Opportunities and Challenges of Biotech Start-Ups Integrating Artificial Intelligence

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ABSTRACT:
Artificial Intelligence (AI) is increasingly implemented in the biotech industry. Despite growing interest in AI, existing research has yet to explore the unique challenges and opportunities start-ups encounter when integrating AI. This is particularly important as these smaller firms operate under different constraints than their incumbent competitors, while driving innovation. This research addresses this gap qualitatively by conducting interviews and assessing AI's role as a potential disruptive innovation in biotech. The results show that AI integration by start-ups is increasing their independence and resource efficiency. However, several significant barriers such as poor data quality, limited funding, and constraining regulatory frameworks continue to restrict AI's potential to fundamentally reshape the biotech industry. Further, the findings suggest that AI in the biotech industry acts as a disruptive enabler, a tool that supports new business models and innovation pathways but is constrained by external barriers to displace incumbent firms. Recommendations to investors include the formation of multidisciplinary advisory teams to bridge the knowledge gap between investors and start-ups to facilitate investment decisions and enable innovative technologies and operational scaling. For policymakers, the development of more agile regulatory frameworks is suggested, which would support the validation of AI-driven innovations and deployment while maintaining quality and safety standards.

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1. INTRODUCTION

The rise of Artificial Intelligence (AI) and its implementation in the biotech industry has been credited with transforming innovation processes, increasing efficiency, and enhancing dependability in production processes (Mehta et al., 2024). Its integration has enabled faster drug discovery, improved drug safety, and, more recently, also seems to promise personalized medicine (Van Der Lee & Swen, 2022). The steady growth in data availability, alongside improved processes for data analysis, provides more accurate predictions stemming from these larger data sets (Artico et al., 2022). Now, companies strategically aligning their business processes with AI-enabled technologies can increase their competitiveness by means such as sustainable innovations and more efficient resource use (Badghish & Soomro, 2024). Next to adopting AI as a tool to enhance (core) processes such as diagnostics or drug discovery, other start-ups provide AI-solutions in the form of software, algorithms, and platforms which are sold or licensed. However, integrating AI mechanisms also poses challenges to the industry as regulations are still being developed, ethical concerns are voiced (Mirakhori & Niazi, 2025), and critical barriers of financing and knowledge gaps are present (Ujjwal, 2024; Walsh, 2025). While start-ups are often seen as the main force in innovation, they face significant constraints in terms of funding, the commercialization of their innovations (Kennedy et al., 2023) and regulatory hurdles which complicate innovative processes (Masarone et al., 2024).

The adoption of AI in the biotech industry can be linked to Clayton Christensen's Disruptive Innovation Theory (DIT) (Christensen, 1997). This theory states that a new technology or business model can be seen as disruptive if it offers an improvement of a product or service that is unexpected by the market. Disruptive innovations differ from mere improvements in offered products and services because they supply novel offerings. Those can redefine market trajectories and ultimately transform industry structures (Christensen, 2014). Therefore, AI is a potential disruptive force in the biotech industry, reshaping preceding processes and enabling further discoveries through AI-powered solutions.

The implementation of AI specifically in biotech start-ups, which face very different challenges and opportunities compared to established, large competitors, is still largely underexplored. Most existing literature either focuses on technical advances in R&D (Fu & Chen, 2025; Van Der Lee & Swen, 2022) or broad implementation challenges in large pharmaceutical companies (Holzinger et al., 2023; Jayatunga et al., 2024), omitting to investigate how smaller firms navigate a demanding environment while stimulating AI-driven innovation and advancements. There is a lack of real-world insight on the main drivers of AI adoption in start-ups, as the current literature rarely covers the operational challenges smaller, resource-constrained firms face. As AI-native biotech start-ups become increasingly prevalent (Fujiwara, 2024), identifying the main drivers for AI adoption and the barriers impacting early-stage biotech start-ups driving innovation is crucial to understand the real-word conditions for their operations in the industry. This also provides current insights on start-up specific perceptions of the growing market of AI in biotech and the environment start-ups integrating AI compete in. Furthermore, it will investigate the transformative potential and role of AI as potential disruptive innovation, as its capabilities are said to be "disrupting" the biotech industry (Bentwich, 2023) and critically evaluate how suitable this assessment is. This research is needed to better understand the concrete opportunities and barriers posed by AI and how they impact the start-up environment.

1.1 Research Objective and Question

Considering the above, this research aims to explore the main barriers and opportunities start-ups in the biotech industry face when adopting AI. The existing research gap will be filled by means of a literature review, followed by conducting semi-structured interviews to identify the unique opportunities and challenges AI biotech start-ups face and how those impact their operations. Therefore, the research question is as follows:

What are the main opportunities and challenges biotech start-ups face when integrating artificial intelligence (AI) into their operations?

1.2 Academic and Practical Relevance

This research contributes to the emerging body of knowledge by providing insights on the unique challenges and opportunities early-stage biotech firms face when integrating AI. Responding to calls for more empirical research on real-world AI integration (Jöhnk et al., 2020), this research goes beyond the mere performance of AI tools and sheds light on organizational and operational realities of implementing AI as a small biotech company. Thus, this paper adds to the scarce empirical evidence of smaller firms' experiences in adopting AI in the biotech industry and how industry-wide dynamics and regulatory pressures influence its adoption. Further, it deepens the understanding of organizational implications of AI integration, while accounting for start-ups' resource constraints and the fast-paced, highly regulated environment of biotech. Lastly, it will expand the understanding of AI as a potential disruptive innovation in the biotech industry and analyze if AI is reshaping current competitive dynamics and potentially displacing incumbents. This provides the basis for further research on AI-driven disruption in biotech and its long-term consequences for the industry. The results will reveal relevant implications for policymakers, as their decisions influence the extent of start-ups' innovative capabilities and implementation of AI-powered technologies. Insights on common opportunities and barriers can provide actionable guidance for other biotech start-ups to inform their AI-integration decision, and to what implications this has for them. Generated insights from biotech start-ups' real-life experiences in acquiring essential funding are especially valuable to investors. The findings can inform suppliers of finance about barriers that influence and commonly complicate investment decisions about AI-related projects in early-stage firms. In addition, the research seeks to inform investors by providing insights that support more informed decision-making and help facilitate the growth of early-stage biotech start-ups adopting AI.

2. THEORETICAL BACKGROUND

This section gives insights into the current landscape of AI's role in the biotech industry and how its integration is transforming traditional industry practices. Furthermore, various challenges and opportunities will be illustrated that are specifically impactful for start-ups integrating AI. To further discuss the significant changes occurring in the biotech industry, Disruptive Innovation Theory (DIT) (Christensen, 1997) will be applied to assess the impact of AI and its transformative power.

2.1 AI in Drug Discovery and Development

2.1.1 AI Applications in Drug (Re-) Discovery

Artificial Intelligence has been applied in the process of drug discovery and target identification for a few years now. The traditional process is very lengthy and costly, usually resulting in

failure and incurring huge losses. Previous methods lack sufficient capability to predict which drug candidates will be safe for the human body, and more specifically to whom. The traditional process can take between 13-15 years and can cost over US$2.6 billion (Bentwich, 2023).

Start-ups are increasingly leading innovations in drug development. For example, Kennedy et al. (2023) found that small pharmaceutical companies produced over three times as many first-in-class oncology drugs as large pharmaceutical firms – and with significantly higher success rates. Although this trend began before AI's increased implementation in the industry, recent trends revealed that AI is further strengthening innovative capabilities of smaller firms. Its integration enables faster, data-driven discovery processes (Jayatunga et al., 2024; Doron et al., 2024). Now, AI-powered algorithms analyze vast amounts of heterogeneous data sets to identify underlying patterns and determine which candidates are most likely to be successful (Bhat et al., 2025). Next to delivering insights on how drug candidates can be optimized, AI also prevents the undertaking of clinical trials that would later turn out to be unsuccessful (Huanbutta et al., 2024). Simply put, AI is increasing the speed of discovery and quality of targets and drug candidates, greatly enhancing productivity.

Further, AI can be used in drug repositioning where existing drugs can be linked to new applications with a pre-determined risk/benefit ratio. Drug repositioning is specifically beneficial for small patient populations for which drug research is usually not considered due to inconsiderably high costs (Van Der Lee & Swen, 2022). This broadens the application of treatments without undergoing the long and costly process.In the development of pharmaceutical formulations, experts can change important characteristics of new medications, which is based on a trial-and-error, heavily resource intensive process. Based on experiential data, AI algorithms enable this process to be more precise, efficient and incur lower costs, which significantly boosts productivity (Huanbutta et al., 2024).

2.1.2 Clinical Trials and Real-World Evidence

Clinical trial phases are critical as drug candidates are tested for their safety and efficacy in the human body. However, they are also the most resource-intensive stage of drug development. With a success rate of only 10% of tested molecules being approved to progress to the next stage, sponsors incur substantial sunk costs (Paul et al., 2020).

Furthermore, implementing AI-powered methods enables more efficiency in the selection of patients, which is one of the biggest challenges at this point in the process. Electronic Health Records (EHR) are commonly used as data sources as they contain information on patients' disease progress and drug response. These data sets are processed to identify patients that meet certain criteria and are most likely to participate. The AI-powered process results in significant cost- and time savings but also prevents an early stop of the trial, which is historically low due to insufficient patient recruitment (Van Der Lee & Swen, 2022). Yet, a significant barrier in extracting EHR data is its complexity, which ultimately burdens AI's efficiency. Data contained in the EHR have varying levels of reliability and contain unstructured text which has significantly lowered accuracy in past experiments (Van Laar et al., 2020). Despite these challenges, the benefits of integrating AI into the process remain substantial, as Jayatunga et al. (2024) found a success rate of 80-90% of AI-derived molecules, scoring a substantially higher success rate than historic averages.

2.1.3 Manufacturing and Quality Control

Once the drug has entered the market, AI also finds useful applications in controlling the quality of products. Conventionally, this has been effective but labor-intensive and vulnerable to human error. With the introduction of AI, norm-deviating behaviors can be detected quickly. This minimizes errors and ultimately increases drug safety and consumer trust in the market (Huanbutta et al., 2024).

2.2 Start-Ups Changing the Industry

2.2.1 Restructuring of Processes

A fundamental change seems to be occurring in the biotech industry, as primary drug discovery processes are slowly shifting from chemical-based to biotechnology-based approaches. Drug discovery processes are no longer carried out by only large pharmaceutical companies but by divisions of labor between biotechnology start-ups, universities, and pharmaceutical companies (Honjo & Nagaoka, 2017). AI technologies in pharmaceutical research are already described to be disrupting various tasks within the R&D innovation process. The future promises increasing implementations of AI and innovation opportunities. Those will further drive efficiency in the industry while enhancing sustainable long-term strategies that support healthcare accessibility (Bentwich, 2023).

2.2.2 Opportunities in Personalized Medicine

Personalized medicine is a rapidly evolving medical approach that aims to consider a patient's individual characteristics. These are derived from the patient's data on molecular, physiological, ecological, and behavioral levels. The successful application of AI would allow personalized and individually targeted treatments, as well as the prevention of diseases, drastically improving the quality of life (Taherdoost & Ghofrani, 2024). In further fields like oncology, identifying appropriate therapies for patients with cancer is burdened by extremely high costs and complicated processes. The integration of AI has enabled highly complex analysis of increasingly large data sets and independent detection of patterns within the data. The application of Machine Learning (ML), a subset of AI, has found a wide application in fields like cancer therapy. Utilized models like the deep learning model DrugCell show great performance in predicting drug responses in human cancer cells, enabling the identification of appropriate therapies for cancer patients (Park et al., 2023).

2.3 Challenges for start-ups in implementing AI

While most literature focuses on AI's transformative potential in biotech, there are contrasting views on the most significant barriers to its adoption and successful development. Van Der Lee and Swen (2022) and Holzinger et al. (2017) stress the insufficient explainability of AI and lack of clinician trust as central issues for adoption. This is especially significant in clinical settings where transparency and accountability are critical. On the other hand, Jayatunga et al. (2024), pose the main barrier in not-yet existing real-world impact of clinically validated AI-discovered drugs; as of now, only a few of the increasing number of those compounds have reached late-phase success or regulatory approval. This reveals an underlying concern of AI-driven innovations alone not being sufficient to be valuable, until they prove to be validated and ready-to-use for therapeutic purposes. Paul et al. (2020), however, illustrate that AI's success in drug discovery is dependent on access to substantial, reliable, and high-quality data. Although data can be purchased from various database providers, it neglects the

financial constraints early-stage firms face. Additionally, the data gained available is not guaranteed to be usable.

This issue remains mostly untouched by Paul et al. but is further examined by Rieke et al. (2020) and Holzinger et al. (2023). The authors frame these data challenges to be infrastructural and systemic. This reinforces that collaborative data-sharing and data preprocessing standards must be fostered to support and enable further AI advancements. These contrasting insights to the commonly positive, efficiency-enhancing literature on AI demonstrate that underlying, foundational misalignments place significant constraints on AI's revolutionary potential.

2.3.1 Financial Constraints

Several authors highlight AI's value in enhancing R&D processes and AI's future impact on healthcare accessibility (Huanbutta et al., 2024) (Bentwich, 2023) but neglect the significant financing barriers early-stage firms integrating AI face. Knowledge gaps and high uncertainty in R&D make bank loans unfeasible, which makes these start-ups reliant on equity funding. When larger funding for R&D is required, many biotech start-ups go public to fund further R&D processes (Honjo & Nagaoka, 2017). Especially in later phases of the innovation process, start-ups encounter significantly lower success rates in clinical trials, which can be attributed to insufficient capital. Deficient funding can lead to poor clinical trial designs and, consequently, under-reporting of the candidate's efficacy. This in the end, impedes start-ups' abilities to independently bring drugs to the market (De La Salle & Thomas, 2020).

To mitigate this barrier to growth, start-ups can form partnerships with larger companies or research institutions. Although McCall (2025) paints the collaboration between start-ups and larger firms to be mutually beneficial, it demonstrates the severe impact of early-stage firms' limited capital. Although smaller firms drive innovation, financial constraints can force them to give up full ownership and control over their operations to progress. Kennedy et al. (2023) further support this, as smaller firms often lose (full) ownership of the drugs by the time of commercialization due to factors such as inferior financial power and late-stage expertise compared to large pharma.

2.3.2 Workforce Scarcity

With the rising popularity, application opportunities, and advancements in AI, the demand for skilled and talented workforce is rising. However, research reports a gap between the availability of qualified personnel in the workforce and demands by the market. The lack of a highly skilled workforce is not only preventing the substantial utilization of AI investments and increased AI adoption but also limits the leverage of AI for national economic growth (Johnson et al., 2021).

2.3.3 Regulatory Constraints

Mirakhori and Niazi (2025) outline challenges for start-ups to maintain data privacy and security to optimize AI. They stress the need to proactively engage with regulatory bodies to navigate the regulatory environment for AI applications. While strict regulatory frameworks aim to protect sensitive data and guarantee patient safety, they also slow technological development and breakthrough innovations. This, again, places further resource-intense demands on smaller firms.

2.4 Disruptive Innovation Theory (DIT)

As AI is finding increased application in the industry, it will be investigated whether the integration of AI in early-stage firms in biotech can challenge competitive dynamics and traditional organizational structures. To analyze the adoption of AI by early-stage firms in biotech, this research employs Disruptive Innovation Theory (DIT) (Christensen, 1997) to assess the role of AI in biotech.

DIT explains the difference between disruptive innovations and sustaining innovations. Disruptive innovations originate in low-end or new markets and move up the market to finally challenge incumbents through improving their performance. This differentiates them from sustaining innovations, which are mere improvements in well-adopted products by incumbents' customers (Christensen et al., 2015). DIT identifies an innovation as disruptive if the innovation helps to establish a new market or value network that will grow and finally disrupt existing markets or value networks (Christensen, 2014). It is important to note that an innovation itself is not necessarily disruptive purely in its nature but made a disruptive force by its business model.

Disruption is an evolutionary process in which innovation moves from the lower or new end of a market upwards to mainstream customers, taking over incumbents' market share and finally their profits. This process is initiated by a smaller company with less resources that can eventually pose a significant competitive threat to established incumbent enterprises. The disruption process can take decades, as these innovations usually target market segments that are firstly overlooked by incumbents, and secondly initially not adopted by customers. This can be due to customers' unawareness of the market gap and new offerings, or simply because of their unwillingness to adopt.

Despite a lower price, customers are usually resistant to adopt the new "inferior" offering until it has reached a quality that is satisfying to them. Once customers are willing to replace the incumbent's old offering with the new, lower-cost item offered by the small company, disruption occurs. However, this does not mean that the disruptive innovation will replace the old offering completely (Christensen et al., 2015).

2.5 AI as Potential Disruptor

2.5.1 New Business Models

As mentioned before, small biotech companies and academic labs are now drivers of innovative drug discovery. They further differ from their bigger competitors by renewing (core) business processes under the influence of AI, increasing their efficiency. Kulkov's (2021) previous research revealed that new business models are emerging from start-ups in the healthcare industry that use AI to create and deliver value. A key finding reveals that targeting niche markets is a central strategy through which these start-ups demonstrate their value. This supports the notion of AI enabling new business models by unlocking access to specialized or underserved market segments.

Mahendra (2023) further demonstrates how AI is an enabler of new business models and contributes to navigating AI's role as a potential disruptive innovation in the biotech industry. As described earlier in the presentation of the theory, AI is creating new business models and targeting "low end" or new markets that are not tapped into by large companies. The start-ups investigated in Kulkov's (2021) research were clearly specialized in narrow markets like urology, diagnostics or orthopedic forecasting, which are ignored by large established companies due to lower immediate profit margins. The specialization improves the chances of start-ups to take over this niche market. Research by Tait and Wield (2019) identified that truly disruptive innovations stemming from start-ups from industries like biotech often have no pre-existing traditional business model to work from. This leaves them to create entirely novel ways of operating within value chains and enables them to be flexible enough to create these innovations. Building new value chains by integrating into existing ones or collaborating to build new ones can be inherently disruptive as it challenges incumbent players.

This supports the view that AI could act as a disruptive force within the biotech industry.

2.5.2 Barriers and Limitations (to Disruption)

Next to superior access to resources needed to successfully launch a new product, large pharmaceutical companies are also firmly established in their business models and in control over value chains. Biotech start-ups, however, are more affected by regulatory systems. A lack of supportive market or policy infrastructure can lead to absorption, failure and limited up-taking of biotech start-ups and hinder their growth. Previous research stresses the importance of governmental policies and their determining effects on the future of potentially disruptive start-ups. Tait and Wield (2019) argue that funding and regulations must be supportive of new value chains and not just existing ones like those of large pharma. These unsupportive circumstances can pose a dilemma for start-ups. While integrating into existing structures or merging with incumbents is the safer choice, it is also less disruptive.

3. METHODOLOGY

3.1 Research Method

This research employs a qualitative and exploratory research approach to efficiently gather complex, in-depth insights into early-stage biotech firms' lived experiences when adopting AI. A qualitative design is most suitable to grasp the organizations' multi-faceted experiences, motivations for, and challenges in adopting AI in a highly regulated and rapidly evolving sector (Yin, 2015). The emergent nature of this research is best analyzed following an inductive approach, which allows the emergence of theoretical insights and concepts from the data, in contrast to concepts being imposed on the data a priori. The Gioia Methodology (Gioia et al., 2012) was applied to organize and systemize the analysis. This approach follows a structured progression from participants' direct statements (first-order codes) to higher-level conceptualizations (second-order themes) and finally overarching aggregate dimensions. This approach generates grounded theory based on empirical data while maintaining transparency between data and interpretation.

3.2 Sampling

The population that this research focuses on are biotech start-ups that either develop AI-based technologies or implement AI in their processes. Primary data were collected through semi-structured interviews of 30-40 minutes with contact persons of five biotech start-ups from that population. Additionally, one consultant advising biotech start-ups in navigating AI adoption, product development, and market access was interviewed.

For the transcription of the interviews, all participants were asked for permission to record the sessions and their right to skip a question or end the interview early. Contact persons also signed a consent form that informed them about the recording and transcription of the interviews, the participants' rights and how (long) the interviews will be stored before deletion. The start-ups are all located in Europe, with no more than two start-ups from the same country. AI was implemented to different extents in the start-ups, ranging from its adoption to streamline operations to making it the core of their products. Each start-up implemented AI for different application purposes within life sciences to foster multifaceted insights. The semi-structured nature of the interview questions allowed flexibility to explore each participant's individual experiences around AI adoption, while maintaining thematic consistency across interviews. Since participants were selected based on their expertise and relevance to the topic of AI implementation in biotech, a purposive, non-random sampling strategy was used to best inform the research (Saunders et al., 2023).

3.2.1 Methodological Limitations

While this research offers in-depth insights on the opportunities and challenges of early-stage biotech firms implementing AI, the following limitations must be considered. First, interviews were conducted with participants from different organizational roles, hierarchical levels, and heterogeneous company contexts. While this captures diverse insights, it also poses a threat to the generalizability of the findings. The differences in functional responsibility and organizational positions may result in diverse interpretations of AI adoption and limit potential pattern detection emerging from homogenous samples.

Secondly, slight variances in start-ups' maturity and subdomains in biotech can have an influence on perceived urgency and relevance of individual opportunities and barriers. Therefore, the representativeness of the findings might be limited and rather seen as indicative of start-ups' main challenges and opportunities of adopting AI in the biotech industry.

3.3 Data Collection

An interview guide was created to collect the most valuable data from experts in the field. The guide consisted of guiding themes covering more specific sub-questions about perceived opportunities and barriers in adopting AI, strategic and operational implications, and regulatory influences. The interview guide can be found in Appendix A. The questions also covered an industry outlook and AI's role as a potential disruptive innovation in the industry as well as competitive dynamics between start-ups and incumbents. The guide was informed by existing literature on this topic to ensure the questions covered relevant topics surrounding AI implementation in biotech start-ups and DIT (Christensen, 1997) to increase the validity of the interview (Babbie, 2019). The flexibility of semi-structured interviews enables questions to be asked in a different order and slightly tailored to each individual participant to receive the most relevant insights. If necessary, follow-up questions were asked to increase understanding and answer the research question better (Saunders et al., 2023). All interviews were held digitally via Teams or Google Meet and recorded for transcription purposes after receiving the interviewee's permission.

3.4 Data Analysis

After the transcription of the interviews, the data was analyzed using the Gioia method (Gioia et al., 2012). This systematic approach is designed to extract rigorous and conceptually grounded insights from qualitative studies. The first step of the analysis is the creation of 1st Order Concepts, which are based on important interview statements as well as common words and statements made by the interviewees. These codes are later grouped into 2nd Order Themes, which reflect emerging theoretical patterns that can be helpful in explaining the research question. Finally, these themes are refined into overarching conceptual Aggregate Dimensions. The analysis resulted in five Aggregate Dimensions highlighting AI value creation opportunities, various barriers and resistance start-ups face. Additionally, the findings reveal evolving forces and AI as a (Partial) Disruptive Innovation in the biotech industry.

Although the sample size of six interviews may seem limited, Guest et al. (2006) argue that thematic saturation in qualitative research is often reached within the first six to twelve interviews. The sample size was sufficient to capture rich, contextual insights into the operational realities of AI integration in biotech.

In line with this, the present research allowed the observation of recurring concepts. By the sixth interview, no new themes seemed to emerge, which supports that thematic saturation had been adequately achieved. To increase the reliability of the coding process and minimize potential researcher bias, all interviews were reviewed several times to verify the accuracy and consistency of the assigned codes. The qualitative data analysis software ATLAS.ti was used for the coding process.

4. RESULTS

The analysis of the interviews following the Gioia Method resulted in five aggregate dimensions, reflecting patterns of second-order themes and first-order codes. The dimensions reveal key perceived opportunities, challenges, and the impact of AI adoption in the biotech industry. The complete data structure is presented in Appendix B, Figure 1. The findings of the analysis will serve to answer the research question.

4.1.1 Identifying Motivations and Opportunities of Adopting AI in Biotech

The implementation of AI in biotech start-ups ranges from AI manifesting itself as the main technology powering a start-up's core offering to the adoption of AI to enhance efficiency of daily operations. The underlying themes can be found in Table 1, supported by a quote that illustrates each theme in the Aggregate Dimension **Value Creation Opportunities of AI in Biotech**. Looking at this dimension, it becomes clear that the adoption of AI in this sector is yielding great advances in areas like operational efficiency and innovation. One key result of integrating AI is shown in the theme *Innovation Acceleration and R&D Transformation.* The interviews revealed AI's role in enhancing the efficiency of key phases in early-stage R&D, accelerating innovation cycles, and yielding significantly better results than legacy drug candidate identification models; "Classically in discovery, one of 20 molecules used to be active, means 5% efficacy of success. In our case, the projects that we have developed, (...) we are moving about 33-35% success". Furthermore, AI enables drug innovations and can help to develop new drugs "for existing pathologies as well as those that have not been catered to before".

The theme *Operational Efficiency and Process Optimization* covers how operational processes and research are more cost-effective, faster, and leaner through AI. Highly repetitive and routine tasks can be automated, which are usually prone to human error. This enhances safety, reduces the required workforce, therefore decreases team size, and frees skilled employees to handle more strategic tasks. The increased efficiency also reduces costs and broader resource intensity of product development. Additionally, AI increases the accuracy and precision of human performance and existing technologies "for productivity and to come with the core technology, the AI really enhances what already exists". The integration of AI is also lowering the barriers to entry for smaller companies. AI integration frees up start-ups' scarce financial resources by automating repetitive tasks. One participant stated, "Thanks to these approaches, it's possible to have companies like us". The *Democratization and Accessibility* theme is further captured in this quote: "I think it's democratized to a certain extent, so you have to imagine that if it just gets better, then of course it will be easier for other companies themselves to do the same research, it will be affordable and the barriers to entry are simply lowered", highlighting the reduction of structural barriers and facilitating access to new actors leveraging AI.

While development capabilities were previously exclusive to large organizations, AI democratizes access to research and advanced development capabilities, which allows start-ups to operate on minimal infrastructure.

Table 1: Motivations and Opportunities

Theme	Quote
Innovation Acceleration and R&D Transformation	"The field is now using the technology around LMS more and more and this can bring new opportunities and entirely new avenues of exploration of the data."
Operational Efficiency and Process Optimization	" It makes the team smaller" "AI is helping us be more productive"
Democratization and Accessibility	"The buy of entry into the segment of drug discovery companies might be lower currently with AI. Especially, (...) if they base their process on some idea based on AI"
Real-World Applications in Healthcare	"And with these (AI) solutions we can provide a better diagnostic to the patients and reduce the time that the doctors need to diagnose a single patient and to provide a second read."
Future-Oriented Innovation and Industry Outlook	"It (AI) will be a central tool to create concepts. And it will also help to make sense of large data sets."

The theme *Real-World Applications in Healthcare* encompasses the practical relevance and impact AI brings. Participants mentioned its successful deployment in oncology, diagnostics, imaging, and clinical decision support. AI's implementation already creates direct value in medical settings, like a participant stated, "When this patient is going to see the doctor, they can actually help them to diagnose or to treat them better". The technology enables better, faster, more precise diagnostics and treatments for patients and enables disease prediction that ultimately detects diseases before symptoms occur and allows for earlier treatment and better outcomes.

The theme *Future-Oriented Innovation and Industry Outlook* captures respondents' optimistic views on AI's future development and firm establishment in the biotech sector as one response about drug development was: "Another important thing that might happen in the next five years is large scale adoption of LLM based solutions because we see this in clinical trials area to some extent".

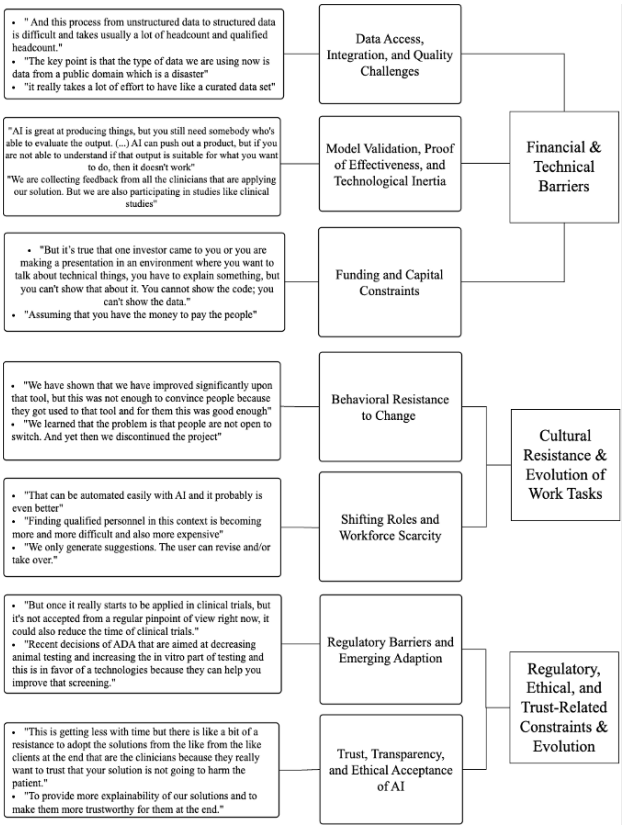
Further developments in AI will enable precision medicine, data-driven enhanced diagnostics and increase access to unserved markets: "It means that maybe you can pay to deal with markets that are not cost effective right now, but maybe in the future if you can raise the cost and investment and time that we'll be able to manage these markets". This not only reflects the transformation of processes, but also system-wide restructuring like providing treatments to currently unprofitable patient populations. Building on the potential outlook on a foundational change and impact for society, a participant stated that through AI "you can also reduce health system costs for the general public, which is why I really consciously make the statement that it will advance humanity, so not only in the in the multitude of

drugs and technologies that are being created, but it will be much more than that".

4.1.2 Barriers to AI Adoption and Development

While start-ups disclosed various opportunities and benefits resulting from AI, a significant number of barriers and constraints were also mentioned. Most of these challenges are reflected in three aggregate dimensions, of which exemplary challenges are presented in Figure 2 (also included in Appendix C), supported by their themes and underlying quotes.

Figure 2



The following Aggregate Dimension **Financial and Technical Barriers** captures the various barriers start-ups face. Participants described major challenges in acquiring and processing data for sufficient use. Data is commonly fragmented, of poor quality or inaccessible to start-ups. This significantly hinders innovation and the sufficient training of AI-driven models, as the model's accuracy and precision of results depend on the quality and richness of the training data.

Data pre-processing challenges often involve the work of a qualified, large group of workforce and multidisciplinary collaboration. A participant described "the main challenge is cleaning this data or understanding how to clean the data" as data comes from different domains. The difficulty of integration across platforms for implementing AI is reflected in the theme *Data Access, Integration, and Quality Challenges.* These resource-intense measures are necessary to avoid generalizability issues and enable higher effectiveness and scalability of the tool in real-life. It was described how training data that was not diverse enough greatly decreased the performance in validation "we realized that if you apply a rigorous validation that reflects the real-world scenario, and the performance of these models just drops to the performance of a random model".

Model Validation, Proof of Effectiveness, and Technological Inertia entails how human supervision and understanding of AI-generated outputs needs to be guaranteed for the technology to be authorized, and/or useful in the application. Regulatory validation of AI-technologies from the EU (CE Mark) or USA (FDA) is described as a difficult, long, and costly process but necessary to ensure patient safety. The proof of AI's effectiveness can be measured by means of multi-readers studies and collection of feedback from users like expert clinicians, which shows that AI is having a real positive impact on traditional methods. Despite AI-technologies performing significantly better than legacy solutions, potential users are reluctant to replace established systems: "But there was already a tool out there which was good enough introduced several years back. We have shown that we have improved significantly upon that tool, but this was not enough to convince people because they got used to that tool and for them this was good enough, right? So, there's also the problem if you develop new technology, which in accuracy improves even significantly upon what's out there. It might not be enough to convince people to switch". The real-world and long-term impact of AI is still limited, and the industry needs hard evidence of AI's powerful capabilities to find increased acceptance and implementation in the industry.

Another barrier interviewees mentioned was *Funding and Capital Constraints*. A significant hurdle is placed in acquiring investors, for reasons like limited investor understanding of technology and domain-specific knowledge or the innovators' need to protect Intellectual Property (IP). These factors significantly complicate funding and leave start-ups "chronically bankrupt". While this leaves start-ups struggling to pay for their workforce, it also forces them to automate operational tasks to reduce manpower, increasing their efficiency.

The dimension **Cultural Resistance and Evolution of Work Tasks** consists of the themes *Behavioral Resistance to Change* and *Shifting Roles and Workforce Scarcity.* The first theme compromises respondents' statements about the resistance of potential customers to adopt the new, better performing AI-solution. Established routines are deeply rooted in company culture which makes it very difficult to persuade a change, "you need to convince the people that have been doing these processes for many, many years. And this can be difficult or impossible in some cases". Limited understanding of the technology is further not only impeding investment decisions, but also customer adoption. This resistance is a significant barrier to implementing and expanding AI-based technologies throughout the industry. Finding the right market to introduce AI-based solutions is critical, as the rejection of previous projects has led to their discontinuation.

AI is also changing traditional work task distribution, automating traditional, repetitive tasks and simple service roles like analytics. This leads to smaller teams, and a shift for human employees to take on more strategic roles. This is beneficial for start-ups as skilled workers are described to be increasingly expensive and difficult to find. Through the automation of tasks, previous roles are falling off and reduce the need for hiring to scale operations: "leave a system that ultimately handles the whole thing scalable for you and that makes it easier for you to grow". The complexity of data for AI also requires interdisciplinary expertise which fosters inter-team collaboration to understand the data and optimize the AI. It was also described that the human remains in control over AI-generated output and can be edited or taken over for further work and approval.

Lastly, the themes *Regulatory Barriers and Emerging Adaption* and *Trust, Transparency, and Ethical Acceptance of AI* form the Aggregate Dimension **Regulatory, Ethical, and Trust-Related Constrains & Evolution** and will be illustrated in the next section.

Regulatory Barriers and Emerging Adaption presents the critical role of regulatory frameworks and developments for AI-innovation and deployment. Respondents noted initial challenges in meeting requirements like Computer System Validation (CSV) or Good Manufacturing Practices (GMP). They also emphasized that the lack regulatory support for AI in clinical trials is slowing development and preventing impeding great benefits in speed and costs, potential time and cost savings: "Clinical trials are the longest and most expensive part of the development of a new drug. (...) investing a lot of millions (...). Maybe you can simulate it. OK, you can do it". Further, the regulatory environment is shifting away from animal testing to increasingly conducting in vitro testing, meaning outside of a living organism, which is usually done in a laboratory setting. This, as a participant stated, "is in favor of technology because it can help you improve that screening" in drug discovery. While resistance to AI adoption is slowly decreasing, *Trust, Transparency, and Ethical Acceptance of AI* remain considerable limiting factors to its real-world implementation. As it is commonly difficult for users to understand how the AI works, they remain skeptical of its adoption and safety for patients in deployment. To increase trust for the end-user, participants stated to take measures to increase the transparency of the AI-solution; "in case that we are using deep learning for example directly on an image, we can provide a hit map, marking in the images the areas to which the AI algorithm was paying more attention to. (...) doctors really appreciate it, and they can also give them additional information for diagnostics". Different measures to increase transparency and explainability to users are crucial for AI's acceptance to be increasingly deployed in real-life.

4.1.3 AI as Potential Disruptive Innovation

The various described opportunities for early-stage firms integrating AI enable them to move faster, leaner, and more focused than their established, larger competitors. This AI-powered agility allows smaller companies and new entrants to develop products cheaper and explore innovative ideas. Evolving industry dynamics shed light on AI's power to potentially shift competitive advantage toward non-traditional, AI-driven players.

Start-Up-Led Market Innovation and Agility describes how AI is increasing the independence of start-ups from big corporations and making them more self-reliant, "For example for domain knowledge or for building or deploying things you don't really have to rely on big corporations or big companies to guide you through it. (...) If you want to do something, you can really build it on your own and deploy it on your own". When asked about the shift from traditional methods to AI-solutions, it was described as something that is at "the very beginning" but has great potential to make processes like drug discovery a lot more affordable and change the well-established biotech business environment.

There are several new business opportunities emerging, either by implementing AI to the core or augmenting tasks to improve a start-up's offering, "So this is a new segment. Or a new set of companies that wouldn't have been possible without AI. On the other hand, some biotechs are highly leveraging their drug discovery processes on AI, and they are definitely benefiting. Sometimes companies that develop their own AI technology and provide it to other companies, they also start their own pipeline of drug discovery to also validate the technology". AI will foster an "increased wave" of innovation and enable technologies which are only made feasible through AI. Several interviewees described the opening of new market segments and the "emergence of new technology-driven niches". To succeed as a start-up and cause some kind of disruption, one participant stressed the fundamental need to integrate AI into the business' core solution or to base their offering around it. The establishment of AI in smaller companies is enabling increased innovation and operational agility, which is a competitive advantage toward their big, established industry players who suffer from large overhead and structural entrenchment, which slows down their (innovation) processes. Although AI creates new market segments and innovation opportunities, biotech start-ups still face significant challenges. These limiting factors are captured in the theme *Start-Up Fragility, Speed of External Developments, and Obsolescence.*

Respondents described that factors like market timing, investor pressure or replication by Big Tech can quickly lead to a start-up's failure. The rapid technological development of AI in the biotech environment is making many start-ups' technological innovations obsolete, either because of other start-ups' higher development speed or because big players release similar features; "The development when it comes to AI is so fast that many of the startup companies will fail early because they become obsolete. There are so many companies who develop a product that is great, and then Google releases a feature of Gemini that can do the same. So that immediately makes the company obsolete. And that happens a lot at the moment". This not only concerns established markets but also niche innovations. The failure rate of start-ups is high, not due to insufficient innovative power, but because of a rapidly evolving environment and big players' superior resources. Another factor affecting the success of start-ups is its financing structure. VC-funded start-ups are often driven toward early exit through acquisition while self-funded start-ups remain more flexible in this decision. The latter, however, is very rare and is highly dependent on the start-up's capital.

Although incumbents appear to be slower through high overhead costs and resistance to let go of legacy tools, their superior financial capabilities and market power ensure that they remain the more powerful players in biotech, which is demonstrated in *Incumbent Adaptation and Barrier to Disruption*. While incumbents are also adopting AI, they exert the most influence through their financial power. Participants described the on-going trend of start-ups being acquired by their bigger competitors or merged with other start-ups "if you look at biotech companies, or start-ups in that field, they are usually bought up by the large companies because they still have the deeper pockets at the moment". "And we do observe that some start-ups are struggling, even the successful ones or role models, so to speak, they go through merchant acquisitions. They're bought by big players, or they are merged with other start-ups", which captures the present and predicted future of the independent existence of start-ups in the market.

This trend also leaves multiple respondents doubting whether or not current power positions in the market can be challenged, which is described in the theme *AI's Role as Disruptor, Enabler, or Enhancer*. AI is enabling the existence of many start-ups, innovative technologies and is finding increased acceptance and real-life applications, which is "going to disrupt the way in which patients were diagnosed, and this is just starting". There were mixed opinions on whether AI alone is disrupting the biotech industry. While one participant stated "the ideas already exist within these fields. It's just the AI analyzes them, or AI makes it easier to implement (...) you would see the same progress maybe in 15 years without AI, but we will see it sooner in like 5 years", another participant disagreed with AI only being an accelerator of innovation: "(I) don't think we would have sophisticated systems like LLMs, for example. Without AI or sophisticated systems based on computer vision or speech recognition. All this I don't see coming from traditional approaches to data analysis".

The same ambivalence was found in whether or not AI was opening new markets. Some interviewees highlighted that there are new markets and "specific things that happen now that didn't happen before", while others reported that the markets were pre-existing. Some interviewees found the term "disruptive enabler", as proposed by the interviewer, to accurately reflect AI's current role in the industry.

AI is now commonly established; virtually all pharma companies now are said to leverage AI in drug discovery. Participants described AI as an augmenting tool which is leading to incremental improvements to fast-track innovations and processes like drug discovery. In drug discovery, the power of LLMs (Large Language Models) was stressed by a participant, describing its role in drug discovery as "a real game changer" and the emergence of "new products based on AI that wouldn't have been possible without it" in the personalized health space.

5. DISCUSSION

This research explored how early-stage firms in the life sciences adopt and integrate AI technologies, especially focusing on the perceived opportunities and barriers start-ups need to navigate to maintain and grow operations in a volatile regulatory environment. By reviewing literature and conducting interviews, this research set out to answer the following research question:

What are the main opportunities and challenges biotech start-ups face when integrating artificial intelligence (AI) in their operations?

The research revealed and confirmed the various application opportunities of adopting AI in the biotech industry. Its integration yields faster and more efficient molecule modelling, enables leaner R&D processes (Mehta et al., 2024), and outperforms legacy models in drug discovery (Jayatunga et al., 2024). This is consistent with existing literature. AI's strong data analysis capabilities support pattern recognition and open new opportunities in fields such as precision medicine (Taherdoost & Ghofrani, 2024) and drug repurposing (Van Der Lee & Swen, 2022). Further, the automation of highly repetitive tasks and simple service roles through AI allows start-ups to maintain smaller teams, scale operations without additional, increasingly difficult to find workforce (Johnson et al., 2021) and be more self-reliant and independent from larger corporations. This agility allows them to lead and explore new innovations (Kennedy et al., 2023) while preserving scarce capital. While AI seems to be replacing certain roles, it is seen as more of a tool to augment human work tasks. This can either be done by offering clinicians diagnostic support or by providing editable suggestions. It is important to note that AI-driven results or outcomes still require human oversight, as the outcomes need to be validated, understood, and possibly further processed by a human. Some start-ups also described AI as the core pillar of their business, meaning that in its absence, their operations would not be possible. This supports Kulkov's (2021) and Mahendra's (2023) findings that illustrate the emergence of new start-ups enabled through AI.

However, the findings also align with various barriers and constraints illustrated in the literature. Limited capital, availability of quality data, pre-processing challenges as well as behavioral and structural resistance to change greatly impede the operational and innovative power of smaller biotech companies integrating AI. While limited capital (Honjo & Nagaoka, 2017) is forcing start-ups to automate parts of their infrastructure to save costs, it also restricts the recruitment of an increasingly expensive work force capable of understanding and progressing with AI and its various deployment opportunities. Another risk lies in AI-development by external competitors. The speed of developments and innovations poses significant risks for an innovation to be obsolete by the time it is launched on the market, either because another start-up out developed them or because a large competitor leveraged their resources to bring a similar product to the market. While regulatory hurdles (Masarone et al., 2024) were not necessarily described as a main barrier, it appears to be more of a limiting force of innovation and possible advances in the industry. The main barrier was commonly related to data challenges, preprocessing efforts and limited AI-specific knowledge by potential customers, users and investors which ultimately plays into efforts to increase the AI's transparency and explainability to foster trust and increase its implementation.

Lastly, the insights confirm Jayatunga et al.'s (2024) findings of the need for real-world evidence of AI's capabilities to increase stakeholder trust and foster its further implementation. From a Disruptive Innovation Theory (DIT) (Christensen, 1997) perspective, the findings of this research do not currently support AI' role to be fully disruptive in the biotech industry, instead, it is best characterized as a disruptive enabler; a powerful tool offering organizations the foundation to new innovative capabilities and the emergence of new actors, with the latter potentially disrupting the industry in the future. So far, however, the findings do not support the displacement of dominant incumbents or a radical restructuring of the industry.

Firstly, the findings do support that AI is enabling low-end market entry through reducing R&D costs for start-ups, decreasing team size, and allowing leaner business models by facilitating them to scale their operations without large infrastructure. Leveraging AI allows especially tech-driven start-ups to develop new solutions that cater to previously untapped or unviable market segments.

Additionally, considering external limitations like funding resources, it fosters innovation at the business model level which ultimately requires AI-driven start-ups to align emerging technologies with new business strategies to exert a transformational impact, which also signals that AI is more than a sustaining innovation. Barriers to entry are lowered, allowing smaller start-ups to enter and use their agility as competitive advantage, leveraging AI to reshape traditional innovation processes, from lab-heavy to data-driven models and operational workflows. This also aligns with Tait and Wield's (2019) framework which highlights that emerging technologies lead to the creation of new business models and reshape traditional innovation paths. AI-driven start-ups are using AI for knowledge creation, task-automation, and development, making standard infrastructure models obsolete. The findings show that regulatory barriers impede AI's further application in areas like clinical trials, which matches the authors' argument that technology alone cannot be disruptive if it is constrained by external factors.

Despite indicators of AI reconfiguring traditional innovation models in biotech, the findings currently do not support that AI-powered start-ups or innovations will lead to displace incumbent firms. It is illustrated that the industry is still firmly dominated by established incumbents that exert their power by incrementally adopting AI or leveraging their superior resources to acquire emerging start-ups and their innovations to remain in control (Kennedy et al., 2023), thereby limiting disruptive potentials. The absorption of start-ups ultimately hinders a reconfiguration of the dominant value chain while also leaving incumbents in control of speed of innovation and adoption. As of now, AI does not fit Christensen's (1997) description of a disruptive innovation, as the results also highlight that AI alone is not sufficient but more of a complementary enhancement to traditional processes that require human oversight. However,

DIT also outlines that the disruption process can take decades to complete. As the findings and previous literature support the increased implementation of AI in life sciences and slowly growing acceptance and adoption by users, full disruption may occur if AI-technologies are supported by regulations and sufficient funding.

5.1 Theoretical Implications

While prior literature focuses on large pharmaceutical firms, this research contributes to the current body of knowledge by examining early-stage biotech firms. The opportunities and challenges faced by these firms when adopting AI were examined through the use of broader structural and organizational factors. Based on Christensen's DIT (1997) and extended by Tait and Wield (2019), this research adds to the binary distinction between disruptive and sustaining innovation by introducing AI as a disruptive enabler. The strategic use of AI is reshaping small firms' resource allocation, regulatory navigation, and operational and organizational design. This aligns with Kulkov (2021) and Mahendra (2023) who found that AI integration is creating new business models. Thus, AI adoption is reframed from a mere technical implementation challenge to the development of strategic capabilities to operate in a resource-constrained, regulated environment for AI-driven innovations.

The results confirm previous research on AI's various applications in biotech, ranging from its adoption to optimize processes (Huanbutta et al., 2024) to enabling new offerings in previously untapped markets, which complicates a clear, definite distinction between disruption and mere improvement. This also contributes to Tait and Wield's (2019) findings, which describe disruption as a system-level process, in which successful disruption requires an enabling interplay between technology, business models and regulatory environments. It explored how human-centered mediating factors like skill gaps, cultural resistance, and trust in AI solutions influence the adoption and expanded application of AI, AI-integrated innovations, and the potential benefit for greater society. Therefore, a potential outlook of AI as a disruptor depends greatly on these external factors, which calls for future research on AI's disruptive potential and industry developments.

5.2 Practical Implications

From a practical perspective, the emerging findings provide actionable insights to policymakers and regulators, as more agile frameworks should be introduced to support the validation of innovative technologies and their integration to processes while retaining safety and quality standards. Concretely, this could mean provisional and conditional approval for AI tools and interventions in biotech. These frameworks allow early deployment of AI tools under strict post-market monitoring while maintaining safety through continuous data collection and oversight, which is aligned with the FDA's Software Precertification Program (FDA, 2021) and EMA's Regulatory Science Strategy to 2025 (EUROPEAN MEDICINES AGENCY, 2020). Increased regulatory agility would increase innovation speed and real-world learning while maintaining regulatory control in dynamic sectors like biotech.

To combat the significant data access challenges, regulators should foster public-private trusts and federated learning to train AI models across decentralized health institutions without sharing raw, sensitive data (Rieke et al., 2020). This can help to overcome the significantly constraining data limitations in R&D, facilitate regulatory compliance and accelerate start-up driven innovation in AI more efficiently and ethically.

For start-ups entering the biotech industry, it is recommended to place the explainability of their models as a strategic priority to build trust with investors, regulators, and relevant stakeholders. However, explainability and IP protection must be balanced by firms to maintain proprietary knowledge and competitive edge. To navigate this, start-ups can adopt interpretable model outputs such as feature importance and decision trees (e.g. LIME technique by Ribeira et al. (2016)) without disclosing core algorithms. Further, they can use third-party evaluators under non-disclosure agreements (NDAs) which independently assess performance and safety while keeping sensitive information internal (Rumbold & Pierscionek, 2017). Lastly, investors can consider building multidisciplinary advisory teams to overcome the communication gap between them and domain-expertise start-ups to facilitate funding decisions and support innovations. The creation of such teams enables a deeper understanding of technical potential and translational feasibility of product-market fit and long-term regulatory approval of a start-up's offering. Still, investors need to be aware of both the transformative potential as well as risks associated with early-stage technologies in a high-speed development industry like biotech and the potential obsolescence of an offering before it reaches market maturity. To mitigate this, investors can examine a start-up's ability to adapt or pivot in response to regulatory changes and market developments.

6. LIMITATIONS AND FUTURE RESEARCH RECOMMENDATIONS

Although thematic saturation seemed to be reached by the sixth interview, this research was done with only European participants whose experiences may differ from regions in different regulatory contexts and market dynamics. As there is no ideal sample size standard for qualitative sampling, the ideal method is to interview until redundancy is reached (Trotter, 2012). The inclusion of participants outside the EU might expand current variability in views and experiences, potentially requiring more data to achieve saturation. Although precautions were undertaken to reduce researcher bias, the inherently interpretive nature of qualitative research cannot guarantee complete objectivity by the researcher, which may still have influenced data collection and analysis (Saunders et al., 2023).

Lastly, the results are based on participants' subjective perceptions rather than market data, which limits clear indication of competitive or structural changes in the market. This offers rich contextual insights but may not be generalized to other contexts (Saunders et al., 2023). Regulatory frameworks continue to change, and new AI-driven technologies are quickly emerging. Therefore, longitudinal studies are especially appropriate to examine how these changes influence the trajectory of biotech start-ups integrating AI. Further, this can investigate whether these smaller firms ultimately disrupt established industry practices over time (Arnold et al., 2011).

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8. APPENDIX A

Introduction

- Brief introduction of myself and my research
- Explain the purpose of the interview and how the data will be used (confidentiality, anonymity if preferred).
- Ask for permission to record.

Company Background and Context

- Can you tell me about your role and your background in the company?
- What does your company do, and what role does AI play in your overall mission or product/service?

Opportunities & Value of AI

- **Adopters**

- What motivated your company to adopt AI in the first place?
- What benefits or opportunities have you seen from using AI? *(e.g., faster target identification, cost reduction, more scalable experiments)*

- **Providers**

- What unique value does your AI solution offer your customers? *(e.g., platform for drug screening, imaging diagnostics, data analytics)*
- How do you ensure your AI technology delivers measurable impact? *(e.g., improving candidate predictions, reducing time-to-discovery)*

Challenges & Barriers

- *(For all start-ups)*

- What have been the main challenges in implementing or developing AI?
- Technical barriers *(e.g., data quality, model generalizability)*
- Human-related barriers *(e.g., hiring skilled talent, internal resistance)*
- Regulatory or legal challenges *(e.g., lack of AI-specific guidelines, approval pathways)*
- How have you dealt with these challenges?

Industry Outlook & Potential for Disruption

- *(For all start-ups)*

- How do you think your AI-based solution changes the way biotech work is traditionally done? *(e.g., shifting from wet lab experimentation to simulation)*
- How has your technology opened new markets or made existing ones more accessible?
- Who do you see benefiting most from your innovation, and are there any stakeholders whose roles or relevance might be changing as a result?
- How is AI changing who can participate in biotech innovation? *(e.g., new roles, democratization of discovery tools)*
- Where do you see AI taking the biotech industry in the next 5–10 years?

Closing

- *(For all start-ups)*

- Is there anything you think researchers or policymakers should better understand about using AI in biotech?
- Would you be open to a follow-up or receiving a summary of the findings?

9. APPENDIX B

Figure 1: Gioia Structure

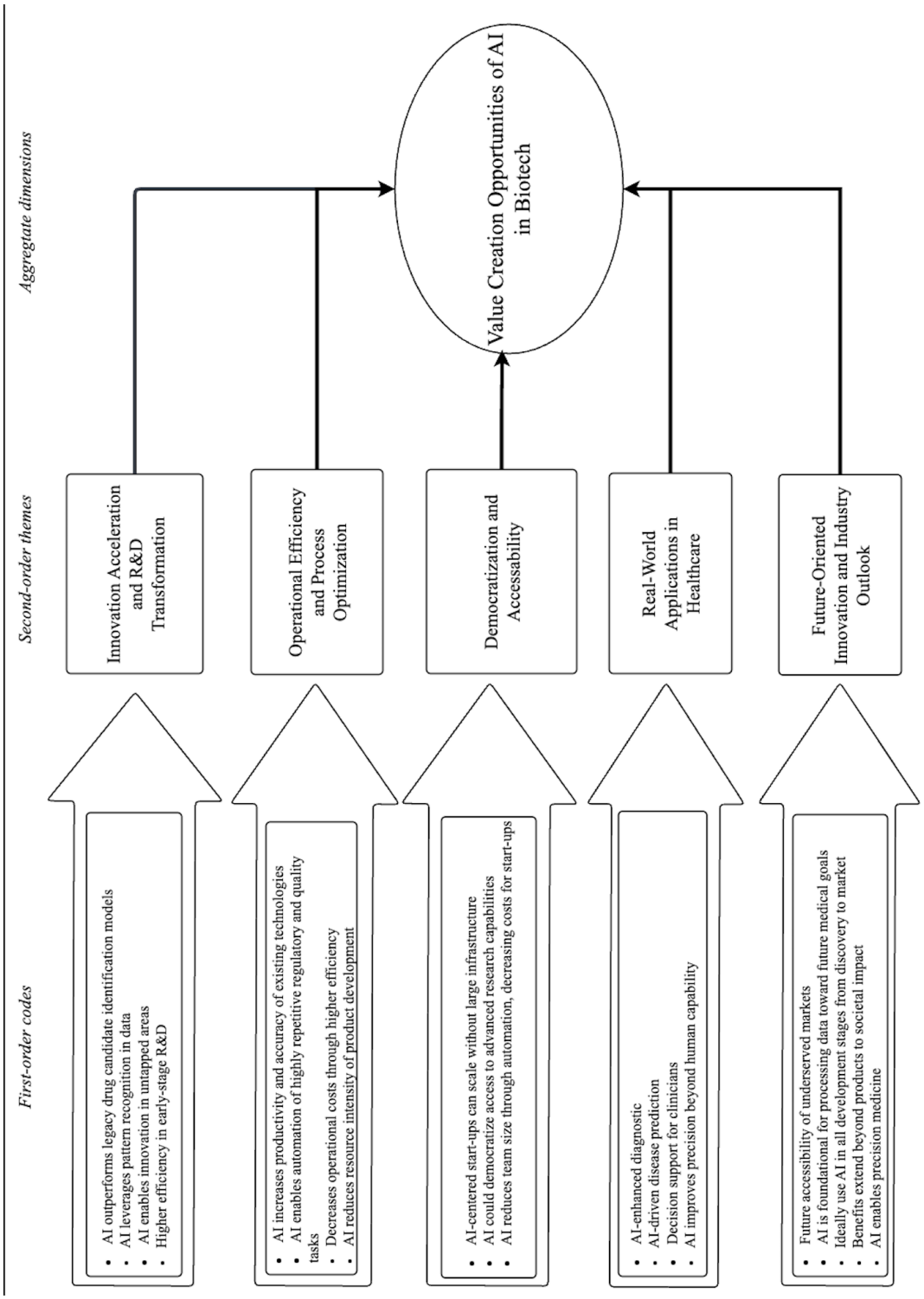


Figure 1 (continued)

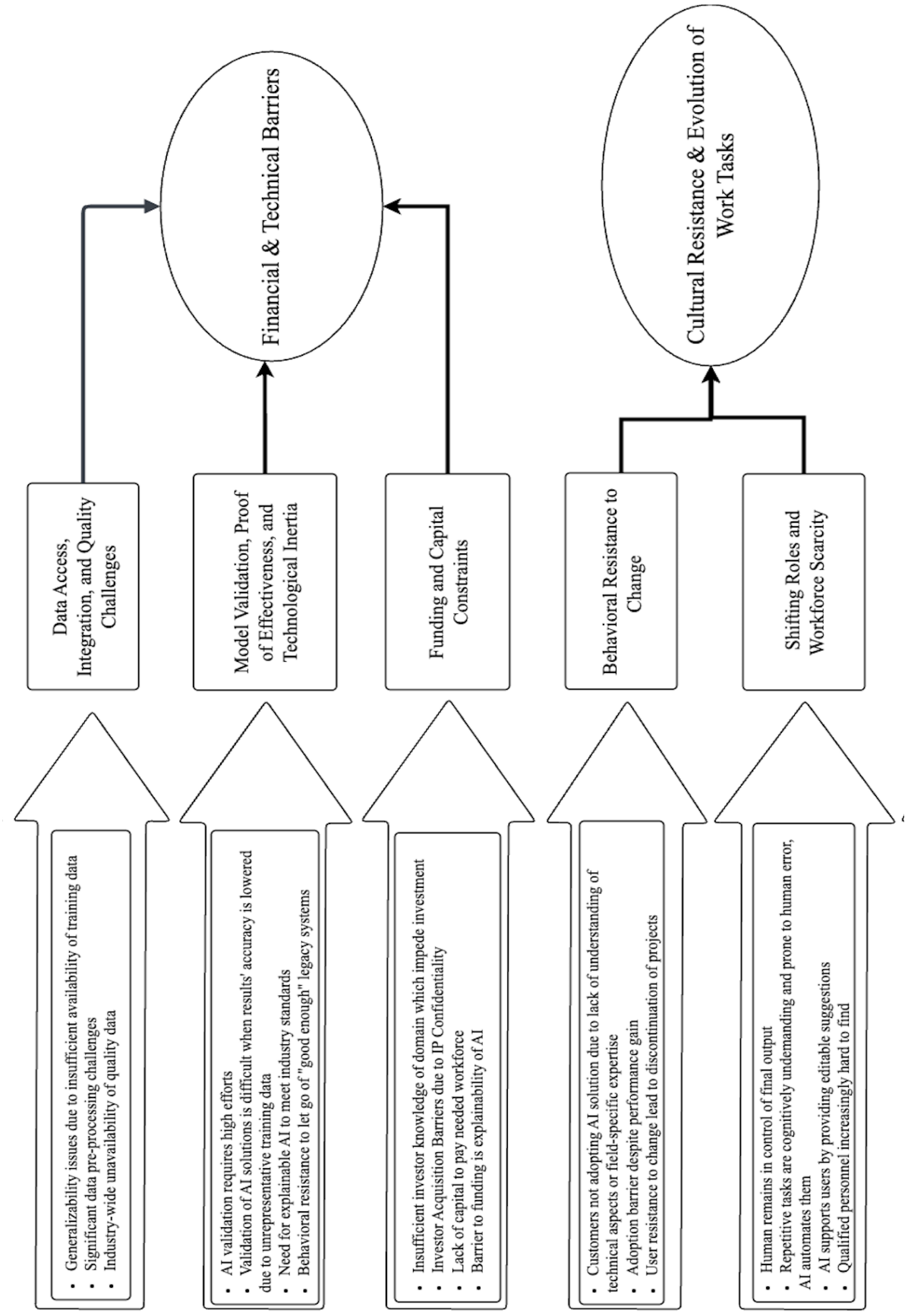
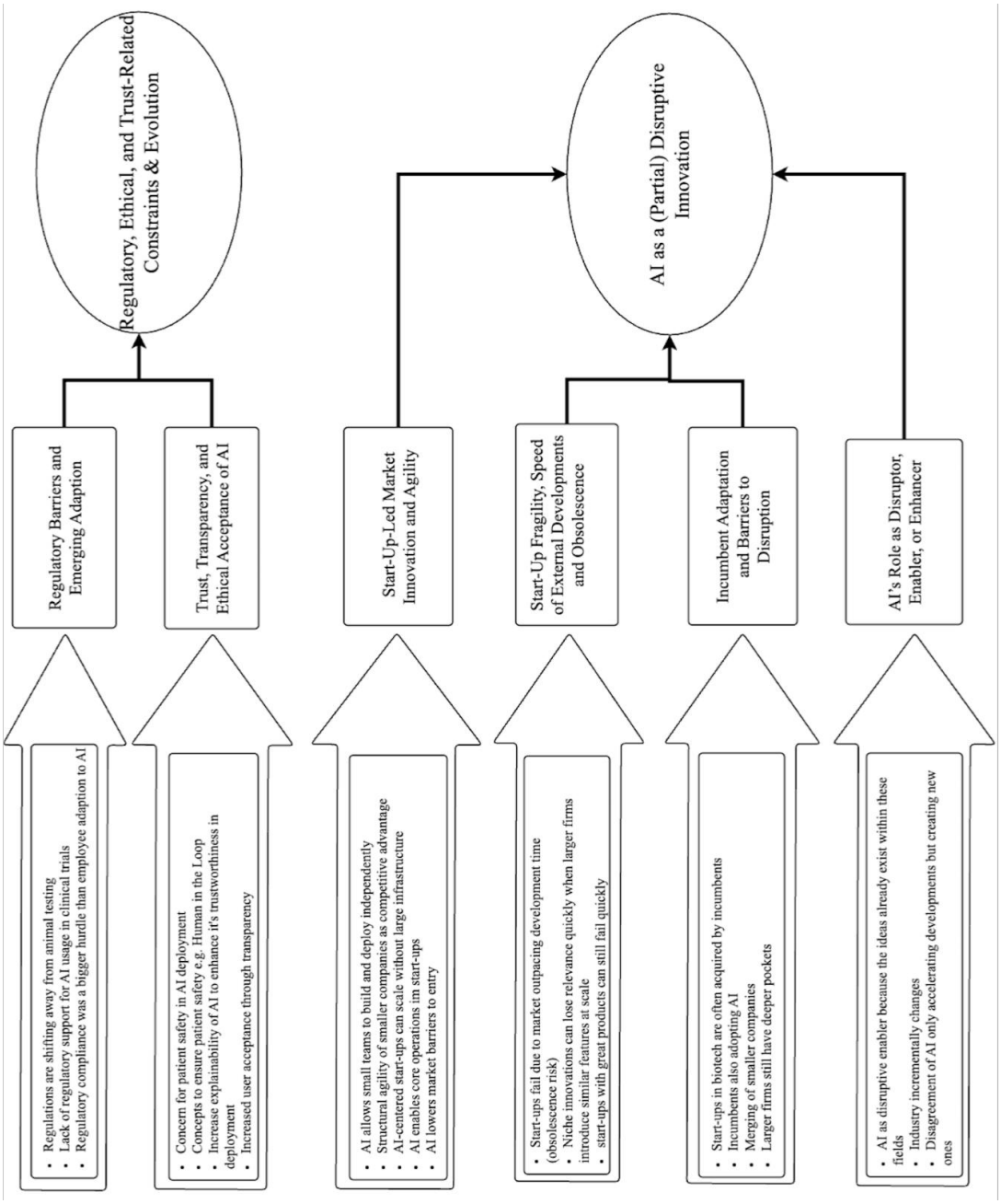


Figure 1 (continued)



10. APPENDIX C

Figure 2: Exemplary Challenges