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Scaling AI-based industry 4.0 projects in the medical device industry: An exploratory analysis

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Abstract

As technological advancements in artificial intelligence (AI) accelerate, the effect it has on the adoption of Industry 4.0 is significant. The adoption of AI-based Industry 4.0 projects creates a significant opportunity to generate new revenue streams and high-value customer-centric products. However, medical device manufacturing organisations are strictly scrutinised by regulatory authorities due to the critical nature of these devices and their impact on humans. This presents a challenging environment for medical device manufacturers to experiment with and implement new technologies. However, the significance and impact of AI-based projects are acknowledged by regulatory authorities such as the FDA and EMA and PMDA, allowing the incorporation of AI-based devices. This change in regulations, although limited, opens up immense opportunities for medical device manufacturers. Although extensive studies on the barriers, challenges, and failure factors of AI projects are available, very few studies explore these from a medical device manufacturing perspective. This is essential due to the significant limitations posed by the regulations governing medical device development. This study analyses the challenges and factors affecting the scaling of AI-based Industry 4.0 projects in medical device manufacturing organisations. The study found three major factors influencing the scaling of AI-based Insutry 4.0 projects. They comprise infrastructural costs, security risks and a change management migration plan. However, investing in these factors with a view to scaling may create additional revenue sources and also help in reaching a faster return on investment. Such investments can also improve the overall productivity of the industry, allowing the creation of high-value customer-centric products. The perceived security risks in the industry were found to be higher than the risks analysed in previous literature, suggesting a need to create an informed workforce. The study also found that for effective implementation of scalable AI-based industry 4.0 projects a skilled workforce with a shared long-term vision is required.

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Keywords: Artificial intelligence scaling; critical success factors; medical device manufacturing; industry 4.0; AI projects.

1. Introduction

As the medical device industry continues its technological shift towards a decentralised network of interconnected devices integrated with AI and machine learning techniques, improved data mining and intelligent decision-making capabilities create tremendous opportunities for new applications across a wide range of sectors [1]. However, the medical device manufacturing industry is heavily regulated to assure the safety of the patient, and these regulations vary depending on location and regulatory bodies [2-4]. Regulations make the adoption of smart technologies difficult. Furthermore, to eliminate health risks to patients and assure their safety, medical devices are categorised into different classes with increasing regulatory control [5]. This makes medical device manufacturing a challenging field for the implementation and experimentation of new technologies [6].

As more companies move towards the implementation of industry 4.0, manufacturing organisations are incorporating digitisation intending to achieve computational self-awareness [7]. This can be characterised by automation, the inclusion of smart manufacturing techniques and using data to make informed business decisions[8],[9]. The main technologies that are driving the industry 4.0 revolution are the Internet of Things (IoT), cloud computing, AI and ML, edge computing, fog computing and digital twin. While the IoTs can implement cloud edge or fog computing to optimise the analytical side of data based on the priority of data analytics to be performed, the insights generated from the data are often based on the data trends observed and predictions based on the same. It is at this stage the importance of AI and Machine Learning (ML) are observed [10-13]. It has been also observed that AI-based industry 4.0 projects can improve the revenue of the medical device manufacturing industry by reducing maintenance costs and creating new revenue streams [9]. Such projects can also improve the quality of products, and the well-being of the workforce and improve customer relations based on the availability of informed decisions made with rich and structured data collected by such projects [14–17]. This creates an urgency to identify the factors that accelerate, enhance and inhibit the adoption of industrial AI-based industry 4.0 projects.

Integration of AI projects has risen in the past decade owing to advancements in technology and the emergence of powerful computing systems. However, prior work suggests that most AI project implementations either fail or make a minimal impact [18],[19]. Integration of connected devices (IIoT) and AI systems in Industry 4.0 projects within medical device manufacturing represent a smaller percentage of overall projects due to the heavy regulation within the medical device manufacturing sector [6]. Although the critical failure factors and critical success factors of AI projects are widely discussed [19], the factors affecting its implementation in industry 4.0 projects in the medical device manufacturing industry are not aptly represented. Consequently, there is a requirement in the industry to identify and analyse the extent of influence of various factors that enable or inhibit the adoption of AI-based industry 4.0 projects within the scope of medical device manufacturing. The main objective of this study is to identify and categorise factors that influence the success of an AI-based industry 4.0 project within the medical device manufacturing industry. Measuring the degree of influence of these factors can provide a foundation for creating a roadmap for future projects within the medical device manufacturing industry while maintaining the essential regulatory standards of the field. This paper proceeds as follows; a literature review identifying the barriers to scaling of AI-based industry 4.0 projects; a discussion of the methodology utilised in the study and the results of the analysis.

2. Literature review

It is estimated by the FDA that AI-based projects in the medical industry have the potential to create a net yearly saving of $150 billion in the next 7 years, with $54 billion focusing on medical devices [20]. Similar to the FDA, the European Medicine Agency (EMA) has also acknowledged the importance of AI-based Industry 4.0 projects in the medical device manufacturing industry, incorporating changes in regulations to accommodate emerging technologies. This was reflected in the draft regulation adopted by the European Parliament in October 2020, provisioning a

comprehensive regulatory framework for AI [21]. Industry 4.0 technologies have been identified as an emerging field in previous studies with 30% focus on Cyber-Physical Systems (CPS), 37% on analytics and 15% on general smart manufacturing concepts [22,23]. While CPS technologies bridge cyber-physical entities, Human-Robot Collaboration (HRC) technologies are essential for a human-centric innovation essential for future projects and smart factories[23–25]. Various IT solutions are employed in fault detection, predictive maintenance, communication, virtualisation and human-machine interface (HMI) within the scope of Industry 4.0 projects but represent a very small fraction of the total implementation of these technologies within the scope of medical device manufacturing [26–34]. A comprehensive analysis of the literature identified three key barriers to scaling AI-based industry 4.0 projects in the medical device manufacturing industry; namely, Infrastructural costs, Security risks and Poor change management practices.

2.1. Infrastructural costs

For scalable AI solutions, businesses must manage data effectively and efficiently. This requires a robust data environment for securely collecting and processing a significant amount of data, requiring heavy computational requirements [35]. Data should be incorporated as end-to-end solutions on comprehensive machine learning architectures [36]. The models should ensure data protection, disaster recovery, fixed-cost computing and powerful analytics while ensuring quality compliance. In addition, for the medical device manufacturing industry, this may also include necessary additions incorporating the regulatory requirements of the sector, adding to the cost [6]. Even though AI projects offer promising benefits, they cannot reduce the actual workforce cost due to the laws and regulations within the industry [37]. A large-scale AI project can take 2-3 years to start generating a return on investment and is a long and expensive process with a longer investment cycle and a lower probability of high returns [38,39]. However, Rao and Verweij (2017) report that the most significant driver to implementing AI-based industry 4.0 projects will be increased productivity due to automation of routine tasks, followed by enhancing employee capabilities creating opportunities for higher value-adding work. These contradictory views on the cost vs benefit of implementing AI-based industry 4.0 projects in the medical device industry create a necessity to analyse and validate them based on the industry's voice.

2.2. Security risks

Although AI projects are lauded to provide a superior advantage in creating personalised and customer-centric solutions, security concerns remain unsolved. The potential security threats posed by AI-enhanced projects can be grouped under digital threats, physical threats and political security [40]. While digital threats include issues like data leak, data poisoning and impersonation, physical threats include device-level attacks [41],[42]. This is significant in the medical device industry. However, having analysable data from connected devices ensures that when industry 4.0 projects are scaled across a distributed enterprise using standardised data structures, the benefits stretch across all departments as they receive data to make informed decisions. This creates a tradeoff between the device control and data that may be obtained to create a scalable AI-based industry 4.0 project. They are hence strictly regulated by the medical device regulatory bodies based on the type of medical device, its critical nature (categorised under the class of medical devices) and the nature of the data collected [43]. This creates a necessity to analyse the awareness of security issues and the methods with which they are addressed in the medical devices industry.

2.3. Poor Change Management Processes

Industry 4.0 is a significant transition for most industries and is particularly challenging for the medical device manufacturing industry due to the involvement of strict regulations within the sector [6]. The real-time data generated by smart and automated production systems will empower employees to make informed decisions dealing with complex systems [44]. This leads to a situation where the employees have to work in tandem with robots and automated machines. Hence the transition to industry 4.0 and projects involving AI and ML within manufacturing sectors involve exhaustive new talent acquisition and thorough training of the current workforce to meet the technical

demand. A report by Cisco [45] suggests that one of the top 5 reasons for failure in AI-based projects is the lack of expertise in such projects, emphasising the requirement of re-skilling the workforce to adapt to the changing industry environment. In 2018, McKinsey Global Institute [15] reported a possible decline in low digital skill and repetitive tasks from 43% to 32% and the demand for high digital skill and non-repetitive tasks might increase from 42% to 53% by 2030, resulting in almost 14% of the workforce changing occupation. Having the right people for crucial roles is critical as research suggests that 5% of the positions drive 95% of the transformational value [46,47]. All of the studies suggest that there is a strong requirement to validate the current technical skills of employees in the medical device manufacturing industry and evaluate their approach towards managing the change for creating an environment for effective implementation of AI-based industry 4.0 projects.

The literature review identified the three main factors affecting the implementation of AI-based projects in industry 4.0 projects within the medical device manufacturing industry, namely; the infrastructural costs involved in the implementation of AI-based projects, which includes the computational and device costs which are in compliance with the existing medical device production standards; security issues that address the critical nature of data collected by the medical device manufacturing industry to create informed decisions and the underlying security layer that prevents from cyber-attacks, data leaks and data poisoning that could potentially affect and alter the critical insights generated; and change management to be affected by the medical device manufacturing industries to incorporate the fast-changing and evolving nature of AI-based Industry 4.0 projects, requiring the additional inclusion of skilled workforce and re-skilling of the existing workforce.

3. Methodology

A mixed method involving both quantitative and qualitative methods was employed in the research design of this study. Quantitative methods were used to analyse the factors identified from the literature review and qualitative method was used to capture the subtle relation within the identified factors and tacit knowledge on implementation barriers to AI-based Industry 4.0 projects within a medical device manufacturing organisation. Purposive sampling methods were used. The study used a survey method to collect opinions from the sample. This included 25 questions based on a 5-point Likert scale. The goal was to measure the effect and influence of the identified factors on the success of an AI-based industry 4.0 project. For the qualitative part of the research, semi-structured interviews were conducted with experts in industry. The rationale for conducting these interviews was to capture the additional data that could be missed in a quantitative survey.

The survey was designed to comply with the GDPR and AAPOR codes of professional ethics and practices [48] guidelines and was rigorously tested to minimise research bias. The technical errors and alignment of survey questions to the research goals were tested by piloting the survey. Following this procedure, the survey was revised to incorporate suggested changes and corrections. The survey was then sent to employees working in a medical device manufacturing organisation. A random sample representing manufacturing and design engineers, decision-makers, project and team leads and quality teams was selected for the survey. A total of 32 responses were obtained. The responses collected represented different departments, allowing data triangulation across the survey population. Peer debriefing was completed via in-depth interviews once the survey results were obtained, allowing an in-depth discussion on the subject.

4. Results and Discussion

Industry 4.0 implementation relies heavily on automated, information-rich, and analysable data to make informed and strategic decisions [35] [36]. From the study, it is observed that the industry experts and skilled employees from the medical device manufacturing sector agree that industry 4.0 will transform the current processes and operations by integrating intelligent systems and supporting IT infrastructure. For the implementation of industry 4.0, information-rich and analysable data are required for efficient decision-making. However, there is a noticeable difference in opinion among the respondents in agreement that having analysable data is critical in decision-making within industry 4.0. The disconnect in an agreement between the former and latter parts suggests that there is a lack of knowledge and general awareness of industry 4.0 and its implications within the medical device manufacturing workforce. However, the gradual acceleration observed within medical device manufacturing in adopting industry 4.0

suggests that the gap due to lack of awareness is closing quickly [48,49]. Creating an operational framework addressing the critical factors that affect the success of such projects can enhance the implementation of future AI projects as regulatory restrictions ease over time, ensuring the workforce and infrastructure are ready for the rapid adoption of scalable AI projects.

4.1. Infrastructural costs

A robust data environment is required to collect data from various intelligent and connected devices. For scalable AI solutions, businesses must manage data effectively and efficiently to ensure that it can be incorporated as end-to-end solutions on comprehensive machine learning architectures. The models should ensure data protection, disaster recovery, fixed-cost computing and powerful analytics while ensuring quality compliance. The study reports that 62.5% of the respondents agreed that significant investments are required in the medical device manufacturing industry for effective transformation to industry 4.0.50% of the respondents also reported that data-intensive AI projects fail due to the high costs involved in the required shift from legacy systems to a new architecture. The rationale for an almost equal distribution of the opinion may be attributed to the recent rise in the adoption of AI projects in the medical device manufacturing industry owing to the change in governing rules [21]. The data suggest that the medical device manufacturing sector has started adopting industry 4.0, hence addressing the critical success factors is crucial for industries to maximise the potential readiness for scaling the AI projects as regulatory limitations relax over time.

4.2. Security risks

Connected devices and an information-rich environment increase the risk of cyber attacks. The draft regulation on artificial intelligence submitted by European Parliament [50] and the report on liability for AI have taken a risk-based approach to categorise AI-based systems[21]. It works in tandem with the Medical Devices Regulation (EU) 2017/745 (MDR) [51], easing limitations and improving the scope of scalability of AI projects while maintaining policies addressing security risks. However, security risks within the scope of AI project implementation may not be overlooked to ensure high security, data integrity and compliance with the regulatory standards. 91% of the respondents felt that there would be an increased frequency of cyber-attacks in future if industry 4.0 is implemented. Hence creating a suitable security infrastructure, educating the employees on the security measures employed and creating trust within the AI project space is crucial for creating sustainable and scalable AI projects.

4.3. Workforce and change management

Change management can be tough in the medical devices manufacturing industry as changes may require re-certification, validation, and quality documentation changes. Replacement of such core practices requires a top-down approach as they can be disruptive. Having the right people for crucial roles is critical as research suggests that 5% of the positions drive 95% of the transformational value [46,47]. 58.3% of respondents report that lack of management in the overall industry affects the success of AI in industry 4.0 projects, and 54.17% report that industry 4.0 projects require leaders who can bridge organisational boundaries, communicate the strategic vision and achieve broad alignment across the cross-functional teams [14]. However, the lower percentages and the recent growth of industry 4.0 projects in the medical device manufacturing industry suggest that the top-level management and decision-makers in the medical device manufacturing industries are adopting newer technologies and scalable AI projects within the space. 62.5% of respondents suggest that there should be an experienced and skilled cross-functional team to effectively deploy and maintain AI projects in an industry 4.0 project. This would require rigorous training of the existing workforce and employing a skilled workforce to implement and manage new AI projects. 75% of the respondents reported that experienced IIoT and AI engineers are essential to the success of Industry 4.0 projects.

The impact of scalable AI projects in the medical device manufacturing industry will likely accelerate, boosting productivity and growth over time, owing to the new regulations and policies [49–51]. Companies need to implement strategies for the long haul in such projects as the net impact may be visible only after a few years [52]. Early investment in AI and industry 4.0 projects also have a two-fold advantage. First is that existing medical device manufacturing industry engineers have limited or introductory knowledge of ML and AI (75% of respondents), and

early introduction of AI and ML-based industry 4.0 projects can increase the skill set of the workforce and create an effective knowledge base for future projects. The second advantage is the long-term financial advantage for the company adopting such industry 4.0 projects. Price Waterhouse Coopers [16] reports that companies adopting industry 4.0 can expect over a 20% increase in revenue over the first 5 years, and the report was seconded by the findings of this study, where 45% of the respondents agreed with this perspective. The additional revenue streams may primarily contribute to this increase in revenue in the medical device manufacturing industry from IIoT and AI-based industry 4.0 projects and a substantial reduction in maintenance costs [9,14,15], both of which were seconded by the study findings with 84% of the respondents agreeing to it. Hence addressing the three main factors, the infrastructure, security risks, and the workforce and change management, can bring about employee upskilling, prepare the industry for the future, create an innovative work culture and improve the adoption rate of scalable AI projects

5. Conclusion

The study focuses on the critical factors that must be addressed to create sustainable and scalable AI-based industry 4.0 projects in the medical device manufacturing industries. With the fast-paced evolution of AI technologies and their rapid integration into medical devices owing to relaxation in regulations, AI-based industry 4.0 projects in medical device manufacturing companies have a significant opportunity to create high-value customer-centric products. Such projects can create unique value streams for companies creating new revenue streams and strengthening the existing revenue streams by having a customer-centric approach. The study found that three major factors influence AI-based industry 4.0 projects. The infrastructural costs required for the inclusion of new technologies, the security issues involved in the collection and processing of data, and the overall change management addressing the skill updating of the workforce and inclusion of changes required from a medical device manufacturing perspective, such as the requirement of re-certification, validation and changes in quality documentation and operational procedures are the major factors influencing such projects. The study identified a disconnect between the existing literature and the voice of the industry within the perceived security risks and changes in the organisational structure required to scale up AI-based projects in the industry 4.0 projects in medical device manufacturing. This creates a requirement of creating and effectively communicating a shared vision within the companies to implement AI-based industry 4.0 projects effectively. Addressing the aforementioned factors with a long-term shared vision can effectively create new revenue streams and create high-value customer-centric products. However, the extent of creating new revenue sources and its significance in the long term for the medical device industry are less explored and unclear. This creates a requirement to further study the long-term effects and the execution plans that could boost the adoption of AI-based projects in the medical device manufacturing sector to create successful and sustainable industry 4.0 projects

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