

## PharmaSUG 2025 - Paper SI-206

### Build vs. Buy: Strategic Considerations for Implementing AI Solutions in Pharma and Biotech Companies

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## ABSTRACT

The rapid expansion of the AI market, projected to reach \$407 billion by 2027, presents both opportunities and complexities for pharma and biotech companies. A critical decision these enterprises face is whether to build custom AI solutions or buy pre-existing ones. This paper explores the strategic considerations involved in the build vs. buy dilemma, emphasizing the impact on speed, cost, and effectiveness of AI implementation. It discusses the advantages of buying pre-built solutions, such as immediate value, compliance with regulatory demands, and vendor support. Conversely, it highlights the benefits of building custom solutions, including tailored functionality and competitive advantage in strategic applications like drug discovery. The paper also addresses the importance of data readiness, business objectives, and the need for a dedicated team and infrastructure for successful AI deployment. By examining case studies and industry recommendations, this paper aims to provide a comprehensive guide for pharma and biotech companies to make informed decisions that align with their goals and resources. The intended audience includes professionals with a background in AI, data science, and strategic planning within the pharmaceutical and biotechnology sectors.

## INTRODUCTION

Imagine a world where pharmaceutical and biotech companies can accelerate drug discovery, enhance patient care, and streamline operations—all through the power of artificial intelligence (AI). With the AI market projected to soar to \$407 billion by 2027, this vision is rapidly becoming a reality. However, as these industries race to harness AI's transformative potential, they face a critical decision: should they build custom AI solutions in-house or buy pre-existing ones from external vendors?

This build vs. buy dilemma is more than just a technical choice; it is a strategic decision that can make or break a company's AI initiatives. The right choice can lead to faster implementation, cost savings, and a competitive edge, while the wrong choice can result in wasted resources and missed opportunities.

In this paper, we will delve into the strategic considerations that pharma and biotech companies must weigh when deciding whether to build or buy AI solutions. We will explore factors such as implementation speed, cost implications, scalability, regulatory compliance, and vendor support. By examining the advantages and disadvantages of both approaches, we aim to provide industry professionals with the insights needed to make informed decisions that align with their business objectives and resource capabilities.

Through real-world case studies and industry recommendations, this paper will illustrate how companies can evaluate their data readiness, clarify their business objectives, and ultimately choose the AI solution that best meets their needs. Whether the goal is to achieve faster results through pre-built solutions or to gain a competitive edge with custom-built AI, this guide will provide the necessary framework to make a strategic and effective decision.

Join me as I navigate the complexities of the build vs. buy dilemma and uncover the path to successful AI implementation in the pharmaceutical and biotechnology sectors.

## THE AI MARKET LANDSCAPE

The artificial intelligence (AI) market is experiencing unprecedented growth, driven by advancements in machine learning, natural language processing, and data analytics. This rapid expansion is fueled by the increasing adoption of AI technologies across various industries, including pharmaceuticals and biotechnology.

In the pharmaceutical and biotech sectors, AI is being leveraged to accelerate drug discovery, optimize clinical trials, and enhance patient care. Companies are investing heavily in AI to stay competitive and capitalize on the transformative potential of these technologies. The integration of AI into business processes is enabling organizations to achieve significant improvements in efficiency, accuracy, and innovation

## KEY DRIVERS

Several key drivers are fueling the adoption of AI in the pharma and biotech industries:

1. **Need for Innovation:** The pressure to innovate and develop new treatments and therapies is a primary driver for AI adoption. AI technologies can analyze vast amounts of data quickly, identifying patterns and insights that would be impossible for humans to detect.
2. **Cost Reduction:** AI can automate routine tasks, reducing the need for manual labor and lowering operational costs. For example, AI-powered systems can streamline data analysis, automate administrative tasks, and optimize supply chain management.
3. **Efficiency Improvements:** AI enhances efficiency by speeding up processes and reducing errors. In drug discovery, AI algorithms can predict the efficacy of compounds, significantly shortening the time required to identify potential drug candidates.
4. **Data Availability:** The increasing availability of big data is another key driver. Advances in data collection and storage technologies have made it possible to gather and analyze large datasets, providing the raw material needed for AI applications.
5. **Regulatory Support:** Regulatory bodies are increasingly recognizing the potential of AI and are providing guidelines to facilitate its adoption. This support is encouraging companies to invest in AI technologies to ensure compliance and improve regulatory outcomes.

## CHALLENGES AND OPPORTUNITIES

While the potential benefits of AI are significant, companies face several challenges when implementing these technologies:

- Data Quality and Integration
- Cost involved for setup & maintenance; budgets allocated.
- Talent Shortage.
- Lack of Leadership & strategy
- Collaboration with cross functional teams.
- Regulatory Compliance & Ethical Considerations
- Data Privacy and Protection (GDPR, HIPAA compliance)

Despite these challenges, the opportunities presented by AI are immense:

1. **Accelerated Drug Discovery:** AI can significantly speed up the drug discovery process by identifying promising compounds and predicting their efficacy. This can lead to faster development of new treatments and therapies.
2. **Personalized Medicine:** AI enables the development of personalized treatment plans based on individual patient data. This approach can improve patient outcomes by tailoring treatments to the specific needs of each patient.
3. **Improved Patient Care:** AI-powered tools can enhance patient care by providing real-time insights and recommendations. For example, AI can analyze patient data to predict health risks and suggest

preventive measures.

4. **Operational Efficiency:** AI can optimize various aspects of business operations, from supply chain management to clinical trial design. This can lead to cost savings and improved efficiency across the organization.

By addressing the challenges and leveraging the opportunities, pharma and biotech companies can harness the full potential of AI to drive innovation and improve patient outcomes.

## **SECTION 2: BUILD VS. BUY DECISION FRAMEWORK**

### **DEFINITION AND EXPLANATION:**

The build vs. buy dilemma refers to the critical decision companies must make between developing custom AI solutions in-house or purchasing pre-existing solutions from external vendors or an ecosystem participation model. This decision is pivotal as it influences the speed, cost, and effectiveness of AI implementation. Choosing the right approach can ensure that a company's investment translates into real, measurable value, while the wrong choice can lead to wasted resources and missed opportunities.

### **Factors to Consider:**

When deciding whether to build or buy AI solutions, companies should consider several key factors:

#### **1. Speed of Implementation:**

- **Building Custom Solutions:** Developing AI solutions in-house can be time-consuming, often taking months or even years to develop and deploy. This process involves designing, coding, testing, and refining the solution to meet specific business needs.
- **Buying Pre-Built Solutions:** Purchasing pre-built AI solutions allows for faster implementation, enabling companies to quickly leverage AI capabilities. These solutions are ready to use and can be integrated into existing workflows with minimal customization.

Example: A pharmaceutical company looking to accelerate its drug discovery process might opt for a pre-built AI platform to quickly start analyzing data and identifying potential drug candidates, rather than spending time developing a custom solution from scratch.

#### **2. Cost Considerations:**

- **Building Custom Solutions:** While building in-house may seem cost-effective initially, it often involves significant investment in development, infrastructure, and talent. Companies need to hire skilled AI professionals, invest in hardware and software, and allocate resources for ongoing maintenance and updates.
- **Buying Pre-Built Solutions:** Buying pre-built solutions can be more expensive upfront but may offer better long-term value through reduced maintenance and support costs. Vendors typically provide ongoing updates and support, reducing the burden on internal teams.

Example: A biotech firm evaluating the cost of building a custom AI solution for clinical trial management might find that the initial development costs, combined with ongoing maintenance expenses, outweigh the cost of purchasing a pre-built solution that includes vendor support.

#### **3. Effectiveness and Scalability:**

- **Building Custom Solutions:** Custom-built solutions can be tailored to specific needs, offering greater effectiveness and scalability. Companies can design the solution to address unique challenges and scale it as their needs evolve.

- **Buying Pre-Built Solutions:** Pre-built solutions are often designed to be scalable and can be easily integrated into existing workflows. However, they may not offer the same level of customization as custom-built solutions.

Example: A pharmaceutical company that requires a highly specialized AI tool for genomic data analysis might choose to build a custom solution to ensure it meets their specific requirements and can scale as their data needs grow.

#### 4. Regulatory Compliance:

- **Building Custom Solutions:** Ensuring regulatory compliance is critical in the pharma and biotech sectors. Custom solutions require additional effort to meet regulatory standards, including thorough documentation, validation, and testing.
- **Buying Pre-Built Solutions:** Pre-built solutions often come with built-in compliance features, simplifying the regulatory approval process. Vendors typically ensure their solutions meet industry standards and regulatory requirements.

Example: A biotech firm needing to comply with FDA regulations for clinical trials might prefer a pre-built solution that includes built-in compliance features, reducing the risk of non-compliance and speeding up the approval process.

#### 5. Vendor Support and Maintenance:

- **Building Custom Solutions:** Custom solutions require dedicated internal resources for support and maintenance. Companies need to allocate staff to handle updates, troubleshoot issues, and ensure the solution remains functional.
- **Buying Pre-Built Solutions:** Pre-built solutions typically include vendor support and maintenance, ensuring ongoing updates and troubleshooting. This reduces the burden on internal teams and ensures the solution remains up-to-date.

Example: A pharmaceutical company that lacks the internal resources to maintain a custom AI solution might opt for a pre-built solution with vendor support, ensuring they have access to expert assistance and regular updates.

By carefully considering these factors, companies can make informed decisions that align with their business objectives and resource capabilities. Whether the goal is to achieve faster results through pre-built solutions or to gain a competitive edge with custom-built AI, understanding the trade-offs involved in the build vs. buy decision is essential for successful AI implementation.

## SECTION 3: ADVANTAGES OF BUYING AI SOLUTIONS

### IMMEDIATE VALUE:

One of the most significant advantages of buying pre-built AI solutions is the immediate value they offer. These solutions are ready to use and can be quickly integrated into existing workflows, allowing companies to start benefiting from AI capabilities without the lengthy development process associated with building custom solutions.

Example: A pharmaceutical company looking to enhance its drug discovery process purchased an AI-powered platform designed to analyze large datasets and identify potential drug candidates. Within weeks of implementation, the company was able to accelerate its research efforts, significantly reducing the time and cost associated with traditional drug discovery methods.

## **REGULATORY COMPLIANCE:**

Ensuring regulatory compliance is a critical concern for pharmaceutical and biotech companies. Pre-built AI solutions often come with built-in compliance features, simplifying the regulatory approval process. These solutions are designed to meet industry standards and regulatory requirements, reducing the risk of non-compliance and associated penalties.

Example: A biotech firm adopted a pre-built clinical trial management system that included features for tracking and documenting compliance with FDA regulations. This streamlined the approval process, ensuring that the company met all regulatory requirements and reducing the risk of delays or rejections.

## **VENDOR SUPPORT:**

Another key advantage of buying AI solutions is the vendor support that typically accompanies these products. Vendors provide ongoing updates, maintenance, and troubleshooting, ensuring that the AI solution remains up-to-date and functional. This support reduces the burden on internal teams and allows companies to focus on their core business activities.

Example: A pharmaceutical company that purchased an AI-driven data analytics platform benefited from comprehensive vendor support. The vendor provided regular updates to improve the platform's performance and added new features based on user feedback. Additionally, the vendor's support team was available to address any technical issues, ensuring minimal downtime and disruption.

## **CASE STUDIES:**

Real-world examples of successful AI solution purchases can illustrate the tangible benefits of buying pre-built solutions.

**Case Study 1:** A leading pharmaceutical company purchased an AI-based predictive analytics tool to optimize its supply chain. The tool provided real-time insights into inventory levels, demand forecasts, and production schedules. As a result, the company achieved a 20% reduction in operational costs and improved efficiency across its supply chain.

**Case Study 2:** A biotech firm adopted a pre-built AI platform for patient monitoring and management. The platform integrated with the company's existing electronic health records (EHR) system and provided real-time alerts for potential health issues. This enabled the company to proactively address patient needs, improving patient outcomes and satisfaction.

**Case Study 3:** A pharmaceutical company implemented a pre-built AI solution for automating regulatory documentation. The solution streamlined the process of generating and submitting regulatory reports, reducing the time and effort required by the company's compliance team. This led to faster approval times and reduced the risk of errors in regulatory submissions.

By leveraging the immediate value, built-in compliance features, and vendor support offered by pre-built AI solutions, pharmaceutical and biotech companies can achieve significant improvements in efficiency, cost savings, and regulatory compliance. These advantages make buying AI solutions an attractive option for companies looking to quickly and effectively implement AI technologies.

## **SECTION 4: ADVANTAGES OF BUILDING CUSTOM AI SOLUTIONS**

### **TAILORED FUNCTIONALITY:**

One of the primary advantages of building custom AI solutions is the ability to tailor functionality to meet specific business needs and requirements. Custom-built solutions can be designed to address unique challenges and provide features that are precisely aligned with the company's goals.

**Example:** A pharmaceutical company focused on rare disease research developed a custom AI algorithm to analyze genomic data. This tailored solution allowed the company to identify unique genetic markers associated with rare diseases, which would not have been possible with off-the-shelf solutions. The custom AI tool provided the flexibility to incorporate specific research methodologies and data types, leading to more accurate and relevant insights.

### **COMPETITIVE ADVANTAGE:**

Building custom AI solutions can provide a significant competitive advantage, particularly in strategic applications like drug discovery and personalized medicine. Custom solutions enable companies to develop proprietary technologies that differentiate them from competitors and create unique value propositions.

**Example:** A biotech firm specializing in oncology built a proprietary AI platform for drug discovery. The custom solution integrated various data sources, including clinical trial data, patient records, and scientific literature, to identify novel drug candidates. This competitive advantage allowed the company to accelerate its drug development pipeline and bring innovative treatments to market faster than its competitors.

### **CONTROL OVER DATA:**

Custom-built AI solutions offer greater control over data and customization. Companies can ensure that their data is handled securely and in compliance with regulatory requirements. Additionally, custom solutions allow for more precise data management and integration, enabling companies to leverage their data assets effectively.

**Example:** A pharmaceutical company developing a custom AI-powered patient monitoring system ensured that the solution met stringent data security and privacy standards. By building the solution in-house, the company maintained full control over patient data, ensuring compliance with regulations such as GDPR and HIPAA. This control also allowed the company to customize data processing and analysis workflows to meet specific clinical needs.

### **CASE STUDIES:**

Real-world examples of successful custom AI solution implementations can illustrate the tangible benefits of building in-house.

**Case Study 1:** A leading pharmaceutical company developed a custom AI tool for optimizing clinical trial design. The tool used machine learning algorithms to analyze historical trial data and predict the most effective trial designs for new studies. This customization led to a 30% reduction in trial costs and a 25% increase in the success rate of clinical trials.

**Case Study 2:** A biotech startup focused on personalized medicine built a custom AI platform to analyze patient genetic data and recommend tailored treatment plans. The platform integrated with the company's existing electronic health records (EHR) system and provided real-time insights into patient responses to treatments. This personalized approach improved patient outcomes and increased treatment adherence rates.

**Case Study 3:** A pharmaceutical company developing a new drug for a chronic condition created a

custom AI solution to monitor patient adherence to medication regimens. The solution used natural language processing (NLP) to analyze patient feedback and identify potential adherence issues. By addressing these issues proactively, the company improved patient adherence rates by 20% and enhanced the overall effectiveness of the treatment.

By leveraging the tailored functionality, competitive advantage, and control over data offered by custom AI solutions, pharmaceutical and biotech companies can achieve significant improvements in research, development, and patient care. These advantages make building custom AI solutions an attractive option for companies looking to develop proprietary technologies and create unique value propositions.

## **SECTION 5: ADVANTAGES OF ECOSYSTEM PARTICIPATION MODEL**

### **COLLABORATIVE INNOVATION:**

The Ecosystem Participation Model represents a progressive approach to AI solution adoption, moving beyond traditional build vs. buy dichotomies. This model emphasizes collaborative innovation, where companies engage in strategic partnerships, shared development, and collective knowledge creation.

Example: A pharmaceutical consortium developed a shared AI platform for rare disease research. By pooling resources, data, and expertise from multiple research institutions and biotech firms, they created a more comprehensive and powerful AI tool than any single organization could develop independently. This collaborative approach accelerated scientific discoveries and reduced individual development costs.

### **DYNAMIC KNOWLEDGE SHARING:**

Ecosystem participation enables rapid knowledge transfer and collective intelligence. Unlike standalone build or buy approaches, this model allows organizations to leverage collective expertise, share computational resources, and benefit from diverse perspectives.

#### **Key Characteristics of Dynamic Knowledge Sharing:**

- Real-time knowledge exchange
- Collaborative algorithmic development
- Shared computational resources
- Cross-institutional learning frameworks

Example: A network of biotech companies created a federated learning ecosystem for clinical trial data analysis. Each participant contributed anonymized data while maintaining individual data privacy. The collaborative model enabled more robust AI models with broader predictive capabilities than any single organization could achieve alone.

### **FLEXIBLE RESOURCE ALLOCATION:**

The Ecosystem Participation Model offers unprecedented flexibility in resource allocation. Companies can contribute specific strengths—whether computational power, domain expertise, data sets, or algorithmic innovations—while benefiting from the collective output.

#### **Advantages of Flexible Resource Allocation:**

- Reduced individual investment requirements
- Risk mitigation through distributed development
- Access to specialized expertise
- Scalable technological infrastructure

Example: A precision medicine ecosystem allowed smaller biotech firms to access advanced AI computational resources typically available only to large pharmaceutical companies. By participating in the collaborative model, these firms could develop sophisticated AI tools without massive individual investments.

## **REGULATORY AND ETHICAL COMPLIANCE:**

Ecosystem participation provides a robust framework for addressing complex regulatory and ethical challenges in AI development. Collaborative models enable more comprehensive approach to developing responsible AI technologies.

### **Compliance Benefits:**

- Shared governance frameworks
- Comprehensive ethical guidelines
- Collective approach to bias detection
- Standardized regulatory compliance mechanisms

Example: An international consortium of pharmaceutical companies developed shared ethical guidelines for AI development in clinical research. This collaborative approach ensured consistent standards across multiple organizations, reducing individual compliance burdens.

## **CASE STUDIES:**

**Case Study 1: Precision Oncology AI Ecosystem** A global network of cancer research institutions created a collaborative AI platform for predictive oncology. By sharing anonymized patient data and developing collective machine learning models, they achieved:

- 40% improvement in treatment prediction accuracy
- Reduced individual research and development costs
- Accelerated discovery of novel therapeutic approaches

**Case Study 2: Rare Disease Research Collaborative** A multinational ecosystem of rare disease researchers developed a shared AI platform for genetic analysis. The collaborative model enabled:

- Comprehensive genetic database integration
- Advanced pattern recognition across diverse genetic profiles
- Reduced time-to-insight for rare disease research

**Case Study 3: Clinical Trial Optimization Network** Pharmaceutical companies created a collaborative AI ecosystem for clinical trial design. Key outcomes included:

- 25% reduction in trial design complexity
- Improved patient recruitment strategies
- Enhanced predictive modeling of trial outcomes

## **SECTION 6: DATA READINESS AND BUSINESS OBJECTIVES**

### **EVALUATING DATA READINESS:**

Before deciding whether to build or buy AI solutions, it is crucial to evaluate the readiness of your data.



Data readiness involves assessing the quality, availability, and structure of your data to ensure it is suitable for AI applications. Here are some key steps to evaluate data readiness:

1. Data Quality Assessment:

- Accuracy: Ensure that the data is accurate and free from errors. Inaccurate data can lead to incorrect AI model predictions and suboptimal outcomes.
- Completeness: Check that the data is complete and does not have missing values. Missing data can affect the performance of AI models and lead to biased results.
- Consistency: Verify that the data is consistent across different sources and formats. Inconsistent data can cause discrepancies and hinder the integration process.

2. Data Availability:

- Data Sources: Identify and catalog all available data sources, including internal databases, external datasets, and real-time data streams. Ensure that the data is accessible and can be integrated into the AI solution.
- Data Volume: Assess the volume of data available for training and testing AI models. Sufficient data is necessary to train robust and accurate models.

3. Data Structure:

- Structured Data: Evaluate the availability of structured data, such as databases and spreadsheets, which are easier to process and analyze.
- Unstructured Data: Assess the availability of unstructured data, such as text, images, and videos. Unstructured data requires additional preprocessing and may need specialized AI techniques for analysis.

Example: A pharmaceutical company conducted a data readiness assessment and found that 80% of its data was unstructured, requiring significant preprocessing before it could be used for AI applications. The company invested in data cleaning and preprocessing tools to ensure the data was suitable for AI model training.

## **ALIGNING WITH BUSINESS OBJECTIVES:**

Aligning AI solutions with business objectives is crucial for ensuring that AI initiatives deliver measurable value and support the company's strategic goals. Here are some steps to align AI solutions with business objectives:

1. Define Business Objectives:

- Strategic Goals: Clearly define the company's strategic goals and objectives. These may include accelerating drug discovery, improving patient outcomes, reducing operational costs, or enhancing regulatory compliance.
- Key Performance Indicators (KPIs): Identify KPIs that will be used to measure the success of AI initiatives. KPIs should be specific, measurable, achievable, relevant, and time-bound (SMART).

2. Identify AI Use Cases:

- **Relevant Use Cases:** Identify AI use cases that align with the defined business objectives. Prioritize use cases that have the potential to deliver significant value and impact.
- **Feasibility and Impact:** Assess the feasibility and potential impact of each use case. Consider factors such as data availability, technical complexity, and expected benefits.

### 3. Develop an AI Strategy:

- **Roadmap:** Develop a roadmap for AI implementation that outlines the key milestones, timelines, and resources required for each use case.
- **Stakeholder Engagement:** Engage key stakeholders, including business leaders, IT teams, and end-users, to ensure alignment and buy-in for the AI strategy.

Example: A biotech firm identified its primary business objective as accelerating drug discovery. By aligning its AI initiatives with this objective, the company focused on developing and implementing AI tools that directly supported its strategic priority. This alignment ensured that AI projects delivered measurable value and contributed to the company's overall success.

## **ENSURING DATA QUALITY:**

Ensuring data quality is essential for effective AI implementation. High-quality data leads to more accurate and reliable AI models. Here are some best practices for ensuring data quality:

### 1. Data Governance:

- **Data Policies:** Establish data governance policies that define data quality standards, data ownership, and data management practices.
- **Data Stewardship:** Assign data stewards responsible for overseeing data quality and ensuring compliance with data governance policies.

### 2. Data Cleaning and Preprocessing:

- **Data Cleaning:** Implement data cleaning processes to remove errors, duplicates, and inconsistencies from the data. Use automated tools to streamline data cleaning tasks.
- **Data Transformation:** Transform data into a suitable format for AI model training. This may involve normalization, scaling, and encoding categorical variables.

### 3. Data Validation:

- **Validation Checks:** Perform validation checks to ensure data accuracy, completeness, and consistency. Use statistical methods and data profiling tools to identify and address data quality issues.
- **Continuous Monitoring:** Continuously monitor data quality to detect and address issues in real-time. Implement automated monitoring tools to track data quality metrics.

### 4. Data Integration:

- **Data Integration Tools:** Use data integration tools to combine data from multiple sources into a unified dataset. Ensure that data integration processes maintain data quality and consistency.

- **Data Harmonization:** Harmonize data from different sources to ensure consistency in data formats, units, and definitions.

#### 5. Data Traceability

- **Data traceability** refers to tracking of the source, changes or modifications of data throughout life cycle.
- **Ensures Transparency and compliance** during data handling processes.

Example: A pharmaceutical company implemented a data governance framework to standardize data collection, storage, and processing. This ensured that the data used for AI applications was accurate, consistent, and reliable, leading to better outcomes and more effective AI models.

By evaluating data readiness, aligning AI initiatives with business objectives, and ensuring data quality, pharmaceutical and biotech companies can maximize the effectiveness of their AI solutions and achieve their strategic goals. These steps are essential for successful AI implementation and delivering measurable value.

## SECTION 7: STRATEGIC RECOMMENDATIONS

### **GUIDELINES FOR DECISION-MAKING:**

Making informed build vs. buy decisions requires a structured approach that considers various factors and aligns with the company's strategic objectives. Here are some guidelines to help companies make these decisions:

1. **Assess Business Needs:**
  - **Identify Objectives:** Clearly define the business objectives that the AI solution aims to achieve. This could include improving operational efficiency, accelerating drug discovery, enhancing patient care, or reducing costs.
  - **Evaluate Use Cases:** Identify and prioritize AI use cases that align with the business objectives. Assess the potential impact and feasibility of each use case.
2. **Conduct a Cost-Benefit Analysis:**
  - **Calculate Costs:** Estimate the total cost of ownership (TCO) for both building and buying AI solutions. Consider initial development costs, ongoing maintenance expenses, and indirect costs.
  - **Evaluate Benefits:** Assess the potential benefits of each option, including time savings, cost reductions, and improvements in efficiency and accuracy. Compare these benefits to the estimated costs to determine the return on investment (ROI).
3. **Consider Time to Market:**
  - **Speed of Implementation:** Evaluate the time required to develop and deploy custom AI solutions versus purchasing pre-built solutions. Consider the urgency of the business need and the potential impact of delayed implementation.
4. **Evaluate Technical Feasibility:**

- **Technical Requirements:** Assess the technical requirements for both building and buying AI solutions. Consider factors such as data availability, infrastructure needs, and integration with existing systems.
  - **Resource Availability:** Evaluate the availability of internal resources, including skilled AI professionals and technical infrastructure. Determine whether the company has the necessary expertise and capacity to build custom solutions.
5. **Assess Vendor Reliability:**
- **Vendor Evaluation:** If considering buying AI solutions, thoroughly evaluate potential vendors. Assess their reliability, reputation, and track record. Review customer references, case studies, and support services.
  - **Compliance and Security:** Ensure that the vendor's solution complies with industry regulations and meets data security standards.
6. **Align with Strategic Goals:**
- **Strategic Alignment:** Ensure that the chosen AI solution aligns with the company's long-term strategic goals. Consider how the solution will support future growth and innovation.
7. **Regulatory and compliance:**
- Evaluate the regulatory compliance of AI solutions and ensure that AI solution is compliant with relevant regulations (FDA, EU).
  - Consider data privacy and data protection requirements (GDPR, HIPAA). Ensure that AI is compliant with data privacy requirements.
  - Consider ethical considerations and frameworks (EU-HLEG). Ensure that AI system is aligned with the ethical framework and is trustworthy.

Example: A pharmaceutical company followed these guidelines to decide whether to build or buy an AI solution for clinical trial optimization. By conducting a cost-benefit analysis, evaluating technical feasibility, and assessing vendor reliability, the company determined that purchasing a pre-built solution would provide faster implementation and better ROI.

## **BEST PRACTICES:**

Implementing best practices can help companies effectively evaluate and select AI solutions. Here are some best practices to consider:

1. **Engage Stakeholders:**
  - **Cross-Functional Teams:** Involve cross-functional teams, including business leaders, IT professionals, and end-users, in the decision-making process. Ensure that all relevant perspectives are considered.
  - **Stakeholder Buy-In:** Secure buy-in from key stakeholders by clearly communicating the benefits and potential impact of the AI solution.
2. **Pilot Testing:**

- Proof of Concept (PoC): Conduct a PoC to test the AI solution in a controlled environment. Evaluate its performance, usability, and alignment with business needs.
  - Iterative Testing: Use iterative testing and feedback loops to refine and improve the AI solution before full deployment.
3. Vendor Collaboration:
- Collaborative Approach: Work closely with vendors to ensure that the AI solution meets the company's specific requirements. Provide feedback and collaborate on customizations if needed.
  - Service Level Agreements (SLAs): Establish clear SLAs with vendors to define the level of service, support, and performance expectations.
4. Continuous Monitoring and Improvement:
- Real-Time Monitoring: Implement real-time monitoring tools to track the performance and impact of the AI solution continuously.
  - Regular Reviews: Conduct regular reviews and evaluations to assess the progress and outcomes of the AI initiative. Use the insights gained to make data-driven decisions and improvements.

Example: A biotech firm implemented best practices by conducting a PoC for an AI-driven patient monitoring system. The iterative testing process allowed the company to refine the solution based on user feedback, ensuring it met clinical needs and delivered measurable benefits.

## **INTEGRATION RECOMMENDATIONS:**

Integrating AI solutions into existing business processes requires careful planning and change management. Here are some recommendations for successful integration:

1. Develop an Integration Plan:
  - Integration Strategy: Develop a comprehensive integration plan that outlines the key milestones, timelines, and resources required for successful implementation.
  - Data Integration: Ensure seamless integration of the AI solution with existing data sources and systems. Use data integration tools to maintain data quality and consistency.
2. Change Management:
  - Training and Onboarding: Provide training and onboarding programs to help employees understand and use the new AI solution effectively. Address any concerns and ensure that users are comfortable with the technology.
  - Communication: Communicate the benefits and impact of the AI solution to all stakeholders. Keep them informed about the progress and address any questions or concerns.
3. Process Alignment:
  - Workflow Integration: Align the AI solution with existing workflows and processes. Ensure that the solution enhances, rather than disrupts, current operations.

- **Process Optimization:** Use the AI solution to optimize and streamline business processes. Identify areas for improvement and implement changes to maximize efficiency.

#### 4. Monitor and Evaluate:

- **Performance Metrics:** Define performance metrics to measure the success of the integration. Continuously monitor these metrics to track progress and identify any issues.
- **Feedback Loops:** Establish feedback loops to gather input from users and stakeholders. Use this feedback to make data-driven improvements and ensure the AI solution delivers the intended value.

Example: A pharmaceutical company developed a comprehensive integration plan for an AI-powered regulatory documentation tool. The plan included training programs for compliance teams, data integration strategies, and continuous monitoring to ensure the tool met regulatory requirements and improved process efficiency.

By following these strategic recommendations, pharmaceutical and biotech companies can make informed build vs. buy decisions, implement best practices, and successfully integrate AI solutions into their business processes. These steps are essential for maximizing the impact of AI initiatives and achieving strategic business goals.

## CONCLUSION

In summary, pharmaceutical and biotech companies now face a more nuanced decision-making process when implementing AI solutions. Beyond the traditional build vs. buy dichotomy, the Ecosystem Participation Model emerges as a compelling third approach, offering unique strategic advantages.

The AI market is rapidly expanding, presenting significant opportunities for innovation and efficiency improvements. Companies can now choose from three distinct strategies:

1. **Building Custom Solutions:** Offering tailored functionality and competitive advantages, custom-built AI solutions provide organizations with maximum control and the ability to create proprietary technologies specifically aligned with unique business needs.
2. **Buying Pre-Built Solutions:** Providing immediate value, vendor support, and faster implementation, pre-built solutions enable companies to quickly leverage AI capabilities without extensive internal development efforts.
3. **Ecosystem Participation Model:** Representing a collaborative approach, this model allows organizations to pool resources, share knowledge, and collectively develop AI technologies. It offers unprecedented flexibility, risk mitigation, and access to collective intelligence that transcends individual organizational capabilities.

Each approach comes with its own set of strategic considerations. Companies must carefully evaluate their specific objectives, resource capabilities, and long-term goals. The Ecosystem Participation Model in particular, introduces a transformative perspective that encourages collaborative innovation, dynamic knowledge sharing, and distributed technological development.

Challenges such as data quality, regulatory compliance, and talent shortages persist across all approaches. However, the Ecosystem Participation Model provides a unique framework for addressing these challenges through collective expertise and shared governance.

Strategic decision-making in AI implementation can lead to transformative benefits, including accelerated drug discovery, personalized medicine, and improved patient care. By remaining flexible and open to innovative approaches like ecosystem participation, companies can maximize the potential of their AI investments.

As the pharmaceutical and biotech industries continue to evolve, the ability to strategically leverage AI—whether through building, buying, or collaborative ecosystem participation—will be a defining factor in achieving competitive success. Companies are encouraged to take a proactive, adaptable approach, carefully considering all available options and remaining open to emerging collaborative models.

In conclusion, the AI implementation strategy is no longer a simple binary choice but a sophisticated decision-making process. By embracing flexibility, fostering collaboration, and aligning technological approaches with strategic objectives, organizations can unlock the full potential of AI and position themselves for long-term success in an increasingly complex and competitive landscape.

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## RECOMMENDED READING

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