Exploring the path to Artificial Intelligence Success in Healthcare: an Empirical Analysis

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ABSTRACT
In the era of the data revolution, we are experiencing an unprecedented increase in data generation. With this explosion of data, Artificial Intelligence (AI) has rapidly developed, transforming scientific processes, innovation, and operational and strategic practices across various sectors. In this scenario, among different fields, the healthcare sector stands out as a particularly promising domain for AI's potential. The present study objective's is to explore how AI can be successfully integrated into healthcare, identify the key factors that enable the effective integration of AI technologies, and finally how effective integration can drive changes in business models and strategies. Following the structure of the study, first, AI applications in healthcare are presented, ranging from clinical research to patient monitoring, outlining the opportunities for innovation that each of these categories presents together with the impacts. Then, employing a qualitative inductive research approach, combining case studies with in-depth interviews with industry experts, the study investigates the main enabling factors for the seamless integration of AI technologies into healthcare, focusing on their implications for both innovation and business strategies. To categorize the key factors, a framework is developed, and three main dimensions emerged: technical, human, and regulatory. Finally, the study underlines AI as a force able to drive a change in healthcare business models, particularly towards Value-Based Care (VBC) model, which prioritizes patient outcomes and fosters collaboration among stakeholders. AI capabilities support this transition and favoures the shift to digital business strategies wherein the value is created by open innovation and collaborative ecosystems.

Keywords: Artificial Intelligence, Healthcare, Digital Business Model, Innovation, Enabling factors, Competitive advantage

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ABSTRACT
Na era da revolução dos dados, estamos a vivenciar um aumento sem precedentes na geração de informações. Com essa explosão de dados, a Inteligência Artificial (IA) tem se desenvolvido rapidamente, transformando processos científicos, inovação e práticas operacionais e estratégicas em diversos setores. Entre eles, o setor de saúde destaca-se como especialmente promissor para o potencial da IA. O presente estudo tem como objetivo explorar como a IA pode ser integrada com sucesso na saúde, identificar os fatores chave que permitem a integração eficaz de suas tecnologias e investigar como essa integração pode impulsionar mudanças nos modelos de negócios e nas estratégias. Primeiramente, são apresentadas as aplicações da IA na saúde, desde a pesquisa clínica até o monitoramento de pacientes, destacando as oportunidades de inovação e os impactos. Em seguida, através de uma pesquisa qualitativa indutiva, combinando estudos de caso com entrevistas aprofundadas com especialistas do setor, o estudo analisa os principais fatores que permitem uma integração harmoniosa das tecnologias de IA na saúde. As implicações dessa integração tanto para a inovação quanto para as estratégias empresariais são exploradas. Para organizar esses fatores, desenvolveu-se um quadro teórico, identificando três dimensões principais: técnica, humana e regulatória. Por fim, o estudo posiciona a IA como uma força capaz de promover a transformação nos modelos de negócios em saúde, especialmente em direção ao Cuidado Baseado em Valor (VBC), que prioriza os resultados dos pacientes e favorece a colaboração entre os diversos stakeholders, permitindo a criação de valor através de inovação aberta e ecossistemas colaborativos.

Palavras-chave: Inteligência Artificial, Saúde, Modelo de Negócio Digital, Inovação, Fatores Facilitadores, Vantagem Competitiva

Titulo: Explorando o Caminho para o Sucesso da Inteligência Artificial na Saúde: Uma Análise Empírica

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INTRODUCTION

In the era of the data revolution, we are experiencing an unprecedented increase in data generation. This explosion of data has recently resulted in the rapid development and deployment of Artificial Intelligence (AI), more specifically, machine learning models, essential to the analyses and derivation of significant insights from these massive data. AI is firstly profoundly transforming the way science gets done and innovation is conducted, consequently revolutionizing how companies operate.

The healthcare sector presents a promising landscape for the transformative potential of AI, mainly for its intersection between research and clinical practices. Rising healthcare costs, an aging population, and increasing complexity in the treatment of patients continue to push the health system and generate diverse challenges. Integrating AI in healthcare is proving a compelling response to such emerging challenges. Applications of AI span from the analysis of genomic data, to personalized medicine, setting the stage for a more data-driven, patient-centered approach to care. However, given that AI represents an emerging trend and is rapidly evolving, there is still a weak comprehension of how companies can fully generate a competitive advantage for it. This study aims to strengthen this view to understand how to integrate AI successfully.

The present study starts by examining AI as a general-purpose technology, highlighting its wide applicability across multiple industries, the potential to drive innovation, and the ability to evolve rapidly. Specifically, it explores how AI is being adopted into the health industry, focusing on how it finds application in clinical research, clinical practices, and patient monitoring.
The present study objective's is to explore the ways in which AI can be successfully embedded into healthcare, identifying the key factors that enable the effective integration of AI technologies, and finally how this integration can drive changes in business models and strategies.

The research methodology adopted includes a qualitative inductive approach since this best fits emerging areas of study where existing theories are limited. A combination of extensive review

of scientific journals and qualitative research, including case studies and interviews with industry experts, is employed in the study.
Interviews with key opinion leaders in healthcare provide significant insights into the current state of the art of AI applications in the healthcare landscape and point to the challenges that need to be addressed for its broader adoption. Findings from the interviews are then employed to develop a framework that describes the main enabling factors critical to the successful implementation of AI in healthcare settings. Finally, the study emphasizes how AI is driving a fundamental shift in healthcare business models and strategies.

This study is structured as follows: Chapter 1 discusses the disruptive nature of AI and its implication in scientific research as well as its impact on firm's strategy. Chapter 2 deep dives into the healthcare sector, exploring AI applications in clinical research, clinical practices, and patient monitoring, thanks to an in-depth review of the main scientific journals. The research methodology is detailed in Chapter 3, including the reasoning behind selecting qualitative interviews and the process of data collection and analysis. In Chapter 4 the findings from the interviews are presented and a framework is developed in order to understand the enabling factors for AI integration in healthcare and its business implications. Finally, Chapter 5 discusses the implications of the results as well as the limitations of the study and directions for future research.

1. ARTIFICIAL INTELLIGENCE: A DISRUPTIVE PHENOMENON

In recent years, evidence suggest that innovation is experiencing a downturn, in particular paper and patents are becoming less disruptive over time (Park et al., 2022). It is known that, knowledge has historically been a necessary element to catalyze advancements, accelerating the innovation process because it provided researchers the opportunity to build on the foundations of intellectual giants and thus making groundbreaking discoveries (Chu, 2021).
Analyzing this phenomena, in the evolution of the scientific and technological landscape an unreveled paradox can be identified that is linked with innovation. While, on one hand, the unparalleled expansion of knowledge would seem to suggest an era of revolutionary innovation. On the other, there is evidence that scientific outputs are becoming less disruptive (Bloom et al., 2020). Even with the exponential growth of available data and information we are experiencing nowadays, there is evidence that innovation is slowing down. As a consequence studies reveal that patents and papers are far less likely to depart from the current body of knowledge, across diverse disciplines. Therefore, this may suggest a lower tendency for research to break new grounds (Park et al., 2022). To explain this trend, various justifications have been proposed. According to Jones (2009), scientists spend more time acquiring current knowledge before producing new ideas as a consequence of the increasing burden of knowledge. Also, a study by Bhattacharya and Packalen (2020) examines how citations-based performance encourages incremental innovations rather than radical ones. Others point out a decline in private benefits combined with an increase in private costs of internal research, indicating this as a factor that limits the engagement of the private sector in basic science (Arora et al. 2018). In this landscape, Artificial Intelligence (AI) comes into play as a crucial factor, as it carries the capacity to essentially transform the innovation process (Schmidt, 2023). Kemp (2023) introduced the concept of Situated AI, when talking about AI as a transformative element. This means that to maximize the impact of this technology, companies need to to “place” it in their own specific context, integrating AI in their practice in order to develop a competitive advantage which is difficult to imitate (Kemp, 2023).
Taking a step back, it's appropriate to provide a definition and an overview of AI, subsequently exploring how it impacts the innovation process.

1.1 AI as a General Purpose Invention of a Method of Invention

According to Minsky, “Artificial intelligence is the science of making machines do things that would require intelligence if done by men” (Minsky, 1968). Analyzing this definition, he described the idea of machines that were able to simulate human intelligence by using language, solving problems, and improving themselves.

Machine Learning is a subset of artificial intelligence where computers improve their learning performance through algorithms, enabling them to learn from and make decisions based on data (MIT Sloan, 2012). Deep Learning is a branch of Machine Learning, defined as a set of automatic learning approaches that improve learning performance through the use of algorithms. Both elements are then encompassed within the broader concept of artificial intelligence (MIT Sloan, 2012).

The term Deep Learning, as the name suggests, refers to learning models based on a structure consisting of multiple layers. This architecture utilizes deep neural networks, where depth refers to the number of layers present. To replicate human learning, neural networks use the backpropagation algorithm. This algorithm compares the output generated in response to inputs with the desired output.

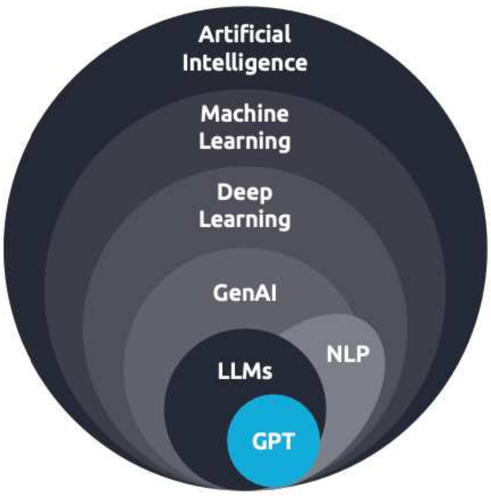
According to Lee & Shin (202), three types of learning can be identified: supervised, unsupervised, and reinforcement learning

- Supervised learning: As the name suggests, this type of learning heavily depends on human effort based on labeling data and desired outputs; through these, the system learns a function that links inputs to outputs. The goal of this learning is predictive. There is a trade-off between complex hypotheses that are very consistent with the training dataset and simpler hypotheses that generalize better.
- Unsupervised learning: The system interacts autonomously with the world without any supervision. The system learns from inputs, even though it does not know the correct answer; errors are identified by comparing the outputs with data provided by the network. Here too, the goal is prediction.
- Reinforcement learning: aims to learn through a mechanism of "rewards and punishments." With no precise endpoint, this type of learning aims to reach innovative responses, endowing the system with creativity (Lee & Shin, 2020).

Applications of machine learning are face recognition software and autonomous driving systems, showcasing the ability of these algorithm to effectively predict and adapt to data.

Until recently, machine learning was largely limited to predictive models, adopted to observe and identify patterns. Now we are experiencing the advent of generative AI. Generative AI can be thought of as a machine learning model that is trained to create new data, rather than making a prediction about a specific dataset (MIT News, 2023).
These models are more adaptable and scalable, as they can process more complex inputs and create new content like text, images, audio and video that closely matches examples made by humans (Eisfeldt et al., 2023).
GenAI opens a new horizon of possibilities for machines to perform repetitive tasks with better efficiency and creative tasks that were until now performed exclusively or mainly by humans (Capgemini, 2024).
For example, the upcoming generation of text-based machine learning models, will be based on self-supervised learning, a type of training in which a model is fed a massive amount of text in order to be able to generate predictions (McKinsey, 2024).

Figure 1: Overview of AI types



Source: Capgemini Invent, 2024

AI is recognized as a General Purpose Technology (GPT), like the internet and electricity (Cockburn et al., 2018). According to David (1990) the wide applicability across multiple industries, the potential to drive innovation, and the ability to evolve rapidly, are three unique characteristics that adefine GPTs. (David, 1990). GPTs generate both vertical and horizontal externalities in the innovation ecosystem. On one hand effective integration between GPTs and application sectors can generate a self-reinforcing cycle of innovation. On the other hand, a lack of coordination may result in underinvestment in research and innovation, since the potential rewards are insufficient to incentivize sufficient investment (Bresnahan and Trajtenberg, 1995).

A second theoretical approach is to consider AI's role as a research tool. According to this view, AI can be defined as an Invention of a Method of Invention (IMI) (Cockburn et al., 2018).

If AI is classified as an IMI, it basically means that not only the use of this technology allows for a reduction of the costs of innovation activites, but it also fundamentally revolutionize the approach to innovation itself, by modifying the "playbook" for innovation (Griliches, 1957).

Following this approach, AI as a research tool represents a paradigm shift in the innovation process itself. It trascendes the mere improvement of existing methods, as it offers completely new approaches to problem solving, resulting in major breakthroughs across different areas of research. AI has the potential to transform scientific research by not only automating classification and prediction activities, but also by expanding the scope of the problems that can be realistically solved. This technology will therefore substantially change the way in which scientific and technical communities frame and approach problems (Cockburn et al., 2018). Consequently, if AI is not only a GPT, but a general-purpose IMI, it would have profound and far-reaching impacts across the economic, social and technological landscape.

The classification of AI as a General Purpose Technology suggests the scale of its potential to transform. Previous GPTs, like electricity and ICT showcase that a substantial impact on productivity is expected over time: technology advances, complementary investments and innovations are introduced, business are reorganized, and learning accrues. At the same time, viewing AI as the invention of a new method of invention underscores its potential to raise the rate of productivity growth (Crafts, 2021).

This classification has strong business implications, underlining a transformative potential, but also challenges and risks. First, it can lead to reinforcing cycle of innovation thanks to its versatility, creating significant competitive advantages for early adopter, allowing to grasp new market opportunities, streamline operations, and personalize customer experiences (Teece, 2018). Moreover, referring to the concept of dynamic capabilities, introduced by Teece, AI is able to improve firm's ability to sense, seize, and reconfigure opportunities to sustain competitive advantage, by improving the capacity to process large amount of information and adapt to rapid changes. However at the same time, Teece highlights the risk of businesses over relying on AI, and thus homogenizing their strategies for innovation; another critical aspect is the potential for AI to disrupt traditional business models, unveling possible coordination and integration challenges.

In the following sections, I will explore the impacts of AI, starting with scientific research and innovation, and into its business implications.

1.2 AI-Driven Transformation of Scientific Discovery and Innovation

Science is poised to become considerably more exciting, and in some ways unrecognizable, with the advent of AI, which is at the edge of revolutionizing each stage of the scientific process (Schmidt, 2023). Scientific discovery is a complex process that includes different steps, involving hypothesis generation, experimentation, data collection and analysis (Wang, 2023). According to Ghosh (in OECD, 2023), AI is increasingly prevalent in every field and stage of science, encompassing hypothesis creation and experiment design to monitoring, simulating, and ultimately, scientific publication and communication.

AI is already used by researchers to review the literature, implement automated data gathering and conduct statistical analysis. However, emerging evidence suggests that AI could also be applied in hypothesis generation, a complex task that usually requires creative and innovative effort (Hutson, 2023).

Until now, AI has proven to be able to produce more concrete and specific hypotheses, rather than abstract and general ones (Hutson, 2023). However, Ludwig and Mullainathan (2023) developed an approach whereby AI and humans jointly generate broad, clear hypotheses. They argue that AI can propose stronger hypotheses that are both interpretable and novel. As AI capabilities evolve, they encourage increased investments into testing infrastructure, which generates a positive cycle: if testing infrastructures improves, further improvements in hypotheses generation are fueled. This suggests a cyclical enhancement between AI development and testing technology, that may guide a new era of scientific exploration (Ludwig et al., 2023).

Proceeding to the experimentation stage, AI can carry out studies more quickly, affordably and on a larger scale. According to Schmidt (2023), a significant portion of research would eventually be done at "self-driving labs", which are automated robotic platforms with artificial intelligence. Lastly, at the analysis stage, these laboratories will transcend automation. Leveraging the experimental data generated, they will analyze results and determine future experiments, thus enhancing the efficiency and depth of scientific inquiry (Schmidt, 2023). Overall, AI has the potential to revolutionize the scientific process and more productive science will also set foundations for breakthroughs in innovation.

1.3 Internal impact on firms

The integration of AI into the scientific process not only accelerates discovery and enhances productivity, but also impacts the strategic landscapes of firms. A key question is how predictive technologies impact firm capabilities and market competition (Iansiti and Lakhani, 2020). Predictive analytics, a discipline within data analytics, employs modeling, data mining, AI and ML to analyze historical and current data in order to predict future trends (Nelson et al., 2019).

Recent research suggests that data driven predictions enables firms to anticipate the value of alternative choices. This means that firms can identify better opportunities thus improving their performance (Gruber et al., 2008). Some studies highlight that the use of these technologies will therefore support organizations lacking domain knowledge, destroying the role of the latter as a source of competitive advantage, and leveling the playing field (Anderson, 2008). However, strong reasons still support the necessity of domain knowledge, notwithstanding the current arguments suggesting that big data may make it obsolete (Tranchero, 2023).

According to Tranchero (2023), in innovative contexts, a dual phase approach should be adopted: first, predictive models leverage data to identify possible successful idea and they generate a range of possible opportunities. However not all opportunities have the same potential in terms of success, therefore in the second stage, domain knowledge is needed to carefully evaluate and rank opportunities. As a consequence, domain knowledge remains a fundamental resource, as it enables firms to prioritize the most promising opportunities, enhancing the efficiency of investments. In his study the example of drug discovery is analyzed (Tranchero, 2023).

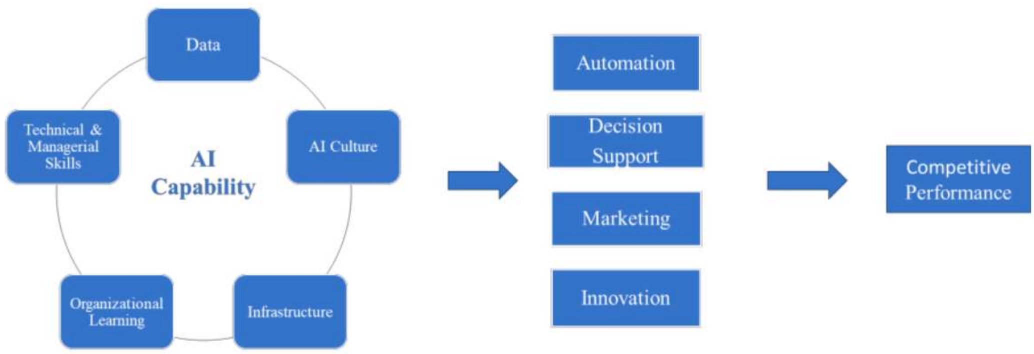
Riasch and Krakowki (2021) highlighted an underlying paradox exists in the adoption of AI. On one side automation, means the substitution of human capacity, improving operational efficiency. Through automation companies can reduce costs and speed processes, however if we focus only on automation, there is a substantial risk of reducing the creative human input, which is essential for radical innovation. Authentic and true innovations come from augmentation, which involves the integration of human competences with AI. In this context, AI emerges as a complementary asset to boost and enhance creativity, decision-making skills and complex problem solutions, tipical of humans. Organization that are able to find the right equilibrium between automation and augmentation, automize repetitive tasks allowing decision makers to focus on high-order level activites. These companies obtain competitive advantage and at the same time generate a operative advantage combined with the ability to create a self-reinforcing cycle of innovation (Riasch and Krakowki, 2021).

From a strategic point of view, different studies emphasizes the role of resources and competencies as necessary elements in supporting continuous innovation (Verona, 1999). In particular, according to the the dynamic resource-based approach, dynamic capabilities are central to maintain a competitive advantage in a shifting market environment (Teece et al., 1997). Dynamic capabilities are defined as “the subset of competence which allow the firm to create new products and processes, and respond to changing market circumstances” (Teece et al., 1997). Companies need to develop dynamic capabilities that enable the simultaneous processes of creating, absorbing, and integrating knowledge (Verona and Ravasi, 2003). Incorporating dynamic capabilities is essential for firms embracing the digital transformation landscape. These competencies enable companies to continuously align their strategic direction with the evolving market, identify and seize opportunities, and adapt their business models in response to rapid technological changes (Warner and Wäger, 2019).

Moving to the strategies, according to Kemp (2023) companies should adop a strategy of “grounding-bounding-recasting”. First, “grounding” means the use of data and specific competencies to train AI models, which allow companies to develop personalized models, based on their specific know-how. This approach allows the development of competencies which are difficult to imitate and generate a competitive advantage based on internal needs and resources. In parallel, “bounding” represents the strategy needed to protect these intangible resources. Through contractual agreements, patents and technological barriers, the competencies eveloped become difficult to imitate from competitors. Finally “recasting”, refers to the continuous adaptation of AI, which is necessary to maintain the flexibility to evolve these models based on new needs, data and market opportunities. This dynamic approach allows to follow a long-term view, continuously adapting AI contribution to internal processes. Overall through, grounding, bounding and recasting, companies create a synergetic approach to AI which creates a fundamental competitive advantage.

The Resource-Based View (RBV) framework has been extensively used to analyze competitive position of organizations (Wade, M., et al, 2004). According to this view, resources that are valuable, rare, non-inimitable, and not easily transferable can be the source of business value (Lockett et al., 2009). A recent study connects RBV with the development of an Artificial Intelligence capability within organizations (Mikalef et al., 2019). Based on RBV firms need tangible resources, such as data and infrastructure, intangible resources, like organizational culture and human skills. These resources together generate the concept of AI capability. According to Mikalef (2019), AI can produce value in four different ways, namely, automation, decision support, marketing and innovation and consequently generate competitive performance gains.

Figure 2: AI capabilities and competitive performance



Source: Mikalef et al., (2019)

1.4 Digital business model transformation

The rise of AI is profoundly disrupting traditional business models across various industries. Although fundamental economic theories remain relevant, the era of digital transformation brings the need to develop new tools and conceptual frameworks. Representation, connectivity, and aggregation represent the three critical factors whose converge support this transformation towards digital business models. First, data are the new oil, the key component of the engine. Nowadays, algorithms may be used to represent large volumes of data and the useful insights they contain. Second, the process of digitization strengthens and forges connections, enabling the emergence of new business models. Finally, the capability to aggregate diverse sets of previously unrelated data, allows for the addressing of complex questions that were previously unanswerable (Adner et al., 2024).
Scope, scale, speed, and value creation and capture are considered the fundamental drivers of a firm's operating performance (Iansiti and Lakhani, 2020). In the context of digital business models, the essential elements that drive a firm's operational performance are evolving distinctly:

- Scope: digital business strategy is expected to become the business strategy, reflecting a future where information, communication, and connectivity are fundamentally linked to organizational success. It is necessary to rethink the significance of digital connections within the firm's scope, its portfolio of products and services, to enhance the digital business strategy more effectively.
- Scale: firms may now scale their operations at an unprecedent rate because of the introduction of AI-driven processes. In information-rich environments, like innovative contexts, this sclability is enhanced by the development of partnerships and strategic alliances. Through these horizontal and vertical integration firms improve their capacity to quickly adjust to market demands.
- Speed: old hierarchical bottlenecks both informational and operational are resolved by the digitalization of business strategies. In this way, firms adapt faster to market changes, resulting in a major acceleration of product launches and decision making.
- Value creation and value capture: value creation in digital environments expands towards multi sided business models where open innovation and exchange of knwoeldge and information is at the basis of these new models. In this context, value is co-created and capture through intricate, dynamically coordinated networks spanning multiple organizations (Bharadwaj et al., 2013).

Aligning value creation and value capture has always been a crucial element, and this remains true also in the age of digital transformation, in order to successfully implement AI business model innovation. AI integration improves decision making, lowers costs and increases efficiency, all of which improve business performance and competitiveness in the market. However, firms must ensure they possess the necessary skills and assets to fully leverage AI. Effective value capture is facilitated through strategic pricing models and governance structures, like outcome-based agreements or licensing agreements, ensuring profitability while mitigating the risks of innovation spillovers. To maximize the benefits from AI, firms must strategically connect value creation and capture, continuously improving AI application and assessing market readiness, thus creating a viable AI business model that guarantees long term success and a sustainable competitive advantage (Aström et al., 2022).
Digital technologies digitize both product and industry architectures, leading to the generation of digital business ecosystems, which are characterized by heterogenous number of participatns

and stakeholders. A crucial element is to understand how companies can capture values from innovation. Recent studies highlight the importance of control points, as elements to capture value within digital business ecosystem, dividing them into technical, strategic, and generic ones. Technical control points include elements such as data and digital infrastructure; strategic ones encompass know how and agility; finally, modularity and scalability are considered as general ones. Organizations need to acquire component knowledge, constant technology-enabled learning, to set technical control points; and industry knowledge to set strategic control points (Bohnsack, 2024).

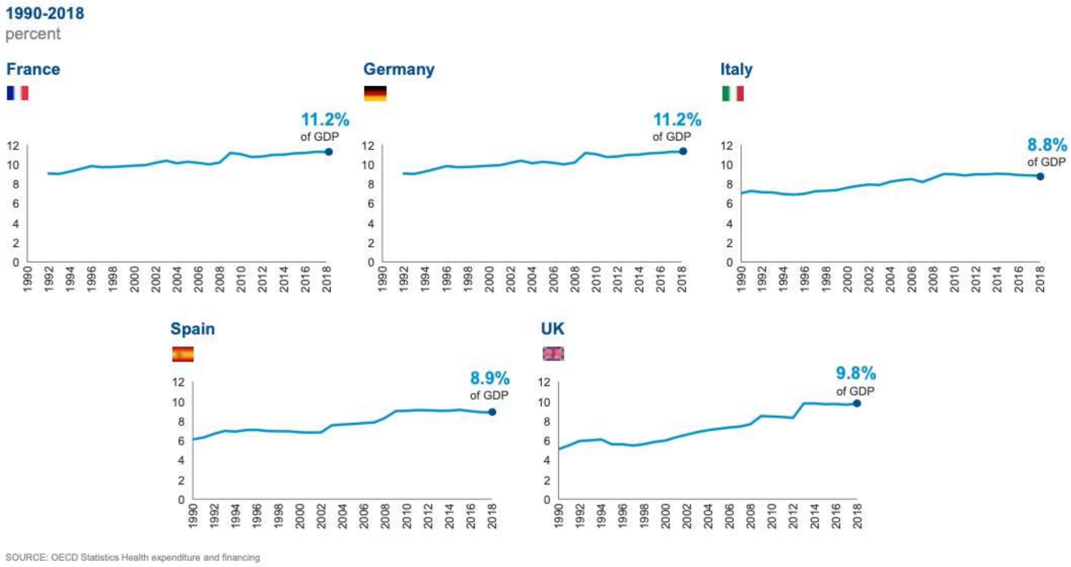
The healthcare sector stands out for its intersection between technological know how and medical industry expertise, in particular oganizations need to possess digital infrastructures and medical expertise. The integration between these two areas, is in line with the view of control points necessary for capturing value from AI in healthcare.

This research will focus on healthcare, where AI not only promises to revoluzionize advanced clinical applications and patient experiences but also plays a crucial role in redefining business models and strategies.

2. ARTIFICIAL INTELLIGENCE IN THE HEALTHCARE SECTOR

The global healthcare system is facing several challenges. Over the past century, the average life expectancy at birth has increased, therefore new issues arised, including growing demand for services, rising costs of care and innovation, and building the workforce required to deliver care. Therefore, demand is propelled by a mix of forces, such as aging population, increasingly patient expectations, new lifestyle choices and perpetual cycle of innovation (McKinsey, 2020). In this regard, a major issue facing European healthcare systems is their ability to remain financially sustainable. Healthcare spending as a percentage of GDP in France, Germany, Italy, Spain, and the UK ranged from 8.8% to 11.2 percent in 2018 and is predicted to rise further. (Figure 3) (McKinsey, 2020).

Figure 3: Healthcare expenditure as a share of GDP



Source: McKinsey, 2020

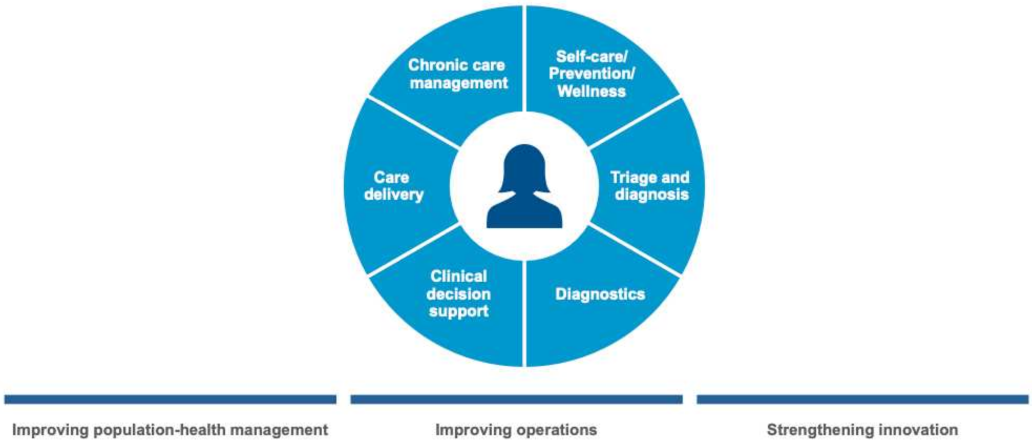
Healthcare systems will struggle to control costs and meet rising demand while preserving standards of treatment, access and patient experience, in absence of significant structural and transformative change (McKinsey, 2020).

Artificial intelligence has the power to revolutionize healthcare and address the challenges present nowadays. The application of AI in the healthcare industry has received increasing attention in recent times. It is expected that the healthcare sector would be one of the most impacted by AI, from drug discovery to service provision, it will experience a rapid growth, with an annual growth rate of 85% predicted until 2027 (BCG, 2023).

In healthcare organizations, the implementation of AI can lead to improvement of care outcomes, patient experience, and access to healthcare services, while at the same time increasing the productivity and efficiency of care delivery. Furthermore, using AI into R&D practices will enhance treatments and help healthcare systems allocating the resources where they can have the biggest impact.

Adopting a comprehensive classification of AI applications in healthcare, it is possible to identify six main areas where AI has a direct impact on the patient: self-care, prevention and wellness, triage and early diagnosis, diagnostics, clinical decision supports (CDS), care delivery and chronic care management (McKinsey, 2020).

Figure 4: Areas of impact for AI in healthcare



Source: McKinsey, 2020

The positive disruptive impact of AI in healthcare is widely discussed, however its full potential still needs to be determined. In particular, despite great interest in AI among healthcare professionals, it has not yet been widely implemented within many organizations, highlighting a gap between research and industry application.

Looking at where AI is being used ion European healthcare today, main applications are in diagnostics followed by clinical decision making and data management (Figure 5).

Figure 5: AI solutions in healthcare today

Source: McKinsey, 2020

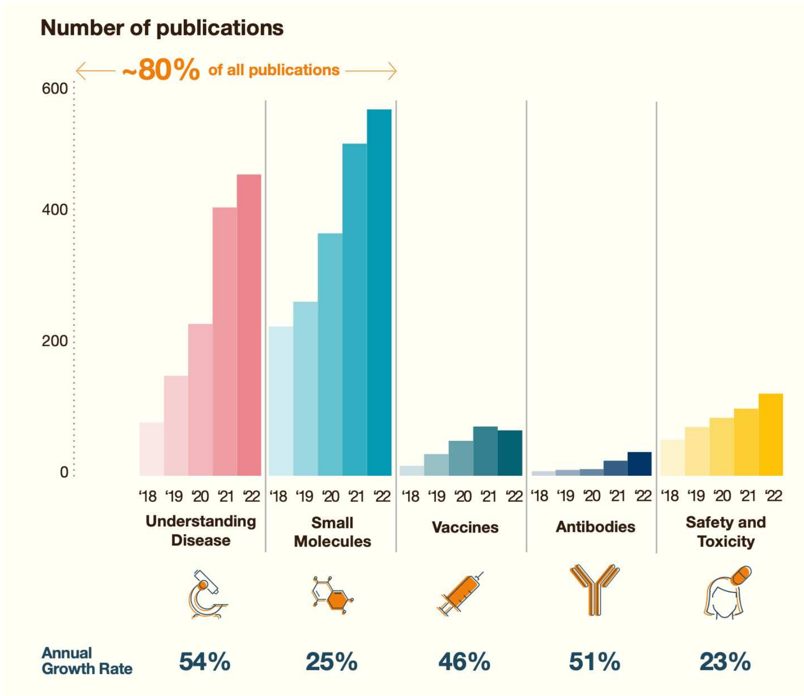
As previously highlighted, data is at the heart of the digital transformation of the healthcare sector. Big data is defined as "large volumes of high velocity, complex, and variable data that require advanced techniques and technologies to enable the capture, storage, distribution, management and analysis of the information" (TechAmerica Foundation's Federal Big Data Commission, 2012). For instance, Volume, Variety and Velocity have emerged as a conventional structure to define big data (Kwon et al., 2014). Over time health-related data are generated and accumulated in real time and at high speed, leading to a huge volume of data. Similarly, as the volume and velocity of data that is collected has changed, so too has the variety (Raghupathi, 2014). There are two primary categories of healthcare data: structured and unstructured. While structured data is carefully organized, like information stored in Electronic Medical Records; unstructured data, which represents nearly 80% of a patient's record is frequently dispersed across multiple systems, including more free form content like doctor's notes or patient feedback. Therefore, healthcare organizations, trying to gather and analyze this data, face major time, money, and accuracy issues as a result of its dispersion. AI is transforming the use of both structured and unstructured data in healthcare, driving productivity gains, improving the experiences of different stakeholders, including patients and providers, and consequently producing better healthcare outcomes (Bain, 2024).

For the purpose of this study, three main application areas have been identified: clinical research, clinical practices, and patient monitoring. In the subsequent sections, a review of the main scientific journals and publications has been conducted for each of these areas.

2.1 Clinical research

Ordinarily, clinical research is a labor-intensive activity centered on hypothesis generation, data analysis, and results interpretation. AI is poised to revolutionize this process, from drug discovery, through development, to approval.
The digitization of scientific knowledge has extended the digital search space and AI is particularly well-suited for leveraging this enlarged data realm to discover new drug candidates (Lou, 2021). Through AI it is possible to overcome three key failure points in the drug development process: selecting the right target within the body, developing the optimal molecule for interaction, and assessing which patients are most likely to receive benefit from the molecule (Heaven, 2023). Therefore, AI not only helps in detecting patterns crucial for identifying novel therapeutic targets, but also helps to narrow down the candidate pool to the most promising one, thereby optimizing the drug discovery process. Moreover, AI allows for more efficiency and statistical power in clinical trials, reducing the chance that the drug will fail the trials, and pushing the frontiers of personalized medicine forward through the integration of diverse data types with computational modeling (EPRS, 2022).
Figure 6 presents an analysis of BCG on publications on AI in drug discovery by use case area. In the analyzed period, the use cases demonstrating greater maturity include understanding disease and small molecules design and optimization.

Figure 7: Publications on AI in drug discovery, by use case family and by year



Source: BCG, 2023

In the area of target identification and validation, several pain points exist. Firstly, to identify credible targets it is necessary to untangle and interpret complex data from experiments and clinical studies; secondly, data come from different sources and formats making it difficult to standardize them; finally, the characterization of proteins and their interactions is a complex and demanding task (BCG, 2023). In this scenario, AI significantly enhances our ability to understand diseases by automating and improving the analysis of various type of biological data. From the analysis of the main scientific journals, the main areas of application in the target identification and validation process have been determined.

Phenotypic screening and image analysis increasingly benefit from the extensive use of deep learning, which improves the accuracy and efficiency of these processes. A study published on Nature (Moen et al., 2019) highlights how AI-based image analysis algorithms are employed to screen phenotypes and identify cellular changes faster than conventional methods. This application is essential for the screening in drug discovery and the identification of possible candidates; key improvements include automated feature extraction, scalability, sensitivity, and reproducibility. Moreover, studies like those of Zhou et al. (2020) has proven AI to be a successful tool in drug repurposing, which means finding new therapeutic uses for existing drugs, an approach that accelerates the drug development process and reduces costs, compared to creating new drugs from scratch.

AI plays a crucial role at analyzing large data sets. With the explosion of -Omics data, this capcity becomes increasingly necessary to integrate data from genomics, proteomics, and metabolomics. The collaboration between AI and genomics, in reality dates back to the 90's, when machine learning models were trained to recognize the characteristic patterns of coding regions within the genome (Zou et al., 2019). Since then, advancements in both domains have led to exponential growth the integration between AI and genomics. Hundreds of genes have been identified for their roles in human diseases, and genetic variability among patients has also been utilized to differentiate individual response to treatment. Stratifying patients based on their unique characteristics, to determine who should or should not receive a treatment: in one word, personalized medicine (Strianese et al., 2020). Personalized treatment is a method that customizes clinical care to patients' specific characteristics, like their lifestyle, genetics, and environment. AI has arisen as valuable technology in advancing personalized treatment: by analyzing complex data and anticipating outcomes, it suggests targeted solutions that are more effective and safer (Subramanian et al., 2020, PhRMA, 2022).

Machine learning algorithms are able to mine genomics data and identify genetic variants associated with disease (Libbrecht & Noble, 2015). A recent study published in Nature Cancer demonstrates how big data and AI are able to identify new markers and "warning bells" in order to predict the risk of prostate cancer recurrence. The study differs from previous ones that tried to explain how specific characteristics of the tumor predict its outcomes, because of the large number of samples analyzed. Researchers found that the tumor's ability to evolve is influenced by the genetic differences and morphological diversity (shape, size, structure of the cells..) measured by AI. The results showed that these characteristics are a strong signal of the tumor's risk of recurrence.

In another study related to colorectal cancer, researchers completed an extensive genetic profiling of over 2.000 intestinal tumors. Published in Nature, this research identified more than 250 genes related with tumor's development; in particular four new subtypes of cancer were detected, each with specific genetic features and prognostic implications (Cornish et al., 2024).

These types of research, even if still in an experimental stage, is crucial to understand how and when to treat tumors. Through the application of AI algorithms, clinicians can optimize drug dosages adapted to specific needs and anticipate potential adverse drug effects (Martin et al., 2022). It is expected that AI will be used in creating new treatments as well as integrating the results of the array with other clinical data to guide the clinical workflow, supporting decision making and precision medicine (Topol et al., 2019). Overall these research advancements not only deepen the understanding of diseases but also directly impact clinical practices, guiding treatment decisions.

2.2 Clinical practices

The potential of AI in the clinical setup is huge, including disease diagnosis, identification, and recommendation of treatments. The data required is sourced from various origins, including clinical notes, laboratory tests, pharmacy records, medical imaging and genomic information (EPRS, 2020).
Both the studies published on Nature (Sottoriva et al., 2024) highlights the applications in oncology and personalized medicine. In particular, emphasize how AI and genetic profiling provide crucial data that clinicals use to develop treatment plans, predict the progression of cancer and adapt decisions based on individual characteristics.

Diagnostic is one of the most promising area for AI implementation; especially for conditions with substantial data availability, AI has the potential to enhance diagnostic procedures. The main applications are the detection of tumors and lesions, early diagnosis and workflow optimization. By leveraging machine learning techniques, AI can assist in identifying abnormalities, detecting tumors, or other conditions, and offering quantitative measurements to speed up and improve the accuracy of medical diagnoses (Alowais et al., 2023).
In a 2020 survey, 30% of radiologists reported using AI in their practice. Among those not currently using AI, 20% indicated plans to adopt AI tools within the next 1 to 5 years (Allen, 2021).
A study published on the Lancet, "Mammography Screening with Artificial Intelligence" (MASAI), is the first randomized controlled trial to evaluate the effectiveness of AI-supported screening. Researchers used AI to identify high risk breast cancer screening exams, which were then subjected to double reading by radiologists, while the remaining exams, classified as low-risk, were read by only one radiologist. The results show that AI support tool led to the detection of 20% more cancers compared to standard screening, without affecting false positives. Also

the time plays a significant role, as with AI the workload of radiologists was reduced by 44% (Lång et al., 2023).
This is the demonstration of how AI tools can speed up the detection of standard cases, in order to prioritize and monitor findings that require more attention, allowing radiologists to focus on images that are more likely to show abnormalities. The main advantages include increased accuracy, cost reduction, and decreased errors.

Another strong area of application is pathology, which represents the intersection of disease diagnosis and research. The term digital pathology was first used to comprehend the process of digitizing whole-slide images thanks to the use of advances slide-scanning techniques; it now also includes AI tools for the detection and analysis of images (Bera et al., 2019). Oncologists and pathologists can enhance AI systems to overcome some challenges as inter-subject and inter-operator variability. Classification tasks, both low-level such as detection, and high-level such as predicting disease diagnosis and prognosis, can benefit from the use of AI (Sornapudi et al., 2018). A study published in Nature Communications demonstrated that patient prognosis could be predicted by analyzing cancer microenvironment characteristics, focusing on immune cell infiltration – a crucial component where the existence of immune cells within a tumor is demonstrated to impact the progression of cancer and the response to treatment. In this study, deep learning was used to assess the immune cell infiltration in tumor tissues (Heindi et al., 2018).
In cardiology, the availability of AI-driven cardiac image processing techniques has transformed clinical practice. Cardiac image modalities produce complex data that are challenging and time consuming to process by clinicians, in this scenario AI enables cardiologists to make more rapid assessment of the patients in their daily practice (Lopez-Jimenez et al., 2020). In recent years, numerous studies have been conducted to investigate the development of AI models (conventional neural networks) generated from large digital ECG datasets. The combination of AI/ECG in clinical practice has increased the ability to identify left ventricular dysfunction (Siontis et al., 2021).

Overall, one of the major advantages of AI in clinical practice is its ability to improve diagnostic accuracy and treatment outcomes. It is possible to identify disease earlier, resulting in improved prognoses for patients, and more effective treatment, thanks to the analysis of large amounts of patient data. All this results in reducing the overall burden on healthcare systems, allowing for more efficient resource allocation.

2.3 Patient monitoring

Thanks to smart devices and technologies, AI can leverage data to provide real-time monitoring. This is crucial for tracking patient adherence to post-treatment advice and providing personalized recommendations (Yaraghi, 2024). The percentage of physicians using remote monitoring services grew from 12% in 2016 to 30% in 2022 (AMA, 2022).
Managing chronic disease can be favored using AI by continuously monitoring patients' vital signs. In a study in Nature Digital Medicine, an analysis of data gathered from weareable devices by AI algorithms was able to predict hearth failure exacerbations. In this way medical professionals can act quickly to improve patient outcomes and lower the risk of readmissions to hospitals (Shah et al., 2020).

Several applications also exist in the post-surgery and recovery phase. AI-based monitoring systems make post-operative care better, giving personalized recommendations, detecting in time possible complications, and tracking medication adherence (PhRMA, 2022).
Population health management progressively employs predictive analytics to determine and advise on health initiatives. Medical providers can substantially improve the management of patients, by increasing efficiency and accuracy, thanks to the exploitation of big datasets from electronic health records and the integration with predictive analytics. AI-powered predictive analytics is able to generate the following beneficial outcomes (Alowais et al., 2023):

- Improve patient outcomes
- Identify patients at risk and target interventions
- Predict hospital readmissions
- Reduce healthcare costs

Moreover, AI is changing the face of public health through increased disease surveillance with digital epidemiology, improved environmental health tracking using sensor data, and targeted health interventions with automated modes of communication, such as text messaging and patient portals (Fihn et al., 2019).

2.4 Business Opportunities and Challenges

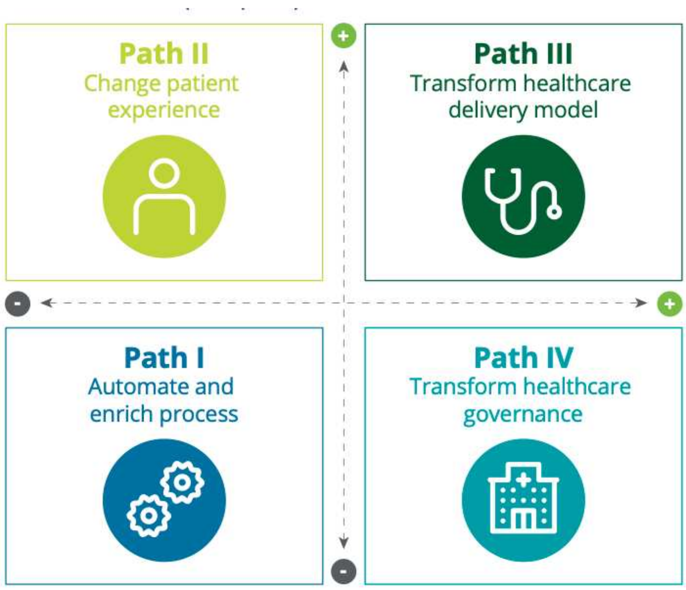
Open models and interdisciplinarity are at the basis for successfully integrating AI in healthcare practices. Healthcare organizations, academic researchers, physicians, patients, and technology companies must collaborate to create open-source large language models (LLMs) and engage in a transparent and inclusive strategy. Such consortia could combine resources, knowledge, and data in a way that will enable the development of an open-source base model, utilizing public datasets. This consortium-led approach provides several advantages. First, the model is likely to be more robust and reliable thanks to multiple testings across the different organizations; in addition, it also makes it possible for the transparent participation of patients, doctors, and AI experts in the processes of evaluation while ensuring security and compliance of data. Finally, this coordinated effort ensures that successful approaches are shared, so that the different members can capture value from the solutions, thus enhancing collaboration and open innovation (Toma et al., 2023). This collaborative approach helps estabilishing control points within the broader digital ecosystem. Open-source model are significantly important for gaining competitive advantage as medical providers can pool knowledge and resources with technology companies and accelerate innovation cycles.

Providing better care for patients and optimizing the use of available resources has always been the goals of healthcare systems worldwide. According to Porter (2010), to maximize value in healthcare, a new strategy must be considered that focuses on maximizing value for patients, shifting the attention from volumes to outcome. In other words, achieving high value for patients is a central challenge, as it consequentially benefits the other stakeholders. This view aligns with the interests of all actors: as value improves, the economic sustainability of the entire system increases. This strategy, which aims to define a new business model in healthcare, refers to Value-Based Health Care (VBHC). Porter argues that since value is defined as outcomes relative to costs, it also includes a measure of efficiency (Porter, 2010).
A study conducted by Deloitte (2019) identifies two main dimensions of contribution of AI to the transformation of the healthcare sector:

1. The ability of AI to modify the relationship with patient and impact the overall ecosystem constituted by providers, payers, and regulatory entities
2. The ability of AI to create new operational and business models

The AI healthcare industry framework (Fig. 6) is developed by integrating these two dimensions.
In the first path (Path I), AI is used by healthcare organizations to accelerate and automate processes, assist the workforce, generate efficiency, and enhance the effectiveness of activities. Continuing with the second path (Path II), AI aims to improve traditional internal processes and alters the patient experience in terms of service delivery. The main goal is to ensure that patients interact with this technology, becoming an integral part of the relationship that the healthcare system builds with them.
The third path (Path III) involves using AI as a tool to build a new patient service model: in combination with other technologies, new business models emerge.
Finally, the Path IV, where the goal is to improve healthcare system governance and promote the development of new devices, treatments, and medications.

Figure 6: AI Industry Framework



Source: Perspectives, potentials, impacts, and models of Artificial Intelligence in the healthcare sector (Deolitte, 2019)

Considering these four paths, it is necessary for medical providers to identify and exploit the control points required in order to generate and capture value. For example, technical control points refer mainly to Path 1 which includes digital infrastructure and data to automate process, and in part to Path 2 to enhance the patient experience. On the other hand, strategic control points are linked to Path 3 and 4, referring to the know how and ability to transform business models and finaly the healthcare governance.

While the integration of AI in healthcare represents a promising opportunity, several challenges need to be addressed to guarantee a safe and effective adoption. In the subsequent section, the major uncertainties affecting AI in the healthcare sector are analyzed (Huddle et. Al., 2023; EPRS, 2022; McKinsey, 2024):

- Cybersecurity and privacy: concerns about cybersecurity and privacy are widespread, especially regarding data leakage risks and vulnerabilities. Patient health data are sensitive and therefore necessitates stringent privacy protections. As a consequence companies that provide AI solutions should clearly define data ownership to protect patient information and strengthen cybersecurity.
- Ethical considerations: The integration of AI in healthcare raises several ethical concerns, which include justice and fairness, accountability and explainability, responsive and sustainable use, inclusiveness and equity.
- Regulation and compliance: the rapidly evolving landscape of AI technologies requires a robust regulatory framework. The existing GDPR provides a good starting point but is not yet comprehensive. Regulatory bodies must develop new guidelines and standards which refers specifically to AI applications in healthcare, and that must be followed in all European countries.
- Inaccuracies: represent one of the most recognized and encountered risk in the use of AI. If the underslying data of the models are biased, AI systems can produce results that may reflect this and lead to unrepresentative results; as models continuously evolve, the outcomes may be inaccurate, a phenomenon known as “hallucinating”.
- Lack of transparency: the “black box” nature, meaning the complexity and lack of transparency in how AI algorithms process data, can disincentivize final users. To build trust and increase adoption rates, clear explanations of how algorithms work, the data they use and how outcomes are generated need to be implemented.

3. METHODOLOGY

3.1 Choice of the approach

The objective of this study is to explore the ways in which AI can be successfully integrated into healthcare, identyfing the kay factors that enable the effective integration of AI technologies, and how this integration can drive a shift in business models and strategies.
Given the nature of the research question of this study, a qualitative inductive research design was adopted, resulting in comprehensive exploration of the phenomena. According to nascent theory research (Edmondson and McManus, 2014), this represents the best approach for topics for which little theory exists, representing new phenomena in the world. Nascent theory proposes tentative answers of how and why, as a consequence research questions are more open-ended than those used to further knowledge in mature areas of the literature. Data collections usually includes interviews, observations, and transversal investigations to ensure an open-minded approach and the identification of key variables in the study. To connect data to existing and suggestive theory, researchers use grounded theory (Glaser and Strauss, 1967; Charmaz, 2006), which entails an iterative process in which data analyses alternate and iterate with the data collection process.

In the present study, data collection and analysis were therefore conducted in two main ways: interviews with experts and presentation of succesfull use cases.
As part of my qualitative research, I conducted in-depth interviews with experts from the healthcare sector. The central objective of this analysis was to dive deep into the clinical, technological, and managerial aspects of the integration of artificial intelligence into the healthcare sector. The interviews conducted in this study allowed me to have a comprehensive understanding, and particularly they served for a dual objective.
Firstly, some of the interviews presented specific use cases that are already in use or in the development phase. This offered a valuable perspective on the current state of the art of AI applications in healthcare as well as future directions. The idea behind including these case studies was to gain access to information that is not readily available through traditional channels, such as online sources and academic pubblications.
Secondly, interviews were instrumental in identifying the enabling factors that are necessary to integrate AI. The factors outlined emerged as common denominators within experts' narratives.

Thanks to this approach, I was able to gain a comprehensive understanding of main trends and recurring challenges that emerge in the integration of AI. At the same time, focusing on these factors and trends provides a pillar for understanding potential areas for improvement and enhancement.

Finally, the business implications for healthcare organizations arise, emphasizing how the integration of AI can drive innovation, introduce new business models and strategies.

For the selection of my interviewees select informants, I turned to my professional networks and sought recommendations.

While acknowledging the limitations of representativeness that may emerge in my research due to variations among organizational contexts given the complexity and dynamism of the healthcare sector, which is subject to regulatory, technological, and operational changes, it is important to note that existing research provides significant support for the idea that qualitative studies offer valuable insights applicable to a wide range of organizations.

In the present study, I opted to use semi-structured interviews as the primary research method for collecting data from different healthcare experts. Due to the interdisciplinarity of the research topic, a purposeful sampling technique was followed to select the experts. Choosing interviews as the primary source of data certainly has advantages, but at the same time it also has limitations.

3.2 Advantages and limitations of Interviews as a research method

Interviews are an advantageous method of collecting data and investigating factors that influence the integration of artificial intelligence into the healthcare sector.
First, interviews are characterized by quality richness, thanks to the collection of detailed and in-depth responses from participants. This represents one of the main advantages of this methodology, as it allows for a comprehensive understanding of the complexities of the system. Delving into participants' experiences and perspectives is of great value in capturing the subtle nuances, challenges, and critical factors associated with the system. This is in line with the work of researcher Patton (2002), who emphasizes the depth of information obtained through interviews as one of the main strengths of this method of data collection.

Another significant advantage is that the interactions with participants generate an active dialogue. The interviwer can ask follow-up questions, deepening responses to focus on specific

aspects he is more interested in. Through this type of method, researchers have the opportunity to clarify, deepen and uncover underlying motivations and beliefs. Some studies highlight the interactive nature of interviews, bringing into light how they foster a dynamic exchange that can unearth valuable information beyond initial responses (Kvale and Brinkmann, 2009).
Other strengths concerning interviews refer to their flexibility as a data collection method. Questions can be tailored by researchers during the interviews based on participants' responses, allowing them to explore emerging themes and delve into areas of interest which had not been anticipated initially. This flexibility allows for a more organic and adaptive research process.
Taken together, these benefits make interviews a valuable tool for gaining a comprehensive understanding of the many aspects that influence the application of AI.

In addition to the benefits mentioned above, interviews as a research method also have some limitations.
A significant limitation of interviews, according to Rubin and Rubin (2012), is the potential for interviewer bias; in other words, the researcher may accidentally bring preconceived perspectives and notions of the topic into the data collection and analysis process. It is critical to address this risk so as to ensure that the data collected accurately reflect the participants' perspectives.
These limitations were mitigated by adopting a few strategies. First, I tried to be aware of my personal biases and perspectives during the interview process, remaining as neutral as possible and adopting an open attitude to avoid influencing participants' responses.
Second, as mentioned above, I used a semi-structured interview approach. Thanks to this approach, I had a consistence guidance to be followed to all participants, represented by an outline of questions to be asked. However, I also had the flexibility to adapt the questions based on participants' responses and ask follow-up questions. This approach helped reduce potential interviewer bias, as I asked general questions in a neutral way, giving respondets the possibility to freely answer, without influencing their responses.
An additional limitation of interviews, according to Tourangeau and Yan (2007) concerns the potential social desirability bias, in which participants might provide answers that they find socially desirable or that align with the interviewer's expectations. This type of bias could affect the authenticity and accuracy of the data collected. To mitigate the social desirability bias, I emphasized the importance of honest and open responses during interviews. I established an atmosphere of trust and respect by anonymizing data to protect participants' privacy, creating a safe and nonjudgmental environment in which participants felt comfortable to freely share

their opinions and experiences. These measures helped foster more accurate and unbiased data collection.

3.3 Sample selection and informants description

When selecting the sample for the interviews, I adopted several methods cited in the scientific literature to ensure a diverse representation of participants. In my study, I took two distinct approaches to selecting the sample of interviewees. Initially, I used a purposive sampling technique, taking advantage of different networks and to identify people who were experts in the healthcare sector. Later, I implemented the chain sampling approach to further expand my sample.

First, I leveraged personal networks, online resources, and professional platforms, to search for different professionals within the sectors with diverse expertise and background. This interdisciplinary approach allowed me to select a number of potential participants who met the desired search criteria of having relevant knowledge across interconnected fields.

Next, I applied the chain sampling approach, also known as snowball sampling (Naderifar et al., 2017), a non-probabilistic sampling technique. In practical terms, during interviews with selected professionals, I asked them to suggest others who might be interested in participating in my research. Thanks to this word of mouth, starting with a small group of participants, I was able to expand my sample and to access a wider range of suitable interviewees. The combined use of these two approaches allowed me to select a diverse sample of professionals with a variety of work experiences and perspectives in the field, contributing to more in-depth and meaningful research.

However, when using the snowball sampling technique, as initial participants suggest other participants, a risk of overconcentration of certain profiles and perspective may occur. This represents one possible limitations of the chain sampling approach.

I interviewed a total of 10 participants, including data scientists, biomedical engineers, clinicians, researchers, and university professors. The interviews were conducted by telephone or by Microsoft Teams, and each interview lasted between 30 and 45 minutes. All interviews were transcribed for data analysis. Table 1 provides an overview of the conducted interviews.

Table 1: Interview overview

Interviewee	Field(s) of experience
INTV#1	Professor in Computing Sciences at Bocconi University. Head of AI & Systems Biology Lab at IFOM Milan. Head of Computational Biology and Integrative Genomics Lab at University of Oxford.
INTV#2	Medical Oncologist and PhD in Bioengineering. Head of AI-ON-Lab (Artificial Intelligence Lab) at Istituto Nazionale Tumori di Milano.
INTV#3	Researcher in Bioengineering at Politecnico di Milano. Cofounder of MLcube.
INTV#4	Full stack developer at MLcube.
INTV#5	Chief Technical, Information & Innovation officer at Fondazione Policlinico Universitario A. Gemelli IRCCS.
INTV#6	Data Scientist at Fondazione Policlinico Universitario A. Gemelli IRCCS.
INTV#7	Research Data Scientist at Fondazione Policlinico Universitario A. Gemelli IRCCS.
INTV#8	Professor in management at Luiss University – specialized in healthcare and biopharmaceutical fields.
INTV#9	Vice President - Head of Lifesciences at Capgemini Invent
INTV#10	Medical radiologist at Sant'Andrea Hospital.

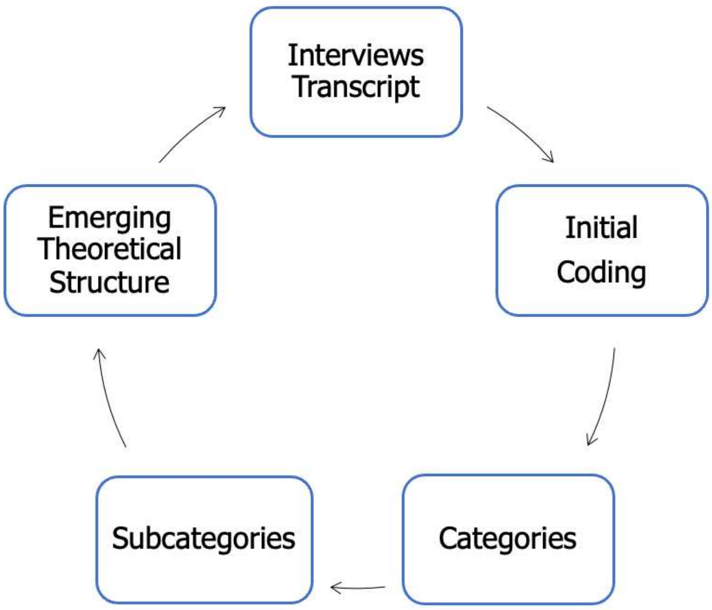
Source: self-elaboration

3.4 Data analysis process

To ensure the quality of the data collected during my interview, I followed a set of procedures. Specifically, before starting the interviews, I developed a structured interview protocol that included a set of key questions and topics to be addressed. This protocol provided me with guidance during the interviews and ensured that all participants addressed the same topics. This helped to ensure consistency and comparability of the data collected.

During the data analysis phase, I used an open coding approach to identify emerging themes and concepts. Through this approach I was able to analyze participants' responses in depth and identify emerging themes and concepts without limiting myself to predefined patterns. Grounded theory, as introduced by Glaser and Strauss (1967) and further developed by Charmaz (2006), is a systematic methodology that involves the construction of theories through methodical gathering and analysis of data. Open coding is the first step of the process, where the researcher examines the data to identify words and phrases that seemed relevant and meaningful. In practice, I began by carefully reading the interview transcripts, looking for significant ideas related to my research question. As I analyzed the interviews, I highlighted these parts to organize the emerging concepts and created descriptive "categories". These categories may have several subcategories, and associated dimensions which are gradually redefines as specific incidents are examined, coded and compared (Langley, 1999). This iterative process of data analysis and idea generation ensures that the theoretical structure emerges directly from empirical data. This strategy allows for high accuracy as starting with empirical details express in interviews, it builds a theoretical structure "bottom up" from this base.

Figure 8: Data analysis process



Source: self-elaboration

4. ANALYSIS

4.1 Findings and interpretation of interview results

The initial objective of the interviews conducted was to give a full overview of the current state of AI in healthcare. This means pointing out where AI solutions are already being implemented and exploring areas where promising developments can be expected.

What has emerged is the following and all the information and implications discussed derive from the interviews.

First, two important premises need to be recognized. AI solutions in healthcare are implemented in different ways across various countries; in some regions, it is easier to implement these technologies, while in others, it is more challenging. Additionally, our knowledge about AI systems, in terms of development and regulation, in certain countries, such as China, is limited.

Second, when discussing AI in this context, I am primarily referring to machine learning methods.

Machine learning (ML) methods have been used extensively in research from many years, particularly in medical and biological studies. From imaging to the analysis of complex data such as genomics and genetic sequences, these methods have applications across various domains. From the interviews, emerged that in research settings, ML is used in both supervised and unsupervised ways. For instance, in studies that analyze biological materials from clinical settings, ML plays a crucial role in processing large datasets, such as sequencing RNA in single cells from hundreds of patients. As one expert noted, "We have 100,000 cells with a million variables in hundreds of patients. These are very large datasets, and there are various steps in processing them. Without machine learning, we wouldn't even be able to proceed." This highlights how data, that would be otherwise unmanageable, can be processed and interpreted through ML.

Imaging is one of the area where the use of ML dates back to the 1980s, when pattern recognition techniques were applied for both biological and clinical purposes. These tools have evolved significantly, leading to the development of deep learning models, which are more sophisticated and are now commonplace in research. With the increase of data generation and computational power, applications of ML in research are without bounderies. As a matter of fact, some ML tools have been specifically developed to handle the challenges presented by large biological datasets, otherwise it would have been imposible to extract relevant insights from these datasets. This includes methods for reducing dimensionality by removing less informative variables.

However, clinical applications regarding AI differ from research and introduce more complexities. First of all, differently from research, the presence of a patient necessitates that all processes are highly standardized; secondly cost-effectiveness of these systems should be demonstrated.

The translation of AI systems from research to practice is not so smooth and easy. While AI-driven methods, particularly machine learning, are extensively used in research to identify patterns, make predictions, and even develop new drugs, these tools often do not translate directly into clinical settings. This illustrates a critical point: while AI plays a crucial role in advancing medical research, its direct use in the clinic remains now limited. The AI tools used in clinical environments tend to be static models that have completed their learning phase, rather than dynamic systems that continue to evolve and adapt based on new clinical data. The AI tools currently in use in clinical settings are often pre-packaged software that has already completed their learning phase before deployment. As one interviewee highlighted, "What is implemented in the clinic right now are software, but the learning phase of this software is already finished. The software that is approved and used routinely in the clinic now is software that has already learned."

The interviews not only provided valuable insights but also gave access to confidential materials that enabled a deeper exploration of three significant AI use cases in healthcare: Virtual Ward, Azimuth at Policlinico Gemelli, and the I3LUNG project.
The selection of these case studies was based on the interviews conducted and thorough analysis of both confidential and publicly available documents and materials. These three use cases significantly illustrate the real world opportunities and challenges that the interviewees highlighted.

The first two applications discussed are both developed and implemented by Policlinico Gemelli. Fondazione Policlinico Universitario Agostino Gemelli IRCCS, is one of the largest private non-profit hospitals in Europe and a place where everyday teaching, innovative research, and care and assistance activities interact for the benefit of the community, to offer all patients access to the best available therapies (Fondazione Policlinico Universitario Agostino Gemelli IRCCS, 2022). “Care, research, education, and commitment. Serving patients every day.” This is the mission statement of the hospital, the most important best practices of made in Italy healthcare.

The hospital’s model is fundamentally inspired by actions that emphasize the constant centrality of the human person, together with the high-quality medical and scientific intellectual capital developed thanks to the Faculty of Medicine of Università Cattolica del Sacro Cuore. The generation of value for human, health, scientific and economic development is at the basis of the distinctive value creation and impact model of Policlinico Gemelli. The hospital is at the forefront of research and development of innovations in medicine, with a constant commitment to technological and scientific advancement.

Before delving into the specific applications, it is useful to first outline how the hospital organizes its data and generates these models.

The value creation process is constituted by three key stages: ontology construction, value extraction, and validation and creation of value.

The data utilized by Policlinico Gemelli for scientific research activities predominantly do not originate exclusively from the clinical practice database. Instead, there is a specialized and dedicated infrastructure, namely a data lake, which is managed daily both from the professional and infrastructural perspectives. The data value chain includes several critical steps, starting with the retention of data without any loss of information. This is followed by an in-depth understanding of the clinical query which guides the creation of a dedicated database developed around an ontological model. Then, anonymization and pseudonymization techniques are applied to ensure privacy while maintaining data integrity, without compromising the information. The process continues in the construction of a Data Mart, a subset of an organization’s data warehouse focused on specific functions, which facilitates tailored data access and analysis. The data value chain then encompasses data modeling, AI and advanced analytics, data enrichment and training and validation to enhance data utilization.

In the context of data-driven research, data visualization and machine learning are the visible components, however they represent only the tip of the iceberg. Beneath the surface, a comprehensive process ensures the integrity and usability of the data.

- Data collection: this consists of identifying data from various sources and operational systems within hospitals and extracting according to inclusion criteria for the selected cohort.
- Data transformation: the data collected needs to be transformed from unstructured forms into structured information. This includes identifying clinical features, such as radiomic features from images, and calculating scores or creating composite variables.
- Data quality control: includes consistency and coherence checks of extracted and processed data, which requires technical and clinical expertise through an ongoing verification and improvement process.
- Ontologies: represent the methodology for aligning research questions with the necessary data, serving as the connection between the data sources, the part below the surface, and the study objectives, above the surface.
- Clustering and classification: statistical methods allow researchers to categorize and cluster data into meaningful groups of patients, clinical pathways and treatment responses.
- Data visualization: only at this stage, complex datasets are transformed into useful insights for clinical and industrial researchers.
- Machine learning: finally advanced algorithms support researchers in developing decision-making systems for diagnostic and prognostic purposes.

The hospital focuses on three key disciplinary areas: data engineering, AI and advanced data analytics, and digital platform development.

In the context of data engineering development, the emphasis is on the construction and management of robust data infrastructure, such as data warehouses and data lakes, which are essential to support advanced research and ensure the protection and privacy of patient data. The data engineering area is dedicated to the holistic management of medical data. The process begins with the collection and storage of data directly from its source, following methodologies that ensure no distortion of the contained information. The priority is to ensure that each piece of data is stored in a way that preserve its original information richness, without compromising its integrity. Once stored, these data undergo anonymization processes that allow the creation of secure data marts compliant with regulations, and ready for use by the research community. This critical step ensures that, while maintaining the anonymity of subjects the data remains of high informational value for studies and analysis. Close collaboration with researchers is essential to ensure the effectiveness of these processes. The team of data engineers works tirelessly to optimize ETL (Extract, Transform, Loaf) procedures, making the data not only accessible but also meaningful for advancing medical research.

In 2023, a comprehensive monitoring dashboard for the data warehouse flows was created, which is indispensable given the size and number of automated procedures. Developed on the SAS Viya platform, it allows for the monitoring of the outcomes of scheduled processes across various data warehouse servers to intervene promptly and consistently ensure data quality. Among the various available tabs, it is possible to quantify machine load, thus always ensuring maximum server performance and avoiding bottlenecks.

Besides the anonymization and pseudonymization of structured data (such as name, surname etc..), a continuously evolving process involves the handling of unstructured textual data. This includes documents like surgical reports, discharge letters, performance reports, and consultations. The process entails the removal or alteration of all information that could reveal the patient's identity, including personal data, unique clinical information, and specific geographic identifiers found within free-form text. To effectively perform this task, sophisticated text recognition algorithms have been developed to automatically identify sensitive data within documents. Significant investment has been made in advancing this procedure, which incorporates Natural Language Processing (NPL) and other Artificial Intelligence tools. Implementing these NPL techniques requires an interdisciplinary approach, combining skills in computer science, linguistics, management, and the support of clinicians to achieve a solid understanding of the medical domain.

The area of AI and Advanced Analytics, represents the core element of the initiative to transform the medical sector through digital innovation. In this domain, the focus is on the development and implementation of artificial intelligence algorithms and advanced data analysis methods that have the potential to revolutionize diagnosis, treatment, and patient management.

By analyzing large volumes of healthcare data, algorithms are capable of identifying patterns and trends that go beyond conventional analyses, offering new insights into disease understanding and the customization of treatments. This not only accelerates research but also allows for more targeted therapies and improved clinical outcomes. A fundamental challenge is the integration of AI solutions into the real clinical context, ensuring that innovations are both technically sound and practically implementable. Collaboration with clinical professionals is essential to tailor AI technologies to the specific requirements of healthcare workflows, thus improving operational efficiency and enhancing the quality of patient care. The envisioned future of medicine according to Policlinico Gemelli is one where artificial intelligence and advanced data analytics are foundational pillars to supporting clinical decision-making, leading to a healthcare paradigm where every therapeutic decision is informed, precise, and personalized.

Finally, the digital platform area aims to develop and maintain effective digital platforms for research and healthcare. This means facilitating access to medical information as well as the sharing infromation, and promoting collaboration among researchers. This area focuses on the development of cutting-edge digital platforms designed to transform both research and healthcare delivery. These platforms act as catalysts for innovation, often ensuring continuity and overlap between research and clinical activities.

The goal is to create digital ecosystems that not only support advanced research but also enhance the patient experience and outcomes. The platforms are designed to be highly secure, ensuring the protection of sensitive data, and to be interoperable, allowing seamless integration with other existing healthcare information systems. These digital platforms enhance the collaboration between researchers and clinicians, thereby accelerating the process of discovery and application of new medical knowledge. Furthermore, the underlying technology of these digital solutions is continually updated to meet the evolving needs of the healthcare sector, ensuring that the platforms remain at the forefront of addressing both current and future challenges.

In the following section, two use cases will be presented on how Policlinico Gemelli, based on the above-mentioned infrastructure, is practically applying new technologies across different medical fields.

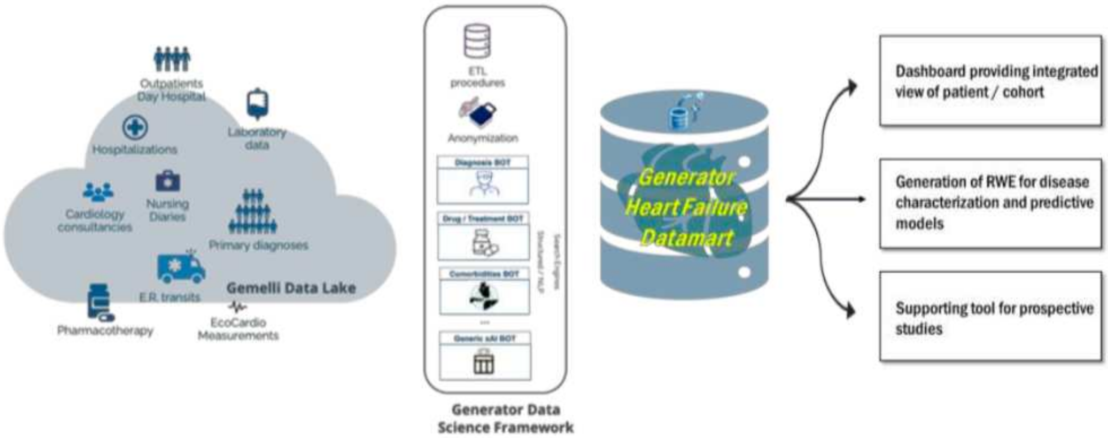
Virtual Ward is an innovative tool developed to extend diagnostic and care processes outside the hospital. The main objectives are: ensuring continuous observation and assistance for gynecological patients, enhancing the effectiveness of management and interaction with the clinical team during the postoperative period, and supporting research directed towards more personalized care models.

In practice, this project ensures continuous monitoring and support for patients post-discharge. Patients engage with Virtual Ward through a free app that can be downloaded onto their mobile

phones. The process begins at the time of discharge from the hospital and lasts 30 days, during which the patient receives a series of questionnaires and shares additional information and files aiming at assessing the progress of her health condition. The team of postoperative care managers utilize this shared information to evaluate and manage the patients effectively. The data sent from the app allow doctors to immediately detect symptoms that could be related to possible complications from the surgery; and through the app it is possible to interact with the patient promptly and continuously.
It is important to note that this service is intended to complement, not replace or modify, standard clinical practices.

Azimuth is an integrated digital health pathway for patients with heart failure. It is a new mode of patient care that utilizes integrated technological solutions based on AI. The focus of the project is an app developed within an open innovation platform, involving experts from Policlinico Gemelli, along with technological partners and industrial collaborators. The developed platform incorporates an app and allows physicians to monitor the patient's health status in real time, even when patient is not physically in the hospital, ensuring more personalized care for patients with hearth failure. Actually, Azimuth is a key component of a broader research program focused on heart failure.
As illustrated in Figure 9, the program starts with the collection of data from multiple sources, including outpatient services, hospitalizations, cardiology consultancies, laboratory data etc; these data sources then converge into the Gemelli Data Lake. Within the framework, the data undergoes rigorous processing through a Generator Data Science Framework. This involves ETL (Extract, Transform, Load) procedures, anonymization protocols and specialized bots, facilitating the automation of complex data analysis tasks. The resulting data is then challenged into the Generator Heart Failure Datamart, a specialized database designed to manage queries related to heart failure.

Figure 9: Data flow and processing framework in Azimuth



Source: internal material

From the DataMart, three key outcomes are generated:

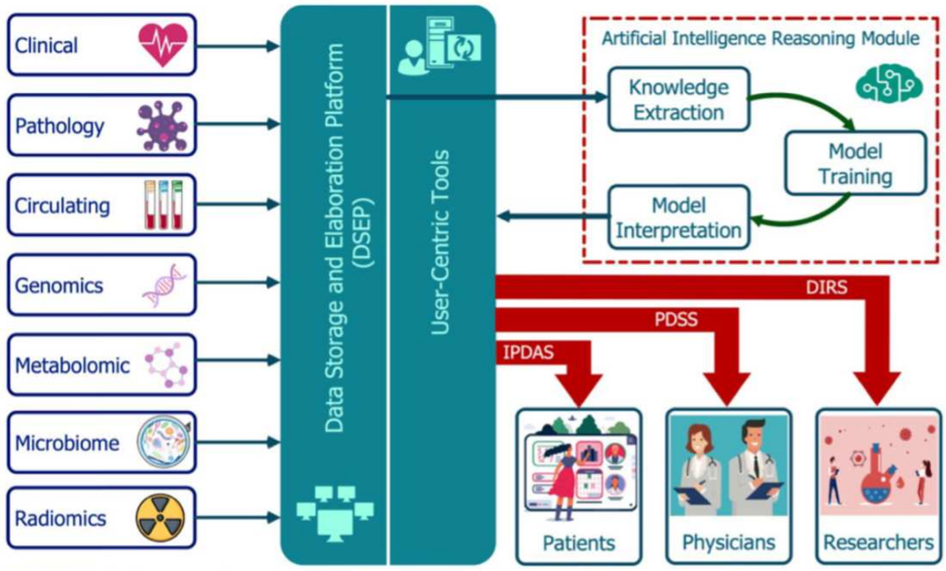
- A dashboard providing an integrated view of patient cohorts.
- The generation of real-world evidence (RWE) for disease characterization and predictive models.
- Supporting tools for prospective studies.

Overall, the heart failure program extends into several main exploitation areas. First, the continuous development and refinement of a specialized DataMart, would be essential to consolidate heart failure data and enable advanced analyses. In addition, the program trives to support a range of clinical research projects, aiming to discover new treatments and improving existing ones. Furthermore, the program includes Azimuth, a digitally enabled care model showing the application of digital innovation in patient management. Thanks to Azimuth, physicians can perform early clinical interventions based on Real-World Data (RWD) and patients can better manage their conditions while maintaining continuous contact with the clinical team. At the time of discharge, the care plan is personalized using the Care Plan Canvas and patients are educated on how to use the app. The care plan is then integrated after the visit into the clinical platform, ensuring continuity and easy access for both the care team and the patient. The patients at home are actively engaged in the management of care by sharing responses to questionnaires and recording vital parameters. A virtual chatbot and a direct messaging system with the hospital are additional optional features of this model, which improve communication and support.

The AI-driven innovations at Policlinico Gemelli are deeply intereconnected with the hospital's strategic goals, because they represent a way to enhance operational efficiency, reduce costs, and create new revenue streams. Both use cases are an example of how care is extended beyond the hospital, and strategically this reflects a shift towards value-based care. According to Porter & Lee, value-based care, where providers are compensated based on patient outcomes rather than the volume of services provided, represent a succesfull strategy in healthcare (Porter & Lee, 2013). As highlighted, these use cases offer differentiated services to patients, therefore improving overall care quality and their satisfaction. Morever, these applications contribute to cost savings by reducing readmissions rates and costs associated with emergency care. Finally patient data collected through the systems behind these models represent meaningful insights that can be monetized through partnerships with pharmaceutical firms, leading to new revenue streams. The investments in AI projects is aligned with the strategic vision of the hospital in order to stay at the forefront of medical innovation while also achieving greater efficienct, better patient outcomes, and enhanced competitive advantage. In particular, the ability to generate and analyze real world data provides the hospital with a valuable assets that can be used for further fresearch and partnerships.

The third use cases is I3LUNG, an European collaborative, 5-year, €10M project that aims to create an AI-based personalized decision-making tool to support both clinicians and patients in selecting the best lung cancer treatment plan. It will enroll more than 2000 patients with lung cancer that are usually treated with immunotherapy, which represents the standard of care, but often presents with strong toxicity, not always producing sustained clinical efficacy and additionally being very expensive for the healthcare system. I3LUNG's objective is to use AI and ML to analyze a huge amount of biological, molecular, radiological, and clinical data collected from patients in order to develop an algorithm that will predict how a specific patient will respond to the therapy (I3Lung.Eu).

Figure 10: I3LUNG Platform



Source: I3Lung.Eu

Figure 10 illustrates the structure of I3LUNG platform. Data from different medical sources is collected and stored in a Data Storage and Elaboration Platform (DSEP), and then processes and analyzed through the Artificial Intelligence Reasoning Module. This module includes three main stages: first, relevant information is extracted from the stored data; then the AI system is trained from data patterns to make predictions; finally complex outcomes of AI model are translated to make them understandable for end users. This process aims at developing interfaces and tools to facilitate interaction between users (patients, physicians, and researchers) and the platform. Overall I3LUNG will support users through the following:

- Physician decision support system (PDSS): enables physicians to easily access predictive models, supporting clinical decision-making process by identifying the most appropriate treatment and improving care appropriateness.
- Individualized Patient Decision Aid System (IPDAS): patients are active participants, as they are provided with tools to understand their treatment options and support a shared decision-making process.
- Data Interpretation and Research Support (DIRS): reinforces research work by making the data gathered during the project available for analysis, supporting the development of new medical insights and innovations.

The project highlights different elements from a business point of view. First, it underscores the potential of AI in personalized medicine, aiming at reduce the economic burden on healthcare systems by avoiding ineffective treatments.
Moreover, the collaborative nature of I3LUNG showacases how diverse stakeholders can work together within a digital ecosystem to achieve a shared goals, leveraging each other's resources to build a single vision. It represent an example of open innovation models where data, expertise, and capabilities of the different partners are pooled together. This collaborative nature not only accelerates the development of AI tools, but also distributes risks and costs.
This use case also reflects a change towards value based care. It demonstrates a strategic shift towards a more collaborative and data driven solution, where continuous feedback create a dynamic platform that evolves with new findings. This model enhances the hospitals' ability to innovate in a more rapid way that they would have been able alone and stay competitive. In summary, I3LUNG is a concrete example of how AI is able to transform the way clinical decisions are made by utilizing technology to personalize care and reduce both costs and risks for patients.

Overall the presented cases highlight the importance of strong data infrastructure, the need for collaboration across different disciplines, and the need for a balance between pushing technological innovation and adhering to regulatory requirements. In particular, these use cases demonstrates how these challenges are being directly addresses, illustrating how AI is integrated into the business models of healthcare institutions, driving not only innovation and efficiencty but also providing them with a competitive advantage.

4.2 Framework development

From the analysis of the interviews, the objective was to understand the impact of AI applications in different areas of healthcare and subsequently identify the key enabling factors for the successful integration of these models in the sector.
First, I dive deep into the impacts of this technology. According to the desk analysis previously conducted, I now explore the impact of AI on three areas, namely, clinical research, clinical practice, and patient monitoring.
By breaking down the impact of AI in these three areas, it is possible to deeply understand how AI is reshaping healthcare landscape.

AI has significant accelerated the pace of research. Regarding target identification and drug discovery, machine learning models are increasingly used to decode complex genomics data. As one interviewee emphasized, AI-driven tools have revolutionized genomic research by analyzing enormous datasets such as RNA sequences, “in research studies, AI processes sequencing data that would otherwise be impossible to interpret manually”. This has a strong impact as it leads to more precise identification of therapeutic targets, reducing time and costs necessary to bring new drugs to market. AI also plays a significant role to understand disease by developing predictive models that combine genetic, phenotypic and environmental data. As one interviewee pointed out, "AI handles mundane tasks in the lab, allowing us to focus on innovation." For instance, in the field of oncology the ability to predict the risk of cancer development and recurrence is an important breakthrough. This capability allows researcher to stratify patients more effectively.

In the clinical practice domain, as highlighted by interviewees the current state of the art of AI applications regards ready-to-use software, mainly in the area of diagnostics.

AI applications enhance the accuracy of medical diagnostics, in particular in specialization like pathology and imaging. For example, AI can identify abnormalities with greater accuracy and speed. As highlighted in the interviews, clinicians are increasingly relying on AI-powered software Rapid, which has been validated for clinical use in stroke diagnosis. Rapid processes CT perfusion scans, allowing clinicians to quickly identify areas of the brain affected by stroke, thereby enabling more timely and effective interventions. This validated tool is routinely used in clinical practice and its outputs are included in patient reports.

Current models are moving towards personalized medicine, even if still in nascent phase. As noted in the interviews, AI helps create "dynamic, personalized treatment plans that evolve with the patient’s needs," which leads to better treatment outcomes and minimizes the risk of adverse effects. The same also involves operational aspects as resource allocation, patient triage, and appointment scheduling. However, this is something still in a work in progress. As noted in interviews “for these AI models to be integrated more dynamically and on a daily basis within clinical settings, robust regulatory frameworks are essential to validate these models in a way that ensures they are safe and reliable”.

Finally, regarding patient monitoring, as highlighted by the case studies and further validated in interview, AI wearable devices and remote monitoring tools allow for real time data collection and therefore timely interventions, which leads to reduce readmissions and improved patient outcomes. This is highlighted by the case of Azimuth presented above. In addition, AI applications can improve patient adherence to treatment through personalized reminders. An interviewee pointed out, "AI keeps patients engaged and compliant with their treatment plans," thereby improving long-term health outcomes and reducing the likelihood of complications. Table 2 summarizes the impacts of AI across these three main areas.

Table 2: Impact of AI across three main areas

Clinical Research	**Clinical Practice**	**Patient Monitoring**
Enhanced target identification and drug discovery	AI-Enhanced diagnostic accuracy	Continuous health monitoring
Improved predictive models for disease research and progression	Personalized medicine	Predictive analytics for early interventions
Automation of routine research tasks	Operational efficiency	Improved patient adherence to treatment

Source: self-elaboration

Having identified the impacts of AI across research, clinical practice, and patient monitoring, I focus on the enhancement elements of AI implementations in healthcare. According to grounded theory a framework was developed. The objective of the framework presented is to provide a structured approach for the understanding of the enabling factors necessary for integrating AI into the healthcare sector. Starting from the broader elements three key dimensions were identified: technical factor, human factor, and regulatory factor. Each dimension is reconducted to specific themes which in turn are based on several underlying concepts.

The **Technical Factor** dimension includes the infrastructure, data management practices, and evidence based approached necessary to support AI technologies. This dimension encompasses two key themes: data access and structure and evidence production. As has been previously highlighted, data is the new oil and the foundation of AI models. Primary challenges include data availability and their structure. The fragmented nature of healthcare data refers to the fact that data are usually available in different forms, such as texts and images, making it difficult to compile a comprehensive dataset for models training. One expert stressed this point “the

number one obstacle is data: without data, nothing can be done; the data must be well done and generalizable”.
Furthermore, the FAIR principles are necessary in ensuring data is usable by AI systems. This means that must be findable, accessible, interoperable, and reusable. The lack of integration between data sources can significantly hinder AI’s potential; taking this perspective, the structure of Policlinico Gemelli represents a good example of how data should be organized inside an organization: creating unified data repositories and standardizing data formats.
The second theme within the technical factor dimension is the production of evidence.
First, efficacy must be demonstrated, and AI tools validated before they can be widely adopted in clinical practice. Later the focus moves on cost-effectiveness.
AI systems in healthcare must undergo rigorous testing to ensure they provide accurate and reliable results. As noted by an interviewee, “first you have to prove efficacy in the sense of scientific evidence that a doctor supported by AI tools reach better quality care, later you need to show cost-benefit.” Without such evidence, healthcare providers may be reluctant to adopt AI technologies. Another expert noted: “We haven't yet demonstrated that they are useful in all cases, and this is a big job that needs to be done”.
In the I3LUNG project, for example, the final goal is to develop AI tools that can assist in clinical decision-making. However, the interviewee emphasized the importance of ensuring that these tools are validated through clinical studies before they are implemented in practice. "The final goal of the I3LUNG project is to answer the question: is immunotherapy the right treatment for this type of patient?" This means ensuring that AI tools not only work in theory but also deliver practical benefits in real-world clinical settings, underscoring the need for evidence production. Moreover, the importance of evidence production is not limited to the initial validation of AI tools, but it is necessary in a continuous way, as a constant validation is needed to ensure that the systems remain effective as they are used in practice. Moreover, in many healthcare settings, particularly in publicly funded systems, cost considerations play an important role in decisions regarding the implementation of new systems. AI tools that can demonstrate both clinical efficacy and cost-effectiveness are more likely to be adopted on a wide scale. One expert appointed “In some countries, like UK, also if a new system is proved to work better than a previous one, but it is not financially sustainable, that tool will not be approved”.

Within the dimension **Human Factor**, two main themes emerged: People and Culture. Both elements have been outlined to be crucial for the integration of AI in healthcare.

First the human resource and adaption theme highlights the need of integrating new professional figures in the workforce as well as training and reskilling your resources.
This refers to the necessity for both technical professionals and the training of medical and managerial personnel. The successful integration of AI into healthcare requires that healthcare professionals develop new skills that are often not part of traditional medical training. For example, professionals may need to understand how to interpret AI-generated insights or work with AI tools as part of their daily practice. One expert noted “You need to bring in resources with the rights skills, which are scarce. Certain profiles are in short supply, so what you need to do is upskill the internal resources you have”.
Human-AI collaboration is a key concept within this theme. AI tools are designed to assist healthcare providers, not replace them. As one interviewee explained, "AI will be a decision support tool for doctors. If a doctor has 100 cases, they cannot focus on all of them. It doesn't make sense to focus on standard cases but on more complex ones." This underscores the role of AI as a tool that can enhance the efficiency and effectiveness of healthcare providers. The presence of multidisciplinary teams, which include researcher, clinicians, data scientist, is another crucial for the successful deployment of AI. Moreover, as AI models evolve, especially those that continue to learn from new data within the clinical environment, the inclusion of multidisciplinary teams becomes even more critical. "Even now, when we develop classifiers for patient outcomes, there are always statisticians, biologists, doctors, and broader clinical figures involved," another interviewee noted, underscoring the collaborative effort needed at every stage of AI implementation.
The second theme within the human factor dimension is “culture and change management”. When practices are intrinsically established inside a system, a resistance to change can arise. This refers to change management, and represents a significant challenge in healthcare which can hinder AI adoption. Healthcare providers may be hesitant to adopt new AI tools, preferring to stick with familiar practices. An interviewee pointed out “I give you a new tool, but how can I be sure this tool will be used? As it’s something new, one can prefer to follow the usual procedure. This is one of the greatest example of resistance to change”.
Moreover, adaptability and flexibility are crucial for healthcare organizations to respond to the rapid pace of technological change. This requires a flexible organizational culture that is open to change and willing to experiment with new technologies. An interviewee from Gemelli pointed out that "Being inside a hospital gives us several advantages, but there is inertia in the start-up process due to the large organization." By fostering a culture of openness and

collaboration, healthcare organizations can facilitate the integration of AI tools and ensure that they are used effectively.

The **Regulatory Factor** dimension addresses the legal and ethical frameworks necessary to support AI integration in healthcare. This dimension includes the themes of Ethics and Privacy. Ethical concerns are essential in healthcare, where AI decisions can have significant consequences for patient care. The development and deployment of AI tools must adhere to strict ethical guidelines to ensure that they are used responsibly. One interviewee noted, "The AI Act is very important because it defines ethical boundaries; it’s an act that establishes a regulation strategy." This underscores the need for clear ethical guidelines to govern the use of AI in healthcare. Another expert stated “In healthcare, you can’t afford to make mistakes with AI. The consequences are too great, which is why ethical guidelines must be strictly followed.” The AI act and similar regulatory frameworks are designed to ensure that AI tools meet stringent ethical criteria before they are used in clinical settings.

Bias prevention is another critical aspect of the Ethics theme. If the data used to train the model are biased, the decisions that the model take as well, and this can lead to inequitable healthcare outcomes. “Bias in AI is a major issue, especially in healthcare, where it can exacerbate inequalities. We need to be very careful with the data we use”. This highlights the need for rigorous data curation and model validation processes.

Model explainability is also a key concept. Explainability is not a purely technological issue, instead it invokes a host of medical, legal, ethical, and societal questions that require thorough exploration. As AI models can take decisions that impact on patient outcomes, it is necessary that healthcare professionals understand what is behind this decision-making process.

The privacy theme includes the protection of patient data in the context of AI integration. First, the importance of GDPR has been repeatedly emphasized during interviews for what concerns protecting patient data. One interviewee mentioned, "Privacy in Europe is governed by GDPR, which requires informed consent and ensures that patient data is used responsibly."

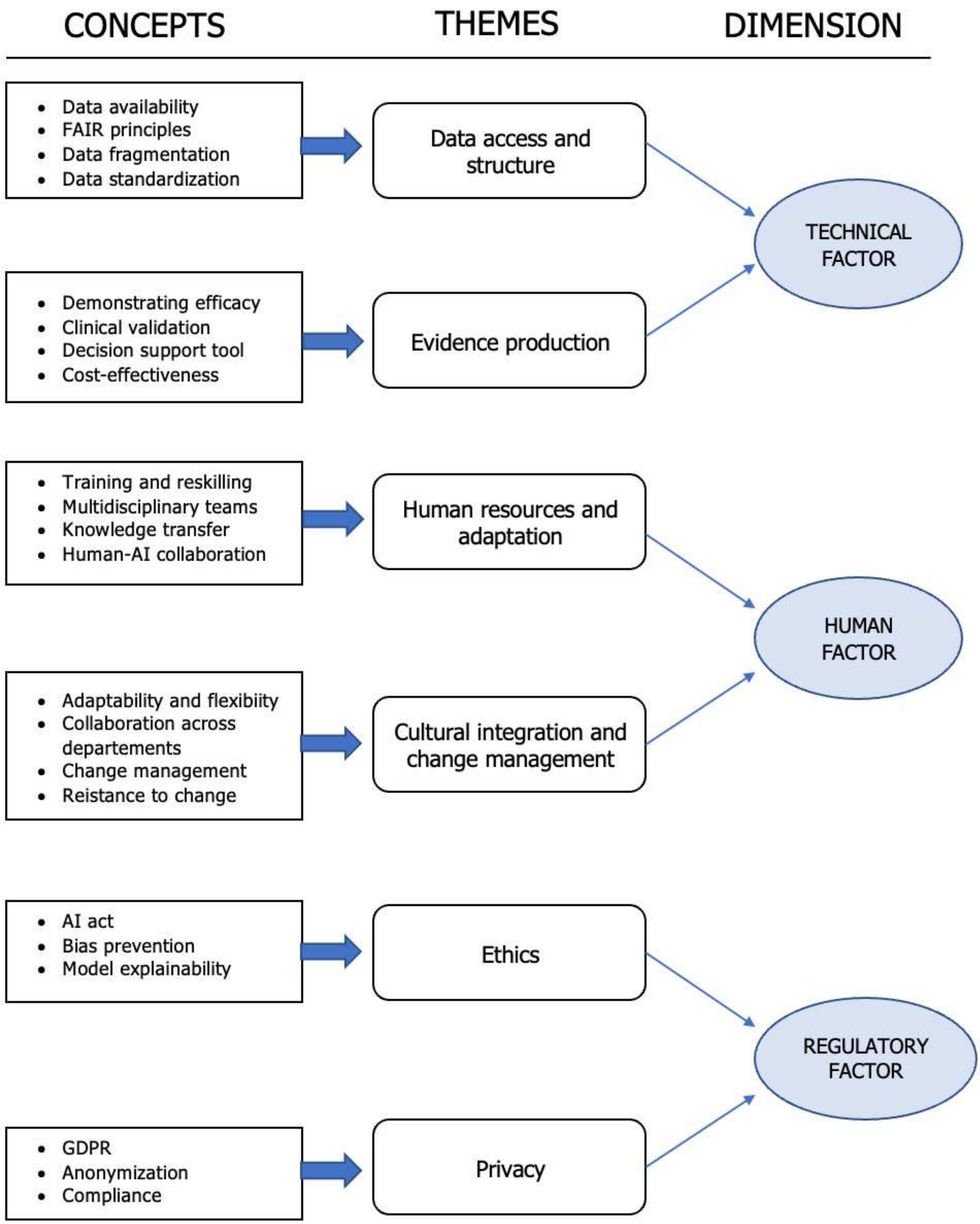
Anonymization is another critical component of the Privacy theme. Ensuring that patient data is anonymized before being used in AI models is essential to protect patient identities. One expert explained, "Anonymization is key to using data ethically and legally." However, anonymization also comes with challenges. As another interviewee pointed out, "While anonymizing data is essential, it can sometimes reduce the richness of the data, making it less useful for certain types of AI models."

Data security is also an important subcategory within regulatory factors as it is essential to protect patient data from cyber threats and unauthorized access. One interviewee stated, "Data security is a top priority; we must ensure that AI systems are protected against cyber threats." Another expert noted "The more data we collect, the greater the risk, which is why security measures must be continuously updated and strengthened", demonstrating the need for robust security protocols to safeguard sensitive health information.
The Regulatory Factor dimension highlights the need of the development of a regulatory framework that encompasses ethical, privacy and legal aspects. As one interviewee strongly stated, "AI has the potential to revolutionize healthcare, but only if we approach it with caution and a strong ethical framework." This is a necessary foundation to harness the full potential of AI in healthcare.

Overall, the framework presented the enabling factors necessary to successfully integrating AI into healthcare. Through the analysis of the interview conducted, I have identified three main dimensions to summarize these enabling factors:

- Technical Factor: including data access and structure and the production of evidence, both in terms of efficacy and cost-effectiveness.
- Human Factor: referring to the reskilling of people inside organizations as well as the culture to embrace the changes driven by new technologies.
- Regulatory factor: encompassing the need for a strong and clear guidance regarding ethical and privacy considerations.

Figure 11: Framework of interview results



Source: self-elaboration

5. DISCUSSION

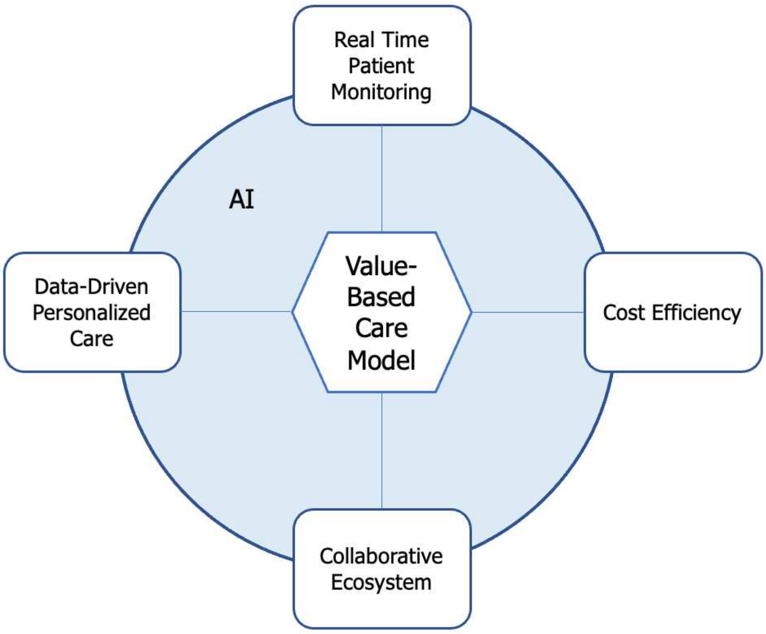
The present study has identified three key factors necessary to successfully integrate artificial intelligence in the healthcare sector: technical, human, and regulatory factors. These factors emerged as common elements across the interviews conducted with key opinion leaders and were further highlighted by the case studies presented. In particular, the cases demonstrated that AI can be leveraged not only to improve clinical outcomes but also to achieve strategic goals of organizations, contributing to innovation and competitive advantage.

The implementation of AI within healthcare institutions represents not only a technological aspect but also a fundamental change in the business model and strategies of these organizations. Patient centricity and collaborative mindset are the two main directions pushed by the integration of AI into healthcare. This transformation aligns with the transition to Value-Based Care (VBC) model, which prioritizes patient outcomes and care quality over service volume and represents a collaborative and patient-centered model.

AI-driven digital transformation is a key enabler in the shift towards VBC. AI capabilities, in particular predictive analytics, real-time decision making, and personalized medicine, directly support the transition VBC, which means the transition from traditional fee-for-service models to models that emphasize patient outcomes. Moreover, as previously highlighted in this work, AI's ability helps improve overall care quality and operational efficiency.

The shift towards the VBC model is also in line with a move towards a digital business strategy where AI and other digital tools generate a strong change in organizations. Traditional functional areas are transcended by AI and digital tools, moreover cross-functional collaboration becomes a critical element. In this new business model, the main element is the centrality of patients, with stakeholders, including providers, payers, and technology companies, collaborating and sharing knowledge with each other. The collaborative approach represents the second critical component of the VBC model, and also in this sense, AI tools can empower the collaboration between stakeholders enhancing communication. In this view, the adoption of AI in healthcare also supports the shift in digital business strategies where value is created through multi-sided platforms and ecosystems where data, insghits, and resources are shared across the network.

Figure 12: Value-Based Care model



Source: self-elaboration based on Bohnsack (2024)

Figure 12 offers a visual representation of how AI supports the development of Value-Based Care (VBC) model, where the central element is to improve value for patients.

First, the ability of AI to analyze large datasets, based on the specific characteristics of patients, could allow the development of personalized care and tailored medical treatments, aligning with the goal of enhancing health outcomes. Moreover, the processing of continuous patient monitoring through the collection of real-time data collection, enables timely interventions, thus improving care quality and reducing readmissions.

In value-based model patient value is measured by:

$$Patient\ value = \frac{patient\ relevant\ outcomes}{cost\ for\ patient\ to\ achieve\ these\ outcomes}$$

Thanks to better resource allocation, workflow optimization, and reduced waste, AI also plays a crucial role in improving cost efficiency. Therefore, by reducing the cost for the patient, the patient value consequently increases for the same.

Last, the collaboration between stakeholders is enabled by AI; healthcare providers, technology partners, and patients work together by providing platforms where data and knowledge are exchanged, fostering open innovation.

Overall this framework summarizes how AI acts as a strategic enabler for healthcare organizations to shift towards Value-Based Care models.

Some concrete examples of how AI is an important factor in the transition to Value-Based Care model are already present and have been mentioned during this study.
Azimuth integrate data from various sources and implement an AI model to monitor patient based on real-world data. This perfectly aligns with VBC's principles, as it reduces the cost of emergency interventions and improves clinical results. Overall, it leads to a better experience for patients. Similarly, Virtual Ward allows for monitoring the patient after discharge from the hospital, so it reduces complexities after surgeries. Therefore also in this case, a reduction in costs of readmissions is achieved, together with optimization of resources, finally leading to better outcomes and increased value for patients, aligning with VBC objective.
At the same time, some potential challenges and resistance to this business model transformation can be identified. This change in business model can bring a general resistance to change which is linked to different aspects. First, the transition from a fee-for-service model, where payments are based on volume, to VBC, where clinical outcomes are the main driver, and measuring clinical outcomes is not always easy. Therefore this can create a misalignment of financial incentives. Moreover, the implementation of AI solutions also entails new revenue streams, like the possibility to monetize data from patients or results from research projects with partners, which are therefore different from the previous one.

There are some limitations to this study. First, the reliance on qualitative data from interviews and case studies may introduce bias because the point of view of the interviewees may not fully represent the healthcare sector; also this type of qualitative research, on one hand allows to gathering deep, context-specific insights, on the other hand there is the problem of subjective interpretations. This limitation may therefore limit the generalizability of the findings. Moreover, the focus of the study on European and Western healthcare institutions may limit the results in other systems, with different structural, cultural, and normative characteristics.
Second, the rapid evolution of AI as a disruptive technology means that its impact is continuously evolving, making it difficult to capture its full effect. As a consequence, the full impact of AI may not yet be realized so the long-term implications remain uncertain.
Future research could consider to testing and validating empirically the framework developed; this would strengthen the validity of the factors identified and the possibility of applying the framework in real contexts. Quantitative approaches could be used to validate the identified factors, as well as the use of longitudinal studies, given the evolving nature of AI, to understand how technologies need to adapt over time to remain relevant.

CONCLUSIONS

The healthcare sector's objective is to reach the best patient outcome, however different challenges are faced nowadays, including high costs and inefficiencies. In this scenario, Artificial Intelligence represents a disruptive phenomenon that can help overcome these issues. AI has the potential to transform the healthcare sector as it has a broad range of applications and finally results in business implications. The goal of the present study hence is to explore the ways in which AI can be successfully integrated into healthcare, identifying the key factors that enable the effective integration of AI technologies, and finally how effective integration can drive changes in business models and strategies.

First, through an extensive review of scientific journals, the study highlights three main areas of applications and the impact of AI utilization in these areas. Starting from clinical research, AI facilitates target identification therefore accelerating drug discovery; in clinical research, AI has strong impacts on diagnostic accuracy and enhances personalized medicine, through the identification of specific markers; finally, regarding patient monitoring AI devices enable real-time data collection allowing for prompt interventions and improved patient outcomes.

The study employed a qualitative inductive research approach, analyzing case studies and in-depth interviews with industry experts to explore the integration of AI in healthcare. Based on the analyses, a framework was developed to understand the key enabling factors for the successful integration of AI into healthcare. These have been categorized under three major dimensions, namely: technical, human, and regulatory. The technical dimension refers to the need for robust data, both in terms of quantity and quality, and the production of scientific evidence to validate the effectiveness and cost-efficiency of AI. The human dimension focuses on workforce and organizational culture, highlighting the importance of reskilling professionals, along with cultural openness to technological change. Lastly, the regulatory dimension, is about responsible and fair use of AI, emphasizing the necessity for clear ethical guidelines and data privacy protections.

The analysis conducted underscores how AI also drives a fundemental shift in healthcare business models towards more patient-centered and collaborative approaches. The transition to Value-Based Care (VBC), which prioritizes patient outcomes over service volume, is strongly supported by AI capabilities. Moreover, AI enhances the collaboration among stakeholders in the healthcare ecosystem, therefore favoring the shift in digital business strategies where value is created through open innovation and collaborative ecosystems.

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