

Artificial Intelligence in Pharmaceutical Industry

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ABSTRACT

Artificial intelligence (AI) is a branch of computer science that allows machines to work efficiently and analyze complex data. It has caused a digital revolution across healthcare sector, including the pharma industry. It is becoming a powerful and helpful tool for modernizing and enhancing critical processes in the pharmaceutical industry. AI technology is transforming the pharmaceutical industry's drug discovery, development, and personalized medicine through enhanced efficiency and data analysis. AI is changing the game in the pharmaceutical world, making things faster and smarter than ever before. This paper reveals how the pharmaceutical industry leverages AI and GenAI to transform its operations.

KEYWORDS: *pharmaceutical industry, pharma, artificial intelligence, machine learning, AI, generative AI*

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INTRODUCTION

Artificial intelligence (AI) is the science of training algorithms to learn from data. It is a combination of various intelligent processes and behavior, developed by computational models, algorithms or a set of rules which supports the machine to mimic the cognitive functions of humans such as learning, problem-solving, etc. AI algorithms optimize everything from discovering new blockbuster drugs to managing clinical trials and accelerating regulatory approvals. It predicts interactions between proteins and drug compounds and whether a substance could work safely in humans. Figure 1 shows AI symbol [1]. The pharmaceutical industry is rapidly evolving, and the number of AI application integrations is increasing day by day, reshaping every facet of pharmaceutical processes from drug discovery to supply chain management.

WHAT IS ARTIFICIAL INTELLIGENCE?

The term “artificial intelligence” (AI) is an umbrella term John McCarthy, a computer scientist, coined in 1955 and defined as “the science and engineering of intelligent machines.” It refers to the ability of a

computer system to perform human tasks (such as thinking and learning) that usually can only be accomplished using human intelligence [2]. Typically, AI systems demonstrate at least some of the following human behaviors: planning, learning, reasoning, problem solving, knowledge representation, perception, speech recognition, decision-making, language translation, motion, manipulation, intelligence, and creativity.

The 10 U.S. Code § 2358 define artificial intelligence as [3]:

1. “Any artificial system that performs tasks under varying and unpredictable circumstances without significant human oversight, or that can learn from experience and improve performance when exposed to data sets.
2. An artificial system developed in computer software, physical hardware, or other context that solves tasks requiring human-like perception, cognition, planning, learning, communication, or physical action.

3. An artificial system designed to think or act like a human, including cognitive architectures and neural networks.
4. A set of techniques, including machine learning, that is designed to approximate a cognitive task.
5. An artificial system designed to act rationally, including an intelligent software agent or embodied robot that achieves goals using perception, planning, reasoning, learning, communicating, decision making, and acting.”

AI provides tools creating intelligent machines which can behave like humans, think like humans, and make decisions like humans. The main goals of artificial intelligence are [4]:

1. Replicate human intelligence
2. Solve knowledge-intensive tasks
3. Make an intelligent connection of perception and action
4. Build a machine which can perform tasks that requires human intelligence
5. Create some system which can exhibit intelligent behavior, learn new things by itself, demonstrate, explain, and can advise to its user.

AI is not a single technology but a range of computational models and algorithms. The concept of AI is an umbrella term that encompasses many different technologies. AI is not a single technology but a collection of techniques that enables computer systems to perform tasks that would otherwise require human intelligence. The major disciplines in AI include [5]:

- Expert systems
- Fuzzy logic
- Neural networks
- Machine learning (ML)
- Deep learning
- Natural Language Processors (NLP)
- Robots

These computer-based tools or technologies have been used to achieve AI's goals. Each AI tool has its own advantages. Using a combination of these models, rather than a single model, is recommended. Figure 2 shows a typical expert system, while Figure 3 illustrates the AI tools. These tools are gaining momentum across every industry. Analytics can be considered a core AI capability.

GENERATIVE AI

Artificial Intelligence (AI) is increasingly a part of our world and it is rapidly changing our lives. Generative AI (GenAI) is a subset of artificial intelligence that uses generative models to produce

text, images, videos, or other forms of data. Generative AI (GenAI) is a term for any type of AI system capable of using generative models to create new forms of humanlike creative content, like text, images, music, audio, video and more. GenAI models include various algorithms able to learn the various patterns and structures of input training data before generating novel outputs with similar characteristics. It is essentially a narrow type and application of the broader artificial intelligence umbrella of technologies. It describes algorithms (such as ChatGPT) that can be used to create new content, including audio, code, images, text, simulations, and videos. It is specifically designed and trained to generate new content. The versatility and potential of GenAI to transform various aspects of business operations make it an attractive investment for companies across industries. GenAI uses neural networks, machine learning, deep learning models, complex algorithms, and large and varied training datasets to produce original content based on user input and how to reason in ways akin to a human brain. The technology is built on AI tools shown in Figure 4 [6]. It uses neural networks to identify the patterns and structures within existing data to generate new and original content.

Generative AI can be thought of as a machine-learning model that is trained to create new data, rather than making a prediction about a specific dataset. Since its inception, the field of machine learning used both discriminative models and generative models, to model and predict data. A generative AI system is constructed by applying unsupervised machine learning or self-supervised machine learning to a data set. The most common way to train a generative AI model is to use supervised learning. Generative AI can also be trained on the motions of a robotic system to generate new trajectories for motion planning or navigation. Generative AI models are used to power chatbot products such as ChatGPT [7].

Generative AI is transforming nearly all aspects of the pharmaceutical industry, revamping the way companies operate and potentially unlocking billions of dollars in value. The pharmaceutical-operations value chain encompasses sourcing, manufacturing, quality, and the supply chain—and gen AI is expected to improve them all

PHARMACEUTICS

Numerous industries are striving to enhance their progress to meet the demands and expectations of their customers, utilizing various methodologies. The pharmaceutical industry is a critical field that plays a vital role in saving lives. In the pharmaceutical

industry, innovation is typically predicated on extensive research and development across various domains, including but not limited to manufacturing technology, packaging considerations, and customer-oriented marketing strategies [8].

We expect the future of pharma and healthcare to be personalized and digital, with increasingly blurred boundaries between prevention and treatment. Artificial intelligence (AI) is accelerating this convergence of pharma, broader healthcare, technology, and consumer products and generates great benefits for each sector. Pharma companies that industrialize AI use cases across their organizations have the potential to double their operating profit. Figure 5 shows AI in pharmaceutical industry [9].

ARTIFICIAL INTELLIGENCE IN PHARMACEUTICS

AI can significantly impact several aspects of pharmaceutical processes, including accelerating drug discovery, optimizing clinical trials, and personalizing patient care. The application of artificial intelligence in pharma covers a wide range of processes, such as drug discovery, clinical trials, precision medicine, personalized medicine, and supply chain optimization. Some applications of AI in pharma are shown in Figure 6 [10]. The applications include the following [11,12]:

➤ *Drug Discovery:* One area where AI has the most significant impact is drug discovery and development. AI has revolutionized drug research and discovery in numerous ways. Traditionally, drug discovery is a long, complex process involving extensive research and trial and error. Discovering new drugs was a time-consuming and costly process, often taking several years and a significant financial investment. AI has revolutionized this process by speeding up the identification of potential drug candidates. AI achieves this by analyzing large datasets, including genetic information and chemical compounds, faster and more efficiently. Machine learning algorithms can identify potential drug candidates and predict the probability that they are effective in certain conditions. AI also plays a crucial role in predicting drug efficacy and toxicity. Supervised learning algorithms can be used to predict the activity or properties of new drug candidates. By training on a dataset of known compounds and their associated activities, the model can learn patterns and relationships between molecular features and desired outcomes. Figure 7 depicts the projected global AI in the drug discovery market from 2023 to 2032 [11].

- *Precision Medicine:* AI is being utilized to advance precision medicine approaches. By analyzing patient data, including genomics, proteomics, and clinical records, AI algorithms can identify patient subgroups, predict treatment responses, and assist in personalized treatment decision-making. AI-enabled precise medicine could categorize patients, predict therapy responses, and customize medicines by analyzing genomes, proteomes, and clinical records.
- *Personalized Medicine:* Traditional treatment methods often take a generalized view of patient care, which may be ineffective for some patients. Personalized treatment plans can be predicted using a patient's unique genetic makeup, lifestyle factors, and medical history. Personalized medicine approaches can be facilitated through AI algorithms that analyze real-world patient data, leading to more effective treatment outcomes and improved patient adherence. This approach ensures that treatments are more effective and less likely to cause adverse reactions. In personalized medicine, AI analyzes a patient's genetic makeup, medical history, and lifestyle to tailor treatments that best suit individual needs. Advanced AI algorithms can analyze complex genetic data to identify mutations or biomarkers associated with specific diseases. Figure 8 shows personalized care [13].
- *Supply Chain:* Supply chain is an area where AI can greatly impact pharma companies. Effective supply chain management is important to ensure that medications are available properly. AI is applied to optimize pharmaceutical supply chains, ensuring efficient manufacturing, inventory management, and distribution. The implementation of AI is poised to bring about a significant transformation in the way the pharmaceutical industry handles supply chain operations. AI models can analyze historical data, market trends, and other variables, forecast and predict demand, and optimize inventory management. This helps reduce the risk of drug shortages and overstocking. Supply chain optimization with AI integration enables forecasting demand more accurately, managing inventories efficiently, and optimizing production schedules. They also enhance quality control processes, contributing to more streamlined and cost-effective operations.
- *Pharmaceutical Manufacturing:* Medications need to meet safety and efficacy standards to help patients' health. By continually monitoring all manufacturing processes, AI plays a crucial role

in quality assurance. In pharmaceutical manufacturing, supervised learning can be utilized for predictive maintenance and quality control. AI improves manufacturing processes by monitoring equipment performance and assuring product quality. Drug discovery and manufacturing will continue to be aided by AI and machine learning. Using artificial intelligence in pharmaceuticals and manufacturing will become more common over time as they become more accessible. Figure 9 shows a typical pharmaceutical manufacturing [14].

- *Disease Diagnosis:* Disease analysis becomes pivotal in designing a considerate treatment and safeguarding the wellness of patients. The inaccuracy generated by humans creates a hindrance for accurate diagnosis, as well as the misinterpretation of the generated information creating a dense and demanding task. With advancements in AI technology, there has been a renewed interest in rare disease treatments. AI can have varied applications by bringing about proper assurance in accuracy and efficiency. Diagnosis refers to the state where, upon certain pre-existing problems, one's condition is designated. It is always advised to maintain every patient's health report forms, so as to collect the majority of reviews that are obtained via performing examinations and testing. Different computerized therapies are available based on computer programming techniques.
- *Clinical Trials:* Clinical trials are essential for bringing new drugs to market, but they are often time-consuming and expensive. AI is changing this by optimizing various stages of clinical trials, from patient recruitment to monitoring and data analysis. AI algorithms can identify the best candidates for a trial by analyzing electronic health records, demographic data, and even genetic information, leading to faster and more accurate recruitment. AI plays a crucial role in enhancing the efficiency of clinical trials. It helps in identifying and recruiting the right patients by analyzing electronic health records, genetic data, and patient demographics. AI also monitors patients in real-time during trials, detecting adverse effects and ensuring better trial outcomes. The importance of clinical trials is shown in Figure 10 [15].

BENEFITS

AI has proven to provide a massive impact on the pharmaceutical industry. AI in the pharmaceutical industry is revolutionizing the drug development process by enhancing the speed, efficiency, and

success rates of drug discovery. It has opened advancements in healthcare treatments for patients. It plays a crucial role in enhancing the effectiveness and efficiency of drug delivery systems within pharmaceutical companies. AI technologies can simplify some aspects of pharmaceutical operations. They can help automate routine tasks and provide insights into market trends and patient needs. Other benefits include the following [16]:

- *Predictive Maintenance:* Pharmaceutical plants are full of temperamental hardware. When equipment fails, it halts production, leading to shortages or dumping entire contaminated batches. AI anticipates problems before they occur. Predictive maintenance algorithms can forecast equipment failures, minimizing downtime, and maintaining smooth production operations. AI monitors equipment performance and ensures product quality through predictive maintenance.
- *Predictive Forecasting:* Disease prediction is a prime example of predictive forecasting. AI and ML technologies can also help predict and monitor epidemic outbreaks or seasonal illnesses. Using a predictive forecast, we can plan our supply chain to ensure the appropriate quantity and timing of inventory is available.
- *Automation:* To meet the growth, companies are adopting more efficient and automated processes to propel data-driven decision making. Traditionally, humans perform tasks that require artificial intelligence using manual algorithms. Verifying raw ingredients, components, and end products conform strictly to specifications is crucial. However, replicated manual inspections have limits. Instead, AI checks everything. Managing scale and throughput manually in big warehouses slows down order processing. Instead, AI automates. Companies submit lengthy technical dossiers covering manufacturing, preclinical and clinical data, etc., when proposing new therapies. But manual agency reviews delay launch decisions. AI is far faster at crunching paperwork. Automated treatment planning is efficiently improving the plan quality, consistency, and error rate. Figure 11 shows automation in pharmaceutical industry [17].
- *Data Management:* Data management today is a highly labor-intensive process, requiring manual trial-by-trial configuration of electronic data-capture systems, as well as detailed review and reconciliation of incoming patient data. By combining traditional and generative AI capabilities, data management can be automated

across multiple steps. The effectiveness of gen AI depends on the quality of an organization's data, which must be continually enriched in order to share across internal functions.

- *Faster Drug Development:* One of the most significant ways AI is benefiting the pharmaceutical industry is through faster drug discovery and development. Traditionally, the process of bringing a new drug to market can take years, even decades, and costs billions of dollars. AI is drastically changing this by streamlining the process. AI-powered platforms can predict the behavior of new compounds, simulate chemical interactions, and identify potential side effects long before human testing begins.
- *Reducing Costs:* AI is helping pharmaceutical companies cut operational costs. The adoption of AI in the pharmaceutical industry contributes to significant cost reductions across multiple areas of operations. From automating routine tasks to optimizing resource management, AI allows companies to operate more efficiently. For example, AI can automate data entry, manage large datasets, and streamline administrative processes, reducing the need for manual labor and lowering the chance of human error.
- *Pharmacovigilance:* Pharmacovigilance, or drug safety monitoring, is a crucial area where AI is making a significant impact. AI systems can analyze vast amounts of real-time data from clinical trials, patient records, and even social media to detect adverse drug reactions. This allows pharmaceutical companies to respond faster to potential safety concerns.

CHALLENGES

As with any new and revolutionary technology, the potential benefits of AI in pharma industry come with significant challenges and considerations, including concerns about data privacy, the complexity of integrating AI systems into existing workflows, and the need for specialized skills. Challenges like data privacy, biases, regulatory issues, and ethical concerns about decision-making need addressing. Despite their benefits, AI-based models have some limitations, such as the need for large datasets, potential biases, and lack of interpretability. Integrating AI solutions with existing systems and workflows can be complex and requires modern infrastructure, which many pharmaceutical companies lack. The AI race is not only a sprint but also a marathon. Other challenges include the following [11]:

- *Privacy:* One of the main concerns faced when integrating AI into pharmaceuticals is assuring

data privacy and protection. Enrolling participants for testing new drugs is notoriously tricky. It was made worse by stricter privacy laws. Security and privacy are of paramount importance when using AI in pharmaceutical research due to the sensitivity of the data involved. Pharmaceutical companies deal with vast amounts of sensitive data, including patient records, clinical trial information, and proprietary research. With AI systems requiring access to massive datasets for training and analysis, ensuring the privacy and protection of this information becomes crucial.

- *Regulations:* Regulatory and compliance issues are significant concerns. Pharmaceutical companies must adhere to strict data protection regulations, such as GDPR in Europe and HIPAA in the US, to ensure that patient data is handled with the highest level of security. Regulatory agencies are tasked with the development of stringent protocols, guidelines, and standardized evaluation processes to effectively integrate AI into drug development.
- *Ethical Concern:* As with any use of AI, there are ethical considerations that must be taken into account when using these technologies in drug development. Integrating AI in pharmaceuticals carries one critical concern and one of the most criticized points: the ethical aspects of involving AI in decision-making. Establishing ethical guidelines and human oversight of mechanisms can help to use AI tools more responsibly.
- *Biases:* The efficacy and precision of AI models are contingent upon the quality of the data utilized for their training. In instances where the data exhibit bias or incompleteness, the resulting predictions may also be biased. The biases in machine learning mainly come from the data collection, which can sometimes not be gathered fairly due to human biases. Algorithms that influence drug development or patient treatment decisions should be transparent and free from biases.
- *Skilled Personnel:* Identifying skill gaps in the workplace is a crucial undertaking within the pharmaceutical industry. Successful implementation and management of AI systems require a skilled workforce. Acquiring a proficient workforce is a prerequisite in all sectors to leverage their expertise, proficiency, and aptitude in product innovation. Data scientists, AI specialists, and other professionals with AI and machine learning expertise are essential for developing, interpreting, and managing these technologies. Recruiting and retaining talent with

the proper skill set can be challenging, especially given the competitive market for tech professionals.

- **Cybersecurity:** Data safety and security represent crucial parameters that demand significant attention and cannot be overlooked. A new technology platform and solution are required for the implementation of effective cybersecurity inside the office and for remote workers. Special attention must also be paid to data security and breach techniques.
- **Lack of Transparency:** AI models use complex algorithms and are often referred to as “black boxes” because it is difficult to understand how the model arrives at its predictions. This lack of transparency can make it challenging to gain regulatory approval for AI-based drug development tools, as it can be challenging to demonstrate that the model is making accurate and reliable predictions. The lack of transparency can also lead to a lack of trust in the model’s predictions.
- **Abuse:** Over the past few years, the term AI has been abused by marketing teams worldwide. Across many different industries, the term has become a convenient shorthand for any consumer-facing technology which shows signs of automation, but not much intelligence. This nonchalant use of the term AI introduced certain confusion and effectively diminished the term’s impact.

CONCLUSION

The impact of AI in the pharmaceutical sector is particularly transformative. The continued investment in and exploration of AI in the pharmaceutical industry offer exciting prospects for enhancing drug development processes and patient care. The pharmaceutical artificial intelligence ecosystem is growing, including more and more AI-vendors, AI-driven biotech startups, and corporations that start building in-house capabilities and expand external partnerships with AI-labs and companies.

In today’s fast-evolving pharmaceutical industry, leveraging the power of AI is no longer optional or a luxury; it is a strategic necessity. Despite the limitations of AI tools, they hold significant potential and cannot be overlooked in the field of pharmaceutical development. AI might revolutionize the pharmaceutical industry in the future to accelerate drug discovery and drug development. More information on artificial intelligence in the pharmaceutical industry is available from the books in [18-24] and the following related journals:

- *Energy and AI*
- *The AI Journal*
- *Journal of Intelligence*
- *Journal of Personalized Medicine*
- *Pharmaceutics*

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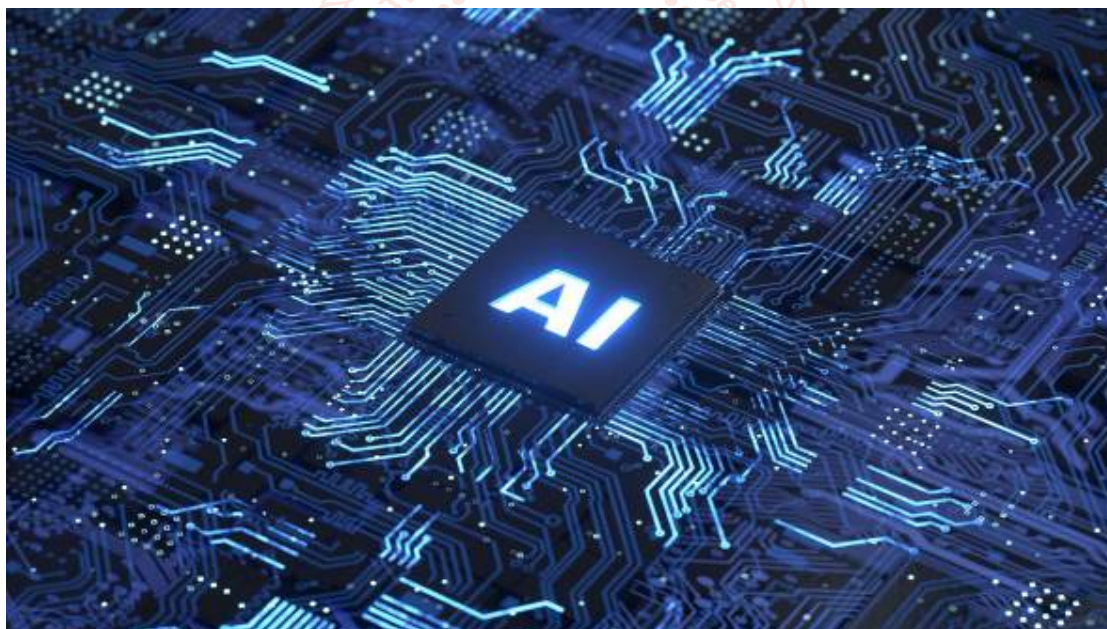


Figure 1 AI symbol [1].

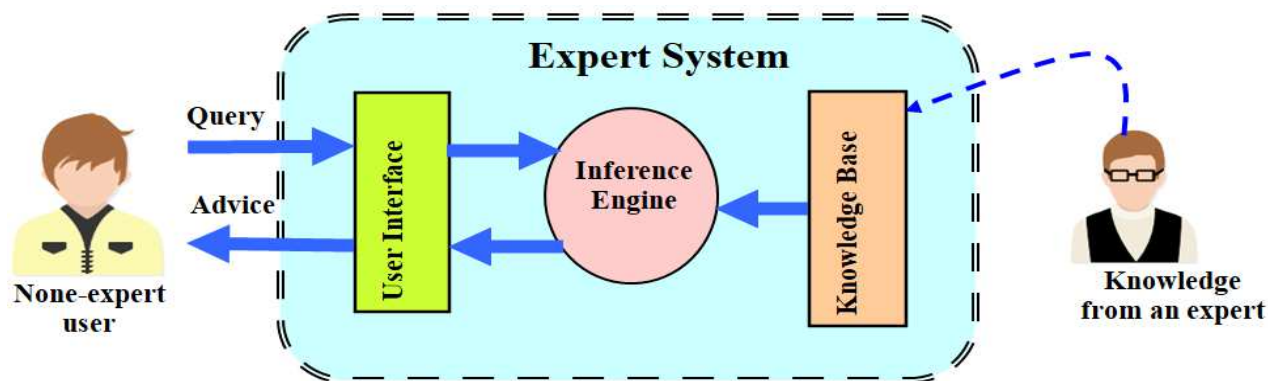


Figure 2 A typical expert system.

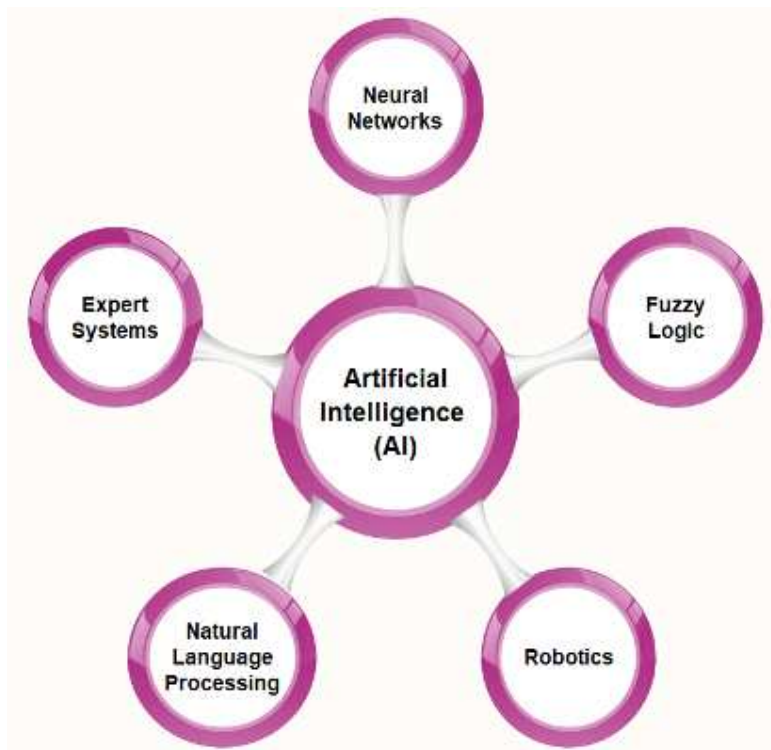


Figure 3 AI tools.

Defining Generative AI

To understand generative artificial intelligence (GenAI), we first need to understand how the technology builds from each of the AI subcategories listed below.

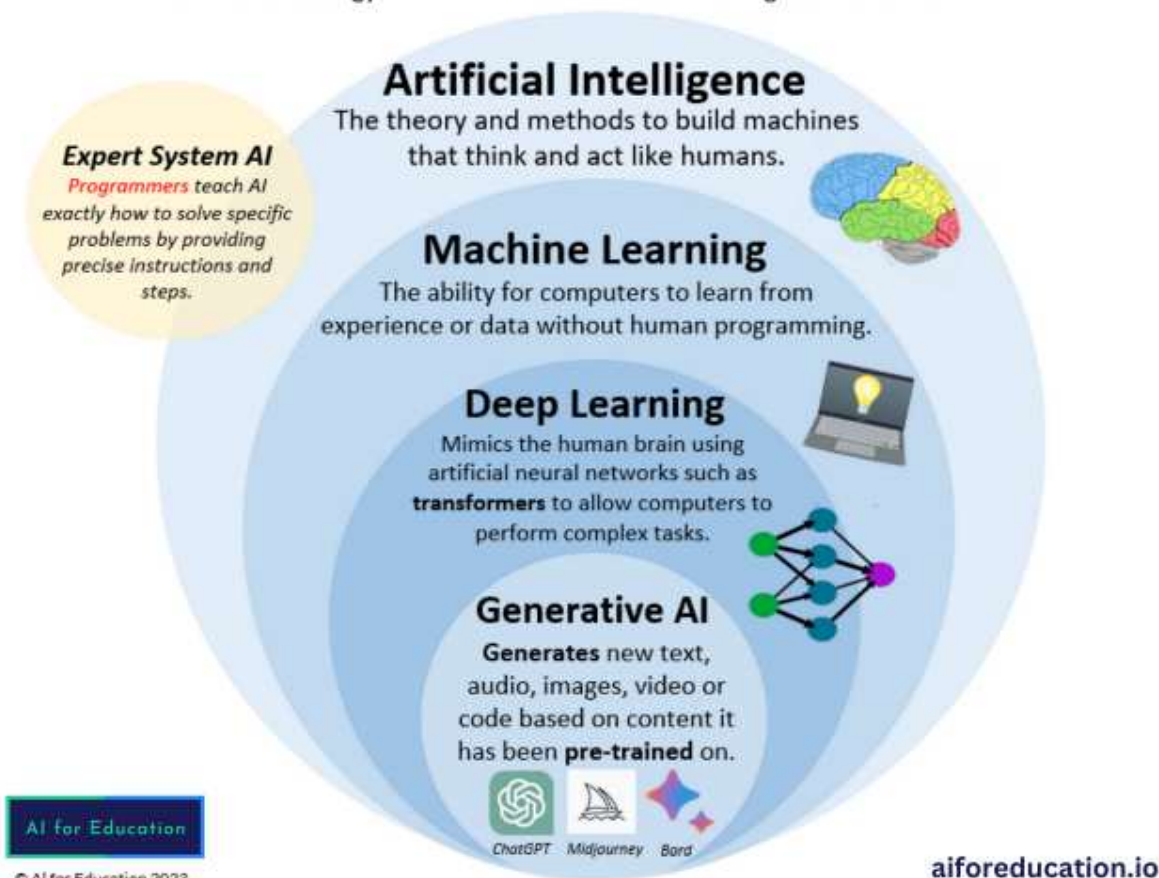


Figure 4 GenAI built on AI tools listed above [6].



Figure 5 AI in pharmaceutical industry [9].

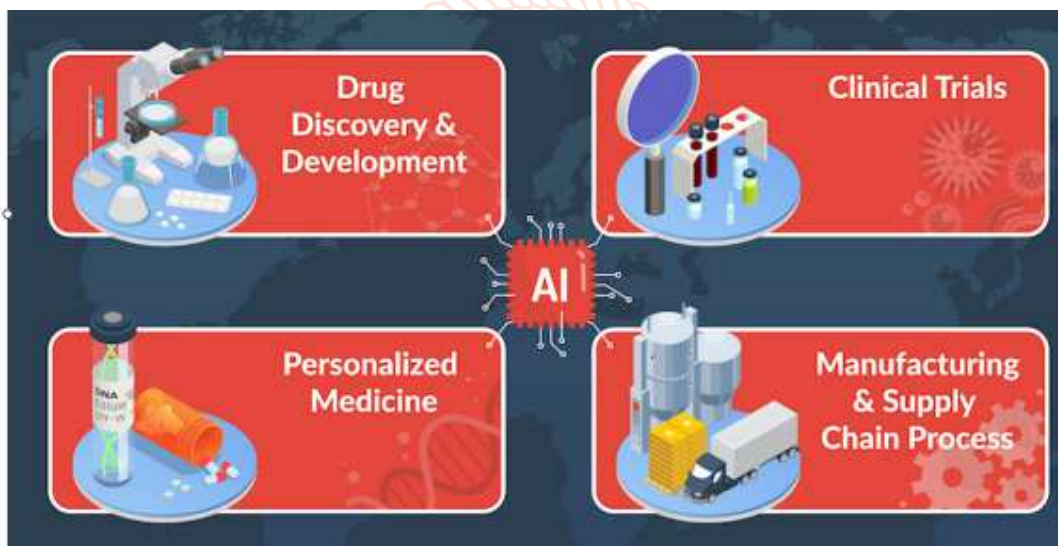


Figure 6 Some applications of AI in pharma [10].

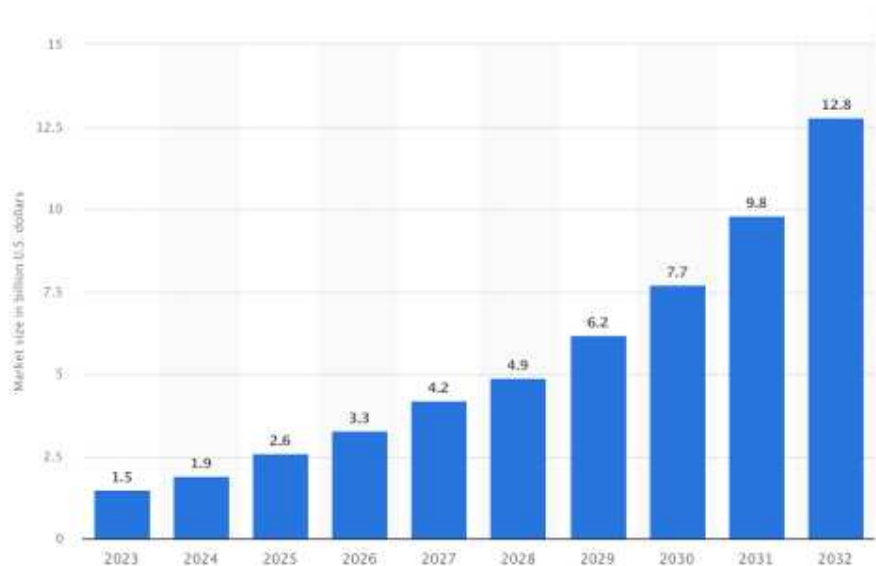


Figure 7 Projected global AI in the drug discovery market from 2023 to 2032 [11].

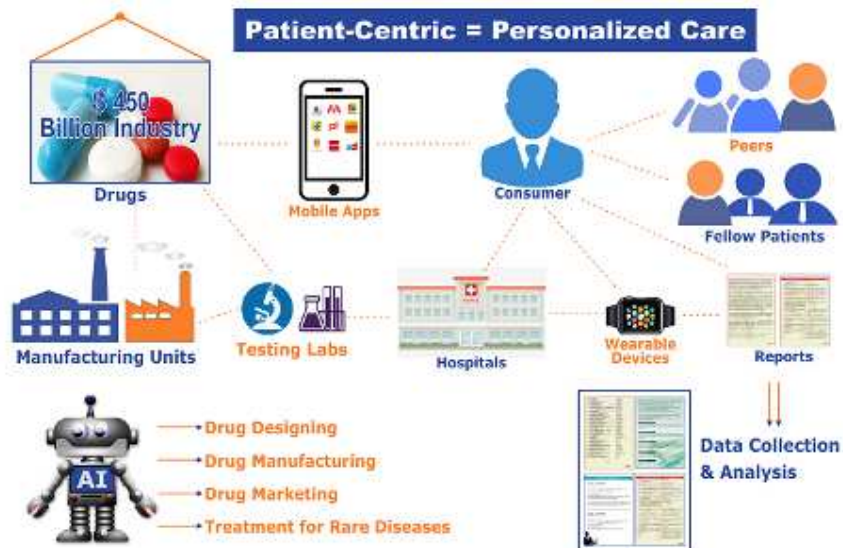


Figure 8 Personalized care [13].



Figure 9 A typical pharmaceutical manufacturing [14].



Figure 10 Importance of clinical trials [15].

