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Exploring the impact of EU tendering operations on future AI governance and standards in pharmaceuticals

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ABSTRACT

This research examines the incorporation of artificial intelligence (AI) into the domain of tender management (TM) within the pharmaceutical industry, with a particular emphasis on operational efficiency, governance, and compliance with European regulatory standards. A comparative analysis of four companies—two that have adopted AI and two that have not—reveals significant discrepancies in the management of TM processes between AI-driven and traditional companies.

The study employs the Delphi method to ascertain expert consensus on eight critical areas of AI governance, including data privacy, transparency, and ethical AI use. The findings indicate that companies integrating AI demonstrate enhanced decision-making capabilities, accelerated processing times, and enhanced stakeholder engagement. However, they also encounter challenges pertaining to ethical governance and regulatory compliance.

The research highlights the necessity of aligning the adoption of AI with the latest European directives, such as the AI Act and General Data Protection Regulation (GDPR), to ensure both operational efficiency and adherence to ethical standards. The broader implications of the study underscore the necessity for pharmaceutical companies to develop robust governance frameworks, prioritize ethical considerations, and maintain regulatory compliance to fully leverage the potential of AI. Additionally, the study contributes to the ongoing scholarly discourse by providing empirical evidence on the interplay between AI, ethics, and governance, thereby encouraging further interdisciplinary research. This work emphasizes the critical role of strategic AI adoption in maintaining competitive advantage while safeguarding societal trust and adhering to legal requirements.

1. Introduction

The incorporation of artificial intelligence (AI) into a multitude of industries has emerged as a transformative force, redefining operational processes, decision-making paradigms, and governance structures. Among the sectors most significantly impacted is the pharmaceutical industry, where the potential of AI to optimize tender management (TM) processes has attracted considerable attention. TM represents a pivotal aspect of pharmaceutical operations, encompassing the procedures through which companies respond to tenders issued by governmental and healthcare organizations for the provision of medicines and associated products (Vallentin, Thórisson, Latapie, 2023). The growing intricacy of the tendering process, coupled with the rigorous regulatory framework that governs the pharmaceutical industry, underscores the need for novel strategies that can boost efficiency while upholding compliance. AI, with its capabilities in data analysis, predictive modeling, and process automation, presents a promising solution to these challenges (Javaid, Haleem, Singh, 2023).

The implementation of AI in TM processes is expected to yield several advantages, including enhanced precision in bid formulation,

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optimized decision-making through predictive analytics, and more efficient operations that reduce the time and resources necessary to respond to tenders (Wamba, et al., 2023). However, the integration of AI also gives rise to significant questions pertaining to governance, ethics, and compliance, particularly in view of evolving regulatory frameworks such as the European Union's AI Act and the General Data Protection Regulation (GDPR). These regulations underscore the necessity for companies to implement AI in a manner that upholds ethical standards, protects data privacy, and ensures transparency in decision-making processes (Eager & Brunton, 2023).

As AI systems become more integrated into critical decision-making processes, concerns about bias, fairness, and accountability have become increasingly prominent. In the pharmaceutical industry, these concerns are particularly acute due to the direct impact that AI-driven decisions can have on public health outcomes. For example, an AI system used to prioritize tenders may inadvertently favor certain suppliers over others due to biased algorithms, potentially leading to unequal access to essential medicines (Jalil, et al., 2023). Thus, as pharmaceutical companies increasingly utilize AI to gain a competitive advantage in the tendering process, it becomes imperative to comprehend how these technologies can be integrated with both business objectives and regulatory requirements (Lee, 2023).

Despite the acknowledged potential of AI in TM, the literature indicates a dearth of empirical studies that critically evaluate the impact of AI on governance and compliance in the pharmaceutical industry. While numerous studies have examined the operational advantages of AI, such as enhanced efficiency and reduced costs, comparatively little attention has been devoted to the governance challenges and ethical considerations associated with AI integration (Dwivedi, et al., 2021). This discrepancy is especially pronounced in the context of pharmaceutical tenders, where the consequences are significant due to the sector's rigorous regulatory framework and the direct impact of tender outcomes on public health (Simoens & Vulto, 2021). It is therefore imperative that research be conducted to evaluate the operational effectiveness of AI in TM; while also examining the way these technologies interact with existing governance frameworks and regulatory standards (Dillard-Wright & Shields-Haas, 2021).

The integration of AI into the domain of pharmaceutical tendering processes presents a significant opportunity for the enhancement of operational efficiency and competitiveness. Nevertheless, this opportunity is accompanied by considerable challenges, particularly in the areas of governance, ethics, and regulatory compliance. (ElBaih, 2023).

This research project aims to address this gap by providing a comprehensive analysis of the integration of AI in pharmaceutical tendering processes, with a specific focus on the governance, legal, and ethical implications. The objective of this research is to contribute to the broader understanding of the role of AI in the pharmaceutical industry and to provide actionable insights for companies navigating the complexities of AI adoption. To this end, the research is guided by two primary questions: (1) how does AI improve the pharmaceutical TM process? (2) What are the critical areas for effective AI implementation programs related to TM governance, legal, and compliance issues?

To achieve these objectives, the study employs a comparative case study approach, in which four pharmaceutical companies are analyzed and 53 involved participants in interviews and Delphi rounds. Two of these companies have integrated AI into their TM processes (Companies A and B), while the other two have not (Companies C and D). This comparative analysis permits a detailed examination of the distinctions between the governance and compliance practices associated with AI-driven and traditional TM approaches. Furthermore, the Delphi method is employed to ascertain expert perspectives on pivotal aspects of AI governance, including data privacy, transparency, and ethical AI utilization. The Delphi method provides a structured process for reaching consensus among experts, thereby ensuring that the findings are grounded in practical, real-world experiences.

This research makes a significant contribution to the field by examining the intricate relationship between AI and governance in the pharmaceutical sector. In this context, governance is defined as the systems, processes, and structures that guide the ethical and responsible use of AI technologies within organizations. Effective governance is a crucial element in ensuring that AI is deployed in a manner that aligns with both organizational objectives and societal expectations. However, the accelerated rate of technological evolution presents considerable obstacles for governance frameworks, which must evolve to address novel risks such as data privacy breaches, algorithmic bias, and the dearth of transparency in AI-driven decision-making.

The findings of this study can contribute to several key areas of scholarly and practical interest. First, the research will provide empirical evidence on the effectiveness of AI in enhancing TM processes, offering insights into how AI can be leveraged to improve accuracy, efficiency, and stakeholder engagement. Secondly, the study will identify the critical areas of AI governance, thereby highlighting the challenges and opportunities associated with AI adoption in a highly regulated industry. This includes an examination of how companies can align their AI strategies with regulatory standards such as the AI Act and GDPR, thereby avoiding potential legal and ethical pitfalls. Third, the study will explore the broader implications of AI integration for the pharmaceutical industry, including its impact on competitive dynamics, regulatory compliance, and public trust.

2. Theoretical framework

2.1. Life Sciences, Pharmaceuticals, and biotechnology – current State, Trends, and research gaps

The life sciences, pharmaceutical, and biotechnology sectors represent a dynamic and rapidly evolving landscape, where the convergence of scientific innovation and technological advancement is driving profound changes. These industries are at the vanguard of developing novel therapies and drugs that address a plethora of health challenges, with the pharmaceutical industry playing a pivotal role in translating biomedical research into efficacious treatments (Chen, Peng, Lu, 2019). This role was brought into sharp focus during the global pandemic, which served to illustrate the industry's capacity for rapid innovation in the face of considerable time constraints. The rapid response to the novel coronavirus, characterized by accelerated research, clinical trials and regulatory approvals, demonstrated the sector's capacity to meet unprecedented demands for speed and efficiency while navigating the complexities of global healthcare needs (Kotcher et al., 2021).

The nexus of life sciences, pharmaceuticals, and biotechnology is distinguished by a relentless pursuit of innovation, which has opened new avenues for research, entrepreneurship, and investment. This convergence has been driven by advancements in biotechnology, which have expanded the possibilities for developing biological products, including vaccines, blood components, and recombinant proteins (Mostafiz et al., 2022). These biologics are derived from natural sources and produced using sophisticated biotechnological processes, which positions them at the forefront of biomedical research (Sturm, et al., 2020). In contrast to chemically synthesized drugs, which possess well-defined molecular structures, biologics are intricate mixtures that necessitate meticulous and regulated manufacturing processes to guarantee their safety and efficacy. The sensitivity of these products to environmental conditions, such as heat, and their susceptibility to microbial contamination necessitate the use of aseptic production techniques. This makes the development and manufacturing of these products both challenging and critical (Gebhardt, et al., 2022).

The development and manufacture of biological products often entail higher costs than that of synthetic drugs. However, these products offer the potential for personalized medicine, which is an approach that tailors treatments to individual patients based on genetic, environmental, and lifestyle factors. This personalization holds the potential to enhance treatment efficacy and patient safety, representing a significant

shift in the design and delivery of therapies. As the demand for biologics continues to grow, driven by their potential to address unmet medical needs, the life sciences and pharmaceutical industries are becoming increasingly reliant on technological platforms (Pesqueira et al., 2020). These platforms, which encompass advanced data analytics, machine learning (ML), and AI, are effecting profound transformations in the processes of drug discovery, development, and distribution. However, the advent of these technologies also gives rise to novel challenges, particularly in domains such as data privacy, cybersecurity, and regulatory compliance, especially considering the enforcement of data protection laws like the GDPR in Europe (Ullah, et al., 2023).

The reliance on advanced technological platforms in these industries has significant implications for employment, as the demand for specialized skills in data science, bioinformatics, and digital health continues to grow. Furthermore, the globalization of pharmaceutical research and development, frequently involving the outsourcing of pivotal functions, further complicates the landscape (Dash et al., 2019).

Although outsourcing can result in cost savings and expedited completion of projects, it also gives rise to concerns pertaining to data security, intellectual property protection, and the quality of outsourced work. The increasingly stringent data privacy regulations, exemplified by the GDPR, introduce another layer of complexity for companies, who must navigate these laws while maintaining the flexibility and speed needed to innovate (Heinonen & Strandvik, 2020).

In the European context, these trends are particularly relevant about the tendering process in the pharmaceutical industry, especially in the context of biosimilar, vaccines, and biologics. The European tendering system plays a pivotal role in guaranteeing that healthcare providers can obtain essential medicines at competitive prices. However, it is also subject to the overarching dynamics of the pharmaceutical market (Prasert et al., 2022). As the industry undergoes transformation, there is a compelling necessity for tendering strategies that are adaptable and cognizant of these changes (Heinonen & Strandvik, 2020). It is imperative to conduct a thorough examination of the impact of technological advancements, regulatory shifts, and market competition on the tendering process to guarantee the continued efficacy and sustainability of procurement strategies. Future research should concentrate on elucidating the way these trends impact tendering outcomes and market dynamics, with the objective of enhancing healthcare procurement strategies in Europe (Jiang et al., 2021).

Despite the considerable advances made in the life sciences, pharmaceuticals, and biotechnology, there remain significant research gaps that require further attention. One of the most crucial areas of investigation is the function of AI in the field of pharmaceutical TM. Although AI has the potential to transform TM by improving efficiency, accuracy, and decision-making, there is a dearth of empirical research on its long-term impact, particularly about governance and ethical implications (Vlasta, 2023). The accelerated integration of AI technologies into the domain of pharmaceutical TM gives rise to several concerns pertaining to data privacy, algorithmic bias, and the transparency of AI-driven decision-making processes. These concerns are particularly pertinent considering the sensitive nature of pharmaceutical data and the potential consequences of biased or opaque decision-making processes (Eager & Brunton, 2023).

Extant literature frequently concentrates on the operational advantages of AI in the context of TM, including the reduction of costs and the acceleration of the tendering process. Nevertheless, there is a dearth of rigorous examination of the far-reaching ramifications of AI implementation. Specifically, further research is required to elucidate the impact of AI on governance structures within pharmaceutical companies, its influence on decision-making at diverse organizational levels, and its interplay with extant regulatory frameworks. Furthermore, the ethical implications of AI in TM—such as ensuring fairness, accountability, and transparency—are insufficiently addressed in the current literature. These gaps underscore the necessity for a more comprehensive approach to studying AI in pharmaceutical TM, one that encompasses not only the technological and economic aspects but also the ethical and governance challenges (Jalil, et al., 2023).

Moreover, the literature demonstrates an increasing acknowledgment of the necessity for adaptive governance frameworks that can maintain alignment with technological advancements. As AI becomes more integrated into TM processes, traditional governance models may no longer be sufficient to address the complexities of AI-driven decision-making (Pettersen, Nyland, Robbins, 2020). There is a pressing need for governance structures that are flexible, responsive, and capable of managing the risks associated with AI, including data breaches, algorithmic bias, and the erosion of stakeholder trust (Barbier, et al., 2021).

Further research is required to ascertain how these adaptive governance frameworks can be developed and implemented in the pharmaceutical industry, with a particular focus on achieving a balance between innovation and ethical and regulatory considerations. The life sciences, pharmaceutical, and biotechnology sectors are undergoing significant transformations driven by advancements in technology and evolving regulatory landscapes (Ball, 2021). While these changes offer numerous opportunities for innovation and growth, they also present new challenges, particularly in the areas of governance, ethics, and regulatory compliance. The extant literature offers valuable insights into the operational benefits of AI and other technological platforms. However, there is a clear need for more in-depth studies that address the broader implications of these technologies. By focusing on the intersections of AI, governance, and ethics, future research can contribute to the development of more effective and responsible practices in pharmaceutical TM, ultimately benefiting both industry stakeholders and society (Kouba, et al., 2023).

2.2. *Generative artificial intelligence in pharmaceuticals*

The integration of large language models (LLMs) and AI models such as generative AI (GenAI) in the pharmaceutical and biotech industries has shown significant potential in several pharmaceutical and biotech applications. Deep learning models trained on publicly available data have demonstrated superior predictive capabilities compared to traditional models on internal pharmaceutical industry datasets (Wamba, et al., 2023). This includes identifying specific needs for biological products based on public health goals, demographics, and epidemiological studies. This highlights the potential of GenAI in areas such as drug target identification. In addition, the applicability of GenAI extends to determining the quantity, type, and delivery schedule of biological products (Ahmed, Mohamed, Zeeshan, Dong, 2020).

In addition, the predictive capabilities of LLMs and GenAI could facilitate the acceleration of drug discovery, potentially reducing the time and cost associated with new drug development. However, significant challenges remain due to the complex nature of biomedical data and the need for accurate models. The trend toward building domain-specific GenAI models that address the unique needs of these industries is likely to increase. This is driven by the need for accuracy and precision (Cifuentes-Faura, 2022).

However, the application of LLMs in specific areas of biotechnology, such as protein engineering and genomics, is still in its infancy. Similarly, the potential of GenAI and LLMs in clinical trial design and personalized medicine has yet to be fully realized. A significant challenge is the ethical and regulatory implications of using GenAI in the pharmaceutical and biotechnology sectors (Eager & Brunton, 2023). As AI models become more prevalent in drug development and patient care, it is critical to address issues of privacy, model transparency, and accountability for decision making. In addition, LLM and GenAI systems require extensive validation and ethical oversight (Kasneci, et al., 2023).

Given the accelerated adoption of GenAI and the current shortcomings in our understanding of its long-term implications and regulatory frameworks, it is imperative to conduct a comprehensive review of this technology at the earliest stages of its development. This is particularly important in the context of compliance with healthcare and privacy

regulations, including the GDPR and other privacy laws. The implementation of AI models in the pharmaceutical and life sciences sectors requires a careful and thorough assessment of the stringent compliance and regulatory requirements, particularly in the areas of security and privacy (Vlasta, 2023).

It is critical to implement robust privacy and security measures, including but not limited to strong encryption, access control, and secure storage solutions, to protect sensitive patient information from unauthorized access and breaches. It is also imperative to de-identify patient data to protect privacy while ensuring that patients and healthcare professionals have provided informed consent. Furthermore, the ethical principles that underpin the design of AI, such as fairness, non-discrimination, and accountability, must be adhered to. In addition, AI models must be regularly reviewed and updated to prevent bias (Vallentin, Thórisson, Latapie, 2023).

As highlighted by Eager and Brunton, it is incumbent upon pharmaceutical and biotechnology companies to conduct regular audits and compliance reviews of their AI systems. These reviews must include data handling, decision-making processes, and system security. It is paramount to establish transparent data governance policies that comply with regulatory requirements and industry best practices. Working with healthcare regulators and compliance experts facilitates compliance with current and emerging regulations. Defining the scope of AI applications, particularly in high-stakes areas such as diagnosis and treatment recommendations, to ensure appropriate use and compliance with regulatory boundaries becomes extremely important (Eager & Brunton, 2023).

Further research is needed to address these challenges and explore new applications of GenAI in biotechnology and pharmaceuticals, paving the way for more sophisticated and personalized healthcare solutions. Taken together, these areas form the crux of the discussion around the integration of AI in European tenders, highlighting the importance of ethical practices, regulatory compliance, and the alignment of AI advances with industry-specific needs, as shown in Table 1.

2.3. Pharmaceutical and biotechnology tendering management in Europe – Focus on Biosimilar, Vaccines, and biologic products

Post-Covid-19, the procurement of new pharmaceutical and biotechnological products such as vaccines has become a focal point for various European regional and local government bodies. The production of these biological products, which are highly regulated and prone to disruption, is influenced by demand as well as the clarity and reliability of evaluation and procurement procedures (Eager & Brunton, 2023). Discussions in European policy circles are currently focusing on the use of joint procurement bodies to ensure an equitable distribution of these biological products across EU member states. A key concern is maintaining a balance in vaccine availability between smaller and economically stronger EU countries, which underscores the need for a transparent, predictable, and supportive procurement process (Simoens & Cheung, 2020).

Reforming the procurement process requires a focus on assessing the value and quality of vaccines, prioritizing the primary health goal of improving well-being over reducing costs. The economic and medical benefits and costs of pharmaceutical products must be evaluated equally on a cost-benefit basis. Tendering, or the procurement of pharmaceuticals through competitive TM, is an increasingly common strategy for managing healthcare costs. The dynamic landscape of life sciences, pharmaceuticals and biotechnology requires a flexible approach to tendering. In addition, navigating regulatory changes and global industry shifts is critical, as is understanding the role of collaborations and partnerships in driving innovation for effective tendering strategies for biosimilar and biologics (Frieden et al., 2019).

The Covid-19 pandemic underscored the importance of these processes in the context of national immunization strategies, emphasizing systematic development and funding. Understanding the broader societal value of vaccines, including their impact on productivity, supports immunization coverage. Most current EU immunization programs focus on children, and adult immunization is often associated with individual risk and cost, which highlights health and socio-economic inequalities. New technologies, such as digital vaccination cards, are being explored to increase vaccination awareness and coverage (Miller, et al., 2019).

The environment for vaccine research needs to be decisively developed, with a focus on improving the predictability and transparency of evaluation and approval processes. Reforming the procurement and tendering process to make new vaccine innovations available at the national level is a complex undertaking. Funding for immunization programs should be contextualized within the broader health budget. Investments and incentives for prevention, including vaccines, are critical to maintaining health, well-being and productivity. Delays in making new vaccines widely available result in lost health benefits and reduced productivity, highlighting the need for increased and sustained funding for both childhood and adult immunization programs commensurate with their preventive benefits (Simoens & Cheung, 2020).

However, research gaps remain, particularly in the tendering of biologics and biosimilar in Europe. The complexity and high development costs associated with these products warrant more focused research. In

Table 1
AI applications in pharmaceutical tendering and governance.

Use Case – Application	Key Research Areas	Description/Findings	References
Drug Target Prediction	Deep Learning, Predictive Modeling	Deep learning models trained on public data maintain predictive power and outperform comparable models in internal pharmaceutical datasets.	(Pettersen, Nyland, Robbins, 2020; Javaid, Haleem, Singh, 2023; ElBaih, 2023)
Biomedical Text Mining	Natural Language Processing, Biomedical Data Analysis	Performance in generating accurate biomedical sentences.	(Javaid, Haleem, Singh, 2023; ElBaih, 2023; Eager & Brunton, 2023)
Ethical and Regulatory Implications	Ethics, Regulatory Compliance	Addressing data privacy, model transparency, and decision-making accountability in the use of LLMs in pharmaceuticals and biotechnology.	(ElBaih, 2023; Eager & Brunton, 2023; Jalil, et al., 2023)
Drug Discovery Processes	AI in Drug Discovery, Model Predictive Capabilities	LLMs and GenAI can accelerate drug discovery processes, potentially reducing time and cost for new drugs.	(Eager & Brunton, 2023; Jalil, et al., 2023; Kasneci, et al., 2023)
Personalized Medicine	Clinical Trial Design, Patient Data Analysis	Integration of LLMs in clinical trial design and personalized medicine, focusing on patient-specific treatment outcomes.	(Dillard-Wright & Shields-Haas, 2021; Ball, 2021; Sturm, et al.,2020; Chen, Peng, Lu, 2019)
Protein Engineering and Genomics	Bioinformatics, Genomic Data Analysis	Application of LLMs in specific areas like protein engineering or genomics is emerging, with potential for significant advancements.	(Ahmed, Mohamed, Zeeshan, Dong, 2020; Wamba, et al.,2023; Vallentin, Thórisson, Latapie, 2023)
Clinical Decision Making	Healthcare AI, Clinical Data Analysis	Potential use of LLMs in improving clinical decision-making processes, requiring validation and ethical oversight.	(Kouba, et al.,2023; Cifuentes-Faura, 2022; Kotcher et al., 2021; Mostafiz et al., 2022)
Data Privacy and Model Transparency	Data Ethics, AI Transparency	Addressing concerns related to data privacy and transparency of AI models in pharmaceutical and biotechnology applications.	(Cifuentes-Faura, 2022; Kotcher et al., 2021; Mostafiz et al., 2022; Gebhardt, et al.,2022)

addition, the impact of tendering on market competition and innovation in the biotechnology sector, particularly for biosimilar and vaccines, is an under-researched area. The literature generally agrees that tendering can reduce direct costs and encourage generic prescribing. However, the complexities of tendering biologics and biosimilar due to their manufacturing and regulatory nuances or technological influence are less explored. Decision support tools in the tendering process have been highlighted as beneficial, particularly for biologics and biosimilar (Javaid, Haleem, Singh, 2023).

Electronic tendering and digital platforms are emerging as key tools to increase transparency and efficiency in the tendering process, especially in terms of their potential to reduce costs. This is particularly relevant in Europe, where digital transformation is emphasized. The European market, with its diverse healthcare systems and regulatory frameworks, presents unique challenges for tendering biosimilar, vaccines and biologics. The World Health Organization (WHO) tendering model may provide valuable guidance to European policymakers in balancing quality and cost (World Health Organization, 2019).

However, the impact of TM on market competition and innovation in the European biotechnology sector requires careful consideration. The effectiveness of tendering in addressing high drug prices and corruption is limited and should be seen as an interim measure alongside broader reforms of pricing methodologies. Key factors such as generic status, alternative types of tenders and high volumes have a significant impact on reducing drug prices (Kouba, et al., 2023).

2.4. Human factor in AI adoption

As AI becomes increasingly integrated into industries such as pharmaceuticals, it is imperative to recognize the crucial role of human involvement in ensuring successful adoption and implementation of AI-based technologies. Although AI tools offer substantial benefits in processing vast quantities of data, optimizing decision-making processes, and enhancing operational efficiency, human expertise remains indispensable in contextualizing AI outputs, formulating strategic decisions, and guaranteeing the ethical and transparent utilization of these technologies.

Recent research underscores the indispensable role of human judgment and oversight, particularly in sectors such as healthcare and pharmaceuticals, where decisions can have direct implications for public health. For example, a study conducted by Dwivedi et al. (2021) demonstrated that while AI has the potential to significantly reduce operational inefficiencies, its integration is most effective when combined with human input in areas such as strategic decision-making, governance, and compliance. The capacity of AI to furnish predictive insights and automated processes should be augmented by human-driven interpretation and ethical oversight to address challenges such as bias and transparency (Hao, Demir, Eyers, 2024).

Furthermore, it is erroneous to assume that AI will replace human creativity, judgment, or emotional intelligence. Rather, it is more accurate to assert that AI will augment these qualities. The integration of AI necessitates novel forms of collaboration between humans and machines, with a particular emphasis on the evolving role of humans as supervisors of AI systems. Furthermore, as AI systems become more autonomous, it is imperative that they are monitored and regulated by humans to ensure that they operate within ethical and legal boundaries. Employees must be trained and upskilled to interact effectively with AI tools, enabling them to utilize the capabilities of AI while mitigating its limitations (Singh & Chouhan, 2023).

These perspectives are particularly relevant in the context of pharmaceutical TM, where AI tools can automate large portions of the tendering process. However, human expertise is essential to interpret AI-generated recommendations, adjust for contextual nuances, and ensure that strategic and ethical considerations are maintained. Without effective human oversight, the risk of AI systems perpetuating biases or making suboptimal decisions based solely on historical data increases, potentially leading to unethical or inefficient outcomes (Ferrara, 2024).

3. Methodology

3.1. Methodological approach overview

The objective of the research was to examine the differential impacts of AI adoption by investigating four companies, two of which have incorporated AI into their TM operations and two of which have not. This approach allowed for a comprehensive and detailed examination of the impact of AI on tendering processes, governance structures, and ethical considerations, facilitating a nuanced understanding of the challenges and opportunities presented by AI-driven versus traditional methods. The case study method serves as the cornerstone of this research, facilitating an exhaustive examination of the internal and external dynamics within each organization. By comparing companies that have integrated AI with those that have not, the research aimed to identify the key drivers of effective AI implementation and the resulting impacts on governance and ethical frameworks (Ebrahimi & Bridgelall, 2021).

The organizations included in this study were selected based on specific criteria, including their market position, scale of operations, and the maturity of their AI adoption. The data collection for these case studies was conducted using a multi-faceted approach, which included semi-structured interviews with key decision-makers, direct observation of TM processes, and a comprehensive document analysis of internal reports and tender documentation. This approach permitted a detailed examination of the impact of AI on decision-making, process efficiency, and compliance within TM, as well as the challenges and ethical considerations that arise during AI implementation. Furthermore, the case studies were enhanced by the incorporation of management team discussions and real-time observations of AI's role in tendering, which provided practical insights into the interplay between technology and human factors in a high-stakes environment. The sample of participants included 53 subject matter experts, representing a diverse range of roles and backgrounds. The participants were selected from a variety of organizational levels to ensure a comprehensive understanding of the integration of AI within TM processes. A further key element of this study was the use of the Delphi technique, which is a structured method for achieving consensus among a panel of experts through iterative rounds of surveys. The Delphi technique served to complement the case study analysis, validating and refining the findings to ensure that the conclusions drawn are both empirically grounded and widely applicable across different organizational contexts (Noori et al., 2020).

Following the case study analysis, the Delphi technique was employed to validate and refine the findings. This iterative process involved the same number of experts from the interviews with extensive experience in AI, pharmaceuticals, and tendering processes. The rounds were designed to elicit expert judgments on critical aspects of AI governance, such as data privacy, algorithmic transparency, and the ethical implications of AI-driven decision-making in TM. In each round, experts were requested to evaluate scenarios and outcomes derived from the case studies, with their feedback being employed to refine and enhance subsequent rounds (Ebrahimi & Bridgelall, 2021).

One potential limitation of this study is the possibility of bias introduced by the respondents' affiliation with the companies under investigation, particularly their inclination to justify their company's decisions regarding AI adoption or rejection. This is particularly noteworthy given that 14 respondents were exclusively drawn from Company A, which may have limited the diversity of perspectives in the sample. To mitigate this bias, several methodological strategies were employed. One such strategy was the triangulation of data sources, whereby responses from interviews were cross-checked with documentary evidence, such as performance reports and TM documentation. This approach was taken to ensure consistency between perceived and actual outcomes. Furthermore, the interview questions were designed to

minimize leading responses, focusing on objective outcomes of AI integration rather than subjective opinions about the technology itself. In addition to reducing response bias, future studies should consider employing blind interviews or anonymized surveys, where respondents are unaware of the specific focus of the study, thereby reducing the inclination to confirm their company's strategic decisions.

This approach would facilitate more objective evaluations of the impact of AI on TM processes, irrespective of the respondents' direct involvement in those processes.

The convergence of expert opinions through the Delphi process constituted a robust mechanism for ensuring that the findings were not only empirically grounded but also relevant and applicable across different organizational contexts. This integrated methodological approach facilitated a comprehensive understanding of both the strategic benefits and potential risks associated with the use of AI in the field of TM. It provided practical guidance for organizations and contributed to the broader discourse on AI governance. The combination of case study analysis and the Delphi technique facilitated a comprehensive and multifaceted understanding of the role of AI in the field of pharmaceutical TM. By contrasting the experiences of companies that utilize AI with those that do not, the research offers a comprehensive view of the current state of AI integration in the industry. This dual approach proved particularly effective in addressing the research questions, as it enabled the capture of both the depth of individual organizational experiences and the breadth of expert opinions across the industry (Ebrahimi & Bridgelall, 2021).

Furthermore, the preparation for the case studies entailed the compilation of a comprehensive list of requirements and potential risks associated with the implementation of AI in TM. These risks were classified into categories such as exposure and preparedness, with a particular emphasis on reputational risks resulting from external sources. The case studies were conducted in real time, thereby capturing the evolving dynamics within each organization as they navigated the complexities of AI integration. The objective of the data collection was to gain insight into the synergistic relationship between AI and TM programs. To this end, both exploratory and descriptive approaches were employed to analyze how AI optimizes TM outcomes. This encompassed considerations of both technological capabilities and human behavioral factors, acknowledging that the success of AI-driven TM processes is contingent upon not only the technology itself but also the organizational culture and management practices that facilitate its utilization. Considering the pivotal role of human supervision in AI systems, this study also examined the ways in which companies strike a balance between AI-driven automation and human decision-making. The interviews included inquiries into the way AI tools are augmented by human input, particularly in contexts where ethical judgments, regulatory compliance, and stakeholder engagement are requisite (Hao, Demir, Eyers, 2024).

Each research question was addressed through a variety of data sources, and the integration of qualitative and quantitative data allowed for the identification of key themes and patterns, which were then analyzed in the context of existing academic literature to highlight the study's novel contributions and broader implications. The objective was to utilize AI to optimize TM programs, with a specific focus on elucidating the interrelationship between technological advancements and human and managerial dynamics. Feedback from senior management was instrumental in comprehending these dynamics, as it elucidated their initial expectations, the challenges encountered during AI implementation, and the insights gleaned from these experiences. This feedback proved invaluable in the refinement of business models and operational frameworks, enabling a closer alignment with organizational objectives and enhancing the overall effectiveness of AI-driven TM processes.

The methodological approach of combining comparative case study analysis with the Delphi technique provided a framework for exploring the complex relationship between AI and TM. The dual-method approach allows for a comprehensive understanding of both the technological and human factors that influence the success of AI-driven TM initiatives.

3.2. Review of relevant initiatives

3.2.1. Multinational Corporation partnerships with external vendors – Company A

Company A is a biotechnology company known for developing, manufacturing, and commercializing vaccines for infectious diseases, rare immunological disorders, and cancer immunotherapies. Headquartered in Europe, the company has manufacturing sites in Europe, South America, and India, and major R&D facilities and offices around the world, including Switzerland, Germany, France, Spain, Japan, the United States, Canada, Brazil, and Singapore.

In 2023, the company launched a global program to partner and collaborate with stakeholders in the healthcare and pharmaceutical industries, including consulting firms, technology providers, two universities, and healthcare institutions. This initiative focuses on using AI to create standardized, efficient platforms and processes that improve data integrity, security, and transparency in pharmaceutical supply chains and commercial operations.

A key proof of concept (PoC) project involves AI technology for large-scale review of legal, operational, and strategic documents across multiple countries and products, primarily biologics. The PoC includes all steps related to the tendering process for a portfolio of biological products, with a focus on document review and submission. Key steps include defining actions for tender processing and execution, including governance elements such as pricing, product distribution, logistics, and decision parameters. AI will be tested for document review based on specific parameters, interactive chatbots linking extensive pricing libraries, and various factors such as product availability, distribution capacity, and manufacturing capabilities.

This PoC aims to securely integrate business parameters, a critical aspect in the pharmaceutical industry where data integrity and traceability are paramount. The consortium includes a diverse group of industry experts and professionals to ensure that the solutions developed address a wide range of industry needs. The PoC also focuses on developing standards and practices for data exchange and interoperability to improve data quality and consistency for effective decision making. The goal is to support more efficient decision making, better regulatory compliance, and improved sales and operations planning (S&OP) outcomes, including forecasting analysis and market performance predictions. A sensitive area of the PoC is regulatory and compliance, with the goal of developing internally compliant solutions with global pharmaceutical regulations, data privacy laws, and industry guidelines by the end of 2024. The initiative is also exploring the use of AI to streamline document management, integrate data into decision-making and improve data accuracy, align cross-functional teams, and facilitate timely TM submissions and process monitoring. By enhancing transparency and data integrity, the company aims to empower internal teams by improving their ability to handle tasks such as document translation and review and strengthen their strategic decision-making capabilities. This ongoing PoC is expected to evolve and potentially shape the integration of technology, particularly AI, to address complex challenges in the pharmaceutical industry.

3.2.1.1. Pharmaceutical and biotechnology – Company B. Company B is a pharmaceutical and biotechnology company based in the United States, known for its portfolio targeting major diseases in areas such as oncology, neuroscience, respiratory and inflammation, with a specialization in orphan drugs for rare diseases. This global company, part of a large American conglomerate, operates in more than 35 locations worldwide.

In 2023, the company launched a global program involving a

comprehensive partnership with various stakeholders in the healthcare and pharmaceutical industries. The initiative aims to use AI to create trusted, standardized, and user-friendly platforms and internal processes to improve data integrity, security, and transparency in pharmaceutical supply chains and commercial operations. One notable project within this initiative is using AI for the large-scale review of legal, operational, and strategic documents related to biologic products across multiple countries.

The company is committed to aligning its AI solutions with international pharmaceutical regulations, including DSCSA in the United States and FMD in the EU. This includes adhering to drug traceability, safety, and quality control regulations, with a particular focus on ethical data use and patient privacy in compliance with strict laws such as the GDPR in Europe.

Since August 2023, a major focus has been on using GenAI to verify legal parameters and assist legal teams with administrative tasks. These efforts also include the development of an AI-specific legal framework that addresses cross-border data transfers, data ownership, and liability for data breaches or inaccuracies. Working with regulators is an integral part of creating a compliant and ethical framework.

Another key aspect is establishing standards for AI use cases to ensure interoperability between systems and stakeholders for ethical data exchange. The company is conducting pilot projects to explore the application of AI in various operational aspects, providing insight into the legal and ethical implications and guiding the development of the framework.

In 2024, an AI-based initiative will focus on data privacy, protection, compliance, GxP, and legal issues, aiming to develop comprehensive data governance policies for legal and ethical compliance. The company will also want to ensure that AI solutions are compliant with pharmaceutical regulations and good practices guidelines, with a focus on interoperability for seamless data exchange and collaboration. A deeper analysis, involving IT and commercial operations, reveals challenges with data dependency on external vendors and decentralized data warehouses, and highlights opportunities for reconsolidation and harmonization. Global privacy legislation, such as GDPR, establishes various rights related to personal data. The project's protocols aim to manage these rights and streamline the management of clinical, medical, and operational data while respecting the rights of stakeholders (Vlasta, 2023; ElBaih, 2023; Wamba, et al., 2023).

3.2.1.2. Remaining companies (C and D) – Selected process for analysis. Remaining companies (C and D) are part of the pharmaceutical industry, specifically in the vaccine and biosimilar segments, where tenders are a critical element of market engagement and commercial success. Overall, the two companies have increased their investment in TM operations, notably without incorporating AI. These efforts represent a conventional approach, with no integration of AI into their TM execution, commercial activities, or market access strategies. The identities of these companies are confidential for the purposes of this study. They were selected based on their growing commitment to improving TM management processes. This commitment is evident in two keyways: increasing human resources dedicated to tender-related tasks and strategically expanding their presence in the European tender market. This dual strategy underscores their emphasis on TM as a critical factor in business performance and market penetration. The role of tenders in these companies, especially in the European market, is critical. Tenders serve as the primary mechanism for the procurement of pharmaceutical products, including vaccines and biosimilar, in both the public and private healthcare sectors. They are critical in establishing competitive market positioning and influencing pricing, distribution, and market access strategies. As such, the tendering process of these companies has a significant impact not only on pricing and supply chains, but also on the accessibility and affordability of healthcare, particularly in areas such as cancer immunotherapy and vaccines for diseases such as COVID-19 and influenza.

By choosing a traditional, human-centric approach to TM over AI integration, these companies are demonstrating a remarkable strategic choice. While AI adoption is growing across industries, these companies have chosen to continue without AI in their TM processes. This decision may be driven by a preference for proven human expertise and the perceived risks of AI in critical operations. Their approach suggests a deliberate reliance on human judgment and experience to handle the nuances of TM and negotiation. In the highly regulated and competitive pharmaceutical industry, where tender outcomes have a significant impact on market presence and revenues, the expertise of seasoned professionals provides control and adaptability that current AI technologies may not fully provide. However, this traditional method may have its limitations. Without the analytical power and efficiency of AI, these companies may struggle to process large volumes of data, identify market trends, and quickly adapt to changing tender requirements and competitor strategies. This could impact their ability to optimize bid submissions and secure lucrative contracts in an increasingly digital marketplace. As TM evolves, contrasting traditional methods with AI-driven approaches is likely to provide valuable insights into the effectiveness and adaptability of different strategies in a competitive, regulated market, and influence the future direction of these companies.

3.3. Data gathering scope and procedures

The principal objective of the quantitative data analysis was to ascertain the way AI contributes to the enhancement of the efficiency and advancement of TM programs. This objective was accomplished through the examination of a multitude of documents and notes derived from the interviews. To address the initial research question, "How does AI enhance the pharmaceutical TM process?" data was gathered from the production of project-related documents pertaining to TM operations, in addition to interviews with teams tasked with market access, TM, and IT management. The data collection approach was designed to be multi-pronged to capture a comprehensive view of the impact of AI. The primary data collection techniques employed were semi-structured interviews, document analysis, direct observation, and the examination of quantitative performance data.

In-depth interviews were conducted with senior managers, TM leaders, and IT specialists within the selected companies. The objective of the interviews was to gain insight into the way AI tools are employed in the context of TM, with a particular focus on areas such as bid preparation, risk assessment, supplier evaluation, and compliance monitoring. The questions were constructed to investigate both the perceived advantages and disadvantages of AI integration. The semi-structured format allowed for flexibility in probing more deeply into specific aspects of AI use, as the interviewees shared their experiences and insights. In addition to the qualitative data collected, quantitative metrics were also gathered to assess the impact of AI on operational efficiencies.

The metrics included the number of full-time employees (FTEs) reallocated due to the automation of tender-related tasks and the direct and indirect costs associated with the adoption of AI. The financial analysis incorporated the costs associated with licensing, training, and ongoing maintenance.

Information regarding the supervision of AI was obtained through interviews with IT and compliance teams and included details on the necessity for human oversight in day-to-day operations. This enabled the study to evaluate the overall cost-effectiveness and efficiency gains resulting from the adoption of AI. Subsequently, an analysis was conducted on a range of internal company documents, including tender submissions, AI implementation reports, performance metrics, and workflow diagrams. This analysis yielded concrete evidence of the implementation of AI tools in practical, real-world scenarios and the resulting outcomes. For example, tender documents were examined to assess the accuracy and efficiency of AI-driven decision-making in

comparison to traditional methods, considering variables such as the time required to prepare bids and the success rates of AI-assisted tenders versus non-AI-assisted ones.

Furthermore, direct observations were conducted to gain insight into the processes employed by the companies in question. This entailed observing the deployment of AI tools at pivotal stages of the tender preparation and submission process, as well as monitoring the interactions between TM teams and AI systems. These observations proved invaluable in evaluating the practical, day-to-day impact of AI on operational efficiency and decision-making accuracy.

Quantitative data on TM outcomes were collected, including the number of successful bids, the speed of tender preparation (measured in days from tender announcement to submission), error rates in submission documents (quantified as a percentage of total submissions), and overall TM process cycle times (the total time taken to complete a tender cycle from initiation to contract award). Subsequently, the metrics were subjected to statistical analysis, employing t-tests and ANOVA, with the objective of ascertaining whether notable discrepancies exist between AI-driven and conventional TM procedures.

The resulting p-values and confidence intervals furnished empirical evidence for evaluating the influence of AI on the efficacy and compliance of tender management. Subsequently, the data points were compared between the AI and non-AI companies to quantify the extent to which performance had been enhanced because of the introduction of AI. In addition to the observations, the assessment of key variables was crucial for addressing the initial research question. The primary variables subjected to analysis included operational efficiency, decision-making accuracy, data analysis capabilities, and stakeholder engagement.

The variables from the operational efficiency domain were measured by the speed of tender preparation and submission, the allocation of resources, and the reduction of manual processes through automation. Subsequently, the variables associated with decision-making accuracy were evaluated by examining the quality and outcomes of decisions made with the assistance of AI tools, such as bid pricing strategies and supplier selection criteria, in comparison to those made without AI assistance. About data analysis capabilities, the assessed variables were evaluated in accordance with the capacity of AI systems to analyze extensive datasets, identify trends, and generate predictive insights that inform TM strategies.

These variables were subjected to a systematic evaluation based on the collected data, thereby enabling the research to draw clear comparisons between AI-driven and traditional TM processes. The combination of qualitative insights from interviews and observations, supported by quantitative performance data, constituted a robust framework for understanding how AI improves TM outcomes. In examining the second research question, "What are the critical areas for effective AI implementation programs related to TM governance, legal, and compliance issues?" document analysis was also conducted, along with specific questions, during the interview sessions.

While the preceding data collection methods remained relevant, there was a shift towards the acquisition of qualitative insights. Information obtained from observed meetings and discussions related to the project, particularly with compliance and legal teams, provided a comprehensive understanding of governance and legal framework development practices within organizations. It was of the utmost importance to assess adherence to internal legal and compliance standards to understand effective governance parameters. This not only ensured accountability and transparency, but also the efficient allocation of resources for technological and environmental innovation. The establishment of a robust technology-driven culture was instrumental in reinforcing the commitment to the operations involved, which had a positive impact on certain outcomes.

4. Results

4.1. Demographic data

The initial phase of the quantitative assessment and evaluation entails the illustration of the hierarchical distribution of participants in the interview rounds and their influence on the prospective governance and standards of the involved processes.

The sample was selected with great care to represent a diverse group of professionals engaged in the practice of TM. As most respondents were from companies that were currently utilizing AI in their operations, while a significant portion represented organizations that had not yet adopted AI, providing a balanced perspective on the subject matter. To facilitate the analytical process, key demographic variables, including years of experience, specific roles within their companies, and involvement in AI-related initiatives, were documented. This comprehensive characterization of respondents ensures that the findings are firmly rooted in a well-represented sample of the industry in terms of proficiency in TM-related areas. The selected participants and companies demonstrated a leading position in the industry about TM development and operations, thereby guaranteeing that the findings are firmly rooted in a well-represented sample of the industry in terms of proficiency in TM-related areas. This characterization of the sample provides the foundation for the subsequent analysis presented, offering a clear and comprehensive understanding of the respondents' backgrounds and roles, and exploring how their insights contribute to understanding the impact of AI on TM processes.

Fig. 1 illustrates a clear predominance of senior-level executives, predominantly vice presidents (VPs) and senior vice presidents (SVPs), followed by a notable representation of associate directors, directors, and executive directors. Furthermore, department heads are represented at a notable level, whereas the involvement of executives, managers, senior managers, and specialists is comparatively less pronounced. The data suggests that senior management is playing a significant role in guiding the integration of AI in TM processes, indicating that strategic decisions and governance policies are being driven at the highest levels. This concentration of senior roles underscores the importance ascribed to AI governance and compliance with regulatory standards as a top-down initiative within the sector. The potential ethical and regulatory challenges of AI are being addressed at the strategic level, with the objective of ensuring that governance frameworks are aligned with overarching business objectives and ethical considerations. The distribution figure also reflects the depth of high-level involvement, indicating a proactive approach to harnessing the power of AI while maintaining rigorous oversight to meet the industry's high ethical and regulatory expectations.

Fig. 2 illustrates the regional distribution of participants, with 14 individuals affiliated with Company A and 13 individuals from other companies. Germany is the country with the highest number of participating individuals, which indicates a significant contribution to the discourse on AI governance within the pharmaceutical industry. Italy is the next most represented country, indicating a robust involvement in the incorporation of AI into pharmaceutical procedures. This is crucial for acquiring a comprehensive grasp on the European market's stance on AI. Moderate engagement is evident in the United Kingdom, Poland, Austria, and Spain, reflecting a shared concern across these nations. Despite their lesser representation, Switzerland and Portugal contribute to the pan-European perspective on AI governance, indicating that this is a widespread priority across diverse economic landscapes with an acceptable number of participants. The following chart illustrates the current state of collaborative efforts among various countries to shape AI policy. This reflects the critical nature of creating unified, ethically aligned AI frameworks that are sensitive to the unique needs and regulations within different European markets.

Fig. 3 delineates the involvement of various departments and participants in European pharmaceutical tendering, with Pricing, Market

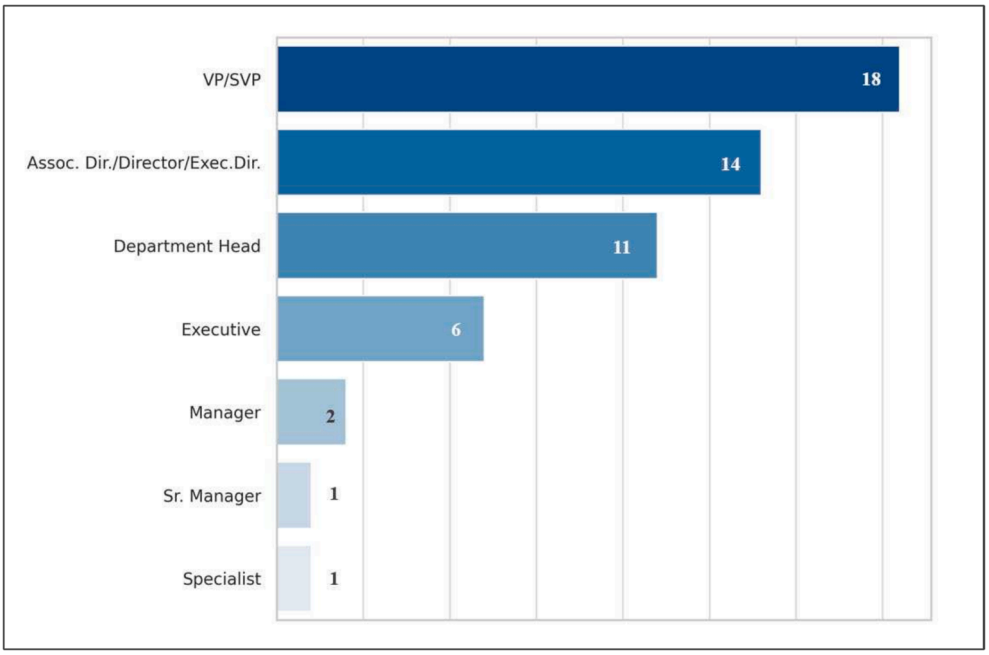

Fig. 1. Distribution of participants positions.

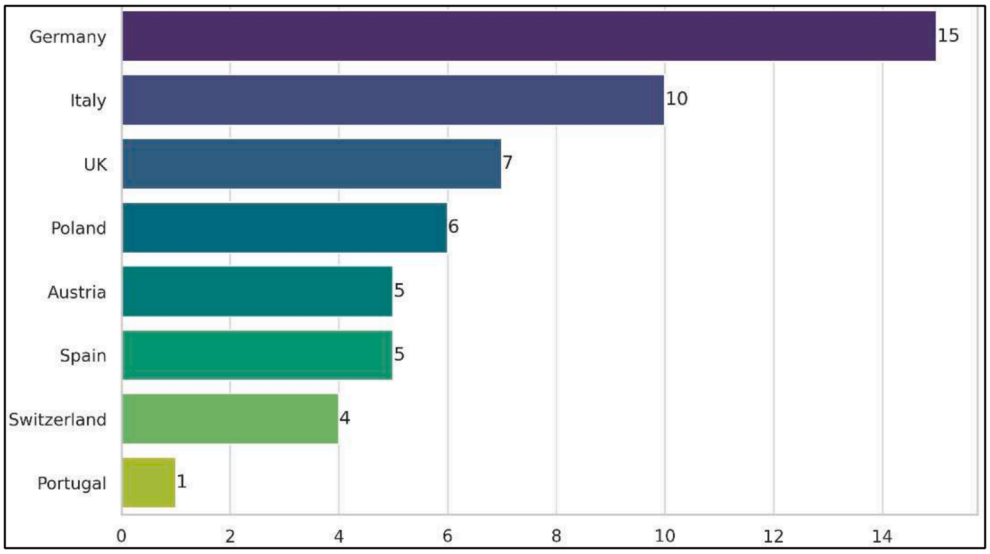

Fig. 2. Regional distribution of participants.

Access, and TM being the most prominent. This suggests the significance of strategic AI implementation in these domains for competitive market positioning, with a substantial representation from diverse departments. Other pivotal departments, such as Market Access and Launch Excellence, illustrate the significance of AI in market introduction and customer relations. Although less prevalent, the role of IT in providing technical support for AI is fundamental. Departments such as Real-World Evidence and Compliance, despite comprising a smaller number of participants, are of critical importance for maintaining AI regulatory compliance and guaranteeing data-driven decision-making. The distribution of participants across disciplines indicates a multidisciplinary approach to AI integration, with an emphasis on ethical, strategic, and compliant AI deployment.

4.2. Case study findings

The following points are directly aligned with the defined research questions, serving to elucidate the insights gathered in response to these inquiries.

RQ1: How does AI improve the pharmaceutical TM process?

The results of the study demonstrate that AI is markedly improving TM initiatives by furnishing profound, data-driven insights that assist organizations in optimizing process steps. Companies A and B have integrated GenAI to enhance data analysis for market insights. This involves the analysis of rich data from multiple sources, including market trends, healthcare policies, patient demographics, competitor activities, and tender information, to inform their tendering strategies. During the tender announcement and documentation phase, when the procuring entity issues a notice inviting bids, Companies A and B found that AI provided substantial assistance in automating certain processes. This

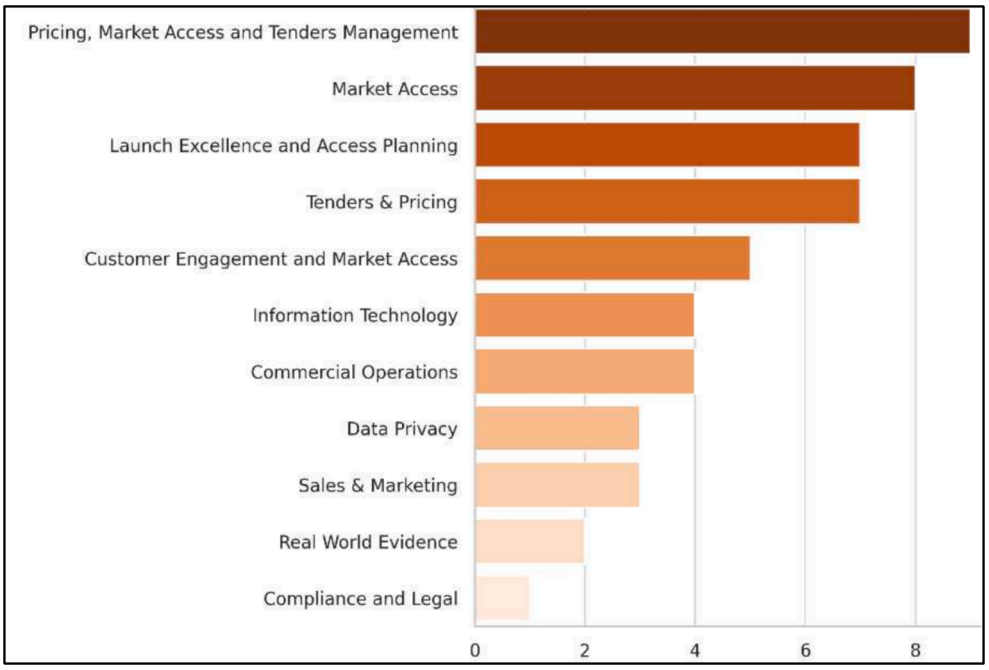

Fig. 3. Departments distribution of participants.

included the processing of comprehensive documentation delineating the requisite specifications and evaluation criteria for TM.

Additionally, Companies A and B evaluated the efficacy of AI algorithms in determining bid eligibility and qualification. The results demonstrated that GenAI was capable of effectively identifying pertinent bids and facilitating the submission of tenders. The role of GenAI in complex negotiations was tested at Company A, where a custom-built ChatGPT was employed to assist with contract drafting and negotiation. Nevertheless, the output of ChatGPT necessitated meticulous examination due to its dearth of comprehension regarding the legal context. The incorporation of AI into the domain of transactional management has demonstrated the potential to enhance efficiency, precision, and strategic decision-making. The optimal utilization of AI hinges upon its integration with human intelligence, whereby the strengths of both are combined to offset the limitations of the other, thereby enhancing the effectiveness of TM.

The incorporation of AI into TM has been shown to hold considerable promise for enhancing strategic decision-making and operational efficiency within the European pharmaceutical market.

The subsequent illustration (see Fig. 4) depicts the various components pertinent to the incorporation of AI into the European pharmaceutical tendering process, ordered according to their relative

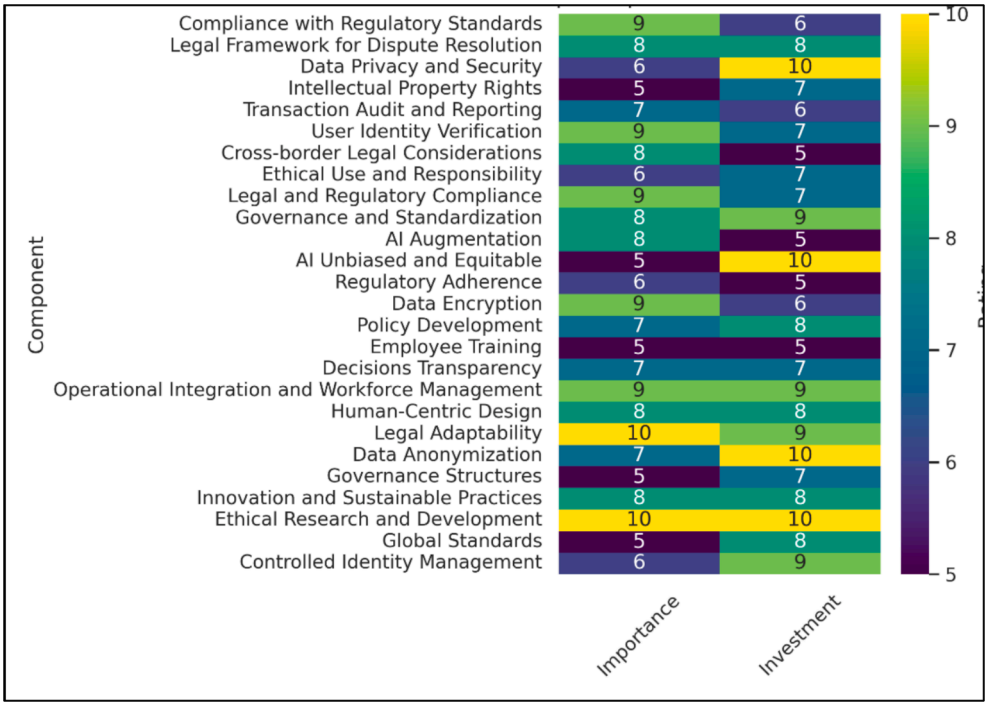

Fig. 4. Heat Map of Importance and Investment Ratings in AI Governance for European Pharmaceutical Tendering.

significance and investment ratings. The highest-priority areas receiving substantial investment include data privacy and security, the legal framework for dispute resolution, and compliance with regulatory standards. This indicates a significant focus on the ethical and compliant use of AI. In particular, the unbiased and equitable use of AI and legal adaptability are identified as critical yet appear to require further investment. This suggests an evolving landscape where adaptability to legal norms and unbiased application of AI are recognized, but not yet fully realized. Conversely, areas such as intellectual property rights and innovation and sustainable practices, while important, demonstrate a discrepancy between their perceived importance and the current levels of investment. Fig. 4 also illustrates that ethical research and development, and global standards are perceived as highly important and well-funded, consistent with the global drive for ethical AI practices and harmonization of standards.

To respond effectively to tenders for biosimilar and vaccines, companies must be aware of the prevailing market dynamics and any relevant regulatory changes. It is of the utmost importance to gain an in-depth understanding of the regulatory framework and the patent landscape in Europe, including the challenges related to patent rights and regulatory data protection that impact the launch of biosimilar products.

To monitor pertinent tender information, pharmaceutical companies typically employ business intelligence tools and pharmaceutical industry databases to collate comprehensive tender, market, and regulatory data. In Europe, tenders are published on a variety of digital platforms and websites. The EMA utilizes the Tenders Electronic Daily (TED) database for the purpose of disseminating information regarding publicly issued tenders. The European Commission's website serves as a repository of information regarding funding opportunities and tendering processes aligned with the objectives of the EU health industry. The European Federation of Pharmaceutical Industries and Associations (EFPIA) offers insight into pharmaceutical procurement, while BidDetail.com provides a comprehensive listing of global tenders, including those within the pharmaceutical sector.

Such platforms offer a combination of tender listings, regulatory insight, and strategic information, which is crucial for companies aiming to engage in European tenders. It is of the utmost importance to conduct regular monitoring of these sites, given the dynamic and competitive nature of the tendering landscape. The specific factors considered in the evaluation of tenders may vary from one country to another. These factors may include, for instance, aspects such as pricing, product safety, public health impact, and cost-effectiveness. Other critical factors include considerations of both clinical efficacy and economic viability, as well as an evaluation of the potential health benefits, affordability, and financial implications.

GenAI has demonstrated efficacy in specific domains, including document processing for procurement purposes, such as the generation of bid notices, the preparation of contract specifications, and the issuance of award decisions. Additionally, it has shown promise in the realms of technical delivery and logistical capacity. In contrast to non-AI companies that rely heavily on manual labor to prove documents such as safety certificates and distribution licenses, AI-integrated companies demonstrate greater efficiency. Companies that utilize AI solutions exhibited a more proactive and systematic capacity to monitor and track TM status, forecasts, and timelines. They benefited from AI's ability to send automated notifications, facilitating more transparent and coordinated tenders' evaluations, early bid/no-bid decisions, and streamlined document fulfillment processes.

The results of the interviews rounds were to identify areas of convergence and divergence between industry practices and regulatory expectations. A Likert scale was used to measure respondent feedback on the significance and implementation of the eight 'critical areas,' which included aspects such as data security, transparency, and accountability in AI systems. This scale ranged from 1 (strongly disagree) to 5 (strongly agree), allowing for a nuanced understanding of expert consensus on each topic. Respondent feedback was further analyzed to assess how well these critical areas align with European regulations, particularly in terms of compliance and governance.

The interaction between the interviews results and the applicable industry related regulations revealed several key insights: where industry practices are well-aligned with regulatory standards, where gaps exist, and where future alignment is necessary to ensure both legal compliance and ethical AI usage. This analysis not only highlights the current state of AI governance in the pharmaceutical industry but also provides actionable recommendations for aligning these practices with evolving European regulations. The detailed comparison and the use of a structured measurement method, such as the Likert scale, ensure that the findings are both rigorous and directly applicable to real-world scenarios.

The discussion centered on how AI implementation in TM aligns with key areas like data privacy, ethical use of AI, and regulatory compliance, and analyzed in relation to the latest European directives, offering a clear picture of how industry practices compare to regulatory standards.

The analysis presented in Table 2 provides a comparison between the impacts of AI on TM processes as observed in Companies A and B versus those not using AI (Companies C and D). This comparison highlights the tangible benefits of AI in improving efficiency, stakeholder engagement, and data analysis.

The results underscore the need for continued alignment with European directives to ensure that AI implementation not only drives operational efficiency but also adheres to the highest standards of governance and ethical conduct. Based.

From the case study interviews, eight key regulatory areas emerged as important for future standardization and clarification. These include data privacy and protection, where GDPR imposes strict data handling rules that are critical for AI model training. Regulatory approval and validation, particularly compliance with European Medicines Agency guidelines for digital health technologies, including AI, is essential. In clinical trials and research, regulations governing clinical trial design and patient selection must be followed to ensure ethical and scientific integrity. Good clinical practice guidelines are essential to maintain the integrity of clinical trial data when AI is used in trial design or data analysis.

Intellectual property rights, particularly the patentability and ownership of AI-generated inventions, are critical areas of discussion. Protection of copyrights and trade secrets is paramount for companies investing in AI, as noted by two companies in the study that have not yet integrated AI due to perceived risks. Transparency and accountability in AI decision-making processes, particularly in healthcare, are increasingly required to address bias and comply with anti-discrimination laws. Ethical frameworks are being developed to guide the responsible use of AI in healthcare, focusing on consent, privacy, and equity. Post-market surveillance of AI applications in medical devices or diagnostics requires continuous monitoring for adverse events to ensure ongoing safety and efficacy. Finally, international standards such as ISO/IEC 27,001 for information security management are relevant to AI systems,

Table 2
Summary of RQ1 Analysis.

Aspect of TM	Impact of AI (Company A & B)	Non-AI Impact (Company C & D)	Key Findings
Efficiency	Enhanced decision-making, faster processing times	Traditional methods, slower processes	AI significantly improves operational efficiency
Stakeholder Engagement	Improved engagement through data-driven insights	Manual processes, less responsive	AI fosters better stakeholder relationships
Data Analysis	Real-time data integration and analysis	Delayed data processing	AI provides superior data analytics capabilities

particularly with respect to data security and quality management.

RQ2: What are the critical areas for effective AI implementation programs related to TM governance, legal, and compliance issues?

It was determined that the integration of AI insights necessitates adherence to established ethical, social, and governance standards. In the context of manufacturing and quality control, it is of paramount importance to adhere rigorously to quality control and regulatory compliance procedures once a tender has been finalized. This encompasses adherence to the EU's Public Procurement Directive 2014/24/EU, Council Regulation (Euratom, EC) No 2185/96, and Regulation (EC) No 883/2013 on OLAF investigations.

Furthermore, the monitoring of tenderers' responses necessitates adherence to data protection regulations, including Regulation (EU) No 2018/1725. In the context of tender procedures, personal data may be transferred to various EU bodies for the purpose of financial security. In certain circumstances, such data may also be registered in the Early Detection and Exclusion System (EDES). Furthermore, tenderers are obliged to guarantee that their data processing activities in relation to procurement contracts comply with GDPR.

Fig. 5 provides a comparative analysis of the governance areas that are critical to the implementation of AI in European pharmaceutical tenders. The visual data illustrates the disparate levels of emphasis and investment that companies A through D have allocated to various aspects, including transparency, privacy and security, ethical use, and intellectual property rights protection.

It is evident that ethical use and operational integration are of paramount importance across the board, reflecting a universal recognition of their significance in the ethical use of AI. In contrast, the area of legal and regulatory compliance demonstrates a lack of uniformity, indicating disparate strategic approaches to navigating the intricate legal terrain. This diversity underscores the necessity for harmonized governance frameworks that can accommodate the diverse priorities of pharmaceutical companies while ensuring compliance with European standards.

Fig. 5 presents heat maps that compare the critical areas of AI governance and ethical standards as identified by companies A and B (which have integrated AI into their TM processes) with companies C and D (which have not integrated AI). The heat maps illustrate the extent and concentration of investment and prioritization across eight critical domains, including data privacy, transparency, and regulatory compliance.

Companies A and B, which have more advanced AI adoption, demonstrated a higher level of investment and prioritization in areas such as data privacy and the ethical use of AI. In contrast, companies C and D exhibited a diminished level of attention to these domains, reflecting their conventional, non-AI-centric approaches.

The comparison elucidates the stark contrasts in how AI-driven companies and non-AI-driven companies address governance and ethical challenges, as evidenced by the heat maps. This visualization highlights the necessity for companies that have not yet adopted AI to re-examine their governance strategies considering evolving industry standards and regulatory expectations.

Fig. 6 delineates the governance areas that are expected to be central to the governance of AI. The figure presents a box-and-whisker plot that illustrates the interquartile range (IQR) of responses pertaining to the perceived importance of various governance areas, including policy and governance, regulatory compliance, and others. The median values indicate the central tendency of the responses, while the range reflects the variability in expert opinions. These calculations were performed by aggregating the responses and analyzing the distribution of scores using statistical software to ensure accuracy and precision.

The range of ratings across governance domains indicates a heterogeneity of stakeholder perspectives. In particular, the Policy & Governance and Regulatory Compliance areas exhibit a more pronounced

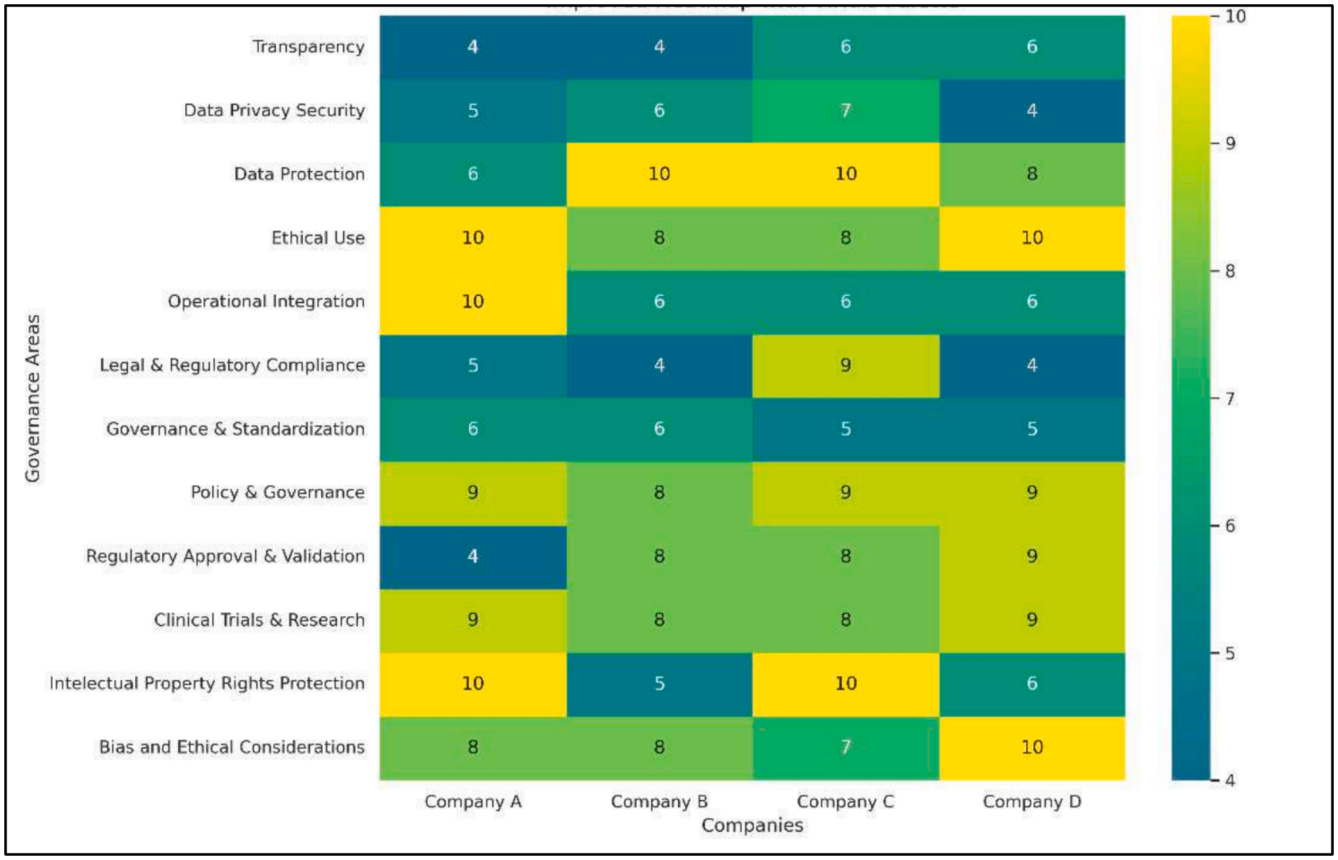

Fig. 5. AI Governance and Ethical Standards Assessment Across Pharmaceutical Companies.

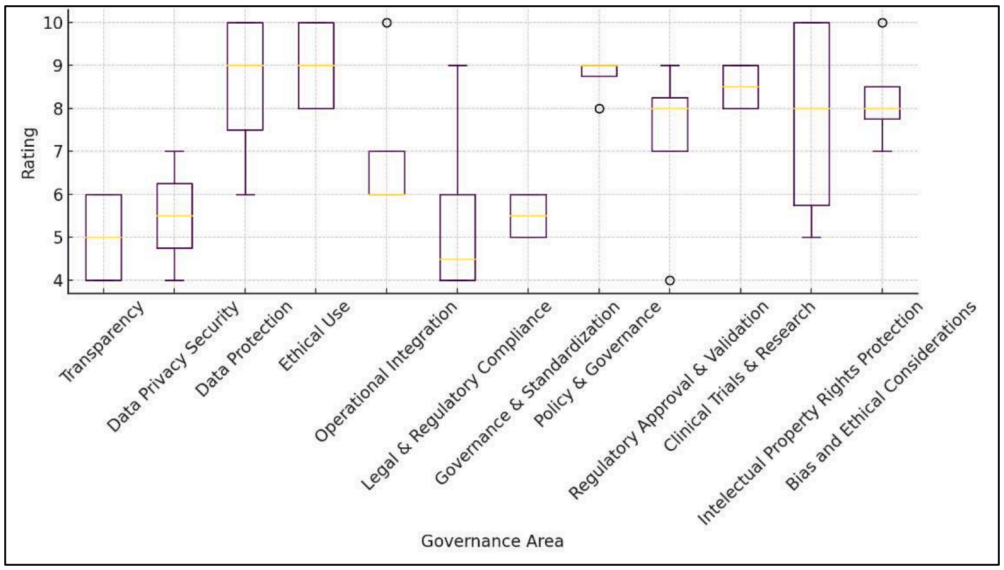

Fig. 6. Governance areas for future AI in pharmaceuticals.

interquartile range, suggesting a divergence in consensus that may reflect the evolving landscape of European AI regulatory frameworks. The medians of the "Clinical Trials & Validation" and "Protection of Intellectual Property Rights" categories, which are situated at the higher end of the scale, serve to underscore the recognition of their importance in maintaining the integrity and innovation of AI applications in the pharmaceutical industry. In contrast, the interquartile ranges for "Data Privacy & Security" and "Ethical Use" are narrower, indicating a more unified stance that may be attributed to the established underpinnings of the GDPR. The outliers in the "Bias and Ethical Considerations" category indicate that there are exceptional challenges or opportunities that may not align with the common trends, necessitating tailored attention. The multidimensional impact of European tenders on AI governance, with a particular focus on policy development, regulatory compliance, and ensuring ethical integrity in clinical innovation, is illustrated in the figure below.

Fig. 7 presents a comparative analysis of the effectiveness of AI implementation across four companies, demonstrating the diversity in their AI application and integration strategies.Fig 8.

The figure depicts the disparate approaches to AI implementation observed across the four companies. The elongated boxes in the plot represent Companies A and B, indicating a broader variation in their AI adoption success, likely due to differing operational strategies and stages of AI integration. The calculations were based on a comprehensive examination of each company's AI initiatives, wherein qualitative feedback was quantified to facilitate a comparative analysis. The considerable divergence in ratings for Companies A and B, as indicated by the elongated boxes, points to a notable discrepancy in their AI implementation success or methodologies. This is likely attributable to differing operational strategies or stages of AI integration. It is noteworthy that Company A exhibits the highest median rating, which reflects a more advanced or successful AI implementation in comparison to its counterparts. This could serve as a guiding principle for strategic enhancements or investments in AI capabilities, with the aim of fostering a competitive advantage. In contrast, Company C exhibits a narrower interquartile range, indicating a uniform, though modest, application of AI across the evaluated metrics. An outlier above the upper whisker for Company C may indicate the existence of exceptional successes or innovative practices that are not widely recognized within the company. Company D is distinguished by the most consistent ratings and the lowest median, which may indicate either a nascent stage of AI adoption or a highly standardized implementation approach. The

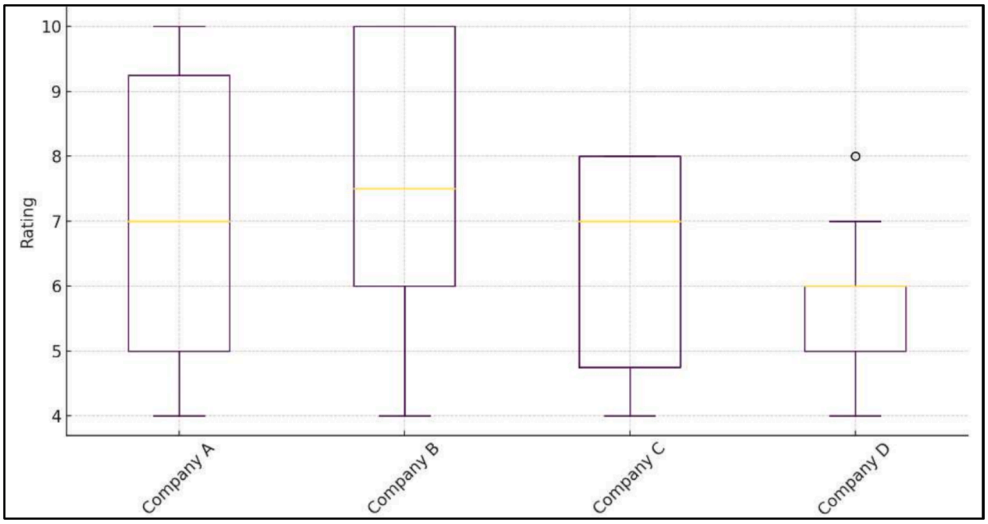

Fig. 7. AI implementation areas across companies.

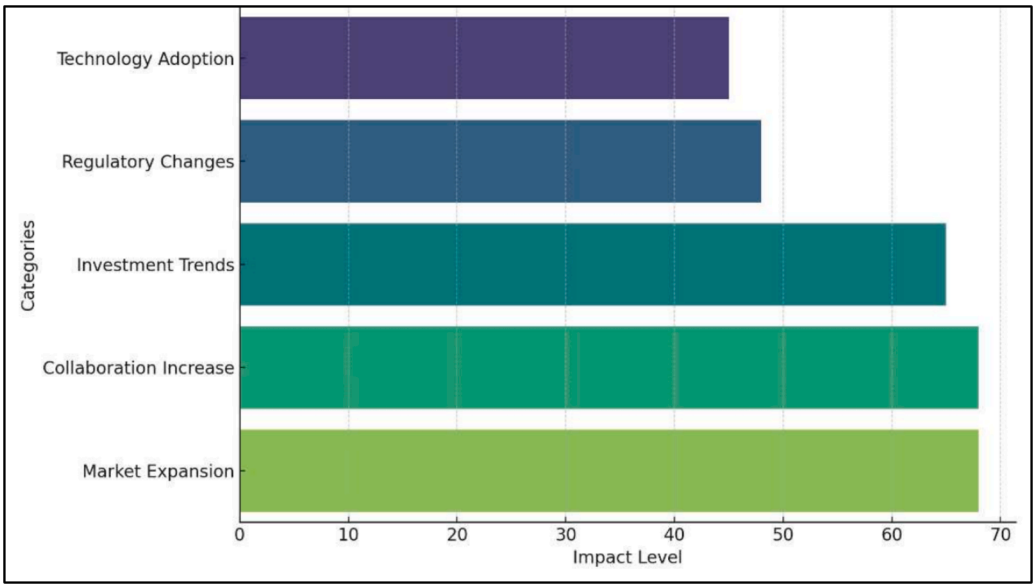

Fig. 8. Impact of EU tendering operations on AI governance.

uniformity observed across AI domains within Company D may be indicative of a deliberate, focused strategy or a constrained scope of application.

Fig. 6 illustrates the most pronounced impact observed in "market expansion," which suggests that tendering operations significantly drive the scale and reach of AI applications. This suggests that there is a correlation between market demand and a favorable environment for growth, which is likely driven by tendering practices that provide incentives for AI integration. Subsequently, "increased collaboration" is observed to have a considerable impact level, indicating that tendering practices are fostering partnerships, potentially due to the necessity for interdisciplinary expertise in AI projects. This phenomenon may be indicative of joint ventures and strategic alliances, which are crucial for navigating the intricate regulatory and technological landscape.

Additionally, the "Investment Trends" data set demonstrates a noteworthy impact, indicating a shift in funding patterns. This shift is likely influenced by tender conditions that favor AI-driven solutions. This may indicate a reallocation of capital towards AI initiatives, in alignment with the strategic objectives of the European Union. The moderate impact indicated by 'Regulatory Changes' may signify ongoing adjustments in the regulatory framework, influenced by tendering requirements, that promote AI governance that meets evolving standards of quality, safety, and efficacy. The least impact, though still significant, indicated by 'Technology Adoption' suggests a steady incorporation of AI technologies, possibly due to established norms and practices within the pharmaceutical sector that are only incrementally influenced by tendering processes.

The elements considered in Fig. 6 were evaluated based on both the internal assessments conducted by Companies A and B and insights from recent academic and industry publications. The figure synthesizes these disparate data points to provide a comprehensive view of the impact of tendering practices on AI governance and operational strategies in the pharmaceutical industry.

The illustration demonstrates how market dynamics, shaped by tendering processes, can either accelerate or impede the adoption of AI, contingent on the regulatory and competitive context. The incorporation of both company-specific analyses and literature sources ensures that the figure is firmly anchored in a robust and comprehensive grasp of the prevailing trends and challenges associated with AI governance in this context.

The incorporation of GenAI into the various facets of market access and TM affords pharmaceutical companies a substantial competitive advantage. This requires not only the incorporation of sophisticated technology but also its strategic integration in alignment with overarching business objectives and market demands. The objective is to leverage AI to enhance decision-making processes, optimize operational procedures, and cultivate more robust relationships with stakeholders within the healthcare ecosystem.

A notable operational enhancement observed with the incorporation of AI tools in Companies A and B is the reduction in the number of FTEs necessary for TM tasks. The implementation of AI for tasks such as bid preparation, document review, and compliance monitoring enabled these companies to reallocate resources, effectively freeing up four to six FTEs per company. This signifies a considerable reduction in the time and labor required for repetitive, low-complexity tasks, thereby enabling human employees to concentrate on more strategic endeavors such as stakeholder engagement and regulatory decision-making.

The prospective role of AI in TM is envisaged in the context of AI-driven market analysis and forecasting. Advanced ML algorithms will analyze a plethora of data, including market trends, historical tender data, competitor pricing, and regulatory changes. This will enable the accurate forecasting of market demand, the identification of tender opportunities, and the adjustment of production and supply chain strategies. Another area of focus is the optimization of TM strategies, which will be determined by AI predictive analytics tools. AI models will simulate tendering and marketing scenarios and predict outcomes based on historical data and market conditions. This will assist in the submission of competitive bids without compromising profitability.

It was determined that regulatory compliance and documentation management were areas of consensus among experts from all four companies. The application of AI will facilitate the automation of compliance checks and document management, thereby ensuring adherence to specific regulatory requirements and reducing the risk of non-compliance while simultaneously streamlining documentation processes. However, personalized stakeholder engagement in the TMs revealed a divergence of interest, with only one company expressing a future intent to develop AI applications for this purpose.

The objective of this approach is to develop communication strategies that are tailored to enhance stakeholder relationships and foster trust. The convergence of AI and human intelligence in strategic decision-making will be pivotal, with AI offering data-driven insights and human experts contextualizing these within broader business strategies and ethical considerations. A comparative analysis of AI use cases within Companies A and B reveals the integration of AI technologies to

enhance operational efficiency in the European pharmaceutical tendering process. Both companies employ AI to analyze market trends and navigate regulatory landscapes, thereby indicating a strategic focus on leveraging technology to maintain competitive market insights and ensure compliance. Regarding the field of TM and market access, Company A employs the use of GenAI as a means of navigating the various regulatory requirements that it faces, in addition to its commercial strategies. Company B, similarly, has adopted a comparable approach to achieve efficient TM and market penetration. This indicates that AI tools are essential for optimizing TM processes and strategies.

About the consolidation of tender information and the negotiation process, both companies employ AI tools for the aggregation of data and the drafting of contracts. Despite the acknowledged limitations of ChatGPT in the context of legal understanding, Company A has opted to utilize this tool for negotiations. This underscores the significance of AI in enhancing the quality and efficiency of TM and contract negotiation. In the context of eligibility evaluation, Company A deploys a range of AI algorithms, whereas Company B utilizes AI for the assessment of economic, financial and technical aspects of bids.

This suggests an increasing reliance on AI to enhance the accessibility and comprehension of tender documents across linguistic boundaries. The application of AI has resulted in the streamlining of TM processes, including the processing of appeals and monitoring of bid status, in both companies. This evidence supports the assertion that AI plays a pivotal role in enhancing the timeliness of bid submissions, the efficiency of appeal processing, and the effectiveness of proactive bid tracking.

In the supervision of AI-generated results, Companies A and B implemented regular review processes to ensure that AI outputs met the necessary accuracy standards, especially for legally sensitive documents. On a day-to-day basis, AI results were reviewed by specialized teams who corrected any errors or hallucinations—instances where the AI generated plausible but incorrect or irrelevant information. While these issues were mitigated through human oversight, they were not eliminated. Feedback from both companies indicates that approximately 10 % of AI-generated documents required substantial revisions, particularly when dealing with complex legal terminologies or regulatory data.

In addition, both companies employ AI to guarantee adherence to quality standards and enhance negotiation outcomes, thereby illustrating AI's capacity to enhance bid preparation and contract agreements. The deployment of AI by these companies signifies a trajectory towards technology-driven efficiency and enhanced decision-making in European tendering processes within the pharmaceutical industry (see Table 3).

Table 3
AI Applications in the two companies with AI presence.

AI Use Case/Area	Company A	Company B
Enhanced Data Analysis for Market Insights	Uses GenAI to analyze data from various sources for market trends, healthcare policies, patient demographics, and tenders.	Similar application of GenAI for comprehensive market analysis.
Tender Management and Market Access	Leverages GenAI in navigating regulatory requirements and commercial strategies for biosimilar and vaccines.	Similar application for efficient TM and market penetration.
Tender Information Consolidation	Utilizes AI tools for gathering comprehensive information on tenders, market trends, and regulatory changes.	Employs similar AI tools for tracking and organizing tender data.
Negotiation and Contract Drafting	Employs custom-built ChatGPT for drafting contracts and supporting negotiations, despite some limitations in legal understanding.	May use similar AI tools for enhancing negotiation processes and preparing legal documents.
Tender Eligibility Assessment	Uses specific AI algorithms to assess tender participation eligibility and qualification.	Applies GenAI for evaluating economic, financial, and technical aspects of tenders.
Document Interaction and Translation	Integrates ChatGPT and Claude for interacting with tender documents, supported by AI translation tools.	Utilizes GenAI for document processing, including translations and summarization.
Tender Submission Management	GenAI assists in managing tender submission deadlines and requirements, including electronic submissions.	Similar use of AI for streamlining tender submissions and administrative procedures.
Appeal Processing and Decision Support	AI applications in handling appeals and providing decision support for procurement notices and contract specifications.	Employs GenAI for technical delivery and logistical capacity documentation.
Monitoring Tender Status and Forecasts	AI solutions enable proactive monitoring and tracking of tenders across countries, brands, and functions.	Similar AI-driven approach for full visibility of tender status and timelines, aiding in timely decision-making.
Automated Tender Notification and Evaluation	AI solutions for automated notifications and coordinated evaluation process for tenders.	Utilizes AI for automating document fulfillment and tender announcement procedures.
Bid Preparation and Submission	AI aids in preparing detailed bid information, ensuring compliance with quality standards and delivery commitments.	Similar application of AI in bid preparation, focusing on product details, pricing, and compliance aspects.
Contract Negotiation and Signing	AI leverages in contract negotiation, focusing on terms, prices, and compliance issues.	Utilizes AI for contract negotiations, enhancing terms finalization and compliance adherence.

4.3. Qualitative analysis

The following insights present a qualitative analysis aimed at deepening the understanding of how the integration of AI into TM processes influences organizational practices, governance, and compliance from the interviews collected feedback. This qualitative exploration complements the quantitative findings by capturing the nuanced effects of AI implementation that cannot be fully elucidated through numerical data alone. The qualitative data were analyzed using thematic analysis, identifying recurring themes and patterns from interview transcripts and other qualitative sources. The analysis was guided by several parameters, including alignment with organizational goals, impact on ethical standards, stakeholder satisfaction, and the effectiveness of adaptation and change management.

The analysis specifically focuses on five key aspects:

- Alignment with Organizational Goals and Expertise: Initial observations reveal a significant demand for technical expertise within engineering teams, including project sponsors and executive management involved in TM programs. Notably, disconnection between project teams and government operations in defining data governance and quality assurance emerged as a critical issue. Furthermore, the analysis highlights the need for innovation in customer experience, adaptation to evolving regulations, technological advancements, and market responsiveness in AI initiatives. Feedback from participants emphasized the complexity of TM processes, which require careful coordination across various functions, including pricing, contract negotiation, supply chain management, regulatory compliance, and sales. The study suggests that AI can significantly enhance the efficiency and effectiveness of these processes by providing detailed insights, automating repetitive tasks, and optimizing decision-making. AI's potential applications span the entire TM process, from bid preparation to contract execution, thereby improving the chances of winning tenders and managing them successfully.

- AI in Bid Preparation and Submission: Participants with positive experiences reported that AI is highly effective in the bid preparation and submission phases. AI can conduct in-depth analyses of historical tender data, competitor actions, and current market conditions. For instance, AI algorithms can process large datasets to identify patterns in previous tender outcomes, enabling companies to tailor their bids more precisely to the tendering authority's specific requirements. AI also supports dynamic pricing strategies by analyzing competitor pricing, demand elasticity, and cost structures, thus recommending optimal bid prices that maximize both competitiveness and profitability. Additionally, AI automates the compilation of tender documents, integrating data from multiple sources to ensure compliance with complex regulatory requirements and reduce the risk of manual errors. This automation accelerates the submission process while enhancing the accuracy and thoroughness of bids, which is crucial for passing qualification stages.
- Leveraging Real-World Data (RWD) and Market Access: The integration of AI into the TM process is further enhanced by leveraging RWD and optimizing market access strategies. RWD, derived from sources such as electronic health records, claims databases, patient registries, and wearable devices, provides valuable insights into patient outcomes, treatment efficacy, and healthcare utilization. This data is increasingly critical in tender submissions, as tendering authorities and payers demand evidence of a product's real-world effectiveness and cost-effectiveness. AI can analyze RWD to generate robust evidence supporting a pharmaceutical or biotechnology product's value proposition. For example, AI can identify patterns in RWD that demonstrate a product's superior efficacy or safety profile in real-world settings compared to competitors. This information is instrumental in crafting a compelling narrative in tender submissions, showcasing the product's tangible benefits to patients and healthcare systems.
- AI's Role in Market Access and Post-Award Management: Market access is another critical area where AI and RWD converge to support TM. AI-driven analysis of market access data can identify potential barriers to entry, such as regional pricing regulations, reimbursement policies, and competitor presence, allowing companies to tailor their tender submissions proactively. By combining RWD insights with market access data, companies can refine their tender strategies to align with the specific needs of different markets. For instance, AI can predict how changes in reimbursement policies or healthcare budgets in a particular region might affect the success of a tender submission, enabling companies to adjust their pricing and value propositions accordingly. This strategic alignment increases the likelihood of winning tenders and ensures sustainable market access post-award. Following a successful tender, AI plays a crucial role in the execution and management phases. AI-powered tools can optimize the supply chain by predicting demand fluctuations and adjusting inventory levels to meet tender delivery schedules. ML models can analyze variables such as production capacity, raw material availability, and logistical constraints to devise efficient supply chain strategies that minimize costs and avoid delays. In contract management, AI can monitor compliance with contract terms by tracking key performance indicators (KPIs) in real-time and flagging any deviations that could result in penalties or disputes. Additionally, AI supports contract negotiation by analyzing various contract scenarios and suggesting terms that are both favorable to the company and acceptable to the tendering authority. AI's integration with sales and marketing functions further refines commercialization strategies by analyzing post-award market data, customer feedback, and regulatory changes, ensuring continued competitiveness and compliance throughout the tender's lifecycle.
- Governance, Compliance, and Ethical Standards in AI Implementation: Successful AI-driven projects demonstrate strong community engagement, fostering innovation in research, development, and navigating regulatory environments. Discussions on governance highlighted the importance of legal compliance, regulatory approval, and ethical standards in AI projects. The analysis identified transparent decision-making and effective corporate governance practices as critical to accountability and responsible corporate behavior. Risks associated with governance failures, including reputational damage and loss of trust due to issues such as aggressive tax avoidance and corruption, were also discussed. Regulatory compliance is emphasized, with companies required to adhere to laws and regulations governing the development, manufacture, marketing, and distribution of medicines. Effective governance ensures patient safety and product quality, supported by transparency and accountability in corporate operations. The role of the board of directors is seen as crucial in overseeing operations, setting strategic goals, and serving stakeholders' interests. The study underscores the importance of patient safety and quality assurance, aligned with social responsibility expectations. Projects are increasingly expected to demonstrate responsibility by supporting healthcare access, environmental sustainability, and community outreach. For future AI-related governance and compliance, organizations are advised to invest in legal and compliance structures, including AI governance procedures, to assess regulatory implications during scalability and expansion. Aligning AI integration with business strategy and goals and adhering to standardized reporting frameworks is essential in a landscape characterized by evolving regulations, technological advances, and changing stakeholder expectations.

The qualitative insights provided here complement the quantitative findings by offering a richer, more nuanced understanding of how AI integration affects organizational practices and governance. As AI continues to evolve, organizations must navigate the complexities of compliance, governance, and ethical standards to maintain trust and achieve sustainable success.

4.4. Delphi method results

In accordance with the tenets of multiple case study procedures, the Delphi method was conducted in a manner that ensured anonymity, incorporated both qualitative and quantitative iterations, provided guided feedback, and facilitated the statistical aggregation of group estimates.

Table 4 provides an overview of the consensus from the Delphi rounds on the most "critical areas" of AI governance in comparison with the relevant European directives. This table demonstrates both the alignment of current practices with regulatory expectations and the identification of gaps that must be addressed to ensure comprehensive compliance and the implementation of ethical AI.

Regarding the projections results, the data indicate a paradigm shift towards transparency in governance and ethical use, which signifies a maturation of AI initiatives under the scrutiny of compliance mandates (Projection 1). The necessity for leadership expertise to direct AI investments towards efficient and ethical applications is a crucial point of

Table 4
Comparison of critical areas with european directives (RQ2).

Critical Area	Delphi Round Consensus	European Directive Alignment	Gap Analysis
Data Privacy	Strong consensus (Likert Avg. 4.5)	Fully aligned with GDPR	Minimal gaps, mainly in implementation details
Regulatory Compliance	Moderate consensus (Likert Avg. 4.0)	Partially aligned with AI Act	Need for more robust frameworks in practice
Ethical Use of AI	High consensus (Likert Avg. 4.7)	Aligned with European AI Ethics Guidelines	Opportunities for enhanced ethical oversight

emphasis, emphasizing the significance of executive foresight in technology adoption and governance implications (Projection 2).

Furthermore, the projections indicate an increasing concern among executives regarding the complexities of AI governance, particularly about environmental, social, and governance (ESG) issues. This suggests a probable intensification of these considerations in future regulatory frameworks (Projection 3). It is anticipated that the incorporation of AI into pharmaceutical procedures will facilitate operational efficiency, diminish administrative burdens, and augment strategic capabilities throughout the sector (Projection 4). It is anticipated that there will be a notable enhancement in organizational learning and agility, which will in turn foster a culture of innovation and adaptability (Projection 5). TM postulates that managerial insights will serve as a catalyst for the adoption of new AI capabilities in areas such as bid management, thereby improving operational efficiency (Projection 6). It is anticipated that there will be an increased impact on internal operations and skills development, which will serve to highlight the critical nexus of TM management for the integration of talent and technology (Projection 7).

Furthermore, as pharmaceutical companies endeavor to enhance operational efficiency, the strategic integration of novel technologies such as GenAI is anticipated to be pivotal in sustaining market competitiveness and compliance (Projection 8).

Ultimately, the projections indicate an increasing demand for transparency in AI-related corporate metrics, reflecting an investor-driven impetus for accountability across the AI governance spectrum (Projection 9). The rapid evolution of business models, underscored by a technology surge, is highlighted, but with an acknowledgement of a readiness gap in IT departments, indicating potential areas for development focus (Projection 10). Taken together, these projections offer analytical foresight into the nuanced and evolving interplay between European tendering and AI governance within the pharmaceutical industry, signaling a trajectory towards enhanced regulatory compliance, strategic leadership, and technology integration (see Table 5).

Key predictions were identified, including P3, P4, P5, P7, and P10, which were rated highly in terms of impact and probability correlation. These predictions highlighted the importance of innovation, internal skills management, talent management, leadership and governance, ethical use of AI, and process efficiency in pharmaceutical-related operations for the future. Other AI-related factors, such as economic impact and management capabilities, are expected to evolve as international leadership becomes a central element. In addition, optimizing supply chains and mitigating privacy and security risks are critical to ensuring ethical AI use. Insights into leadership and managerial skills development are essential to achieving these goals.

The collected future perceptions suggest that the operational effectiveness and governance impact of AI, especially in complex processes such as distribution, logistics, sales, operations, and bid management, will increase as AI becomes more cost-effective and subject to increased regulation and oversight. Concrete actions such as defining roles, researching regulations, drafting, and implementing protocols, conducting cybersecurity audits, updating privacy policies, implementing encryption and consent processes, and conducting training will be necessary.

To analyze participants' feedback and opinions, 20 statements were presented, including both open-ended and closed-ended questions. These were designed to assess the likelihood and impact of various scenarios in the two rounds of discussions and interviews. The following table (see Table 6) summarizes key data collected across two rounds of the Delphi methodology, focusing on the key elements, areas of intervention, future recommendations, operational efficiencies, and major risks associated with the governance of AI in pharmaceuticals in the context of European tenders. The key elements of AI in pharmaceuticals identified include 'Ethical Use & Responsibility' and 'Legal and Regulatory Compliance', with high mean scores that persist across rounds, indicating a consensus on their criticality. A slight decline in 'Privacy & Security' and 'Governance & Standardization' suggests a marginal shift

Table 5
Delphi resulted projections.

ID	Projections	Impact	Probability
1	The economic impact and management capabilities that are part of future AI initiatives will undergo certain changes if we consider the need for governance, transparency, and ethical use as core components.	4.1	74 %
2	For organizations to get the most out of their AI investments, leadership skills will become increasingly important, as will improving the ethical use and efficiency of AI, especially in terms of technology development and governance implications. Leadership in the context of ethical use of AI will be very important.	3.9	81 %
3	AI governance uncertainties are growing, regulatory and industry standards are changing rapidly, and executive management teams are increasingly concerned about environmental, social, and governance (ESG) issues. However, the concerns and challenges will only increase, not decrease, until robust legal, compliance, and ethical frameworks are in place.	4.7	86 %
4	With the introduction of GenAI practices and adaptation to pharmaceuticals, various companies will be able to reduce their intensive human administrative burden while reducing costs and increasing productivity in other strategic areas.	4.6	79 %
5	In complex times, many business leaders are using leadership, strategic thinking, and learning agility to deepen their organizations' sense of purpose, engage employees, and retain them as they develop new skills and competencies in AI-related environments. And it will grow.	4.7	75 %
6	Whether it is reducing costs, optimizing operational components or administrative tasks, or eliminating repetitive tasks, insights from executive leadership and managerial skill development can help companies reach improved levels of AI and adopt new Gen AI capabilities to manage various processes such as managing tenders and many others.	4.1	84 %
7	In pharma, internal talent and skills impact operations such as distribution, warehousing, and logistics, which drive some of the biggest challenges, including decision-making capabilities and processes such as TM. And the shortage of skilled professionals will increase in critical technology and business-related areas that can bring GenAI into development phases.	4.7	90 %
8	The operational effectiveness and impact of pharmaceutical companies, particularly in commercial, market access, and supply chain management, will improve as new technologies such as GenAI become more cost competitive and advanced management capabilities are critical for compliance, legal and regulatory approvals, and validations.	4.1	64 %
9	The focus on governance metrics will continue to grow, and investors, boards, and corporate leaders will demand greater transparency and performance in AI-related areas.	4.3	87 %
10	Product, service, and business model innovation is being driven by rapid developments in digital technologies and GenAI solutions, but pharmaceutical information technology departments are not yet ready for the full transformation.	4.9	95 %
11	AI will become increasingly important in the pharmaceutical and healthcare industries, especially for implementing digital transformation initiatives and sustainable practices.	3.7	57 %
12	GenAI and digital transformation will continue to be important governance parameters for future demand in the pharmaceutical industry.	4.3	78 %
13	The relationship between AI and complex processes such as tender management will become increasingly important in the pharmaceutical industry.	3.7	60 %

(*continued on next page*)

Table 5 (*continued*)

ID	Projections	Impact	Probability
14	Future efforts to improve the capabilities of pharmaceutical systems can focus on leveraging AI, such as international leadership, to create value and improve operational efficiency, sustainability, and impact, and can also be linked to various ESG parameters.	3.6	74 %

in expert opinion, perhaps reflecting evolving perspectives on the balance between privacy and operational imperatives. In terms of intervention areas, 'Decision Making' and 'Global Standards and Sustainability' have seen a decrease in scores, possibly indicating a reassessment of their direct impact, while 'Regulatory Cooperation' and 'International Standards' remain stable, highlighting the importance of cross-border and inter-agency cooperation.

In terms of future recommendations, there is a notable increase in the mean score for 'Develop AI-specific pharmaceutical compliance protocols', underscoring the growing recognition of the need for industry-specific guidelines. The consistent emphasis on 'AI ethics and compliance training programs' and 'Ethical AI in marketing and sales strategies' reflects an ongoing commitment to ethical considerations. Operational efficiency metrics such as 'Managerial Capabilities' and 'Data Technostructure' show little variance, indicating a continued recognition of their importance. However, 'Internal Capacity and Skills' shows a decline, suggesting possible overestimation in the early rounds or a realignment of expectations. The top risks identified include 'Failure to comply with evolving regulations, legal challenges', which shows an increased concern in the second round, which may be attributed to the dynamic nature of the regulatory environment influenced by European tenders.

Regarding the statistical analysis resulted from the Delphi rounds, the study began with a concordance analysis using Kendall's W coefficient for both rounds of scoring. In the first round, Kendall's W was determined to be 0.56 ($X2 = 1410.81$, $p < 0.00$), indicating a remarkable agreement among the experts and allowing the rejection of the null hypothesis of no agreement. This was followed by a second round where Kendall's W increased to 0.60 ($X2 = 1522.52$, $p < 0.00$), indicating increased consensus in subsequent responses.

Participants received feedback on the average responses to the 20 statements that lacked consensus, allowing them to reconsider and possibly revise their ratings. This process, conducted from November 12–24, 2023, yielded a complete response rate, and resulted in several statements reaching consensus. The mean and standard deviation (SD) of the agreement ratings for each statement were calculated, demonstrating a stable level of consensus (W) across both rounds.

The decision to end the study after the second round was based on the marginal potential benefit of additional rounds versus the risk of participant dropout or forced consensus. This was due to a plateauing of consensus after two rounds, as indicated by Kendall's W. In the absence of consensus on certain statements, a second phase of analysis revealed insightful discussions. The 12 statements without consensus were examined for bimodal distributions and three distinct expert groups with unique intragroup agreements identified, particularly in areas such as V1, V3 and V4 relevant parameters. Interquartile range (IQR) analysis was also performed to identify the most informative statements. The internal consistency of all statements was confirmed with values greater than 0.7, except for the continuous Improvement aspect of the V1, indicating reliable measurement consistency.

The third phase of statistical analysis involved comparative and

Table 6
Overview of collected round 1 and 2 data. IQR = interquartile range. Mean and SD Cha. = Mean and SD Change.

Statement	Round 1 N = 53			Round 2 N = 53			Round 1 vs. Round 2	
	IQR	Mean	SD	IQR	Mean	SD	Mean Cha.	SD Cha.
GenAI Key Elements (Variable One – V1)								
Ethical Use & Responsibility	1.0	4.4	0.8	1.0	4.6	0.6	0.2	−0.2
Legal and Regulatory Compliance	1.3	3.9	1.1	1.0	4.4	0.9	0.5	−0.2
Data Privacy and Security	1.3	3.9	1.0	1.0	4.2	0.8	0.3	−0.2
Governance and Standardization	1.0	4.1	0.7	0.0	3.9	0.7	−0.2	0.0
Patient-Centric Initiatives	1.0	4.2	0.8	1.0	4.1	0.7	−0.2	−0.1
Transparency and Accountability	1.0	3.6	1.0	1.0	3.7	0.9	0.1	0.0
Intervention Areas (Variable Two – V2)								
Decision Making	1.0	3.5	0.9	1.0	3.3	0.9	−0.3	0.0
Regulatory Collaboration	1.0	3.9	0.9	2.0	3.9	0.9	0.0	0.1
Global Standards and Sustainability	2.0	3.1	1.1	1.0	3.4	1.0	0.3	−0.1
International Standards	1.0	3.7	1.0	1.0	4.1	1.0	0.3	0.0
Bias and Ethical Considerations.	1.0	3.8	0.8	1.5	3.9	1.0	0.0	0.2
Future Recommendations (Variable Three – V3)								
Establish AI Ethics Board	1.0	3.7	1.0	1.0	4.2	0.8	0.4	−0.2
Develop AI-Specific Pharma Compliance Protocols	0.0	3.9	0.8	1.0	4.3	0.7	0.4	−0.1
Enhanced Cybersecurity for Research Data Privacy in Patient Interactions	0.0	3.9	0.8	3.0	3.3	1.5	−0.6	0.7
Regular AI System Audits	2.0	3.2	1.1	2.0	3.2	1.3	0.0	0.2
Implement Pharmacovigilance AI Systems	1.0	3.9	0.9	1.0	4.2	1.0	0.4	0.1
Training Programs on AI Ethics and Compliance	1.0	4.0	0.9	1.0	3.5	1.0	−0.5	0.1
Ethical AI in Marketing and Sales Strategies	1.0	3.4	1.1	1.0	4.1	0.9	0.7	−0.2
Operational Efficiency (Variable Four – V4)								
Managerial Capabilities	1.0	3.3	0.8	1.0	3.4	0.8	0.1	0.0
Digital Transformation	2.0	4.1	1.0	1.0	4.4	0.9	0.3	−0.1
Data Technostructure	1.0	3.9	0.7	1.0	3.6	1.0	−0.2	0.3
Internal Capacity and Skills	1.0	3.6	0.7	1.0	3.4	1.1	−0.1	0.3
Project Management	1.0	3.5	1.1	1.0	4.1	1.0	0.7	−0.1
Major Risks (Variable Five – V4)								
Non-compliance with evolving regulations, legal challenges	1.0	3.3	0.8	1.0	4.0	0.9	0.7	0.2
Cyberattacks, data leaks, adaptation challenges	2.0	4.1	1.0	2.0	3.9	1.1	−0.2	0.1
Major compliance issues, resistance to change	1.0	4.0	0.8	1.0	3.7	1.0	−0.3	0.1
Data bias, false negatives in drug reaction reporting	1.0	3.6	0.7	1.0	3.7	0.9	0.1	0.2
Misinterpretation of needs, design inefficiencies	1.0	3.5	1.1	2.0	3.9	1.0	0.4	−0.1
Ethical dilemmas, transparency challenges	1.0	3.6	1.0	2.0	3.1	1.1	−0.4	0.1
Public distrust, miscommunication of capabilities	2.0	3.0	1.1	1.3	3.5	1.2	0.5	0.1

relational logic models, which enhanced the understanding of the variable relationships. Given the ordinal nature of the independent variables from the Likert scales, linear regression, Mann-Whitney, and Spearman ranking tests were used for quantitative analysis. Alpha Cronbach correlation tests yielded positive reliability coefficients, confirming significant statistical associations between various variable pairs such as V1 and V2 ($p = 0.977$), V1 and V3 ($p = 0.982$), V2 and V3 ($p = 0.978$), V4 and V5 ($p = 0.941$), and V1 and V5 ($p = 0.934$). This indicates robust relationships across all variable subgroups examined.

5. Discussions

The successful adoption of AI by companies such as those exemplified by Companies A and B in this study demonstrates that AI can substantially enhance operational efficiency, decision-making, and stakeholder engagement. These companies are better positioned to leverage real-time data analysis, optimize tendering strategies, and maintain competitive advantages in a rapidly evolving market.

However, the study also identifies the challenges associated with AI adoption, particularly for companies that are slower to integrate these technologies. For Companies C and D, which rely on traditional TM processes, there is an increasing risk of becoming less efficient, less accurate, and of failing to comply with evolving regulatory standards. It is evident that companies must prioritize AI integration to maintain competitiveness, while also exercising caution to ensure ethical considerations and regulatory compliance are upheld. This necessitates a strategic approach that encompasses investment in AI-driven tools, training for personnel, and the formulation of robust governance frameworks to mitigate risks and maximize the benefits of AI.

The societal implications of integrating AI into pharmaceutical tendering processes are profound. AI has the potential to transform the procurement and distribution of pharmaceutical products, which could result in more efficient and effective healthcare delivery. By enhancing the precision and velocity of TM procedures, AI can facilitate more expedient access to essential medications and vaccines, particularly in the context of public health crises like the ongoing pandemic. This, in turn, can enhance public health outcomes and reduce disparities in access to essential healthcare resources.

Nevertheless, the study also highlights the ethical and social risks associated with AI, particularly about data privacy, algorithmic bias, and the transparency of AI-driven decisions. In the absence of effective risk management, these risks could result in public distrust of AI technologies, particularly in domains such as healthcare that are perceived as sensitive. It is therefore imperative that companies and regulators collaborate to guarantee that AI is deployed in a manner that upholds societal values, safeguards individual rights, and fosters public confidence in technological progress.

The findings from the case studies yielded significant insights into the transformative impact of AI on TM projects. In the companies that have integrated AI, the technology's precision and effectiveness in managing TM programs were particularly noteworthy. The capacity of AI to address challenges in real time, including data analysis for market insights and AI-driven forecasting for supply chain optimization, was a pivotal factor in the success of these companies' TM initiatives. The implementation of specific AI capabilities, including document review, contract preparation, and submission processes, has led to notable improvements in the efficiency and accuracy of TM operations. These advancements were reflected in the outcomes of the projects, where AI-driven strategies resulted in higher success rates, increased profitability, and improved stakeholder engagement.

Nevertheless, the study also revealed a disparate impact of AI across diverse projects. While AI significantly improved overall success in certain situations, not every project achieved the same level of efficiency or programmatic goals. The variability in outcomes underscores the significance of context-specific factors, including the organization's preparedness for AI adoption, the degree of senior management involvement, and the alignment of AI initiatives with overarching business objectives. Feedback from senior management was instrumental in comprehending these dynamics, as it provided insights into their initial expectations, the challenges encountered during AI implementation, and the lessons learned from these experiences. This feedback proved invaluable in refining business models and operational frameworks, aligning them more closely with organizational objectives and enhancing the overall effectiveness of AI-driven TM processes.

The capacity of AI to simulate diverse tendering scenarios, analyze historical bidding outcomes, and propose competitive pricing and contractual terms proved invaluable in assisting organizations to navigate the intricacies of the tendering process. Nevertheless, the efficacy of these AI-driven strategies hinged on the organization's capacity to seamlessly integrate AI into its existing operational framework and to navigate the cultural and operational shifts necessitated for successful implementation. The involvement of senior management from the outset of the AI initiatives was identified as a critical factor in their success, as it ensured that the necessary resources, support, and strategic direction were in place to facilitate AI adoption.

A comparative analysis of AI-integrated companies (A and B) and non-AI companies (C and D) demonstrates not only the operational advantages of AI but also the emerging disparities in how these organizations manage governance and compliance. Organizations that have fully embraced AI demonstrate a notable enhancement in real-time decision-making, process automation, and stakeholder engagement. Furthermore, these companies have initiated the development and implementation of comprehensive ethical frameworks to address potential issues related to data privacy, bias, and transparency. However, the study also indicates that the implementation of AI is not without its challenges. The transition to AI-driven processes necessitates a substantial investment in technology, training, and restructuring, which can present a significant obstacle for companies with limited resources or those operating in highly regulated environments.

The reduction of between 4 and 6 FTEs in TM tasks illustrates the tangible operational efficiencies brought about by AI. This reduction highlights the ability of AI systems to automate repetitive tasks like document processing and compliance checks, which were previously labor-intensive. However, this efficiency gain must be weighed against the financial costs associated with AI implementation. The annual costs of AI systems, averaging, include not only software licensing and training but also the supervision of AI-generated results. Approximately 1 to 2 FTEs were dedicated to overseeing AI outputs to ensure compliance with regulatory standards and accuracy in document submissions. While AI has substantially improved document production, it is important to address the issue of 'hallucinations' often seen in large language models like ChatGPT. Both Companies A and B noted instances where AI-generated content, particularly in complex legal and technical documents, contained inaccuracies or extraneous information. To mitigate this, companies implemented robust supervision processes, requiring human review for all AI-generated outputs. This supervision reduced the occurrence of hallucinations but did not eliminate them entirely, suggesting that further refinement of AI tools or enhanced training protocols may be necessary to ensure consistently accurate outputs.

Furthermore, the study highlights the pivotal function of regulatory frameworks in influencing the uptake of AI in the field of pharmaceutical technology management. The latest European directives, particularly the AI Act and GDPR, have established rigorous standards for compliance, necessitating the implementation of robust measures for data protection and ethical AI use. The heat maps and statistical analyses in this study demonstrate that companies at the vanguard of AI adoption are aligning their practices with these regulations, frequently exceeding the minimum requirements to circumvent potential legal and reputational risks. However, companies that have been slower to adopt AI are experiencing difficulties in keeping pace, which could result in compliance issues and a potential loss of competitive advantage as regulatory oversight intensifies.

In consideration of these findings, it is evident that the successful integration of AI in pharmaceutical TM processes is contingent upon not only technological adoption but also the development of comprehensive governance and ethical frameworks. It is incumbent upon companies to proactively address the challenges posed by AI, ensuring that their implementation strategies are aligned with both industry standards and societal expectations. This entails the continuous monitoring of AI systems for potential bias, the maintenance of transparency in AI-driven decision-making processes, and the engagement with relevant stakeholders to foster trust in these technologies.

The broader implications of this study suggest that as AI continues to evolve, it is imperative that the pharmaceutical industry—and indeed all industries adopting AI—prioritize ethical governance and compliance as central components of their AI strategies. For the scientific community, this research underscores the necessity for sustained interdisciplinary collaboration to develop AI governance models that are both resilient and adaptable to disparate regulatory environments. As AI reshapes the landscape of TM and beyond, it is imperative that these developments are guided by principles that ensure the technology benefits all stakeholders equitably, promoting both innovation and accountability.

6. Conclusions

6.1. Identifying limitations and Proposing future recommendations

This research was constrained by several factors, primarily the logistical challenges associated with remote interviews and the time constraints imposed by the Delphi rounds. The most significant challenge was coordinating schedules across time zones and managing the diverse schedules of participants, who were in various European countries. The remote nature of the interviews presented a challenge in establishing rapport and effective communication, which are typically more accessible in face-to-face interactions. This occasionally resulted in a reduction in the depth and quality of the information obtained, as nuances may be lost in virtual settings. The collection of comprehensive case study data was a protracted process, spanning several months. This was due to the necessity of meticulous data verification, the undertaking of iterative information gathering from a multitude of sources, and the occurrence of logistical coordination delays.

In terms of recommendations, this research proposes practices for future studies and a more integrated approach to the use of AI in pharmaceutical initiatives. The application of AI has the potential to markedly improve the innovation process within pharmaceutical companies, particularly in the domains of market access and commercialization.

AI can be employed to analyze market trends, patient needs and competitive landscapes, thereby identifying unmet medical needs or market gaps. This facilitates the generation of innovative ideas for new drugs, therapies or go-to-market strategies. The management of regulatory processes is a crucial aspect of any organization. The application of AI can facilitate the regulatory approval process by ensuring compliance with evolving standards, reducing the incidence of documentation errors, and enhancing communication with regulatory agencies.

Regarding market access and pricing, AI can be employed to analyze global market data to develop effective pricing strategies and market access plans. It can also be used to set competitive prices, gain insight into the perspectives of payers, and navigate the complexities of reimbursement landscapes. Further research should build on the findings of this study by exploring the impact of AI on other aspects of pharmaceutical operations, such as clinical trials and supply chain management. Additionally, studies that investigate the scalability of AI governance frameworks across different regulatory environments would provide valuable insights for global pharmaceutical companies.

6.2. Conclusions

This research has investigated the potential for AI to transform the pharmaceutical industry's TM processes, with a particular focus on its impact on operational efficiency, governance, and ethical considerations. The study employed a dual-methodological approach, combining comparative case studies and the Delphi technique, to provide a comprehensive analysis of the integration of AI into TM processes and the resulting implications for organizations that have adopted these technologies versus those that have not.

The findings indicate that AI provides substantial benefits in terms of enhancing the precision, speed, and effectiveness of TM operations. The integration of AI into TM processes has been shown to markedly enhance an organization's capacity to manage complex tasks, including data analysis for market insights, AI-driven forecasting for supply chain optimization, and real-time decision-making. These developments not only result in increased success rates in the tendering process but also contribute to enhanced profitability and more effective stakeholder engagement. However, the study also indicated that the successful implementation of AI is contingent upon several factors, including organizational readiness, senior management involvement, and the alignment of AI initiatives with broader business goals.

While AI presents considerable opportunities, it also introduces new challenges, particularly in the realms of governance and ethics. The study identified eight critical areas of AI governance, including data privacy, transparency, and ethical AI use, which are essential for ensuring that AI adoption aligns with both regulatory standards and societal expectations. The research highlights the necessity of developing comprehensive governance frameworks that can adapt to the accelerated pace of technological advancement, mitigate the risks associated with AI, and maintain public trust.

The Delphi technique was employed to corroborate and refine the findings through expert consensus, thereby ensuring that the conclusions drawn are empirically substantiated and pertinent across diverse organizational contexts. The Delphi technique was employed in an iterative manner, thereby enhancing the credibility of the research. Moreover, the technique illuminated the far-reaching implications of AI in TM and furnished actionable recommendations for organizations that are navigating the complexities of AI adoption. It is recommended that future research give priority to the mitigation of potential biases by the employment of methods such as blind interviews and more diverse sampling. This will ensure that the outcomes of AI integration are assessed objectively and free from the influence of company-driven perspectives.

This research contributes to the growing body of knowledge on the role of AI in the pharmaceutical industry by providing a detailed and nuanced understanding of the benefits and challenges associated with the integration of AI in the context of TM processes. The study highlights the necessity for a strategic approach to AI adoption, whereby technological advancements are balanced with ethical governance and compliance with regulatory standards. The findings offer valuable insights for organizations seeking to leverage AI for the enhancement of TM operations, while also underscoring the importance of organizational readiness and ethical considerations. For the scientific community, the research provides a foundation for further interdisciplinary inquiry into the nexus of AI, governance, and ethics, with the aim of developing optimal practices for AI implementation.

As AI continues to evolve and become more embedded in critical business processes, its impact on industries like pharmaceuticals will undoubtedly increase. The challenges identified in this research underscore the necessity for sustained dialogue and collaboration between industry stakeholders, regulators, and the scientific community to ensure that AI is implemented in ways that maximize its benefits while safeguarding ethical and societal values. The role of the human factor in ensuring the ethical and effective use of these tools will become even more critical. Future research should explore how companies can foster

human-AI collaboration to maximize the benefits of AI systems while safeguarding against potential risks. The upskilling of employees and the fostering of a culture of ethical AI use will be essential in navigating the complexities of AI-driven transformation in industries like pharmaceuticals.

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CRediT authorship contribution statement

Antonio Pesqueira: Validation, Supervision, Resources, Project administration, Methodology, Investigation. **Andreia de Bem Machado:** Project administration, Methodology, Investigation. **Sama Bolog:** Validation, Supervision, Data curation.

Declaration of competing interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

Data availability

Data will be made available on request.

References

Ahmed, Z., Mohamed, K., Zeeshan, S., & Dong, X. (2020). Artificial intelligence with multi-functional machine learning platform development for better healthcare and precision medicine. *Database, 2020*. baaa010.

Ball, P. (2021). What the COVID-19 pandemic reveals about science, policy and society. *Interface Focus, 11*(6), 20210022.

Barbier, L., Simoens, S., Soontjens, C., Claus, B., Vulto, A. G., & Huys, I. (2021). Off-patent biologicals and biosimilars tendering in Europe—a proposal towards more sustainable practices. *Pharmaceuticals, 14*(6), 499.

Chen, Q., Peng, Y., & Lu, Z. (2019). BioSentVec: Creating sentence embeddings for biomedical texts. In *Proceedings of the 2019 IEEE International Conference on Healthcare Informatics (ICHI)* (pp. 1–5). IEEE. https://doi.org/10.1109/ICHI.2019.8904632.

Cifuentes-Faura, J. (2022). European Union policies and their role in combating climate change over the years. *Air Quality, Atmosphere & Health*, 1–8.

Dash, S., Luhach, A. K., Chilamkurti, N., Baek, S., & Nam, Y. (2019). A neuro-fuzzy approach for user behavior classification and prediction. *Journal of Cloud Computing, 8*(1), 1–15. https://doi.org/10.1186/s13677-019-0128-8

Dillard-Wright, J., & Shields-Haas, V. (2021). Nursing with the people: Reimagining futures for nursing. *Advances in Nursing Science, 44*(3), 195–209.

Dwivedi, Y. K., Hughes, L., Ismagilova, E., Aarts, G., Coombs, C., Crick, & Williams, M. D. (2021). Artificial Intelligence (AI): Multidisciplinary perspectives on emerging challenges, opportunities, and agenda for research, practice and policy. *International Journal of Information Management, 57*, Article 101994.

Eager, B., & Brunton, R. (2023). Prompting higher education towards AI-augmented teaching and learning practice. *Journal of University Teaching & Learning Practice, 20*(5), 02.

Ebrahimi, S., & Bridgelall, R. (2021). A fuzzy Delphi analytic hierarchy model to rank factors influencing public transit mode choice: A case study. *Research in Transportation Business & Management, 39*, Article 100496.

ElBaih, M. (2023). The Role of Privacy Regulations in AI Development (A Discussion of the Ways in Which Privacy Regulations Can Shape the Development of AI). Available at SSRN 4589207.

Ferrara, E. (2024). The butterfly effect in artificial intelligence systems: Implications for AI bias and fairness. *Machine Learning with Applications, 15*, Article 100525.

Frieden, T. R., Varghese, C. V., Kishore, S. P., Campbell, N. R., Moran, A. E., Padwal, R., & Jaffe, M. G. (2019). Scaling up effective treatment of hypertension—a pathfinder for universal health coverage. *The Journal of Clinical Hypertension, 21*(10), 1442–1449.

Gebhardt, M., Kopyto, M., Birkel, H., & Hartmann, E. (2022). Industry 4.0 technologies as enablers of collaboration in circular supply chains: A systematic literature review. *International Journal of Production Research, 60*(23), 6967–6995.

Hao, X., Demir, E., & Eyers, D. (2024). Exploring collaborative decision-making: A quasi-experimental study of human and Generative AI interaction. *Technology in Society, 78*, Article 102662.

Heinonen, K., & Strandvik, T. (2020). Reframing service innovation: COVID-19 as a catalyst for imposed service innovation. *Journal of Service Management, 32*(1), 101–112.

Jalil, S., Rafi, S., LaToza, T. D., Moran, K., & Lam, W. (2023). ChatGPT and software testing education: Promises & perils. In *Proceedings of the 2023 IEEE International Conference on Software Testing, Verification and Validation Workshops (ICSTW)* (pp. 4130–4137). IEEE, 10.1109/ICSTW58661.2023.00128.

Javaid, M., Haleem, A., & Singh, R. P. (2023). ChatGPT for healthcare services: An emerging stage for an innovative perspective. *BenchCouncil Transactions on Benchmarks, Standards and Evaluations, 3*(1), Article 100105.

Jiang, M., Li, P., Yao, X., Hayat, K., Gong, Y., Zhu, S., & Fang, Y. (2021). Preference of influenza vaccination among the elderly population in Shaanxi province. *China. Human Vaccines & Immunotherapeutics, 17*(9), 3119–3125.

Kasneci, E., Seßler, K., Küchemann, S., Bannert, M., Dementieva, D., Fischer, F., & Kasneci, G. (2023). ChatGPT for good? On opportunities and challenges of large language models for education. *Learning and Individual Differences, 103*, Article 102274.

Kotcher, J., Maibach, E., Miller, J., Campbell, E., Alqodmani, L., Maiero, M., & Wyns, A. (2021). Views of health professionals on climate change and health: A multinational survey study. *The Lancet Planetary Health, 5*(5), e316–e323.

Kouba, P., Kohout, P., Haddadi, F., Bushuiev, A., Samusevich, R., Sedlar, J., & Mazurenko, S. (2023). Machine learning-guided protein engineering. *ACS Catalysis, 13*(21), 13863–13895.

Lee, H. (2023). The rise of ChatGPT: Exploring its potential in medical education. *Anatomical Sciences Education. Advance Online Publication.* https://doi.org/10.1002/ase.2359

Miller, F. A., Lehoux, P., Peacock, S., Rac, V. E., Neukomm, J., Barg, C., & Krahn, M. (2019). How procurement judges the value of medical technologies: A review of healthcare tenders. *International Journal of Technology Assessment in Health Care, 35*(1), 50–55.

Mostafiz, M. I., Musteen, M., Saiyed, A., & Ahsan, M. (2022). COVID-19 and the global value chain: Immediate dynamics and long-term restructuring in the garment industry. *Journal of Business Research, 139*, 1588–1603.

Noori, A., Bonakdari, H., Morovati, K., & Gharabaghi, B. (2020). Development of optimal water supply plan using integrated fuzzy Delphi and fuzzy ELECTRE III methods—Case study of the Gamasiab basin. *Expert Systems, 37*(5), e12568.

Pesqueira, A., Sousa, M. J., & Rocha, Á. (2020). Big data skills sustainable development in healthcare and pharmaceuticals. *Journal of Medical Systems, 44*(11), 1–15.

Pettersen, I. J., Nyland, K., & Robbins, G. (2020). Public procurement performance and the challenge of service complexity–the case of pre-hospital healthcare. *Journal of Public Procurement, 20*(4), 403–421.

Prasert, V., Thavorncharoensap, M., & Vatcharavongvan, P. (2022). Acceptance and willingness to pay under the different COVID-19 vaccines: A contingent valuation method. *Research in Social and Administrative Pharmacy, 18*(11), 3911–3919.

Simoens, S., & Cheung, R. (2020). Tendering and biosimilars: What role for value-added services? *Journal of Market Access & Health Policy, 8*(1), 1705120.

Simoens, S., & Vulto, A. G. (2021). A health economic guide to market access of biosimilars. *Expert Opinion on Biological Therapy, 21*(1), 9–17.

Singh, A., & Chouhan, T. (2023). Artificial intelligence in HRM: Role of emotional–social intelligence and future work skill. In *The Adoption and Effect of Artificial Intelligence on Human Resources Management, Part A* (pp. 175–196). Emerald Publishing Limited.

Sturm, N., Mayr, A., Le Van, T., Chupakhin, V., Ceulemans, H., Wegner, J., & Chen, H. (2020). Industry-scale application and evaluation of deep learning for drug target prediction. *Journal of Cheminformatics, 12*, 1–13.

Ullah, H., Manickam, S., Obaidat, M., Laghari, S. U. A., & Uddin, M. (2023). *Exploring the Potential of Metaverse Technology in Healthcare: Applications, Challenges, and Future Directions*. IEEE Access.

Vallentin, A., Thórisson, K. R., & Latapie, H. (2023). In *May). Addressing the Unsustainability of Deep Neural Networks with Next-Gen AI* (pp. 296–306). Cham: Springer Nature Switzerland.

Vlasta, M. (2023). Methodological framework for European regulation of (artificial) intelligence and its limits. *Journal of European Regulation Studies, 15*(2), 45–62.

Wamba, S. F., Queiroz, M. M., Jabbour, C. J. C., & Shi, C. V. (2023). Are both generative AI and ChatGPT game changers for 21st-Century operations and supply chain excellence? *International Journal of Production Economics, 265*, Article 109015.

World Health Organization. (2019). Meeting report: WHO technical consultation: Nutrition-related health products and the World Health Organization model list of essential medicines – practical considerations and feasibility: Geneva, Switzerland, 20–21 September 2018 (No. WHO/NMH/NHD/19.1). World Health Organization. https://apps.who.int/iris/handle/10665/327437.