies (Vennemann, 2019) a remarkable improvement and transformation of the *customer experience*, enabling organizations to offer personalized services, faster response times and better engagement. For example, the implementation of

chatbots, the use of data analytics to better understand customer needs, and the provision of online self-service have improved the interaction between organizations and customers.

In addition to this, a change in organization and corporate culture can be observed as a result of the advent of digital: the adoption of digital innovations has, for obvious reasons, required organizations to make changes in their organizational structure. It has become extremely important to be agile, flexible and ready to adapt quickly to technological changes. In addition, innovation has promoted greater collaboration and communication between business departments with a focus on a *customer-centric approach*.

Last but not least is the discussion of data *management and data security*.

The increased use of digital technology has led to an ever-increasing collection of data by organizations. It is more crucial than ever to manage and use data safely and responsibly. Therefore, organizations must take appropriate measures to protect sensitive data and ensure compliance with privacy regulations.

In conclusion, digital innovation has transformed the way organizations operate, interact with customers, develop products, and manage their resources. Digital innovation has, for all intents and purposes, created new opportunities and challenges, requiring organizations to be agile, adaptable, and future-oriented to remain competitive in the marketplace in an ever-changing digital environment.

1.1.2 *Lifesciences overview*

The Pharma industry constitutes one of the markets that currently innovates at an important speed compared to other sectors, with an advanced research and development system that bases its specificity on a wealth of highly specialized human resources. The characterizing elements are thus:

- High research and innovation intensity;
- Safety;
- Effectiveness;
- Regulation;
- Patent protection.

The Lifesciences sector includes pharmaceutical, biotechnology and medical device companies.

The health sector accounts for 5.3 percent of the global economy and is characterized by a trend of steady growth in public and private spending. Precisely, the OECD (Organization for Economic Co-operation and Development) reported an average growth in health spending of 5 percent in 2020 (driven by an exceptional +8.1 percent growth in spending by government and mandatory schemes in response to the COVID-19 pandemic and a decrease in private spending of more than 3 percent) (OECD Health Statistics, 2022). As a result of the consistent growth in spending and widespread economic recession, health spending in OECD countries as a percentage of GDP (Gross Domestic Product) increased from 8.8 percent in 2019 to 9.7 percent in 2020. In 2021, health spending continued to grow steadily (by about 6 percent) even as the pandemic slowed and is expected to maintain the same trend in subsequent years (OECD Health Statistics, 2022).

This sector consists of companies that offer drugs and medical equipment as well as health care and clinical services (PatResearch, 2021). It includes several subsectors, which are in turn divided according to their activities:

- *Drug research and development*, carried out by biotechnology companies, large pharmaceutical companies, and generic drug manufacturers. Biotechnology applies biological and biochemical knowledge to technical processes or products and focuses on the development and production of enzymes, proteins, antibodies, and other active substances for medical and other purposes, while the pharmaceutical industry includes companies involved in the research, development, production, and marketing of drugs. The difference between biotech and pharmaceutical companies is that while biotech companies are characterized by small sources of revenue, pharmaceutical companies have large financial resources, are more reliable, and have a more diverse pipeline of drugs under research and development, making them less dependent on "make or break" drug trials.

Pharmaceutical companies engage in research and development but tend to focus more on manufacturing and marketing the existing range of drugs than biotech companies and tend to specialize in generic drugs. As a result there is often competition for identical drugs resulting in lower prices and reduced profit margins. Examples of biotech companies include Novo Nordisk (NVO), Regeneron (REGN), Alexion (ALXN), and Celgene Corp. (CELG), while examples of pharmaceutical companies include Johnson and Johnson, Roche, Pfizer, Eli Lilly, Novartis AG, and AstraZeneca.

- *Medical technology (Medtech)* combines engineering and technical knowledge with medical expertise; it includes medical equipment manufacturers, from those making standard and familiar products (such as scalpels, bandages and gloves) to those conducting cutting-edge research and producing expensive high-tech equipment, such as MRI machines and surgical robots. Medtronic PLC is an example of a medical equipment manufacturer.
- *Managed Healthcare*, includes companies that provide health insurance policies. The "Big Five" that dominate the Managed Healthcare sector are UnitedHealth Group Inc, Anthem Inc, Aetna Inc, Molina, and Centene.
- *Healthcare Facilities* include all those activities carried out by hospitals, clinics, laboratories, psychiatric facilities and nursing homes.

The Lifesciences industry with its Big Pharma⁶, patents and large investment in research and development constitutes one of the world's most important industries with not only economic but also social goals. Because the pharmaceutical industry is concerned with public health, it is always seeking a balance between commercial interest and improving the lives of citizens.

The pharmaceutical industry is a broad area that includes the research, development, production, and marketing of pharmaceuticals, medical devices, and other solutions for human and even animal health. This sector is of great importance to public health as it contributes to the development of innovative drugs and therapies to treat diseases, improve quality of life and prolong its life.

The pharmaceutical industry has well-known characteristics, but it is worth mentioning them to better understand the following chapters that address the challenges and opportunities of digital innovation. First, it should be kept in mind that pharmaceutical companies usually have a complex structure. Of course, it varies from company to company, but there are still some common characteristics (such as the presence of an R&D department, production sites, and specific business services and corporate functions). Pharmaceutical companies have several business units, each dedicated to a specific therapeutic area that includes specific functions (e.g., medical, sales and marketing) and support functions common to all franchises (market access, regulatory affairs, legal, tax, financial, etc.). Normally business units and support

⁶ 1° Johnson & Johnson: \$428 miliardi, 2° Roche Holding: \$281 miliardi, 3° Pfizer: \$217 miliardi, 4° Merck & Co: \$183 miliardi, 5° Novartis: \$180 miliardi. Statista, 2019

functions are regulated locally (each country has its own system) while R&D and drug development processes, manufacturing and services are common to all countries and are regulated globally. The core business of pharmaceutical companies is product development along with sales activities that enable the company to earn revenue (Gupta, 2008).

Lifesciences companies, as mentioned, invest huge sums in scientific research to discover new drugs, therapies and medical treatments.

The development phase involves laboratory tests, preclinical animal studies and clinical trials on human volunteers.

The pharmaceutical industry is certainly highly regulated in fact before a drug can be marketed it must first be approved by regulatory agencies such as the Food and Drug Administration (FDA) in the United States or the European Medicines Agency (EMA) in the European Union. These agencies evaluate the efficacy, safety, and quality of drug products before granting the necessary approvals to be put on the market.

The next step, having obtained the appropriate approvals, is to manufacture the drugs on a large scale. This process involves the production of active ingredients, drug manufacturing, packaging and labeling. Then the pharmaceuticals are distributed to pharmacies, medical centers and hospitals.

Companies in the industry also carry out marketing activities to promote their products among physicians, health care professionals, and consumers: this may involve visits to physicians by health care representatives and sales representatives, conducting advertising and promotional campaigns, and attending congresses and conferences.

Once a drug is launched, companies closely monitor its safety and report any side effects or adverse reactions to regulatory authorities.

In terms of business operations, pharmaceutical companies have different peculiarities than other companies. Their business strategy must consider the preferences and needs of not one, but three different parties: the one who needs to take the therapy, the one who can prescribe it, and the one who pays for it. In many other industries these three figures coincide while here further and more complicated reasoning is required.

If we compare a commons company with a pharmaceutical company, we quickly realize the complexity of the pharmaceutical world:

	Subject who needs the product	Subject who buys the product	Subject to whom advertise
Good Y Manufacturer	Client x	Client x	Client x
Pharma company	Patient	Healthcare system	Doctor/ Specialist

Table 1: Types of customers for a pharmaceutical company and a commons company.

The presence of three different stakeholders implies a greater level of complexity in overall business strategy and organizational coordination especially when one considers that each of these stakeholders is embedded in a larger framework that includes other actors (pharmacies, trade associations, insurance companies, treatment centers) (Ganesh Pandit Pathak, 2014). This means that every time a new industrial revolution occurs many actors and elements are involved that need to be adapted.

Another peculiarity of pharmaceutical companies is that they are characterized by a very long production cycle from preclinical and clinical studies to the large-scale production phase, market commercialization, management approval process, and product marketing. The longest phase of drug development is the clinical trial, the purpose of which is to determine the safety and efficacy of the newly developed drug; it requires selected physicians to recruit patients, provide them with the drug under consideration, evaluate the drug's effect on them, and record the observations and clinical data according to so-called GCP (Good Clinical Practices).

Clinical trials are divided into two phases:

- *Preclinical phase* (3-6 years) evaluates the efficacy, toxicity, pharmacokinetics and safety of the drug through animal studies and trials.
- *Clinical phase* (6-7 years), which provides information on safety, tolerability and pharmacodynamics through studies conducted in humans. The first phase involves a limited number of patients (20-100), then if the evaluation goes well, more patients are tested (100-500) in the second phase, 500-1000 in the third phase to then be tested on an unlimited number of patients in the fourth phase when the drug reaches the market, and more side or adverse effects are reported from the population (Nawrat, 2018).

The nature and length of the production cycle of pharmaceutical products implies incurring high costs and also a high rate of risk: the drug development process takes a lot of time and money with a probability of success of only about 5-10% (Innate-pharma.com, 2019). The industry manages to cover its costs due to the high revenues and high margins on products that manage to reach the market. In addition, the high level of expertise and investment required, along with licensing, regulation, intellectual property protections, and research and development costs allow a few large companies to survive in the market, and because of this, potential new players are discouraged. This makes it possible for the few pharmaceutical companies to maintain their competitive advantage.

Pharmaceutical companies are characterized by a deep level of knowledge in various fields ranging from chemistry to engineering and technological expertise applied at every stage of production, from initial (synthesis, purification and sequencing of target genes; gene cloning, importation; culture and screening of engineered bacteria) to final (protein purification and process amplification, testing and quality assurance of the product, etc.). As mentioned, large investments are required for research and development of new products, plant construction, and equipment configuration. It is not uncased that the pharmaceutical and biotechnology industry contributes 15.4 percent of the world's total R&D spending (Efpia, 2021).

In recent years, the pharmaceutical industry has been increasingly moving toward biotechnology and advanced therapies, such as gene and cell therapy.

New technologies developed for Covid 19 vaccine research promise to revolutionize the treatment of complex diseases such as cancer, genetic diseases, and neurodegenerative diseases.

Another aspect that is important to consider concerns globalization and the resulting collaborations, which will be discussed in detail later, however. Pharmaceutical companies operate on a global scale and often collaborate with research institutions, nonprofit organizations, and governments to address common challenges in discovering new drugs and improving public health. Collaboration can include the exchange of knowledge, financial resources, and access to diverse patients and populations.

The field in question is continually growing-fueled certainly by scientific and technological innovation; it faces significant challenges in enabling access to affordable drugs; the pandemic has certainly underscored this focus. Even during these unprecedented times, many organizations specializing in Lifesciences have participated in a shift in science. Indeed, the shift to data-driven approaches throughout the value chain, greater collaborations, digital transformation, and the advancement of CEO priorities are driving change. A new standard is emerging, and companies are willing to go beyond convention to tackle tough challenges and prepare for many benefits.

1.1.3 *Digital Innovations in Lifesciences*

As has been widely stated, digitization is affecting every sphere of human activity. Indeed, digital technology has come to stay and the fourth industrial revolution continues to expand, evolve and impact our lives in countless ways. Despite the widespread impact of digitization, academic studies on the topic, particularly with reference to the Lifesciences field, are not many. Still few scholarly articles refer to digital technologies applied to the operation of a Lifesciences business, let alone the user experience. This is precisely what we set out to understand and investigate.

The industry is known for its strict regulations, expensive research and development, and unique and complex process (Kaitin, 2010; Khilji et al., 2006; Maak & Wylie, 2016; McKenzie et al., 2006). Within Lifesciences, digitization has been employed since the introduction of process analytical technology.⁷

⁷ Process analytical technology involves online measurements, real-time control, risk analysis, application of statistical and multivariate analysis, laboratory automation, miniaturization, design of experiments, and use of physical organic chemistry (McKenzie et al., 2006). One example is the use of a high-throughput screening (HTS) instrument. This tool plays a significant role in miniaturization, automation and parallelization of pharmaceutical processes (Bhambure et al., 2011).

The digital transition is also running in Italy. According to a recent report by Farindustria,⁸ investment in the sector reached 3.1 billion euros, 1.4 billion of which was invested in high-tech facilities and 1.7 billion in research and development. An important example of digital transition has been the increase in telemedicine service developed in the past two years. It has been a cultural transition even before a technological one because it has involved the commitment not only of investment and expertise but also of businesses and healthcare professionals.

Through technology, health professionals and companies can establish a direct relationship with the patient, placed at the center of the ecosystem of services and products.

It is clear that in order to deliver innovative care to the patient in the shortest possible time, the company's productivity plays a key role, and when we talk about increasing productivity and product quality through the use of technology, we refer not only to production areas but to an involvement of all levels of the company.

Digital transformation is no longer just delegated to the IT and Digital departments of companies but is being dealt with by all teams directly. The need for digital then is integrated into every operational function starting from research and development to supply chain and commercial activities as well as into products, in our case drugs or medical devices.

Transforming the business and scaling up digitally requires agility and adaptability, one of the biggest challenges facing large Lifesciences and MedTech companies. Succeeding in being flexible requires a radical change in operational and management philosophy.

The shift that is crucial is to move from a traditional hierarchical mode to a startup mentality through autonomous networks of teams that can act to meet changing needs.

In 2021 McKinsey surveyed senior executives in business roles in global pharmaceutical companies to understand the changes taking place as a result of the pandemic.

More than 80 percent believe companies will fully embrace an agile way of working.

There is a strong link between basic research and innovation in the pharmaceutical and biotechnology industries. According to Gambardella (1992), the more basic research a pharmaceutical company conducts, the more patents it produces. He points out that "the winning models of the U.S. pharmaceutical industry during the 1980s were companies like Merck, which organized their internal research as academic departments" (p. 404). Cockburn

⁸ https://www.farindustria.it/app/uploads/2022/07/LEAFLET-2022_web.pdf

and Henderson (1998) found that pharmaceutical companies with a strong research orientation produced more major patents. According to them, successful companies decentralized decision making on the allocation of research and development resources and promoted scientists on the basis of their publications.

For companies developing new drugs, investing in basic research brings tangible benefits. First, the nature of knowledge is unique to the pharmaceutical industry. Unlike many other fields, medical research seeks a fundamental understanding of phenomena and yet is motivated by practical goals (Stokes, 1997). Second, appropriateness is very high in the pharmaceutical industry. Patent protection is extremely effective (Levin et al., 1987), and the rate of imitation is slower for ethical drugs than for other products (Mansfield et al., 1981). Third, industry has barriers to entry because purchasers have low bargaining power, because drug development is a complex process requiring specialized knowledge, and because extensive human studies are needed to meet regulatory requirements (Pisano, 1997, pp. 55-57). The link between drug discovery and basic science has increased over time (Pisano, 1997, Cockburn et al., 1999). Companies avoid screening many potentially useful compounds by moving toward a more systematic approach called "rational drug design." This involves exploiting knowledge of the biochemical mechanisms that cause a disease to identify or develop chemicals that inhibit those mechanisms (Pisano, 1997, P. 64). Companies use biotechnology as a process technology and as a research tool to improve their search for new drugs (Cockburn et al., 1999, pp. 379-381).

In addition to direct benefits, basic research helps pharmaceutical and biotechnology companies absorb outside knowledge. Encouraging such research activity allows a company to hire high-quality researchers and develop strong social networks so that they are "actively connected to the broader scientific community" (Cockburn and Henderson, 1998). The ability to hire highly talented researchers is underscored by the search for "star" scientists, scientists who produce many articles, are highly cited, and collaborate on public science. Hiring "star" scientists has a broad and positive impact on the research productivity of biotechnology companies (Zucker and Darby, 1995).

As a result of the direct and indirect benefits mentioned above, pharmaceutical companies engage heavily in basic research. The research produced by these companies is of the highest quality and is widely cited.

The growth of many companies has been driven by the Covid-19 pandemic, but further transformation of Lifesciences companies is expected. Many companies, particularly those that have always adopted traditional and limited methods, have emerged from the pandemic adopting a digital first model and challenging the norms that have always characterized the industry.

Companies that made significant digital investments prior to the pandemic benefited from their vision, at the time bold as digital transformation improved, made more dynamic every part of the value chain in the Lifesciences world.

A 2022 Deloitte report looks at how the leadership of Lifesciences companies will continue to deploy investments focused on strategic, long-term goals using automation, smart factories and artificial intelligence with the aim of transforming manufacturing and using new technologies to build supply chain resilience.

"Collaboration and digitization have played a key role in bringing Covid vaccines and therapies to market at an unprecedented rate, saving some 750,000 lives in the United States and Europe alone. As an industry we need to bring the same speed and sense of urgency to all our efforts."⁹

In recent years, in fact, there has been a sense of how pharmaceutical companies are manifesting a "need for speed," starting with the acceleration of vaccine trials for Covid-19, and then moving on to other drugs and their performance. The business model continues to change, to evolve with the goal of creating, delivering, and capturing value. The challenge of continuing to innovate is one that the industry must continue to face now but also in the near future.

Ernst & Young, in its 2019 annual report on the state of the industry, "Beyond Borders," defined three models: pharma 1.0, pharma 2.0, and pharma 3.0.

Today's focus is on the last stage, Pharma 3.0, which uses an "outside-in" approach. Digital transformation is accelerating and leading to a situation where healthcare, traditional biopharma, and technology are collaborating as the pharmaceutical industry shifts to a user- and patient-centered business model.

Lifesciences is an industry from which there is much to learn. It leverages its strengths from multiple sources: patients, providers, social networks, data analytics companies. We are already

⁹ Paul Hudson, CEO, Sanofi

seeing solutions that combine drugs, diagnostics and devices as well as digital technologies, including social media, to connect the entire healthcare system by centering it on the patient.

1.1.3.1 *Digital Health*

When we talk about digitization of the Lifesciences sector (Kasoju et al., 2023) we refer to the use of digital technology to improve health outcomes, care, and all aspects of the organization's value chain—all of which can be summarized by the term Digital Health.¹⁰

In the medical device sector, for example, several smart biomedical materials and digitally controlled medical devices have been patented. In the pharmaceutical and related fields, health-focused digital technologies are used extensively in the various stages of drug development: computer-aided drug design, computational modeling for predictive toxicology, and big data analysis for clinical trial management.

In the field of biotechnology and bioengineering, investigations are rapidly focusing on Digital Health, such as omics¹¹ biology, synthetic biology, big data, and personalized medicine.

Although innovations centered on Digital Health are broadening the horizon of Lifesciences in different ways, we will focus on understanding what developments these changes have brought about, what the trends and opportunities are, and the related future challenges.

Electronic Health Records (EHRs), telemedicine, health apps on smartphones, wearable devices, the Internet of Things, and cutting-edge digital technology are examples of technological innovation in Digital Health.

Let's run some numbers: the industry has been valued at about \$211 billion in 2022 and is expected to grow at a compound annual growth rate (CAGR) of 18.6 percent from 2023 to 2030.¹²

Digital medical devices are devices that use digital technologies to improve health and health care; they are also playing an increasingly important role by enabling remote patient

¹⁰ Telemedicine, electronic health records, wearable devices, mobile health applications.

¹¹ Field of study in medicine that includes various sub-disciplines such as genomics, transcriptomics, proteomics, metabolomics, and epigenomics. The goal of omics is to understand the mechanisms underlying biological processes and diseases by observing the collective behavior of all molecules involved, such as genes, proteins, and metabolites. By combining data from these various omics disciplines, researchers can gain a more comprehensive understanding of the molecular basis of health and disease, which can lead to the development of new diagnostic tools, therapies, and personalized medicine approaches.

¹² Digital Health market size analysis report, share and trends by technology (health analytics, mHealth, telehealth, digital health systems), by component (software, hardware, services), by region, and segment forecast, 2023-2030.

monitoring, increasing access to medical services but most importantly reducing health care costs.

The latest trends and developments in this area are:

- *Augmented reality (AR) integrated wearable devices*, is an area that has seen significant growth in recent years (Venkatesan M, Vinolo Gil MJ et al., 2021). Researchers are investigating ways to have information displayed directly in the user's field of view or provide additional real-world topics.
- *Wearable devices integrated with artificial intelligence (AI)*, artificial intelligence is integrated with reality to provide users with advanced features and capabilities. Devices leverage artificial intelligence to analyze data from sensors and make health predictions or provide personalized advice.
- *Wearable devices for energy harvesting*, this area includes devices that can generate energy through movement or body heat.
- *Wearable telemedicine devices* are devices that enable continuous patient monitoring and are able to record heart rate and blood pressure and transmit the data to health care providers.

Telemedicine devices enable remote patient monitoring and teleconsultation, with webcams and portable devices with cameras and communication capabilities.

- *Remote diagnostic and intervention tools* are being developed to enable detailed diagnosis and treatment to be made remotely. Some devices are equipped with cameras that allow caregivers to intervene to assist remotely.
- *Integration with electronic health records*: devices are being integrated with electronic health records to get a more comprehensive view of a patient's health status. Integration can help providers make more informed decisions for a patient's treatment by being able to access the complete medical history.

Computer-aided drug design (CADD) is the process of creating new drugs based on a thorough understanding of the biological target and its interaction with potential other drugs. It is a multidisciplinary field that combines knowledge of chemistry, biology, pharmacology, and computational models to develop new drugs.

Computer-managed drug design includes:

- *Pharmacophoric modeling* is a computational approach that involves studying the molecular features responsible for a molecule's biological activity. It allows researchers to identify structural features important for the interaction of a molecule with its target protein;
- *Drug target fishing* is a computational approach used to identify potential drug targets for a particular disease or biological process.

Another key aspect involving radical change is the use and analysis of Big Data. This is an extremely large and complex set of data generated from various sources, including electronic health records (EHR), medical imaging, genetic sequencing, and other sources.

According to research, the global Big Data market in Digital Health and Lifesciences in general has been valued at about US\$39.7 billion in 2022 and is expected to grow at a CAGR of 19.2% from 2022 to 2032.

However, the use of Big Data in medicine also raises concerns about the security, privacy, and ethics of its collection and analysis.

Big Data plays a key role in Digital Health by providing a wealth of information needed to drive innovation and improve performance.

- *Data analysis of electronic health records*: this is one of the main ways Big Data is being used. By analyzing demographics, medical histories, lab results, and other information, healthcare providers can gain insights into patient populations, identify trends in order to be able to undertake proper decision making
- *Wearable device data analysis*: they generate huge amounts of data, including information on physical activity, sleep patterns, and other health-related information, and can be used, for example, to monitor a disease and make a sound treatment plan
- *Genetic data analytics*, advances in genetic sequencing technologies have enabled the rapid generation of large amounts of genetic data that can be used to identify the genetic basis of diseases and thus develop personalized medicine
- *Big imagine data analytics*, algorithms can be used to analyze medical images with the goal of identifying patterns and abnormalities
- *Big data and predictive analytics* can be used to identify various patterns and relationships in order to create a process that leads to making the best decisions to improve the course of disease.

As we have seen, the spread of digital technologies in modern society has opened up access to unlimited volumes of data from multiple sources. Data that are being analyzed to study the health of entire populations but are also used to make personalized therapies for individual patients.

1.2 *Collaboration as a new strategy of doing innovation*

It is now time to get to the heart of the second pillar of the discussion: collaboration. Indeed, it is important to understand how pharmaceutical companies are actually changing their approach to innovation through Open Innovation. The paper will be developed in such a way as to give an excursus of what Open Innovation is and how it comes about and why attention is being focused on it. It will then go into how the pharmaceutical sector is approaching this new way of doing research, collaborating with partners, and how it all affects and changes organizational arrangements.

The crux will be to delve into the function of Innovation Hubs, the means by which pharma companies open themselves up to innovation. With what goals do Innovation Hubs come into being and what innovations actually take place within them?

1.2.1 *Open Innovation*

The term of Open Innovation was born when Henry Chesbrough, professor and executive director of the Center for Open Innovation at Berkeley, University of California, published his book "Open Innovation: the new imperative for creating and profiting from technology."

He defines Open Innovation with a very meaningful phrase: " [...] the use of purposive inflows and outflows of knowledge to accelerate internal innovation, and expand the markets for external use of innovation, respectively.

[This paradigm] assumes that firms can and should use external ideas as well as internal ideas, and internal and external paths to market, as they look to advance their technology"¹³.

¹³ H. Chesbrough (2003)

According to what has just been quoted, the paradigm refers to the key concept that in order to grow, firms can and should make use of external ideas as well as internal ideas, and internal and external paths to market, as they look to attack the market.

Companies must leverage external technologies and ideas with respect to their business, leaving ideas that are not being used to be leveraged by others.

This can only happen as companies embrace an open business model that allows ideas and technologies to flow from outside the company to inside the company and vice versa.

In his book "Open Innovation," Henry Chesbrough analyzes the transition from a Closed Innovation model to an Open Innovation model in which companies are willing to absorb ideas and knowledge from the external environment.

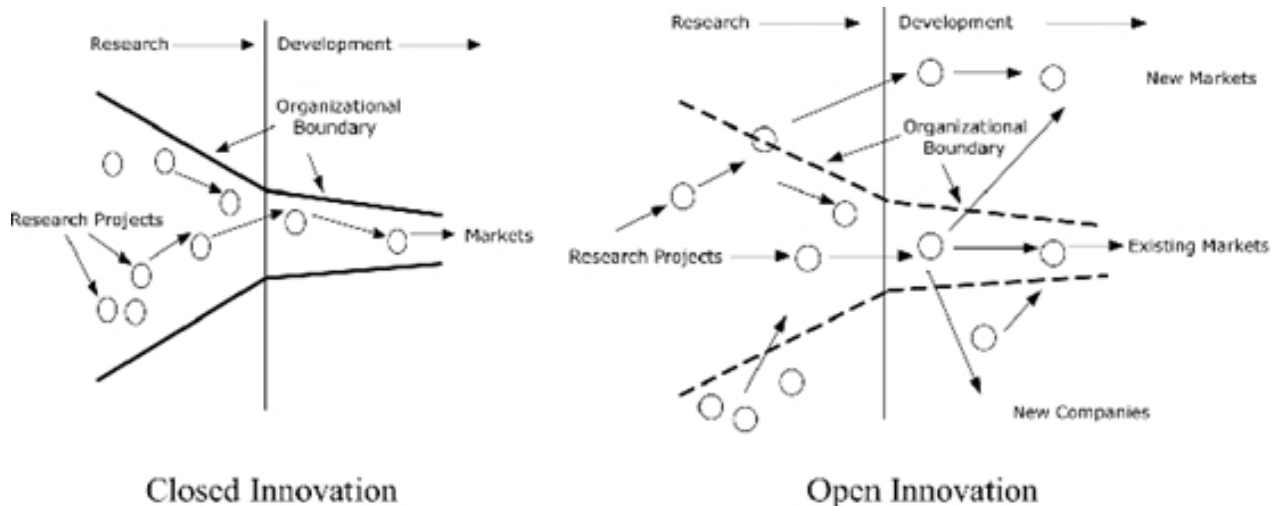


Figure 1: Closed and Open Innovation Fonte: Rielaborazione da Chesbrough, 2003

Figure 2 represents the innovation model from a closed model. Here, starting from a scientific and technological base, ideas born from a research project pass through a "funnel."

It simply functions as a filter: some projects are blocked, others are accepted and developed and then brought to market.

Everything takes place within the confines of the company, hence the term "closed."

Therefore, the closed innovation paradigm represents a fully vertically integrated model of innovation (Gassmann, Enkel, & Chesbrough, 2010). Moreover, there are no mechanisms for ideas to flow from the outside world into the firm's R&D process.

An innovating firm has an internal knowledge base that it relies on to create new ideas and relies on its development capabilities to bring them to market. Some companies that have adopted this model of innovation have been Xerox and AT&T. Specifically, Xerox's entire innovation process wanted to minimize so-called false positives. What is a false positive? It is an idea that is born in the lab, goes through the funnel and comes out. It was developed into a wonderful product, then it comes out and fails.

The second thing is to disregard false negatives. These are ideas that have no relevance to their product. They are ideas that have great potential outside the funnel, but not for Xerox itself, and that is where players like Apple come in, who have leveraged Xerox's GUI for their devices.

The lesson is that Xerox created value but did not capture value for itself; someone else did by stealing its work.

The difference between open and closed lies precisely in the "control" over its outputs (S.Darwin, 2015).

Compared to this model always Figure 2 shows the Open Innovation paradigm.

The first difference is that ideas born with technologies inside the company can be exploited by other companies and do not necessarily become internal property (Inside-Out). In fact, companies that produce ideas may decide to develop and commercialize their idea in the marketplace. As can be seen in the illustration, there is licensing and technology spin-off.

Another difference from the closed model is that commercialization can also occur through the flow of ideas developed externally and received within the company (Outside-In). This is the case with acquisitions. Inside-out and Outside-in mechanisms can also occur simultaneously.

In this case, so-called joint ventures or strategic alliances and partnerships are formed. This outside-in flow of ideas sums up the concept of "Open Innovation."

IBM, Intel and Procter & Gamble use the open model.

In the case of IBM there has been a transition from a closed to an open model.

Specifically, the newly hired CEO decided to transform the company's business model from a product to a service. In doing so, he increased licensing revenues and opened up his IP and reduced R&D costs through alliances.

It is now able to create value for itself, but also share its knowledge to develop other business models. The main example of open innovation is the \$90 billion in revenue from activities that did not exist 15 years ago.

How can the process of knowing be made easier? By helping others to become:

- *Instrumented*: able to measure virtually anything
- *Interconnected*: able to connect people, systems and objects.
- *Intelligent*: able to respond to change quickly and accurately.

In Open Innovation, the business model is the device that focuses the evaluation of R&D projects within the company (Chesbrough and Roosenlboom, 2002).

Although it is easier to capture value with the Open Innovation model, this topic has not received much attention.

Among the various definitions that emerge from the literature, it is necessary to dwell especially on the duality that this concept can encapsulate: "Open Innovation shows two sides: Open Innovation IN is the basic model in which ideas flow into the enterprise from different sources (crowdsourcing); Open Innovation OUT occurs when a group of people, a movement, sometimes a company, create an operating system or a platform, with some tools, on which everyone can add their own ideas and contributions. Open Innovation IN narrows a broader set of contributions into the funnel of enterprise development. Open Innovation OUT is designed to enable an evolutionary innovation process that grows and develops whenever a person adds their own source of information, code or module".¹⁴

To sum up, the first dimension goes in search of innovations from the outside world to complement those that have been developed internally (Inbound), while the second seeks new paths aimed at commercializing innovations that internally have not been used due to lack of compatibility with the business model in which it usually operates (Outbound).

In the Inbound perspective there is a flow of knowledge from the outside world across corporate boundaries and into the enterprise, which is why it is also called the "outside-in process" (Enkel et al., 2009).

In today's markets where there is a high variety of products, rising research costs and shortened life cycles, companies more than ever are looking for quick ways to collaborate that can help them sustain the innovation process and launch new products to market in the short term.

¹⁴ Source: Leadbeater. C. (2007).

Establishing alliances that last over time with one or more partners would not lead to any results in terms of innovation, as opposed to system that provides a continuous turnover of players involved with the guarantee of continuous new ideas, innovations and technology. Knowledge is sought not only from other companies but also from universities, customers, suppliers, industry experts, and in any case anyone who can bring added value to the company's growth strategy.

The second phenomenon involves companies opening corporate boundaries downstream of the production process by seeking new avenues of commercialization, of ideas and technologies developed internally and then not used.

The flow of knowledge passes from the original organization to another organization that may be able to put it to good use. In the literature, the phenomenon is called the "inside-out process" (Enkel et al., 2009). This process allows the company to derive two advantages: the first purely economic deriving from revenues from the commercialization of the developed technology, and the second of a strategic type generated by the possibility of discovering new markets in which to apply the innovative technology.

Referring again to Chesbrough (2003), Open Innovation emerged in the early 2000s as a response to the need to address issues that were undermining the traditional model of innovation.

Companies, therefore, were faced with the need to increase the effectiveness and efficiency of their innovation processes by taking advantage of the availability of external resources, never previously considered, that could be integrated internally.

Through the Open Innovation model, companies truly trade external and internal ideas; they can market internal ideas through channels that do not reflect their specific business to bring value to the organization. At this point, a reverse flow is integrated that internally leverages ideas originated outside the company.

Until recently, innovation was more of an internal affair. But now there is a need for innovation processes to change to make sure that the gap between the promise of technologies and poor business outcomes decreases.

Open Innovation is a new way forward; two recent surveys of large companies in the United States and Europe found that 78 percent of them use the new approach.

Until 10 years ago there was no trace of Open Innovation; now it is everywhere.

"The idea behind this new approach is that useful knowledge is now present throughout society. No company has a monopoly on great ideas, and all of them, no matter how effective internally, need to collaborate intensively and extensively with networks and knowledge communities." (Chesbrough, 2003).

A firm that applies the open innovation model uses external (outside-in or outside-in) ideas and technologies, but at the same time accepts that ideas and technologies from its own production and untapped flow externally so as to be made available to firms that could better exploit that technology (inside-out or inside-out).

Starting with some data (Chesbrough, 2017) Procter & Gamble found great success with its version of Open Innovation called Connect and Develop, as did many other companies (Huston and Sakkab, 2006). General Mills, a consumer goods manufacturer, analyzed the one-year sales performance of 60 products and found that those containing some component from Open Innovation sold more than twice as many as others. A recent study of 489 projects from a European manufacturing company concluded that those based on collaboration with external parties provided the company with large economic returns (Du, Leten and Vanhaverbeke, 2014).

Further confirmation comes from some statistical surveys. Studies based on the Community Innovation Survey show that firms that use a lot of knowledge from outside report better innovation performance in contrast to those that do not use it frequently (Laursen and Salter, 2006).

Out of 125 firms, the same conclusion was reached: firms that leverage Open Innovation strategies perform on the most promising innovations (Brunswick and Chesbrough, 2014, 2015).

Chesbrough, in his book, discusses how different meanings are given to the words Open Innovation in the literature. The best way to understand this paradigm, in his view, is to consider it in opposition to the traditional model of vertical integration in which internal innovation activities lead to products and services developed internally and marketed by the company. The vertically integrated model as mentioned is called the "closed innovation model." In summary, Open Innovation is a "diffuse innovation process based on the management of knowledge flows into or out of the enterprise realized using monetary and nonmonetary mechanisms depending on the enterprise's business model."¹⁵

¹⁵ Chesbrough, 2017

And again, "innovation is generated by accessing, exploiting and assimilating the flows of knowledge that cross the boundaries of the firm either by entering or leaving it. However, this is not a universally accepted definition, an issue to which I will return later. In this definition, it is assumed that companies, in seeking how best to innovate, can and should use both internal and external ideas and avenues to market. Open Innovation processes weave internal and external ideas into platforms, architectures and systems, and use business models to define the requirements of these architectures and systems. The business model uses external and internal ideas to create value and defines internal mechanisms to appropriate some of this."

On the distinction between inside- out and outside- in Open Innovation, Chesbrough explains that the former can be done by licensing one's own technology, thus creating by spin-off a new venture, by giving up one's own project to an open common, or by forming a new joint venture with outside partners. The second, on the other hand, is less understood in both academia and business. This mode of innovation enables the discovery of new business models for unused or underutilized ideas and technologies.

It is good at this point to clarify what Open Innovation is not since it is a very common misunderstanding. It is definitely not crowdsourcing¹⁶, it is not about better managing one's customers or resorting to Open Source software and the Open Source methods these software have inspired.

Open Source Innovation does not refer to the business model, does not take into account the inside-out component of the innovation strategy, and sees intellectual property (IP) as a possible barrier to innovation (Von Hippel, 2005).

Linus Torvalds, the creator of the open Linux operating system, embraces the same definition that Chesbrough proposes in his book. A company invests in a project and expands it over time because it has a business model. In H. Chesbrough's conception of Open Innovation, intellectual property is not only permissible but allows companies to collaborate and coordinate with others because it is what provides them protection from direct imitation. This is precisely why many companies invest in extending innovations if they can demonstrate that they will produce a return from these investments.

¹⁶ Asking a group or multitude of individuals outside the company to come up with the strong idea or solution you need

Despite the very favorable assumptions for this type of innovation strategy, Open Innovation is not without its challenges and limitations.

Managers are increasingly aware of this: in one survey, nearly 80 percent of large companies surveyed reported practicing some element of open innovation but most reported being dissatisfied with the measures for managing innovation (Brunswick and Chesbrough, 2014, 2015).

Two challenges emerge as important: managing the impact on internal innovation processes and transferring the related results to the business unit. Open outside-in innovation brings new ideas into the pipeline, and this is one of its strengths.

But if an outside effort brings new ideas into a company's innovation pipeline and the company has not invested in the downstream capacity to process these ideas, the influx can create bottlenecks that slow down the overall innovation process.

On the other hand, the results of an open innovation effort must be transferred to the business unit to be brought to market.

An organization's business model helps to understand which knowledge flows can help fuel innovation and which knowledge should be released to other organizations. In Chesbrough's 2006 book, *Open Business Model*, ways to innovate the business model are examined, and since then business model innovation has become an area of increasing interest for researchers and practitioners alike.

Most organizations still treat research and development completely separately from business model design. It appears from H.C.'s explanations that this is a mistake because linking technology innovation and business model innovation can amplify the value of each.

To create an appropriate Open Innovation strategy, the company must be clear about the type of business model to follow. The meaning of business model was clarified by Chesbrough, who pointed out two main functions of the business model.

The first is value creation and the second is value capture.

Therefore, a business model allows technology and concepts to be linked to economic performance.

The following are other main aspects of the business model found in the literature that should not be underestimated:

- *Value proposition*: is the company's promise to the consumer to satisfy his or her needs with the product or service (Hedman & Kalling 2003).
- *Market segment*: a group of people with one or more common characteristics, grouped together for marketing purposes (Hedman & Kalling, 2003; Teece, 2010).
- *Value chain*: understood as the positioning of a company within the value chain and with its complementary assets maintains that position (Hedman & Kalling, 2003; Teece, 2010).
- *Cost Structure/ Profit Potential*: analysis of the costs and benefits that lead the firm to generate profits (Johnson, Christensen, & Kagermann, 2008).
- *Value Network*: The connections between individuals or organizations that bring benefits to the whole group (Amit & Zott, 2001)
- *Competitive Strategy*: the way the company acts to be able to beat its competitors and receive greater profits than others (Teece, 2010).

A business model is used to decide whether to leverage technology internally within the company or externally. Specifically, technology that helps improve the value proposition or reduce costs can be developed internally.

Conversely, technology that is adopted within the customer environment and thus has marginal influence on the internal business might be marketed externally.

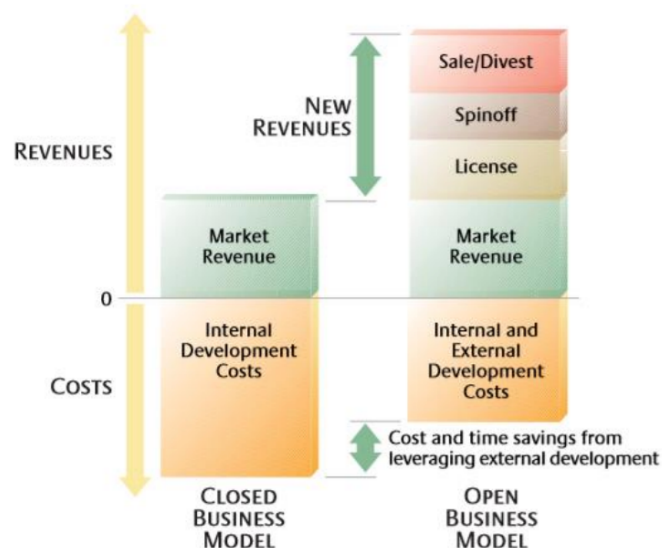


Figure 2, Source: Why Companies Should Have Open Business Models, Chesbrough, 2007

With the introduction of open business models, however, companies must be able to continuously support this innovation process.

P&G is an example of how CEO CEO commitment and support can lead to effective innovation. In fact, open innovation requires continuous research and experimentation to achieve new revenues and business value.

Figure 3 shows the New Business Model of Open Innovation.

As seen above, to offset the trends of rising development costs and shortening product life cycles (left bar), companies must experiment with new ways to open up their business models by using external ideas and technologies in internal product development and allowing internal intellectual property to be commercialized externally (right bar).

Teece's model on how to earn revenue from innovations is illustrative of what we refer to at this stage:

- *Changing appropriability regime*: It concerns patents, copyrights and trade secrets. Possible practices that are part of this strategy are the aggregation of patents and the acquisition by innovative companies of the value benefits this generates. In processor- and semiconductor-based industries that also rely on many different technologies and cross-licensing arrangements, strategic uses of a patent portfolio are particularly important (Teece, 1997). But product-oriented industries, such as pharmaceuticals, rely more on formal product patents. Generally, formal IP protection is more efficient for codable and tacit technologies (Winter 1987).
- *Control complementary assets*: this is a determining factor when deciding whether to commercialize a technology internally or license it (Arora & Ceccagnoli, 2006). Arora and Ceccagnoli have shown that more effective patent protection has a different effect on firms that control complementary assets than on those that do not; the former are more willing to commercialize internally, while the latter are more likely to license the technology.
- *Influencing the dominant design*: may have two different reasons, the first being to gain knowledge in a potentially profitable area and the second being the possibility of sharing

risks among multiple players, for example, because an industry-wide accepted standard has not yet emerged. (Grindley & Teece, 1997)

- *Intermediary markets for innovation*: these are "places" where companies can sell the rights to their intellectual property rather than directly market products and services (Gambardella, A., & McGahan, A. M. 2010). Technology innovation markets can create additional value for firms.

The future of open innovation is very broad and collaborative with the prospect of engaging a wide range of participants. It will extend beyond technology to business models and embrace both product and service innovation.

"Before open innovation, the lab was our world. With open innovation, the world has now become our laboratory."¹⁷

Digitization has radically changed the ease and nature of information flows. In this context, open innovation has become an imperative.

The techno-economic environment has changed since the widespread adoption of the Internet. Digital platforms are ubiquitous. Digital data and signals provide a common basis for handling different types of information, words, sounds and images.

The widespread use of common standards enables connectivity between different computing devices.

"Multi-invention" and "co-innovation" contexts are more common (for example, there are more than 100,000 patents involved in the iPhone).

Digital convergence requires more connectedness and platform involvement. Few companies can dominate all value chain activities in the era of digital convergence. The Internet of Things (IoT), is spreading to industries such as automotive (e.g., flying cars that require convergence of technologies) and Smart Cities. IoT business models require the collaboration of many partnerships to provide solutions.

Although external sourcing of innovation is not new, the current open innovation model is different from previous ones.

Today, in almost every company, the best ideas and people are found elsewhere.

¹⁷ Henry Chesbrough, 2007

This is partly the result of the globalization of business and advances in education and technology catch-up. Companies are now able to connect rapidly with large, global technoscientific communities, which inevitably translates into a more efficient way of finding the right solutions to problems that would otherwise have been difficult to solve. More and more work activities have become digitally connected, and new patterns of cross-functional collaboration have emerged.

Timely access to technological and industry expertise is critical to business competitiveness. In line with the dynamic capabilities' perspective, there is now a need for active engagement by almost all enterprises in technology scouting/out-sourcing. Scouting/sensing tools need to be developed.

Detection/orchestration/integration capabilities are now paramount. These developments are so fundamental that today's open innovation is qualitatively and quantitatively different from that of the pre-Internet era.

1.2.2 *Open Innovation in Lifesciences*

Open innovation (OI) promises to accelerate, diversify, and innovate pharmaceutical industry research and development (A. Schuhmacher, 2022).

It is now necessary to understand the extent to which OI is exploited in practice by pharmaceutical R&D organizations. In a recent study (Schuhmacher et al., 2022), 21 pharmaceutical companies were analyzed to compare their application of Open Innovation, which types are prevalent in the industry.

A distinction was made between outside-in (inbound) and inside-out (outbound) processes, but the focus was more on inbound processes, i.e., the practice of exploiting others' discoveries.

The concept of Open Innovation is spreading widely in academic and organizational circles. However, there is no detailed literature on value creation and how to profit from this type of innovation.

Although some authors have tried to deal with Open Innovation with a focus on value capture: the link between Open Innovation and value capture is still very weak (Henkel & Fischer, 2012). Indeed, there is a lack of a theoretical framework that can link Open Innovation, value creation and value capture.

Therefore, in an attempt to fully understand the aspects of Open Innovation, creation and value capture, the pharmaceutical industry will be examined for its highly innovative business environment and R&D crisis that led to the open business model as the key to success.

There are various reasons for internally leveraging external knowledge. For example, in academic centers of excellence, companies are increasingly investing in collaborations with universities and other research institutions to access complementary expertise.

With innovation incubators, companies create regional hubs or networks to facilitate collaboration with academia and outside scientists to enable the rapid launch of new business ideas. Outcubation is an inbound process that brings together academia and industry. Unlike academic centers of excellence, this process provides opportunities for a broad group of people and not just universities.

This section will also focus on assessing trends in the use of Open Innovation and collaborations in major pharmaceutical companies.

In the above study, 21 leading pharmaceutical companies (based on 2019 global sales) were analyzed regarding their inbound R&D activities to establish relationships with external organizations or individuals to enrich the company's knowledge base. Three categories of innovation were identified: traditional IO processes, network-based processes, and crowd-based processes.

The former relies heavily on internal knowledge and expertise. Traditional then means all processes commonly used by major pharmaceutical companies, such as M&A funds, in-licensing, co-development, research collaborations, joint ventures, and corporate ventures (VCs). These partnerships are usually narrow in scope, focused on a specific research objective, and tied to particular research.

Network-based processes, on the other hand, focus on building and maintaining a network of long-term relationships with a defined number of external partners. The value creation process, therefore, shifts from linear to 'networked'. This type of innovation includes academic centers of excellence, innovation incubators and PPPs.

The last type of innovation is characterized by:

- a. *Integration* of a large number of contributors outside traditional corporate boundaries.

- b. The *exploitation* of technologies, such as social networks and peer-to-peer technologies
- c. The *transfer* of activities that create value for a crowd.

As this type of innovation refers not only to crowdsourcing initiatives, but also to outcubation, open source, and virtual R&D. These practices aim to bring in as much community involvement as possible and make working practices transparent.

In line with these definitions then companies were classified according to their predominant type of Open Innovation in R&D:

- *Traditional R&D*: companies of this type have carried out their innovation process substantially on internal R&D, supplemented by M&A, in-licensing, VC funds, and selected R&D collaborations with academia and industrial partners. Although these companies use some external sources of knowledge, they control most innovation activities internally. There may, however, be attempts to apply OI and access external innovations.
- *Network-based R&D*: in addition to having a traditional R&D base, these companies use large-scale network-based OI processes to maintain long-term R&D relationships. This refers to R&D collaborations of several years or processes applied to multiple partners.
- *Ecosystem-enabled R&D*: these companies leverage all types of OI to acquire technologies and learn about multiple sources, realizing that they cannot operate alone and need to move beyond network-based R&D. They strategically build their R&D ecosystem by integrating a large number of collaborators outside the company's traditional boundaries and networks and initiate various crowd-based OI processes. In contrast to the previous type of innovation, the boundaries of these companies are very defined. Collaborations occur not only when there are project needs or specific jobs. Internal and external boundaries are gradually shifting.

Externally developed pharmaceutical projects that were in the companies' pipelines at the end of 2019 were then evaluated.

To do this, the report Pharma Intelligence Pharma R&D, Annual Report, 2020 was consulted. Drugs in the pipeline were mapped against externally developed drugs. The degree of external knowledge sourcing was ranked as follows:

- Low grade, with < 40 % externally developed pipeline projects
- Medium grade, with a range of 40- 55%
- High grade, with more than 55% of pipeline projects acquired from external sources.

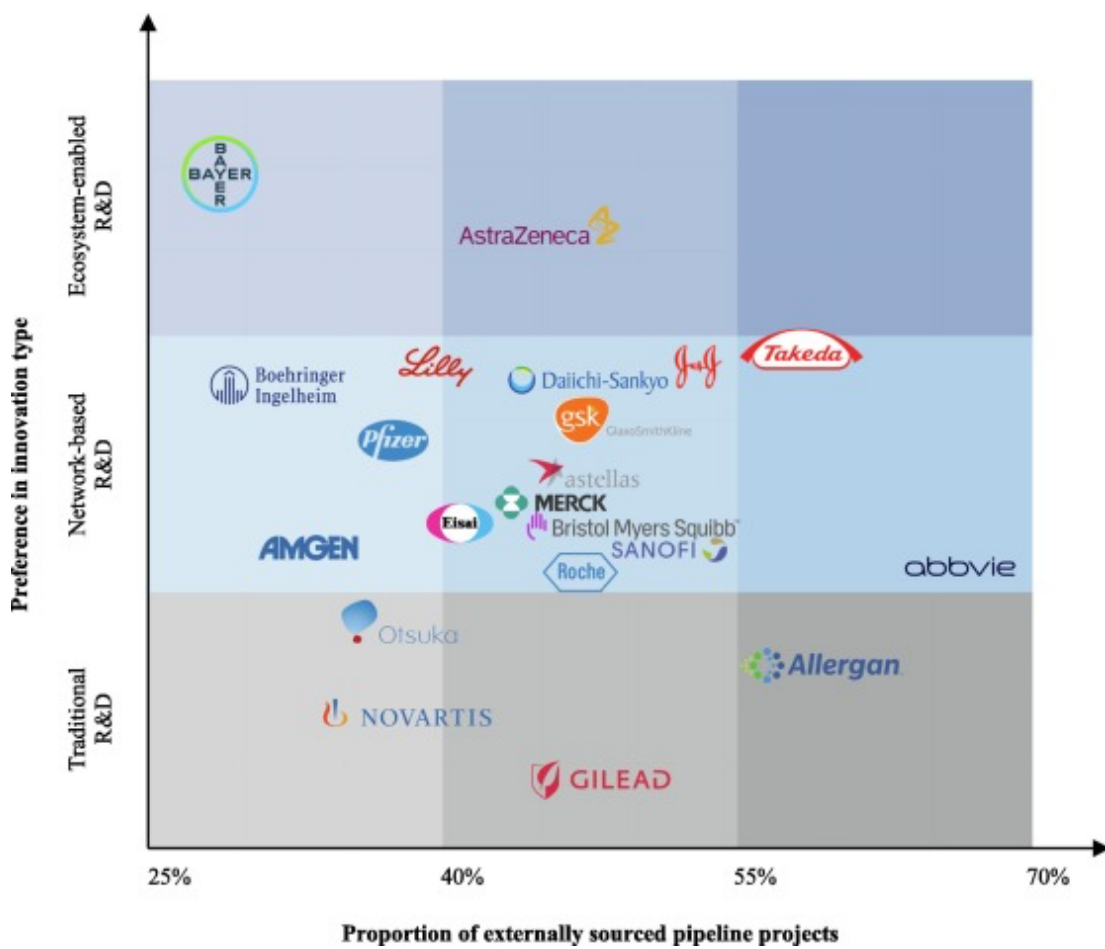


Fig. 3, Framework di OI Source: Alexander Schuhmacher, Oliver Gassmann, Doria Bieniok, Markus Hinder, Dominik Hartl, Open innovation: A paradigm shift in pharma R&D?, Drug Discovery Today, Volume 27, Issue 9, 2022, Pages 2395.

The companies in Figure 3 were ranked according to the type of innovation and the proportion of externally sourced projects in the pipeline. The figure shows the extent to which companies use external knowledge sources and helps identify the IO strategy used by each.

On the y-axis, companies were grouped according to their preferred type of innovation, defined based on a qualitative analysis of the content of practices published between 2015 and 2019. The level of IO increases with advanced use of external research and development. On the x-axis, companies are further broken down by the percentage of external projects in their pipeline.

Over the past decade, Open Innovation has found its way and has become a widely used research and development model in the pharmaceutical industry.

The depth and breadth of implementation differs among the major players in the industry. The companies that were examined in this study use mergers and acquisitions, selected research and development collaborations to access external knowledge. Most companies (15 out of 21) use network-based OI processes to integrate research and development.

Only two companies make significant use of all OI processes.

According to Alexander Schuhmacher et al.'s 2022 research, research and development collaborations with technology- or market-based partners remain one of the most popular forms of knowledge sourcing.

Partnerships with entrepreneurs and academia are playing an increasingly important role in this space.

As a result, 15 out of 21 companies run a VC fund, just as one in four companies run an innovation incubator.

In addition, several companies have formed joint ventures with biotechnology and/or pharmaceutical companies, as well as research institutions.

Joint ventures allow companies to share costs, risks and expertise as well as increase flexibility. However, the unstable and volatile nature of joint ventures and the difficulties associated with managing such alliances lead to a rather low success rate.

As a result, most companies have no or only one active joint venture. Others have established innovation incubators to connect with entrepreneurs and provide a "one-stop shop" for any potential partners. This model is used in particular by Bayer, Johnson & Johnson and AstraZeneca, which operate numerous incubators in major Lifesciences hotspots around the world such as Bayer's CoLaborator or LifeHubs, Johnson & Johnson's Janssen Labs (JLABS) or AstraZeneca's BioVentureHubs.

Another new form of partnership between academia and industry, outcubation, has recently been discussed in the literature as a combination of incubation and outsourcing.

Schellekens and Moors (2015) cite the BioMedX Innovation Center at the University of Heidelberg as an example of an outcubator model. However, because this is a specific IO model, our analysis could not identify other examples where a new biotechnology company is established to play the role of an intermediary.

Pharmaceutical companies can establish academic centers of excellence and strengthen relationships with scientists. The research analyzed so far showed that one in two companies had announced at least one new center of excellence between 2015 and 2019.

The pharmaceutical industry has been a huge driver of PPPs; while companies initially included publicly funded organizations such as academies now members have diversified and now include patient organizations, health insurers, other pharmaceutical companies, or partners outside the healthcare industry.

The literature on the impact of crowdsourcing and open source in drug discovery and research shows how these practices are growing. Seven out of twenty-one companies have initiated a crowdsourcing¹⁸ approach, and 13 companies apply at least one Open Source approach.¹⁹

Open source is an emerging IO model used by several pharmaceutical companies, and especially during the early stage of drug discovery an open community approach can bring numerous benefits to R&D stakeholders.

However, the challenge is that, following the Open Source philosophy, all potential solutions and discoveries are in the public domain. This contradicts the traditional pharmaceutical R&D model based on intellectual property (IP), in which only exclusive ownership leads to differentiation and reliable sources of revenue.

¹⁸ The term crowdsourcing was coined by Jeff Howe and indicates the entrustment of a task, traditionally carried out internally, to a very large and undefined group of people. The trend in which this phenomenon is inserted is obviously that of the exploitation of mass collaboration enabled by web tools. Crowdsourcing is therefore a distributed problem-solving model: problems are transmitted to a community of solvers [crowd] in the form of an open solution request. The proposed solutions can then be selected by the crowdsourcer or by the same community of participants and the proponent of the winning solution receives a reward, which can be monetary or even just a recognition by the community. InnoCentive and Ninesigma were the first networks to exploit this method of problem solving

¹⁹ Hippel and Krogh define open source innovation as a joint individual-collective user-driven innovation model. Steve Hamm summarizes open source innovation as a collaborative development process that includes more participants (contributors).

Consequently, so far, the Open Source model has only played a significant role in the field of poverty-related infectious diseases and neglected tropical diseases, where substantial public and philanthropic funds are available (M. Balasegaram et al., 2017).

This research shows that most pharmaceutical companies build their research and development operations on traditional Open Innovation processes in combination with external networks.

Crowd-based OI is still rare or often limited to a defined group because it is difficult to manage, with high uncertainty and the risk of misuse of sensitive and IP-relevant business information. Finally, OI implementation can be hampered by operational difficulties, and it is critical for the pharmaceutical industry to reduce business-relevant operational risks and better manage decentralized processes.

As the complexity of the operational and collaborative network increases, there are clearly many more related activities to coordinate. There is a risk that companies that are unable to properly manage such complex knowledge networks may find it difficult to apply OI effectively.

As such, most of the companies analyzed did not demonstrate a clear statement of intent on how to implement and leverage OI in research and development.

As mentioned earlier, the focus of an Open Innovation strategy is how to capture the value generated and how to manage and minimize potential risks. There are several challenges and difficulties associated with capturing value in Open Innovation; a high level of value capture is not always assured.

Open Innovation normally uses a variety of different elements in the value capture process: the free sharing of intellectual property, the absence of protection mechanisms, and the enormous difficulties in the process of sharing results. While property rights can be easily identified and tracked, companies tend to use a control system with fewer unilateral agreements, such as long-term supply contracts or research and development contracts.

Conversely, if property rights are unclear and enforcement is difficult, firms will choose a hierarchical arrangement such as a capital-based alliance (joint venture) or research company. Cohen, Nelson, and Walsh pointed out one of the main obstacles that prevent companies from

patenting their innovation: the need to disclose information could be useful to competitors (Cohen, Nelson, & Walsh, 2000).

1.2.3 *Innovation Hubs*

Before going into the details of the pharmaceutical industry, it is good to define what an Innovation Hub is and what it is about.

An Innovation Hub is a physical or virtual environment where various organizations, companies, research institutions, startups and talent can collaborate, share resources, ideas and expertise to foster innovation and the development of new solutions.

Innovation Hubs serve as focal centers for the creation, development and acceleration of innovative projects.

They can provide shared workspaces, laboratories, equipment, consulting and mentoring services, and connections to investor networks and business partnerships

Benefits include the creation of a stimulating environment in which ideas can flourish, access to skills and resources that would otherwise be difficult to obtain individually, knowledge sharing and collaborative learning, and the opportunity to create synergies between different organizations.

Innovation Hubs can specialize in specific areas, such as digital technologies, artificial intelligence, biotechnology or clean energy.

They can be promoted by governments, universities, private companies or nonprofit organizations, with the goal of encouraging innovation, economic development and job creation.

Specifically, one cutting-edge sector will be explored, namely digital technologies.

The Digital Innovation Hub (DIH) is a territory-based ecosystem that is tasked with stimulating the knowledge and adoption of 4.0 technologies by the production system. The DHI, alone or with partners (Universities, Competence Centers, Clusters, Research Centers), helps SMEs approach the new industrial revolution.

They have the task of stimulating and promoting the production system's demand for innovation, strengthening the level of knowledge and awareness with respect to the opportunities offered by digitalization, and are the "gateway" of companies to the world of Industry 4.0.

The strength of a DIH is to be able to offer a qualified level of services by making use of a network of innovation players, national and European.

- Training activities through workshops, seminars and one-to-one meetings with companies
- Assessment activities (assessment) on the degree of digital maturity of companies in the area
- Mapping of innovation providers to learn about the ecosystem and direct SMEs to technological solutions.

In pharmaceutical companies, Innovation hubs are specialized centers for all-round innovation. There are still few pharmaceutical companies today that have established these centers and through them are trying to approach the Open Innovation strategy.

An Innovation Hub in the pharmaceutical sector is an environment dedicated to promoting and accelerating innovation in the field of research and development of drugs, therapies and medical technologies. These hubs aim to create a collaborative ecosystem that fosters interaction among pharmaceutical companies, research institutions, start-ups, investors and other key players in the industry.

Characteristics of an Innovation Hub in the pharmaceutical sector may include:

1. Shared workspaces: providing a physical environment where different organizations can work together, share ideas and expertise.
2. Laboratories and equipment: providing laboratory infrastructure and specialized equipment for new drug research and development.
3. Expert network: connecting industry experts, researchers, academics, and healthcare professionals to foster collaboration and knowledge exchange.
4. Accelerator programs and incubators: offering support and mentoring for start-ups and emerging pharmaceutical companies to help them develop and commercialize their innovations.
5. Access to financing: connecting innovators to investors, venture capital funds, and funding programs to support the growth and development of new pharmaceutical solutions.

6. Collaboration with research institutions: facilitating collaboration between pharmaceutical companies and academic research institutions to foster the discovery and development of new drugs and therapies.
7. Emerging technologies: exploring and adopting new emerging technologies, such as artificial intelligence, machine learning, data analytics, robotics, or 3D printing, to improve research and development processes and create more effective solutions.

The main goal of an Innovation Hub in the pharmaceutical sector is to accelerate innovation, reduce drug development time, facilitate the discovery of more effective therapies, and improve patients' health and quality of life.

An example of this is the pharmaceutical company Novartis, which has engaged in several initiatives and programs with institutional and private partners with the aim of stimulating innovation capacity in the Lifesciences sector, especially by leveraging the potential of digital. The company's goal is to develop a network that nurtures collaboration among entities to support the development of solutions to support the mission of re-imagining medicine through a combination of scientific expertise and knowledge of the Lifesciences sector with those offering advanced technological solutions, for a direct approach to Open Innovation.

The Novartis Group, in fact, has established a network of Digital Innovation Hubs called Biome. They are cross-divisional units to support the development and implementation of Open Innovation initiatives-the goal is to speed up connections between the pharmaceutical company and partners who are part of the health and technology ecosystem.

The Innovation Hubs that are currently active were all born around 2020 under the impetus of the Covid-19 pandemic in response to a critical moment for pharmaceutical companies.

They were therefore born with the purpose of doing science-technology research-intensive innovation and as a hub for startups, research centers and companies.

"Investing in research has always been crucial for our country and Europe to become sovereign in production and access to innovation".²⁰

These are the words of Alberto Chiesi, the chairman of the Chiesi Group, which in 2022 started work on the construction of its new center of excellence, the Biotech Center of Excellence.

²⁰ Alberto Chiesi, President of Gruppo Chiesi, 2022

The pandemic has made it clear how important it is to give weight to scientific research and pharmaceutical development as well as the role that industries in the sector can play in this regard.

The overburdened health care system demands faster scientific and medical innovation that can meet the challenges of today and years to come. Innovation Hubs therefore serve the function of ensuring strategic autonomy and access to innovation in the pharmaceutical sector.

Innovation Hubs are a key step in fostering an innovation pipeline and creating opportunities for long-term collaborations.

CHAPTER II – Research Methodology

This chapter will focus on providing a deep dive view of the strategy used to conduct the case study in all its steps and considerations made.

2.1 Objectives

Once we have reviewed the state of the art on the subject, we have come to the focal point. With the research questions outlined at the beginning of the discussion, the goal was to understand how the implementation of new digital technologies in a pharmaceutical company has impacted mainly on two aspects.

The first concerns the way companies conduct research, how the strategy deployed for new drug discovery and development varies. Following the introduction of digital technologies into organizations through Innovation Hubs, what is the approach to research that they are putting in place? What has changed? Is the digital transformation bringing benefits, including perceived benefits?

The second aspect relates to the introduction of Innovation hubs into the enterprise: this time as a means through which to do Open Innovation. How does sharing and collaboration improve the way innovation is done? Why open up to this new approach?

From these two questions we will ask through the interview what are the perceived benefits of the stakeholders. Has the innovative way of drug research and development, collaboration with universities and startups improved processes in terms of efficiency and speed in delivering services and products?

2.2 Case study

Following a careful review of published literature and having established what we know and what we do not know about the topic, the above research questions were formulated.

Based on the research question, it was deemed appropriate to take the case study route, precisely because the holistic and meaningful characteristics of real-life events within the Innovation Hub of the company under study will be analyzed. Attention will be placed on contemporary events

over which the researcher has little or no control. The case study thus involves a narrow unit of analysis, limited to a work team. The "case study" type that has been preferred is the exploratory type, the purpose of which is to improve knowledge of a given reality in the absence of hypotheses and a lesser structuring of data collection tools. It, in fact, focuses on the exploration of ideas and insights through open-ended questions that allow for a better understanding of reality and, above all, to center the focus and objective of the research questions. The responses are not statistically measurable but provide valuable information that can lead to new insights and future research.

2.3 Interview participants

First, it is good to briefly describe the unit of analysis considered. Pfizer's Innovation Hub, the Center of Digital Innovation (Cdi) in Thessaloniki, will be examined. The center was born during the pandemic, in 2020, with the impending need to speed up processes at all levels of the organization. Thus, we can say that the Cdi was born with a need that soon turned into a virtue.

The individuals who were involved for this case study all belonged to the same team and filled some of the key roles within the Innovation Hub, the subject of the study.

They were selected based on a careful analysis of what they needed to know.

A total of 5 individuals were interviewed and the profiles of the interviewees are given in the table below, as well as in the next rows through a more in-depth description of the roles and responsibilities of each.

Nico Gariboldi is the Site Lead of the Thessaloniki Innovation Hub and Senior Director. It plays a key role within the hub because it guides the strategic approach of the site, develops an L&D strategy that promotes the learning culture of the organization, as well as defining the External Outreach and Partnering strategy to develop innovative digital solutions and research initiatives with ecosystem stakeholders. Nico started his career at Pfizer Italia 16 years ago, serving as Brand Manager of peri-LOE products, Commercial Effectiveness Manager, Business Intelligence Advisor, Supply Policy Specialist and Junior Analyst. Since then he has held roles of increasing local, regional and global responsibility. More recently, Nico has been a Global Capability Lead for the healthcare portal experience within the Customer Experience team and

previously served as Senior Director, Global Lead for Customer Engagement and Content Strategy for Pfizer Essential Health. In that role, he managed the team responsible for creating corporate customer engagement strategies (digital and face-to-face) to support commercial, scientific and business goals, based on an omnichannel approach and content marketing strategy.

Lidia Fonseca is the Chief and Technology Officer and Executive Vice President. It deals with digital strategy, data, technology, products and solutions at the enterprise level, as well as learning and development and business process excellence. responsible for developing and implementing a digital strategy at company level. Lidia leads all digital, data and technology solutions across the company, as well as learning and development and business process excellence.

He leads numerous transformation programs and initiatives to support Pfizer's goal of delivering life-changing innovations for patients, applying digital capabilities and products, including digitizing drug discovery and development; Improve healthcare outcomes and patient experiences; improve operational processes through automation and robotics; and provide in-depth information with advanced data and analytics for better decision making.

Jeff Hamilton, Senior Vice President of Pfizer Digital. Lead the Finance, Global Supply and Pfizer Digital & Technology Hub organization within Pfizer Digital. Jeff and his team are focused on achieving the strategic goals of the Finance and Global Supply functions through the use of digital analytics, automation and predictive. Jeff is also responsible for the Pfizer Center for Digital Innovation (CDI) in Thessaloniki, which operates as an extension of Pfizer Digital's global operating model to promote digital patient-centric solutions. In addition, Jeff and his team lead the digital activities needed to perform Pfizer acquisitions, collaborations and disposals.

More recently, Jeff led the Client Partner organization of Pfizer Digital, responsible for the involvement of all Pfizer functions for digital services, with the aim of bringing drugs to market faster, improve health outcomes and foster operational efficiency. Jeff was also responsible for the digital team that supported Pfizer's business with the goal of improving customer engagement and improving healthcare outcomes through the innovative use of digital, artificial intelligence and analytics. Prior to this, Jeff successfully completed Pfizer's global SAP ERP

program in 135 countries and more than 40 production sites as a key driver of Pfizer’s operational strategy.

Thanos Stavropoulos, Technology and Innovation Senior Manager at Center of Digital Innovation (CDI). He is also a member of the Open Innovation Team (OIT) and is responsible for collaborative innovation projects with the Greek ecosystem of universities, startups and research centers.

Thomas Kareklas, Technology and Innovation Senior Manager at Cdi. Its role is to manage the portfolio of technology projects, collaborate with technical and business groups to collect requirements and improve existing processes and manage projects with Agile and Waterfall frameworks.

The roles and subjects under consideration have been summarized in a sample table for a quicker reading of the sample considered.

Role	
Nico Gariboldi	<ul style="list-style-type: none"> ○ Site lead of Thessaloniki Innovation Hub ○ Senior Director
Lidia Fonseca	<ul style="list-style-type: none"> ○ Chief Digital and Technology Officer ○ Executive Vice President bringing the art of the possible in digital
Jeff Hamilton	<ul style="list-style-type: none"> ○ Senior Vice President, Pfizer Digital
Thanos Stavropoulos	<ul style="list-style-type: none"> ○ Technology and Innovation Senior Manager at CDI ○ Member of Open Innovation Team (OIT)
Thomas Kareklas	<ul style="list-style-type: none"> ○ Technology and Innovation Senior Manager at CDI

Table 2: Interlocutors interviewed.

There are several main reasons why the above candidates were considered.

First, they all work within the team at the Center of Digital Innovation in Thessaloniki, which is precisely the subject of our study, as we will see in the next chapter.

The candidates deal on a daily basis with what goes on within the Center for Digital Innovation so they have extensive expertise and experience relevant to the case in study which is why they were considered interesting for an interview. Given their track record, it is believed that they can offer an in-depth perspective and specific knowledge of the field and topic at hand.

The roles they play in the Innovation Hub were considered key roles as well as crucial influences in decisions affecting the Innovation Hub. Thus, their experiences and opinions can offer an in-depth understanding of the factors influencing the development of the case.

Taking different roles into consideration allows for an overview of different perspectives. All of this is important in order to get a more comprehensive framing of the case study. Thus, it is believed that interviewing people involved in different positions within the organization or representatives of different stakeholders can contribute to a better understanding of the ongoing dynamics and challenges.

Nico Gariboldi represents the candidate who has most significantly introduced significant innovations in the center and has achieved outstanding results since the hub was established; his experience and strategy is certainly useful for drawing lessons and best practices to be applied in the future.

The fact that the Cdi came into being at the same time as the spread of the Covid-19 pandemic makes us realize how even the controversies and issues faced by candidates can lead to incredible opportunities.

Also considered was the team's broad willingness to provide the answers needed for the research: from the outset, the Thessaloniki team showed great interest in providing the information and taking part in this project.

Ultimately, these candidates were chosen because they created a balance between quantity and quality with respect to the variety of perspectives, experiences, and roles to get a comprehensive overview of the case without overloading resources.

2.4 Method selection

As mentioned in order to study the case under analysis in detail, a qualitative method was chosen.

It allows the phenomena to be explored and understood in greater depth and detail and still in line with the research questions posed. Through interviews, observations and document analysis, it was possible to gather nuanced contextualized and in-depth information.

Qualitative methods are particularly suitable for understanding the complexity of the topic as well. It made it possible to explore the context, dynamics and social interactions that may influence the case study.

Through this methodology, it was possible to give voice to participants' personal perspectives and experiences. Interviews or focus groups allow for an in-depth understanding of the perceptions, values, emotions and motivations of the people involved in the case study.

When it comes to exploring new topics or little-studied phenomena, this method is particularly suitable: in fact, it allows for gaining initial knowledge and generating hypotheses, theories that could be the subject of further future research.

The qualitative method also offers more flexibility than the quantitative method. Interview questions or research protocols can be adapted according to new information that emerges throughout the process; the flexibility allows for further exploration of relevant points and adaptation to the unique characteristics of the case study.

The qualitative method was able to provide a thorough and detailed understanding of the phenomena studied. This is particularly useful as the goal is to gain in-depth knowledge and all its nuances rather than extracting mere numerical data.

In summary, the selected method is able to analyze the case study under consideration in a way that provides an opportunity to explore the phenomena in detail, understand the contexts and personal perspectives, and thus delve deeper into the complexity of the processes under consideration.

2.5 Data collection

Following the choice of method, the mode of data collection was selected: interview.²¹

A brief presentation of the study and research protocol was provided to the respondents, along with the 2 categories identified from the literature review. A file was created with the questions to be asked of the interviewees, which was then sent via e-mail prior to conducting the online meeting to allow the subjects to already have a clear understanding of the topic to be discussed. Subsequently, it was possible, thanks to the willingness of the Innovation Hub members, to be able to conduct the interview in a call on Teams that was attended by the subjects summarized in the table above. The interview lasted about an hour and a half: the interviewees responded to the questions in great detail and were so strongly interested that they directed the discussion to different topics that gave rise to new insights.

The interview provided detailed and in-depth information about the case study. It was possible to ask specific questions that provided a richer understanding of the factors and dynamics they wanted to investigate.

This made it possible to explore the motivations and reasons behind the actions and decisions taken to establish the Cdi, do research, and subsequently implement digital innovations in the organization. Respondents set out their views, offering considerations that guided their choices and the implications of the decisions made.

The method led to greater flexibility than other data collection methods. It allowed questions to be adapted in real time, as they actually happened, following the participants' paths of thought or delving further into aspects they deemed most relevant.

It also allowed for direct interaction with participants by creating an environment in which it was possible to clarify obscure points, investigate responses further, and establish trust.

The data collected were contextualized as participants provided specific details, experiences, and perspectives. This helped to further clarify the situations occurring in the Innovation Hub and the complex dynamics whose nuances they were interested in learning about.

²¹ Reported internally in the "Appendix" section of this discussion

2.6 Data analysis

Once the interviews were completed, the information obtained was collected and then proceeded to analyze it.

The focus was on exploring and categorizing the content of the collected data. Recurring themes, categories and concepts were identified and systematically organized to understand the trends described by the interviewees.

From the information collected, an attempt was made to identify the prevalent patterns of strategies implemented, concepts, and key ideas.

All the themes and categories are summarized in the following table:

<i>THEMES</i>	<i>CATEGORIES</i>
Research and development	<ul style="list-style-type: none">• Employment• Training• Digital technologies used• Innovations made• Drug creation process• Financial return• Leadership & governance• Perceived benefits
Open Innovation	<ul style="list-style-type: none">• Collaborations• Digital innovations made• Financial return• Perceived benefits

Table 3: Themes and categories from the interview

This mode of analysis provided an in-depth understanding of the meanings of the connections present in all the responses collected.

The interview was one of the main methods of data collection, but specific analysis of the documentation and published sources found online and shared by the interviewees prior to the interview was also conducted. It was on the basis of this documentation that the questions to be asked of the interlocutors were formulated to avoid touching on issues already discussed. In fact, the aim was to fill in the gaps left by previous research and draw new insights.

2.7 Organization and interpretation of results

The data collected were organized based on a framework that builds on the two pillars of the treatment mentioned earlier: research and collaboration with the ecosystem of stakeholders present. The two categories were identified to straddle the themes that emerged from the interviews.

Interpretation and conclusions will be addressed in detail in the next chapter.

CHAPTER III - Results

Before analyzing the results, it is good to give a brief overview of the company and its approach to better contextualize the findings.

Pfizer is a leading US pharmaceutical company operating in several therapeutic areas, including cardiovascular diseases, oncology, immunology, neuroscience, vaccines, rare diseases and others. The company is known for having developed and marketed many successful drugs, to name a few:

1. Vaccines:

- a. Prevenar 13 (vaccine against pneumococcal pneumonia)
- b. Trumenba (vaccine against meningococcus B)
- c. Comirnaty (BNT162b2), the first vaccine against Covid- 19

2. Pharmaceuticals:

- a. Lipitor (atorvastatin, a cholesterol-lowering drug)
- b. Lyrica (pregabalin, a drug for the treatment of epilepsy, neuropathic pain and generalized anxiety)
- c. Celebrex (celecoxib, a non-steroidal anti-inflammatory drug)
- d. Viagra (sildenafil, a drug for the treatment of erectile dysfunction)
- e. Xeljanz (tofacitinib, a drug for the treatment of certain autoimmune diseases such as rheumatoid arthritis)

3. Oncology products:

- a. Ibrance (palbociclib, a drug for the treatment of breast cancer)
- b. Xtandi (enzalutamide, a drug for the treatment of prostate cancer)
- c. Sutent (sunitinib, a drug for the treatment of several types of cancer)

4. Animal health products:

- a. Revolution (selamectin, an antiparasitic for dogs and cats)
- b. Rimadyl (carprofen, an anti-inflammatory drug for dogs).

Pfizer is now the talk of the town because of the vaccine that bears its name; in collaboration with BioNTech, the company developed and marketed one of the first COVID-19 vaccines approved for emergency use, known as the Pfizer-BioNTech vaccine. This vaccine has played a significant role in the fight against the spread of the virus worldwide.

But Pfizer is also committed to the research and development of new innovative drugs and therapies to address global medical challenges with a primarily innovation-oriented approach, which will be detailed in the next section.

3.1 Pfizer's approach to innovation

Pfizer's goals and strategies, as mentioned, are not limited to the discovery and commercialization of the Covid-19 vaccine but expand to many different branches of the pharmaceutical industry. Its approach to innovation is based on several pillars:

- *Research and development (R&D)*: the company invests heavily in R&D to discover and develop drugs and therapies. Research centers around the world focus on a wide range of therapeutic areas, including oncology, infectious diseases, cardiometabolic diseases and rare diseases. The aim is to find innovative solutions to unmet medical needs.
- *Collaborations*: Pfizer collaborates with other pharmaceutical companies, universities, research institutes and governmental organizations to foster innovation. Partnerships in particular enable the sharing of knowledge, expertise and resources to accelerate the development of new treatments.
- *Technology and digitization*: adopt advanced technologies and engages in digitization to improve drug discovery, production efficiency and treatment delivery. This includes the use of artificial intelligence, big data, data analysis and predictive models to accelerate the drug development process and understanding of diseases.
- *Investments in start-ups and venture capital*: Pfizer invests through its Pfizer Ventures program. The investments aim to support innovation in technology and pharmaceuticals by offering opportunities for growth and collaboration.
- *Commitment to access to medicines*: Pfizer is committed to ensuring equitable access to its innovative medicines and therapies. The company works with international organizations, governments and stakeholders to address challenges related to drug accessibility, especially in low- and middle-income countries.

Pfizer's ultimate goal is to make available 'innovations that change patients' lives'. The principle behind the company's culture is one of *accountability*, and its global leadership role in biopharmaceutical innovation leads Pfizer to collaborate with healthcare facilities, governments, patient groups, non-profit organizations and local communities to support healthcare systems, promote wellness, prevention and therapies to conquer today's most dreaded diseases, and give patients access to reliable, safe and sustainable treatments that can significantly extend and improve their lives.

"For Pfizer, commitment to research means meeting society's needs, anticipating responses and identifying effective and safe therapeutic solutions with the aim of improving people's living conditions. In Italy, Pfizer interfaces not only with healthcare facilities but with all the interlocutors of the Health System."

Digitalization and innovation have been Pfizer's 'top drivers' for years. In recent years, many projects and proposals have been launched in this area, including the creation of websites, web-based devices and smartphone applications.

Pfizer is approaching the market with a new, increasingly 'patient first' outlook, thus turning more and more attention to patients by providing services and products developed also for caregivers, ensuring more accurate and constant information. The company is therefore targeting communities of people and patients seeking practical advice on their condition and services to improve their quality of life.

Pfizer's Pipeline is currently relentlessly pursuing medicines and vaccines that will benefit patients around the world. They are committed to treating 225 million people with innovative treatments by 2025. The ambitions are great and the product pipeline has never been stronger:

Every drug used today has been studied on thousands of people in clinical trials. Participating in a clinical study can make a difference in other people's lives. Research for Pfizer is a strategic activity and Independent Study Research (ISR) is supported.

Pfizer Pipeline As Of May 2, 2023



Figure 4, Pfizer Pipeline, Source: Pfizer.com

Areas of innovation

1. Gene therapy: has the potential to offer patients with rare genetic diseases a transformative clinical advantage and improve their quality of life. Experience and commitment to gene therapy research together with strategic investments have provided end-to-end capabilities facilitating the discovery and development of gene therapies and enabling scalable high-quality manufacturing with the goal of providing therapies for the next generation.
The development of this therapy is a complex task because it requires innovative and specialized methodologies as well as a high level of expertise.
2. Medicinal sciences: Pfizer invests in the next generation of science and technology so that we can invent tomorrow's therapies and help patients around the world today. Diversified research includes work on potential small molecule drugs, biotherapeutics and large molecules (antibodies), cell and gene therapies and vaccines. They are all created and studied with one goal in mind: to bring better and safer drugs.
3. Precision medicine: this studies the biological basis of diseases, using emerging technologies to support the development of innovative therapies tailored to patients who benefit most. Pfizer's portfolio focuses on the exploration of genetic, phenotypic and functional biomarkers to help guide clinical research strategies. The goal is to develop drugs and vaccines with potentially transformative outcomes for patients with an integrated approach to the development of each product.

4. Maternal immunization²² : Pfizer is working to research and develop vaccines through maternal immunization that can help protect children from certain diseases. It is using scientific expertise to provide vaccines that have the potential to boost maternal immunity, the natural ability of a pregnant person to provide protection to growing fetuses through the transfer of antibodies across the placenta.
5. mRNA technology: the very rapid delivery of the first mRNA-based Covid-19 vaccine²³ has highlighted the promise of mRNA technology. The next wave of scientific innovation is upon us and Pfizer is working hard to harness the power of mRNA to find drugs against various types of cancer. Expertise in disease biology coupled with robust and rapid manufacturing capabilities and talented scientific minds will help advance the potential of this technology.

Nico Gariboldi, Site Lead of Pfizer's Innovation Hub, the Center of Digital Innovation in Thessaloniki, on the link between the world of digital innovation and pharmaceutical manufacturing, says "the link between these two worlds is huge. Digital is impacting both the way patients access health-related services and benefits and the way companies work in general. And this is something quite recent: Pfizer appointed its first Chief Digital Officer, Lidia Fonseca, just three years ago. This figure now sits on the executive board, which underlines how central this area is and how it influences the entire structure of the company. Indeed, digital is supporting the company's activities at all levels, from the research and development of drugs to their production and distribution, but also with regard to relations with health stakeholders. To give one example, digital played a key role in the development of the Covid-19 vaccine: 46,000 patients at 150 sites participated in the trials by connecting remotely, and the coordination and management of data could not have been done so efficiently without strong digital support."

²² Maternal immunisation is a tool to help pregnant women transmit disease-specific antibodies to the foetus during the second and early third trimester, helping to protect the baby during the most vulnerable period of life: the first six months.

²³ mRNA, or messenger RNA, is a molecule that contains the instructions or recipe that directs cells to produce a protein using its natural mechanism. To enter cells smoothly, mRNA travels inside a protective bubble called a lipid nanoparticle. Once inside, our cells read the mRNA as a set of instructions, building proteins that correspond to parts of the pathogen called antigens. The immune system sees these foreign antigens as invaders, sending out defenders called antibodies and T-cells and training the immune system for potential future attacks. Thus, if and when the real virus arrives, the body may recognise it, sounding the alarm to defend itself against infection and disease.

3.2 *The Centre of Digital Innovation (Cdi)*

Pfizer's Center for Digital Innovation (Cdi) established in 2020 in Thessaloniki, Greece, is an integral part of Pfizer's innovation strategy: great innovative ideas for drug discovery and development, for improving public health and the patient experience come and go from here. The Cdi was created to develop transformative digital solutions that lead to life-changing discoveries for patients but also for the organization itself.

The pharmaceutical company Pfizer was one of the first to introduce an Innovation Hub in the organization during the pandemic and expectations on the Cdi were very high.

"When we said in 2020 that Cdi came to change the facts in the field of digital innovation in Greece, there were certainly very high expectations. The pandemic was like an 'unwritten map', and no one could say for sure where it was leading. Three years later, however, I think the result of our work not only lives up to expectations but confirms that CDI has also changed things for the local economy - beyond innovation!" Nico Gariboldi's words about the hub's work in recent years.

Cdi was born in Greece after an analysis of several countries and the possibilities they offered, but it represents a center that operates internationally. "We chose Thessaloniki first and foremost for the talent: here, in fact, there is the University of Aristotle, the largest in south-eastern Europe, the University of Macedonia, but also an environment full of entrepreneurial energy made up of start-ups, incubators and research centers dedicated to digital."

The Greek government in recent years has been pushing hard on digital and innovation through targeted strategies and dedicated government bodies. The results to date are evident and in fact they have been the only ones to establish themselves in this area, which is now very rich in digital competitors and companies. "There is also a very practical issue: Thessaloniki is a city in a strategic position in Europe and in the world, because it is located in a melting pot that allows us to work at times that are useful for communicating with both the West and the East."

The work of the CDI is based on four fundamental pillars:

- *Adopting a patient-centred approach to develop digital solutions.*
- *Belonging to a global network:* the team is a diverse group of people with global connections engaged in the external local ecosystem to facilitate co-development partnerships.
- *Delivering results-oriented multidisciplinary services:* state-of-the-art processes are pursued that lead to measurable results in many fields, from therapy to design thinking, analysis and artificial intelligence.
- *Use an agile co-creation process:* create collaborations with colleagues, partners, patients, healthcare professionals and others around the world to accelerate discoveries and deliver scalable solutions as quickly as possible.

The vast network of experts collaborating with the Cdi ranges from start-ups and health spin-offs to established technology companies to universities and research centers. The Cdi thus becomes a member of numerous innovation initiatives:

- Creation of advanced analysis platforms bringing together data from Pfizer and external partners, as well as tools for decision-making, modelling and scientific and clinical insights.
- Initiatives to reimagine clinical trials through robotics, automation and technological processes that improve patient experiences, as well as improve the selection and recruitment of clinical trial participants in order to reduce their time.
- Launch of the Pfizer Digital Companion, a suite of digital products and solutions to deepen engagement between patients and doctors.
- Five new solutions: Mabu® Wellness Coach, Champix Chatbot to help stop smoking, LivingWith apps to support patients undergoing cancer treatment and their loved ones, drug delivery via drones in the Dominican Republic to increase patient access to medicines in remote and hard-to-reach locations, and a partnership with Fitbit to support early diagnosis of atrial fibrillation.
- Initiatives to empower and simplify work by automating it with robotics, machine learning and predictive analytics that enable better and faster decisions while promoting efficiency. As of 2019, in fact, Pfizer has automated 40 per cent of approximately 100 million transactions across the company.

In 2 years of activity, the Cdi has achieved a number of goals:

- Promoting innovative solutions that have changed patients' lives,
- Contributing to the national and local economy in many ways, including creating employment opportunities with numerous high-quality jobs and contributing to the development of an ecosystem of high-potential scientific collaborations, investing in the human capital and talents of the city and the country. In this context, they have announced collaborations with the National Centre for Research and Technology, the Aristotle University of Thessaloniki, the University of Patras, the University of Ioannina, as well as with the startup ecosystem, both through open calls and specific collaborations with companies (startups) that stand out.

The Cdi was opened in 2020 with the aim of employing 200 employees; in 2022 it reached the target of 400 employees and is aiming for 500 at the Thessaloniki site. This shows how Pfizer is investing in this global center of excellence and how much it believes in its important work. These interesting employment figures in addition to the ever-growing involvement of numerous start-ups allow the company to have excellent relations with local government bodies as it contributes significantly to the local and national economy.

According to research by the Foundation for Economic and Industrial Research (IOBE), over the period 2020-2030, the operation of the CDI will support a total of 8,100 jobs per year across the spectrum of the Greek economy. The Centre's direct contribution to employment for the same period is estimated by research at 3,600 jobs per year. This means that every 1 position in the CDI supports 2.3 positions in the entire Greek labour market. Equally important is the CDI's contribution to the country's GDP for the specific period, which will amount to EUR 486 million.

It was confirmed that Pfizer's Cdi came to Greece to change things in the local labour market and globally change the pharmaceutical industry with excellent digital innovation.

Further confirmation comes from the 'Start4Health' program, the healthcare innovation accelerator of the Thessaloniki Cdi. The aim is to bring together the Greek startup ecosystem to sculpt the future of healthcare through digital innovation with visionary ideas.

The challenge for Pfizer's Cdi is to foster innovation and increase engagement and collaboration with the local innovation ecosystem by creating mutually beneficial relationships. The startup accelerator program has already been very successful in 2022 and during the current year they are looking for an increasingly broader range of solutions, beyond digital healthcare and across the entire digital innovation value chain of the pharmaceutical industry.

The themes²⁴ focus on solutions that fall under one or more of the following thematic pillars:

- **eHealth:** is a solution that improves patients' lives through the use of technologies ranging from digital biomarkers, diagnostics and therapy, biomedical devices, health literacy to digitally supported clinical decision-making.
- **Bioinformatics:** concerns computational techniques, algorithms and platforms that process, analyze and interpret biological data and efficiently help new and faster discoveries in the field of Lifesciences.
- **Business Intelligence:** these are data-driven solutions that encompass data analysis, reporting and decision-making, optimizing operations and strategies.
- **Green Innovation:** these are sustainability-focused initiatives within the pharmaceutical industry value chain, ranging from production to delivery, such as buildings and waste management.

This program is aimed at all start-ups in the Greek ecosystem with remarkable talent and skills in technology, products, services and business models.

3.3 Cdi point of view: Findings

The research question of this paper is: “How has the introduction of digital technologies and Innovation Hubs in the pharmaceutical sector changed the way of doing research and also opening up to the world, to collaboration with external partners to share knowledge and discoveries. What benefits has it brought?”

Through this case study, we aim to answer the above-mentioned question.

The case study of Pfizer was selected because the company is one of the few that has embarked on a major digital innovation journey and answers perfectly what was asked at the beginning of the discussion. The data was collected from a thorough desk analysis and through personal

²⁴ <https://centerfordigitalinnovation.pfizer.com/start4health>

qualitative interviews with key players within Pfizer's Center of Digital Innovation, from which useful and interesting information was extracted to bridge the gap with the previously analysed literature.

The following chapter is structured in such a way that the analysis touches on the two fundamental themes on which the discussion is based: *research* and *collaboration*.

We will understand how digital innovations have changed these two aspects and what benefits the members of the CDI have perceived since its establishment.

3.3.1 *Research and development*

Regarding the first focus, that of research, we aim to first understand what the Thessaloniki CDI is about and what digital innovations the members working there are focusing on.

The model used for this hub is that of *digital twinning*: all the capabilities and work areas present in Pfizer's New York headquarters are now also in Thessaloniki, the Cdi is part of an international digital organization that includes all Pfizer research centers.

"We work on various state-of-the-art technologies, on machine learning, on artificial intelligence; our team includes data scientists, software developers, and there are also groups working on Agile principles. In short, all the main areas of digital innovation are represented and are being used to bring value to the whole drug and health supply chain. Digital is improving drug production and distribution. With tools based on artificial intelligence and big data analysis, we are studying factors that can predict a patient's risk of developing a serious disease and identifying patients who could benefit from timely preventive measures'. (Nico Gariboldi, Site lead of Cdi)

The primary goal of the Cdi team is to get new drugs to patients as quickly as possible and this can only be achieved by using digitization at the highest level at every stage of ***research, development and production***.

Revolutionary therapies are simplified by accelerating scientific research through machine learning, data science and process automation. In essence, the whole chain has one common denominator: digital innovation.

In this regard, it should be noted that the competition, specifically the Novartis group, has also set up an international network of Digital Innovation Hubs: Novartis Biome. Biome is a cross-divisional unit supporting the development and implementation of Open Innovation initiatives: its aim is to accelerate connections between Novartis and all partners in the health and technology ecosystem. Today, the Biome network has more than 12 local hubs already operating worldwide and from 2022 it will also be operational in Italy.

Pfizer, since the establishment of the Innovation Hub in 2020, has taken part in numerous innovation projects involving support for diagnosis, treatment, and new drug development.

In particular, one of the most significant projects concerns *supercomputing* and *quantum computing* tools that can speed up and thus make the search for new drugs and treatments much easier through the creation of *virtual labs* that make it possible to understand how and whether new molecules can help improve patient health.

Pfizer Digital's strategic priorities are threefold:

- Better health outcomes for patients
- Faster access to medicines
- Contributing to the development of tomorrow's pioneering treatments

The three aims just mentioned are all directly related to the digital transformation of the company and will be specified later in the words of Nico Gariboldi²⁵. The Cdi was the key to digital transformation and the realization of these priorities. A key aspect to reiterate is that the Cdi, in Pfizer's operating model, is a global, international center: the first one established where all colleagues work globally.

Regarding the objective of the CDI and how this center acts to take advantage of digital transformation Nico Gariboldi, Site Lead replies as follows:

"Digital for Pfizer is truly fundamental, a strategic imperative. It has been able to accelerate and support most of the company's objectives".

Improving patient health is certainly important, working in the field of vaccines and drugs, but providing patients and doctors with digital solutions to better manage illnesses is also a goal.

²⁵ Site Lead of Center of Digital Innovation at Pfizer

For example, the CDI has implemented a smartphone application that supports the patient in managing the disease as well as being in contact with doctors and relatives at all times.

Getting drugs to patients faster, speeding up clinical trials, the development of a drug or vaccine. "This is crucial, through digitization it is possible to improve processes, digitize everything from data collection to data management and remote clinical trials." (Nico Gariboldi, Site Lead of Cdi)

Regarding the return that digital innovations are bringing to business, Jeff Hamilton points out a key aspect. The digitization of processes and the consequent speed with which activities are carried out have made it possible to accelerate the testing and development of drugs. In fact, there are now 38 drugs in phase 1, 28 in phase 2 and 23 in phase 3 in Pfizer's pipeline, plus 12 in the registration phase, making a total of 101 drugs in the pipeline.

In addition to this, the implementation of new technologies or innovative processes has increased productivity and work efficiency and has led to more results with the same resources and a reduction in the time it takes to formulate and test a drug, thus improving overall profitability.

Some innovations have also helped to reduce operating costs and improve the efficiency of business processes. Process automation has reduced dependence on labour and optimized the use of resources, resulting in lower production costs.

In addition to process transformation, digitization is therefore accelerating the production of drugs or vaccines. The fact that through digital we can do very constant monitoring and understand what needs to be done to be more effective has meant that the vaccine against Covid-19 was developed so quickly.

Supporting the drug discovery process are *advances analytics and cloud computing* with which different digital solutions can be modelled and tested and a rapid response to researchers' hypotheses can be obtained.

The CDI has developed state-of-the-art capabilities, has data scientists, cybersecurity, artificial intelligence, machine learning, robotics and process automation. The results the CDI is delivering, being a global center, support all activities at all levels of Pfizer.

The hub is currently working on more than 200 projects internationally. But the plan is to do more. In two years, i.e. from 2020 to 2022, "we have found the right capabilities, developed an

operating model, we are part of important projects, but the near future is definitely to expand the organization even further and become more and more a reference point within Pfizer. The center could increasingly become a key component of the global digital organization." (Lidia Fonseca, Chief Digital and Technology Officer).

With regard to the staff employed on the 200 existing projects, it was highlighted that Pfizer is working on improving the skills of employees. It is not only about training but also about imparting the so-called 'ability to learn' by giving people the tools to grow, experiment and innovate. It is about investing in knowledge through a Learning and Development program, that aims to nurture growth and innovation through training in 7 different technological areas, 3 levels of knowledge and 5 different ways of approaching the educational experience. Cultivating the mindset of growth and innovation changes the way employees approach their development: it does not only mean better position or promotion but development on an individual and collective level.

The great challenge of the digital transformation that Cdi is facing has a very particular strategy: 'we are as agile as start-ups but aware that we are part of a big company, but we need speed and we also often have to learn from failures. We are as agile as a small company but within a big corporation. I think that's really key to innovation.' (Jeff Hamilton, Senior Vice President, Pfizer Digital).

Digital transformation is affecting all departments.

It starts from drug discovery with the acceleration of processes because there is the possibility to test hypotheses made in a virtual space and thus reduce the time for experimentation.

Then we move on to the next step, drug development where clinical trials, through digital, are becoming faster and faster. Digitalization is supporting all processes. Connecting patients from all over the world is also leading to unprecedented results, and all operations have reduced time thanks to the different management of data from clinical trials.

In fact, data management, control and analysis are one of the fundamental parts of clinical trials.

At the organizational and governance level, digital innovation has also brought about some changes:

- Redefining the organizational structure
- Changes in existing operational processes
- Updated skills
- Changing corporate culture
- Readjustment of leadership and governance

Dealing with organizational changes in a strategic and appropriate manner was crucial for the transformation to be successful and help maximize the benefits of technological innovation, which will ensure the company's long-term success.

"Digital is now everywhere and through it we are making processes more efficient and profitable". (Lidia Fonseca, Chief Digital and Technology Officer).

3.3.2 Collaborations

One of the greatest philosophies underlying Pfizer's corporate culture is that of Open Innovation: those working in the Cdi collaborate with universities, research centers, start-ups and incubators to do research and innovation together. Increasing the possibilities and continuously giving new energy to research are certainly important factors for the Innovation Hub team. "We always have the perspective of the big company, external perspectives can instead add value to the research and innovation process". (Nico Gariboldi).

When we talk about collaborating with external partners for now we only refer to collaborations with the Greek ecosystem, hence local. The center was recently established and in the last year a lot of work has been done on Open Innovation, especially in collaboration with local research centers and universities such as the Aristoteles University of Thessaloniki, the University of Patras and the Centre of Research and Technology Hellas (Certh). The international collaboration character is represented by sharing and collaborating with Pfizer centers around the world.

Through these collaborations, Pfizer is not only growing but also helping to raise the level of research in institutions and bring out talent; it is supporting universities by providing resources and exchanging know-how.

There are open calls for start-ups through which it is planned to establish strong relationships with the ecosystem; calls for cash prizes but also opportunities for collaboration for companies producing innovative ideas.

To this end, Pfizer has initiated a program called 'Start4Health'. The aim is to identify talented individuals and start-ups that share innovative ideas to be transformed with the support of the Cdi into technological solutions, with a view to multiplying health benefits and improving patients' lives.

The winner of last year's accelerator program was e-Nios (e-Nios Inspired Operational System), representing an ambitious collaboration aiming at the personalization of patient treatment for a wide range of diseases.

"Bioinformatics is the 'key' to our work, as it enables more efficient and faster discoveries in the life sciences through computational techniques, algorithms and platforms that process, analyze and interpret biological data. And we really look forward to working in these areas with more startups as Start4Health and other similar programs bring us closer to the research and innovation ecosystem." (Thanos Stavropoulos, Technology and Innovation Senior Manager at Cdi).

The 'Start4Health' program for 2023 has recently been reopened; it is becoming an institution for the Greek innovation ecosystem. In the current year, Pfizer is expected to come in contact with unique and pioneering proposals that will help raise the Cdi's goal of developing new solutions that will change patients' lives.

Through this program, the Centre invites the entire ecosystem of Greek start-ups with visionary ideas to shape the future of healthcare by harnessing digital innovation.

"It is a very strong motivation to participate from Greek startups that through this program have the opportunity to optimize their business model, strengthen their position in the market and also claim a future collaboration with Pfizer. This year startups will have a larger space." (Thanos Stavropoulos, Technology and Innovation Senior Manager at Cdi).

The change that is taking place in Open Innovation in the pharmaceutical sector is creating even more visionary solutions by giving more start-ups the opportunity to participate in development programs. It is emphasized that the solutions proposed at the Cdi can serve at any stage of the pharmaceutical process, from drug discovery to production and supply chain.

Specifically, this year's startup selection process started in early May 2023 with the Open Call and will last one month; it will end with the selection of five proposals that will be included in the six-week Acceleration program. During the Acceleration phase, the five startups will be able to work with an exclusive international mentor and participate in various activities with experts to improve their technology, products and services but also their business model and maximize their value.

The program then concludes with the Final Pitch Day during which the most advanced and mature proposals will be scrutinized by a jury of distinguished personalities from the world of technology, innovation and business.

In essence, cooperation with the Greek research and innovation ecosystem is an integral part of the CDI's vision and actions.

"Through programs like Start4Health we are given a double opportunity: on the one hand to see the high quality of the ecosystem put into practice and on the other hand to expand the scope of our Centre's cooperation." (Thomas Kareklas, Technology and Innovation Senior Manager at CDI).

"For Innovare it is important to be open to various partners and in any case to the outside world. Right now we are collaborating with the University of Aristotle and the University of Athens, with start-ups, incubators precisely because through these collaborations you can find companies that are much smaller but much more agile than a big company like Pfizer. These structures can find a solution, a technology to support innovation'.

Going outside certainly speeds up the innocent process. Ideas and insights are then gathered to develop solutions.

Collaboration for innovation goes through these steps:

- It starts with the relationship with the patient to understand the need and what needs to be managed.
- You take part in a government-sponsored project that connects the company with the start-up world:
- Working with start-ups to find a solution and develop it.

One of Cdi's ambitions is to develop more and more Open Innovation projects with the help of the Greek ecosystem.

"In the Cdi but in general in Pfizer we are doing a lot of innovation. We are inspired by the principles of agility in innovation, we are patient and customer-centered; one thing we strongly believe in, especially in the digital innovation center, is to do innovation in partnership with other stakeholders outside our center and in collaboration with other institutions as well." (Nico Gariboldi, Site Lead of Cdi)

The Open Innovation team is working really hard and doing Open Innovation means "having different perspectives, opening up to the outside world in order to maximize capabilities and having a decisive approach to the problem during the innovation process. Digitalization is giving a great impetus to our work and is helping us to maximize our effort to find solutions that can have a meaningful and real impact on patients and consumers." (Lida Fonseca, Chief Digital and Technology Officer).

CHAPTER IV - Discussion

The following chapter is dedicated to a discussion of the findings on the previous pages. The ultimate goal will be to analyze, in relation to the research carried out on the existing literature, which aspects are confirmed by the state of the art, which are new implications and which information differs from what was reported in the first chapter concerning the snapshot of the current situation in the sector.

The chapter will be structured following as a thread the two macro-areas identified at the beginning of the discussion in order to continue the assumptions with continuity.

4.1 Research and collaboration discussion

From the literature review, analyzed above, it emerged that digitization is able to create benefits related to internal efficiency, improved quality and consistency of business processes, resulting in the elimination of manual steps to make way for a significant improvement in accuracy.

In the case study examined, these statements seem to be confirmed.

Members of Pfizer's Innovation Hub explained how introducing digital technologies into their organization has been a very strong success factor.

Processes have become faster, research times shorter, drug trials more accurate and development as well. The ultimate goal has always been to become more efficient, faster and deliver drugs as well as vaccines in record time to patients with maximum precision, accuracy of performance.

Indeed, digital innovation offers advanced tools for research and development of new drugs. Computational modelling, artificial intelligence and machine learning have made it possible to accelerate the discovery of new molecules, the design of tests and the study of drug safety and efficacy. This can reduce development time and lead to faster commercialization of products.

Also confirming the existing literature is the notion that all new innovation processes are diametrically opposed to the innovation processes of the previous era. Organizations, Pfizer in particular, have been under increasing pressure to implement digital technologies and introduce new business models that have, however, disrupted the way research is done.

Indeed, through technologies such as *supercomputing*, they are able to make the drug *discovery and development* process much smoother, faster and more efficient.

The increased use of digital technology has also led to an increasing collection of data by organizations. Data has played a key role in Pfizer's digital transformation. In fact, it has been explained how advanced systems for analyzing large amounts of data have speeded up processes enormously, achieving incredible results in a very short time.

The case of Pfizer confirmed that this type of transformation was able to collect and analyze large amounts of clinical and genetic data. This has paved the way for the personalization of therapies, thus enabling more precise and targeted treatment to the individual needs of patients.

Access to advanced data analysis and research tools and technologies has enabled Pfizer to identify new business opportunities, understand market patterns, identify trends and the effectiveness of implemented strategies.

The literature analyzed showed how the imperative for companies has become to innovate digitally in order to realize new products, processes or business models with technology platforms; digital innovation contributes to the transformation of both industry and society. This point, too, was confirmed by the research in fact it was repeatedly emphasized by our interviewees how much the process of innovation and the consequent transformation took place at all levels of the organization, starting from the research and development level and ending at the organizational, management and production level.

In fact, they talked about how even the *production* aspect has undergone changes: digital enables constant monitoring of all the processes and steps involved in the production of a drug or vaccine. Through Advances Analytics and Cloud Computing, in fact, Pfizer has been able to test different digital solutions and have their insights and hypotheses answered very quickly.

A recent study by Gregory et al. has been analyzed in the literature, according to which digital technologies help organizations achieve both economic and operational goals.

There has certainly been an economic return for Pfizer due to the very rapid development of the Covid-19 vaccine, as well as the fact that digital technologies have enabled the company to currently have more than 100 drugs in its pipeline.

On the organizational side, there have been considerable changes. The members of the Innovation Hub explained how digital innovations have transformed the way they approach their work, now adopting an agile methodology, also thanks to the sharing of know-how and collaboration with external stakeholders, as we will see later.

Traditional strategic rules have changed at Pfizer and competitive advantages have been redefined.

Following the interviews, some interesting insights emerged with respect to this point that had not been found in the existing literature.

The introduction of a new innovative strategy required a redefinition of the organizational structure. At Pfizer, new organizational units were required to manage specific responsibilities that arose with the Cdi, related to the implemented technologies.

Modifications were made in existing operational processes to integrate the technologies and take full advantage of their benefits. And from the analysis carried out, this led to important results.

Another aspect of which no literature was found is the aspect of roles and responsibilities that inevitably changed to adapt to the new requirements. For Pfizer, it was necessary to provide training and support to acquire the new skills essential to work successfully with the new innovations. In addition to this, another important aspect concerns the corporate culture. Pfizer placed great emphasis on the concept of Agility, on the adaptability of new technologies to tried and tested processes. Investing in this has been crucial in getting the company to these levels. Pfizer has taken the path of an open mindset to change and a culture that supports continuous learning, often from outsiders, and collaboration.

In this regard, clear and effective communication has been promoted by Pfizer to initiate cross-functional collaborations and encourage the sharing of technology-related knowledge and information.

Ultimately, the implementation of technological innovations through the Centre of Digital Innovation required a transformation also at the level of leadership, which certainly became stronger, accompanied by equally effective governance. Here, little is reported in the literature analyzed about the role of leadership in its task of driving digital change in a pharmaceutical company.

The leaders, especially Nico Garboldi, demonstrated the ability to drive change, establish a clear vision for technology adoption and provide the necessary support to the entire team. The appropriate governance for the transformation helped manage risks, make critical decisions and ensured a successful implementation of the technology, to say the least.

These digital solutions have improved inventory management, logistics and drug distribution. The use of traceability systems and production management based on data analysis technologies has reduced errors and optimized times to reduce patient reach time.

In general, digital innovations on the research and development side, in the case analyzed, have offered significant opportunities to improve above all production efficiency, personalization of therapies, speed of drug delivery to patients and the organizational approach, which has become more agile and flexible.

As mentioned, open innovation is now a strategic imperative.

The scientific literature on open innovation applied to the field of pharmaceutical companies was very poor, so we took advantage of this study to delve deeper into the topic and try to provide answers to the many questions on the subject.

Pfizer decided to approach Open Innovation and used the Centre of Digital Innovation as a medium. In fact, it was the CDI that promoted the company's openness to external collaboration, to sharing information. We can say that it was a choice that bore fruit.

The new approach prepared Pfizer to access a very wide range of ideas and knowledge from external stakeholders. This has enabled a better and earlier understanding of the problem to be addressed and, consequently, the possible solutions to solve it. Once again, Pfizer's strategy is to reduce trial and test times.

Through these collaborations, the company has been able to benefit from the expertise and skills of researchers, academics, start-ups and universities, while at the same time allowing these structures to grow and increase their technical and scientific knowledge.

Accelerating innovation is a concept that is now fundamental and repeatedly stated, but it is again necessary to point out that Open Innovation has accelerated Pfizer's pharmaceutical innovation process.

Indeed, Lidia Fonseca was keen to point out that this type of strategy has created benefits, to say the least, compared to the pre-Innovation Hub period; drugs have been brought to market more quickly, thanks to the overall reduced development time.

It fostered the development of networks and partnerships, in this specific case, with the Greek ecosystem, long-term, solid partnerships that contribute to growth and continuous innovation.

At the organizational level, Open Innovation has certainly changed the game. As a result of the openness to sharing ideas and insights, Pfizer also had to change its approach strategy. The interviewees often emphasized how collaborating with start-ups, which are normally more agile than a corporation like Pfizer, has led the company itself to behave like a small business. This has led to incredible benefits. The ability to reach the patient quickly and satisfy needs in real time.

In fact, a customer centric strategy was adopted. Through collaboration with patients, caregivers and patient organizations, Pfizer gained a deeper understanding of patients' needs and preferences. This has indeed guided the development of effective and personalized therapies.

In the literature we quoted what Henkel & Fischer had said: they had explained that, in their view, the combination of Open Innovation and value capture was still very weak. According to the study, things are very different for Pfizer today: as a result of digital innovation and openness to the outside world, it now has more than 100 drugs in its pipeline.

For Pfizer, taking a decisive approach to the problem, maximizing capabilities and accessing a wide range of external knowledge, opportunities and resources helped drive innovation and value creation throughout the organization.

CONCLUSIONS

Beginning with the research questions that guided the discussion:

RQ1: How has the introduction of Innovation Hubs changed organizational arrangements, the way research is done, and the way pharmaceutical companies open up to the world?

RQ2: What are the perceived benefits generated by the implementation of digital technologies in pharmaceutical organizations?

And moving on to the answers from the qualitative analysis conducted through interviewing some members of the team that runs Pfizer's Center of Digital Innovation in Thessaloniki, the evidence reported in the next few lines emerged.

Accompanied also by a careful analysis of the Cdi's internal processes, it was possible to highlight the role of digital technologies and "open" collaboration in the advancement and creation of value in a company that is at the forefront of innovation in its industry.

Pfizer's Cdi works as a kind of start-up within an established and structured company. It thus finds itself harnessing the best of both worlds: the agility, creative freedom, and courage to experiment of a start-up, along with the scale, human and economic resources, and connections of a large company.

But this is only the first level of its ability to function. Pfizer's Cdi has in fact absorbed, by virtue of a model inspired by "digital twinning," all the capabilities and areas of work of the parent company and the prerogative to connect to all Pfizer research centers. Its mode of action is thus together vertical on all digitization processes and "networked" on the level of international collaboration.

Even more in detail, the interviews and associated analysis showed that:

1. On the *research* side, all the potential of digital technologies, even the most advanced and "experimental" ones, are deployed to bring value to the drug supply chain: from the conception of new molecules to their virtual testing, through the digitization of the human trial phases, to the improvement of distribution and patient feedback. The help of multidisciplinary teams, consisting of artificial intelligence and machine learning experts, data scientists, software and algorithm developers, leads to concentrating and speeding up all processes within a single Hub however hyper-connected. The result is threefold: better patient health outcomes, faster access to new drugs, and clear trajectories for pioneering development of future treatments. To understand the effectiveness of the Cdi approach, a few numbers are enough: in Pfizer's pipeline today there are 38 drugs in phase 1, 28 in phase 2, 23 in phase 3, and 12 in registration. Not to mention the miraculous fact that it has produced a Covid- 19 vaccine in just a few months compared to the years it normally takes for a new vaccine to reach the market. All of this was accompanied by a reduction in operating costs, better utilization of manpower-thanks to digitization Pfizer was able to initiate a major "reskilling" and "upskilling" plan of its employees with obvious effects on personal fulfillment and teamwork-and improved business processes.
2. On the *collaboration* side, the Cdi has charted new entrepreneurial paths. At Pfizer we talk about Open Innovation to describe a network of open and transparent collaborations with the surrounding manufacturing, academic, and innovation ecosystem. In the case we are talking about the Greek context, where Cdi, starting from Thessaloniki has radiated to universities such as the Aristoteles in Thessaloniki, the one in Patras, and the Center of Research and Technology Hellas-Certh. But its "start-up" nature has also allowed the Cdi to build a network of collaborations with similar entities in the area, small innovative companies, study groups, and individual talents. Thanks in part to programs like "Start4Healt," designed to bring Pfizer into contact with the best of the creativity and cutting-edge technology available, with a powerful and reciprocal fertilization. The idea then is that of a propulsive center open to collaborations, where the traditional confidentiality of pharmaceutical industry processes gives way to transparency and openness to contamination with new ideas and free talent. Again, the dual nature of the Cdi-half start-up, half large company-also allows the

network of collaborations a strong international projection through its relationship with all of Pfizer's research and manufacturing centers around the world.

The case study addressed is clear that it demonstrates that when well used and centered on the true interests and well-being of human beings, technology, even the most advanced, the most unexplored should not scare us but rather show us the way to a better world for all.

Limitations and future research

This research is also subject to certain limitations that are important to consider at this point in order to guide any future research. This research can therefore be seen as a starting point to continue along the line already drawn on digital innovations in the Lifesciences sector.

The first aspect on which it is crucial to focus is generalizability. The case study under consideration is unique and therefore may not be very general, i.e. the results obtained may not be adaptable to the entire industry or other contexts. This limits the ability to draw broad conclusions and apply the results universally.

The selection of the case study was based on specific criteria of compatibility with the research questions and the type of approach shared by Pfizer.

This case study may be subject to limitations on the resources drawn upon and this may therefore affect the ability to analyze the results in depth.

Unlike an experimental study, this case study does not allow direct control over the variables, which may therefore limit the ability to establish a clear cause-effect relationship between the variables studied.

Despite these limitations, the Pfizer case study provides an in-depth and detailed understanding of the object of study by offering a wide range of qualitative information. However, it is important to consider these limitations and carefully evaluate the results obtained for future research.

Possible future research could be to take a longitudinal approach, following the case over time to observe the evolution of factors, outcomes and dynamics over time.

In fact, it opens the way for a further research question:

Do the implemented technologies and the Open Innovation strategy have long-term prospects? The Innovation Hub under review came into being during the pandemic, in 2020, a relatively short time ago, but so far the results speak for themselves. But will this still be the case in the coming years?

It might be interesting to assess the long-term impact of the innovation on the organization, its stakeholders or the wider context.

In future research, it would be appropriate to analyze in depth a specific aspect of the case, one of the two focuses analyzed, in order to better understand the dynamics and processes involved.

An interesting solution could also be to extend the search: to include other similar or comparable cases. This would make it possible to broaden the scope of the analysis and identify any similarities or differences between the cases. The addition of further cases could provide a more complete view of the phenomenon and contribute to a greater generalization of the results. Subsequently, a comparative study comparing the analyzed case with other similar cases or with different contexts could be food for thought. It could help to identify key factors influencing the results and to establish more solid cause-effect relationships.

During the analysis, the need to explore additional variables or factors in the research framework and investigate how these interact with existing ones emerges.

The results of the case study contribute to the formation of new theoretical models or the modification of existing models. Future research could focus on the construction of conceptual or theoretical models based on the results of the case study and their empirical verification.

APPENDIX

This section contains the full text of the interview submitted to the involved interlocutors.

1. When was the CDI born and with what objective? *Question for Nico Gariboldi*
2. In an interview I read that you talk about artificial intelligence and machine learning.
 - a) Which digital innovations is Pfizer focusing on at the moment?
 - b) Why?
 - c) Can you explain to me in an analytical and detailed manner all the digital innovations you have implemented starting with the first two mentioned. *Question for Nico Gariboldi and Lidia Fonseca*
3. What promoted you to take the digital route?
 - a) What is the strategy behind your choices? If possible, give examples. *Question for Nico Gariboldi and Lidia Fonseca*
4. Pfizer set up the CDI, how is the competition doing? *Question for Nico Gariboldi*
5. How has the introduction of digital innovations impacted your core business, in particular on data collection in the trial phase of a drug as well as on production and distribution?
 - a) Has it brought benefits?
 - b) If yes, which ones?
 - c) What were the major difficulties in implementing these changes? Could you share some examples? *Question for Nico Gariboldi and Jeff Hamilton*
6. What about governance? What differences emerge at the organizational level compared to the period before the introduction of the hub? *Question for Nico Gariboldi and Jeff Hamilton*

7. Investment in digital technologies has had positive financial returns, compared to the pre-innovation hub period? *Question for Jeff Hamilton*

8. Does the CDI help the company embrace Open Innovation?

a) In what terms does the CDI do Open Innovation?

b) Who are the main partners and what role do they play in the innovation process?

Question for Thanos Stavropoulos and Thomas Kareklas

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EXECUTIVE SUMMARY

Introduction

In an era when everything is changing at high speed and Industry 4.0 is driving all industries to embrace timeless digital transformation, the Lifesciences sector is also witnessing its own revolution and the emergence of disruptive technologies that are revolutionizing the patient experience and all organizational and decision-making processes in general.

This discussion is structured as follows:

In the introduction, the topic under consideration will be framed, its importance and why it will be studied through an overview of the state of the art of the topic, what we already know and what is proposed to be known.

Next, the first chapter will review the literature on the topic with a particular focus on two main aspects, which are then the two pillars of the discussion and on the basis of which the final conclusions will be constructed.

The first aspect is research. An overview of the current situation of pharmaceutical companies will be given, starting with what digital innovations are, what has already been implemented in the industry, and what has been discovered so far until an overview of the Lifesciences sector examined.

The second section will be devoted to the second macro-theme, that of collaboration and sharing of experience and knowledge: open innovation. In fact, it will start with a general overview of the concept of Open Innovation with a thorough analysis of the texts of the greatest scholar on the subject, Henry Chesbrough. The next step is to analyze Open Innovation in the Lifesciences sector to understand what is meant when a pharmaceutical company implements this type of strategy.

And it is from the concept of Open Innovation that we move on to analyze those who are the promoters of this strategy: the Innovation Hubs. It is through these innovation hubs that pharmaceutical companies are undertaking collaborations with universities and startups to expand their portfolio of knowledge in digital innovation.

The second chapter is devoted to describing the research methodology deemed most appropriate for analyzing the case study, which will be detailed in the next chapter. A meticulous analysis will be made of the steps that were taken from the choice of the research object to the actual qualitative interview with selected interlocutors.

The pharmaceutical company Pfizer is, however, the subject of this research. In the last chapter of the discussion, an overview of the company, its approach and goals achieved in recent years will be made. It will then go on to explicate the work that Pfizer's Innovation Hub does and how the digital technologies that spring from it impact the organization through quotes from the qualitative analysis conducted.

The ultimate goal of the discussion, then, is to answer the following research questions:

RQ1: How has the introduction of Innovation Hubs changed organizational arrangements, the way research is done, and the way pharmaceutical companies open up to the world?

RQ2: What are the perceived benefits generated by the implementation of digital technologies in pharmaceutical organizations?

to ultimately get a 360-degree perspective of the digital transformation taking place in pharmaceutical companies.

Chapter I

The first chapter reviews all the literature on the two main threads of the discussion. In fact, it is divided into two paragraphs that serve as a deep dive of both topics under consideration, digitization in research and Open Innovation.

In the first paragraph, the literature and the state of the art of digital innovations in general are analyzed, an overview of the Lifesciences sector is given, and finally the detail of digital innovations in the pharmaceutical industry, with a focus on Digital Health.

The digital innovations that are still being implemented in companies are:

- Artificial Intelligence (AI) and Machine Learning (ML)
- Blockchain
- Internet of Things (IoT)
- Cloud computing
- Virtual and augmented reality
- Big data analytics

Currently, the new technology represented by artificial intelligence, blockchain, cloud computing, Big Data and the Internet of Things is growing the economy and bringing about major changes to the organizational structure, business processes and business model of enterprises. Information Technology (IT) has become a driver of business transformation. Indeed, companies see investment in IT as a way to gain a competitive advantage in an increasingly competitive and dynamic market.

In addition to artificial intelligence and machine learning, certain technologies such as blockchain, cloud computing and big data analysis have helped organizations manage their activities by implementing medium- and long-term strategies.

Technology in healthcare has massively deployed blockchain-based platforms to *track the spread of the virus among patients by constantly monitoring them*.

One of the most exploited digital technologies is cloud computing, which allows users access to shared resources such as networks, servers, storage, applications and online services, thus reducing the costs of deploying services. It expands knowledge, resources and applications, thus enabling people to use resources for long-term development.

Big data analytics collects, stores, formats, organizes, processes and analyses data for its end users and customers to use in order to make informed decisions.

The characteristics of digital technology enable new types of innovation processes that are diametrically opposed to the analog innovation processes of the industrial era.

As market and business paradigms change, organizations are under increasing pressure to implement digital technologies and introduce new business models.

Digital innovation has now become a key to survival for all these challenges as well as an answer to the need to evolve rapidly and conform to the dictates of Industry 4.0.

Some of the main impacts correspond:

- *Improved operational efficiency*; digital technologies have enabled organizations to *automate and streamline business processes*, reducing operating costs and improving overall efficiency.
- The adoption of cloud solutions for *data storage and access* and the use of collaboration tools (Zoom, Teams etc) has simplified and accelerated time-consuming daily tasks.
- Significant improvement and transformation of the *customer experience*, enabling organizations to offer personalized services, faster response times and better engagement. The implementation of chatbots, the use of data analytics to better understand customer needs and the provision of online self-service have improved the interaction between organizations and customers.
- Changing *organization and corporate culture*: the adoption of digital innovations has, for obvious reasons, required organizations to make changes in their organizational structure. It has become extremely important to be agile, flexible and ready to adapt quickly to technological changes. Innovation has also promoted greater collaboration and communication between corporate departments with a focus on a customer-centric approach.
- *Data management and data security*. The increase in the use of digital technology has led to an ever-increasing collection of data by organizations. It is more crucial than ever to manage and use data safely and responsibly. Organizations must therefore take appropriate measures to protect sensitive data and ensure compliance with privacy regulations.

The Lifesciences sector comprises pharmaceutical, biotechnology and medical device companies.

Firstly, it should be borne in mind that pharmaceutical companies usually have a complex structure.

For companies developing new drugs, investing in basic research brings tangible benefits. The nature of knowledge is a unique aspect of the pharmaceutical industry. Unlike many other fields, medical research seeks an understanding of phenomena and is motivated by practical goals (Stokes, 1997). Secondly, appropriateness is very high in the pharmaceutical industry. Patent protection is extremely effective (Levin et al., 1987) and the imitation rate is slower for ethical drugs than for other products (Mansfield et al., 1981). Thirdly, the industry has barriers to entry because purchasers have low bargaining power, drug development is a complex process

requiring specialized knowledge, and extensive human studies are required to meet regulatory requirements (Pisano, 1997, pp. 55-57). The link between drug discovery and basic science has increased over time (Pisano, 1997, Cockburn et al., 1999).

When we talk about the digitization of the Lifesciences sector (Kasoju et al., 2023), we refer to the use of digital technology to improve health outcomes, care and all aspects of the organization's value chain: all of this can be summarized by the term Digital Health. In particular, reference is made to telemedicine, electronic health records, wearable devices and mobile health applications.

The second paragraph is dedicated to the concept of Open Innovation and how this strategy has been implemented in pharmaceutical companies.

The term Open Innovation originated when Henry Chesbrough, professor and executive director of the Centre for Open Innovation at Berkeley, University of California, published his book 'Open Innovation: the new imperative for creating and profiting from technology'.

He defines Open Innovation with a very meaningful phrase: " [...] the use of purposive inflows and outflows of knowledge to accelerate internal innovation, and expand the markets for external use of innovation, respectively.

[This paradigm] assumes that firms can and should use external ideas as well as internal ideas, and internal and external paths to market, as they look to advance their technology'.

In the literature, there are two types of Open Innovation: the IN model based on ideas flowing into the enterprise from different sources and the OUT model, whereby a group of people create an operating system to which everyone can add their own ideas.

To sum up, the first dimension looks for innovations from outside to complement those that have been developed internally (Inbound), while the second looks for new paths to commercialize innovations that have not been used internally due to lack of compatibility with the business model in which it usually operates (Outbound).

The concept of Open Innovation is spreading widely in academic and organizational circles. However, there is no detailed literature on value creation and how to profit from this type of innovation.

Although some authors have tried to deal with Open Innovation with a focus on value capture, the link between Open Innovation and value capture is still very weak (Henkel & Fischer, 2012). Indeed, a theoretical framework linking Open Innovation, value creation and value capture is lacking.

The medium through which pharmaceutical companies are starting to do Open Innovation is the Digital Innovation Hub (DIH) is a territory-based ecosystem whose task is to stimulate the knowledge and adoption of 4.0 technologies by the production system. The DIH, alone or with partners (Universities, Competence Centres, Clusters, Research Centers), helps SMEs to approach the new industrial revolution.

They have the task of stimulating and promoting the production system's demand for innovation, strengthening the level of knowledge and awareness of the opportunities offered by digitization, and are the 'gateway' for companies to the world of Industry 4.0.

The main objective of an Innovation Hub in the pharmaceutical sector is to accelerate innovation, reduce drug development time, foster the discovery of more effective therapies and improve the health and quality of life of patients. Innovation Hubs are a key step in fostering an innovative pipeline and creating opportunities for long-term collaborations.

Chapter II

The following chapter concerns the methodology used to analyze the case study examined: Pfizer's Center of Digital Innovation.

There were two main questions:

The way companies conduct research and how the strategy is deployed for new drug discovery and development varies. Following the introduction of digital technologies into organizations through Innovation Hubs, what is the approach to research that they are implementing? What has changed? Is the digital transformation bringing benefits, including perceived benefits?

Following the introduction of Innovation hubs in companies, as a means through which to do Open Innovation, how does sharing and collaboration improve the way innovation is done? Why open up to this new approach?

Following the analysis of the literature from which the research questions were derived and an in-depth desk analysis, the interview was created to be submitted to the members of the Innovation Hub of Pfizer, the pharmaceutical company subject of the case study.

Five team members were interviewed via a video call in which the topics, which had already been sent in advance by e-mail, were addressed.

The interview provided detailed and in-depth information on the case study. It was possible to ask specific questions that provided a richer understanding of the factors and dynamics they wanted to investigate.

In order to study the case under analysis in detail, a *qualitative method* was chosen, which provided the opportunity to explore the phenomena in detail, understand the contexts and personal perspectives, and thus deepen the complexity of the processes under investigation.

Chapter III

In chapter three, the results and thus the findings of the interview were summarized. Before doing so, it was necessary to give a brief description of the case examined, then a small description of Pfizer, its approach to innovation and in particular its Innovation Hub, what it does and what innovations it is implementing.

How the introduction of digital technologies and Innovation Hubs in the pharmaceutical sector has changed the way of doing research and also opening up to the world, to collaboration with external partners to share knowledge and discoveries. What benefits has it brought?"

Through this case study, we aim to answer the above-mentioned question.

There are three main strategic priorities for Pfizer Digital:

- Better health outcomes for patients
- Faster access to medicines
- Contributing to the development of tomorrow's pioneering treatments

Improving patient health is certainly important, working in the field of vaccines and drugs, but providing patients and doctors with digital solutions to better manage diseases is also a goal. In addition to process transformation, digitization is therefore accelerating the production of drugs or vaccines. The fact that through digital we can do very constant monitoring and understand what needs to be done to be more effective has led to the vaccine against Covid-19 being developed so quickly.

Digital transformation is affecting all departments.

- Drug discovery with the acceleration of trials because there is the possibility to test hypotheses made in a virtual space and thus reduce the time for experimentation.
- Drug development where clinical trials, through digital, are becoming faster and faster.

Digitization is supporting all processes. Even connecting patients from all over the world is leading to unprecedented results, and all operations have reduced time due to the different management of data from clinical trials.

In fact, data management, control and analysis are one of the fundamental parts of clinical trials.

There has also been much discussion about the financial return that has been generated as a result of the implementation of digital innovations, Pfizer currently has more than a hundred drugs in the pipeline and this is quite an interesting detail because it makes us realize how much digital innovations are helping to speed up the drug testing and discovery processes.

In addition to this, the organizational and governance transformation that took place within the organization is certainly worth considering. Strict governance had to be established and the leaders, including Nico Gariboldi, were able to provide leadership that was, to say the least, essential for the strategy to succeed.

Regarding the second focus, that of collaboration, we know that one of the greatest philosophies underlying Pfizer's corporate culture is that of Open Innovation: those who work in the Cdi collaborate with universities, research centers, start-ups and incubators to do research and innovation together.

In fact, Pfizer has created an acceleration program with the aim of identifying talented individuals and start-ups that share innovative ideas to be transformed with the support of the Cdi into technological solutions, with the prospect of multiplying health benefits and improving patients' lives.

Chapter IV

The last chapter is dedicated to the discussion of the interview results. It too is organized following the structure of the previous chapters, thus with the focus on the two main themes.

Much of the literature has been confirmed in fact, processes have become faster, research times shorter, drug trials more accurate and development as well. The ultimate goal has always been to become more efficient, faster and deliver drugs as well as vaccines in record time to patients with maximum precision, accuracy of performance. The increased use of digital technology has also led to more and more data collection by organizations. Data has played a key role in Pfizer's digital transformation. In fact, it has been explained how advanced systems for analyzing large amounts of data have speeded up processes enormously, achieving incredible results in a very short time.

In general, digital innovations on the research and development side, in the case analyzed, have offered significant opportunities to improve above all production efficiency, personalization of therapies, speed of drug delivery to patients and the organizational approach, which has become more agile and flexible.

On the concept of Open Innovation, through the case study, compared to the literature, progress was made. Indeed, it was shown how the new approach prepared Pfizer to access a very wide range of ideas and knowledge from external stakeholders. This enabled a better and earlier understanding of the problem to be tackled and, consequently, the possible solutions to solve it.

Open Innovation has, in fact, accelerated Pfizer's pharmaceutical innovation process, enabling it to take a decisive approach to the problem, maximize capabilities and access knowledge and opportunities to create value for the company.