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# Mapping the AI Landscape in Life Sciences: A Framework for Evaluation and Adoption

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## Abstract

**Background:** The adoption of Artificial Intelligence (AI) is accelerating in the life sciences sector, offering opportunities to enhance biopharmaceutical research, development, and commercialization. However, the sector lacks structured tools to prioritize AI initiatives across varied business domains.
**Objective:** This study presents a framework to categorize and evaluate potential AI applications in the life sciences industry, organizing use cases along two critical dimensions: Phase of Product Lifecycle and Operational Domain.
**Methods:** A structured mixed-methods approach was employed, including a modified Delphi consensus process with industry experts, a qualitative case study review, and iterative framework refinement between August 2023 and August 2024.
**Results:** The resulting matrix framework enables life sciences professionals to assess AI opportunities across research, clinical development, commercialization, and post-marketing activities. Key findings highlight the pervasive nature of AI impact, the emphasis on data-driven strategies, and the regulatory and ethical challenges facing biopharma firms.
**Conclusions:** This framework provides a practical model for strategic AI adoption decisions within the life sciences sector and lays the groundwork for future research, policy development, and enterprise transformation efforts.

## Plain Language Summary

Artificial Intelligence (AI) is starting to reshape how pharmaceutical companies discover new drugs, test them in clinical trials, and bring them to patients. However, with so many possible uses for AI, it can be hard for companies to decide where to begin and how to prioritize. This article presents a simple framework that organizes potential AI projects by the stage of drug development, such as early research or post-market monitoring, and by how much the project involves people outside the company, like doctors or patients. The goal is to help life sciences companies think more clearly about where AI could add value and what risks to monitor. With thoughtful planning, AI can make biopharma companies and the healthcare system they support, smarter, and more focused on patient needs.

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Recent advances in Artificial Intelligence (AI) are prompting discussions across various scientific and business sectors regarding where, how, and why AI technologies might be deployed, and what the implications will be. The medical and life sciences fields are exploring how AI might be incorporated throughout

the drug development process, from discovery to patient care, including through commercialization, marketing, and market access strategies.[1]

As of mid-2024, the AI adoption in the life sciences industry has progressed from theoretical discussions to practical implementations, albeit many in the 'pilot phase'. stage. Clinicians, pharmaceutical manufacturers, and policymakers are currently evaluating whether these technologies offer substantive opportunities for innovation, enhanced efficiency, and improved patient outcomes or if they are subject to inflated expectations characteristic of a 'hype cycle'.[2]

AI represents a range of technologies, including large language models, machine learning, natural language processing, and computer vision.[3] Some researchers propose that AI and related technologies represent significant shifts in how researchers and clinicians approach complex problems in life sciences and healthcare.[4]

Some potential AI applications hold particular interest to biopharmaceutical manufacturers because they promise to reduce the time and/or investment involved in bringing new therapies to market. In the earliest stages of drug discovery, AI algorithms aim to speed the identification of new therapeutic targets and potential drug candidates.[5] In clinical development, AI might optimize study designs, improve patient recruitment, or enhance data analysis.[6] Post-commercialization, AI-driven tools may be deployed to enhance patient engagement or medication adherence or to automate the collection of real-world evidence (RWE).[7]

While AI technologies might be promising, they also present several challenges to the industry, ranging from ethical, legal, regulatory, and data security issues to more extensive concerns that organizations might need to change long-standing operating procedures as technologies advance.[8] Compounding these issues is the pace of advancement. Examples include the rapidity of AI development far outpacing the ability of regulatory and legal frameworks to keep up.[9] This asymmetry adds significant complexities in a highly regulated industry that is notably averse to legal risk.

Despite the risks, the potential benefits of 'leading the pack' on AI adoption might be significant. Companies that successfully integrate AI into their operations might gain competitive advantages, from accelerated research and development to more optimized market access strategies. Conversely, those who fail to bring AI on board may increasingly miss out on growth opportunities.[10]

In the light of these challenges and the rapid pace of advancement, the authors aim to provide a framework that professionals across various functions within life sciences companies can use to understand and evaluate the place of AI technologies in their workflows and firms. By aligning AI applications along two key axes that we refer to as *Operational Domain* and *Phase of Product Lifecycle*, we offer a structured approach to evaluating and prioritizing AI initiatives. This framework is designed to assist those in positions of leadership with making informed decisions about AI adoption, balancing potential benefits against risks and challenges.

## Methods for Framework Development

This study employs a structured mixed-methods approach, including a modified Delphi Method. It draws from the authors' industry experience, consultations with external biopharmaceutical experts, a qualitative review of case studies from literature and business reports, and an iterative process of elicitation and consensus-building. The research was conducted between August 2023 and August 2024, allowing for the incorporation of recent developments. It is expected to continue iteratively, incorporating elements of realist synthesis to further expand the framework and refine example use cases.

An initial framework was developed based on the collective expertise of the research team and additional consulting experts. These included professionals with extensive experience in pharmaceutical commercialization, clinical development, and AI applications in research and patient-facing settings. This sector expertise guided the creation of the two axes that form the foundation of the framework: Phase of Product Lifecycle and Operational Domain.

Once the axes were established, examples of AI applied to typical tasks within the life sciences industry were identified and mapped onto the framework based on expert discussion and consensus. The identification process involved (1) consulting industry case studies, publications, and expert knowledge, (2) selecting biopharma industry activities indicative of various phases and operational domains with existing or proposed AI use cases, and (3) highlighting examples that could highlight potential benefits and challenges of AI adoption in each section of the framework matrix, given that these examples are most likely to spark discussions on the requirements, risks, benefits, and objectives of AI as applied to specific industry use cases.

The initial framework and use case examples underwent iterative refinement based on the incorporation of additional feedback from industry experts. In summary, we followed these steps (Table 1).

This methodology allowed us to create a framework that is grounded in real-world industry understanding and reflects the current state and potential future directions of AI applications in life sciences.

### *Ethical Considerations*

This study did not require formal ethics review, as it did not involve human subjects research, clinical trials, or the



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*Table 1.* Initial framework and use cases based on incorporation of additional feedback from industry experts

| Use case | Framework |
|---|---|
| Step 1 | Conceptualization and axis development |
| Step 2 | Expert consultation |
| Step 3 | Framework refinement |
| Step 4 | Identify business activities and map AI use cases to the framework. |
| Step 5 | Iterative improvement as the field advances |

collection of personal data. The research was based on publicly available information, the expertise of the core research team, and consultations with field experts. All experts consulted in this study provided consent to share their professional insights and expertise in an anonymous fashion as a contribution to the framework development.

## Results

Our research resulted in the development of a proposed framework for understanding and implementing AI technologies in the life sciences sector. This framework aligns AI applications along two key axes: *Phase of Product Lifecycle* and *Operational Domain.*

### *Phase of Product Lifecycle (Horizontal Axis)*

This axis aligns approximately with the traditional stages of drug development and commercialization in the life sciences industry. It recognizes that AI might have differential impact at various stages of the drug product journey from concept to market.

#### *Research & Discovery*

Research and discovery represent the early stages of drug development before human testing and encompass a range of computational and biological research methods.

#### *Clinical Trials and Regulatory Approval*

Clinical trials and regulatory approval represent the clinical development phase of activities that typically start with first-in-human testing and culminate with the completion of registrational clinical trials and regulatory/marketing approval.

#### *Commercial Launch*

This phase overlaps here as a parallel process, with planning starting well prior to Regulatory Approval and continuing through that launch date and beyond, and including a range of commercial, medical, and access-related activities.

#### *Post-Market Activities*

Post-marketing commercial and scientific activities support pharmacovigilance, the collection of RWE, ongoing communication with healthcare professionals, and continued patient support.

### *Operational Domain (Vertical Axis)*

This axis represents a continuum from internal operations to increasingly external interactions, reflecting not only the diverse operational areas where AI technologies are applied in the life sciences sector but also the growing complexity of regulatory, data, and ethical considerations as we move from internal operations toward patient-facing applications. *Internal Operations* include activities within the company's boundaries, including those that deal with proprietary data and processes. While still subject to regulations, these activities carry the least external exposure and thus lower regulatory and ethical risks. *B2B Engagements* represent the first step from internal activities into external interactions, involving partnerships, suppliers, and other businesses, either scientific or commercial in nature. Here, collaborative processes and data sharing introduce additional regulatory considerations and data protection needs, but with less regulatory overhead than engaging with healthcare professionals or patients.

#### Healthcare Professional Engagements

These cover interactions with healthcare professionals, introducing significant regulatory oversight due to data protection, transparency laws, ethics, and the impact to patient care.

#### *Patient Engagements*

As the last operational domain, patient operational domains represent direct patient interactions and the highest level of external engagement. Patient-facing activities face the most stringent regulatory requirements, data privacy concerns, and ethical considerations given the impact on patient care and individual health outcomes.

Table 2 illustrates this matrix and provides representative examples of AI applications at each intersection of Lifecycle Phase and Operational Domain, showcasing potential use cases for AI technologies across common biopharma business areas.

## Key Findings

In parallel with our development of this framework, we identified the following themes as applicable to biopharmaceutical manufacturers considering AI adoption:

### *Pervasive Impact*

AI use cases span across all phases of the product lifecycle and all addressed operational domains. The breadth of potential applications suggests a fundamental shift in how the industry will operate in the future.

*Table 2.* Matrix framework for understanding AI use cases and applications in life sciences

| Phase of product lifecycle | Operational domain | | | |
|---|---|---|---|---|
| | Increasing levels of regulation and risk with more external-facing activities towards the right | | | |
| | Internal operations | B2B engagements | HCP engagements | Patient engagements |
| *Phases of drug discovery, development, and launch* | | | | |
| Discovery and Pre-Clinical Development | *AI-driven target identification and validation* | *Federated learning platforms for collaborative research* | *AI-curated research insights for KOL engagement* | *AI analysis of patient-generated health data for biomarker discovery* |
| | *Machine learning for in silico drug design* | *AI-optimized partnering selection for CRO, investment, and BD* | *Natural language processing for clinical expertise mapping* | *Machine learning models for patient stratification in rare diseases* |
| | *AI-powered predictive toxicology models* | *AI-driven compound sourcing and synthesis prediction* | *AI-powered scientific conference and KOL matchmaking* | *AI-driven patient advocacy network analysis* |
| Clinical Development and Regulatory Submission | *AI for adaptive trial design and protocol optimization* | *AI-driven site selection and performance prediction* | *AI-powered investigator relationship management* | *AI chatbots for patient screening and enrollment* |
| | *Machine learning for patient recruitment forecasting* | *Machine learning for CRO performance optimization* | *Virtual assistants for protocol clarification and support* | *Machine learning for personalized patient retention strategies* |
| | *NLP-powered automated regulatory submission preparation* | *AI for optimizing multi-regional clinical trial designs* | *Machine learning for investigator site feasibility assessment* | *AI for real-time patient monitoring and adverse event prediction in trials* |
| Commercial Launch and Market Access | *AI for dynamic pricing models and market access strategies* | *AI-driven payer negotiation simulators* | *AI-powered personalized HCP engagement platforms* | *AI for personalized patient support program design* |
| | *Machine learning for sales force effectiveness optimization* | *Machine learning for distribution channel optimization* | *NLP for real-time HCP sentiment analysis during interactions* | *Machine learning for medication adherence prediction and intervention* |
| | *NLP for competitive intelligence and market sentiment analysis* | *AI for automating and optimizing RFI and tender processes* | *AI for predicting and optimizing HCP prescription behaviors* | *AI-driven chatbots for patient education on complex therapies* |
| Lifecycle Management and Post-Marketing Activities | *AI for signal detection in pharmacovigilance* | *AI for real-world evidence study design and partner selection* | *AI-driven personalized medical information services* | *AI for detecting and predicting medication non-adherence* |
| | *Machine learning for product lifecycle optimization strategies* | *Machine learning for supply chain risk prediction and mitigation* | *Machine learning for predicting and addressing HCP information needs* | *Machine learning for personalizing patient support interventions* |
| | *NLP for automated medical literature monitoring* | *AI-powered forecasting for long-term product performance* | *NLP for processing and analyzing HCP feedback at scale* | *NLP for analyzing patient-reported outcomes and social media data* |

AI: Artificial Intelligence; B2B: business-to-business; CRO: contract research organization; HCP: healthcare professional; KOL: key opinion leader; NLP: natural language processing.

*Efficiency and Innovation*

Many AI applications focus on improving efficiency (e.g. automation of regulatory submissions) or driving innovation (e.g. AI-powered drug discovery). AI applications are frequently framed as tools that will reduce effort, time, and/or cost.

*Enhanced Customer Engagement*

AI technologies may be leveraged by both commercial and medical field teams, particularly in digital or 'omnichannel' marketing initiatives or in medical communications.

*Data-Driven Decision Making*

Across the matrix, there is a strong emphasis on data sources and data access as inputs to AI models. These data may be internally or externally derived, speaking to the value of high-quality data assets. Access to data assets is likely a competitive advantage or differentiator.

*Patient-Centricity*

The framework reveals numerous AI applications focused on improving patient experiences and outcomes, aligning with a general shift toward more patient-centric approaches and the need to communicate patient-centric value, especially in the commercial phase. Patient-centricity aligns with value-based care models and evolving regulatory expectations around the incorporation of patient reported outcomes (PROs) in drug development and post-marketing phases.

*Interconnectedness*

Several AI applications bridge multiple domains or phases, hinting at the potential for these technologies to change industry structures or processes over time. This interconnectedness suggests the need for integrated AI strategies that consider the full spectrum of pharmaceutical operations and stakeholder interactions.

*Ethical and Regulatory Considerations*

AI uses cases in biopharma that raise numerous ethical and regulatory questions. These include questions around data privacy and security, algorithmic bias, data ownership and consent, and the interpretability or generalizability of AI-driven decisions.

## Limitations

Our methodology has limitations, including an acknowledgment that the rapid pace of AI development is likely to outpace even expert knowledge. Another limitation in expert consensus methods is the introduction of potential bias based on the team's collective experiences and perspectives. We mitigated these limitations to the extent possible through engaging diverse experts and iterating through the framework development process.

Furthermore, this framework is not likely to be exhaustive, given the challenge of comprehensively capturing all possible AI applications in a rapidly evolving field. For example, biopharmaceutical manufacturing companies also perform a number of corporate functions in finance, legal, human resources, training, and similar operational domains considered out of scope in this project. However, there may be areas where AI innovation can also be applied.

## Conclusion

This article presents a new framework for understanding and categorizing AI technologies across the life sciences product lifecycle and operational domain. By mapping along two axes representing paradigms well-understood by professionals in the biopharmaceutical industry, we provide a structured approach for such professionals to evaluate and prioritize AI technology initiatives.

Our findings demonstrate the pervasive potential of AI to transform various aspects of the life sciences sector, but not without risks and challenges to navigate, including data quality and availability, algorithmic biases, privacy and security, ethical and regulatory considerations, and the need for organizational change management.

As the field continues to evolve rapidly, ongoing research and industry collaboration will be crucial to fully harness the potential of AI while addressing its associated challenges. The framework presented in this article provides a foundation for these future efforts, offering a common language and structure for discussing and analyzing AI applications in the sector.

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## Conflicts of Interest

Ms. Hinkel is co-Editor-in-Chief of Blockchain in Healthcare Today. The authors declare no competing interests related to the subject of this article.

For transparency, all authors are employed by or have formerly worked in the life sciences and adjacent sectors, including working for and/or consulting for biopharmaceutical manufacturers. Miss. Hinkel and Dr. Kidd have worked for and/or consulted for health informatics firms.

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## Authors' Contributions

## Data Availability Statement (DAS), Data Sharing, Reproducibility, and Data Repositories

## Application of AI-Generated Text or Related Technology

All data produced in this study are available upon reasonable request to the corresponding author.

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