

Chapter 7

Artificial Intelligence and Machine Learning for Drug Safety



7.1 Background

Artificial intelligence (AI) and machine learning (ML) are two interrelated terms that are commonly used in the field of computer science. Both these terms refer to the ability of a machine or a computer system to learn from data and perform tasks that would typically require human intervention. AI is a broad field of study that focuses on creating intelligent machines that can perform tasks that usually require human intelligence, such as learning, problem-solving, decision-making, and natural language processing. AI systems are designed to work autonomously, without human intervention, and are expected to improve their performance over time through experience and learning. Machine learning, on the other hand, is a subset of AI that focuses on developing algorithms that can learn from data and improve their performance without being explicitly programmed. It involves training machines on large datasets to enable them to identify patterns and make predictions. The goal of ML is to develop algorithms that can generalize well to new data and make accurate predictions. The field of AI has been around for several decades, but it has gained significant momentum in recent years due to advancements in computing power, data storage, and algorithms. The availability of large amounts of data has also fueled the growth of AI, as machine learning algorithms require vast amounts of data to learn and improve their performance. AI and ML are now being used in a wide range of applications, from self-driving cars and speech recognition systems to medical diagnosis and financial fraud detection. AI and ML are also being used to automate routine tasks, improve efficiency, and reduce costs in various industries [1–6]. One of the most significant benefits of AI and ML is their ability to make predictions and identify patterns that may not be visible to the human eye. This has enabled AI systems to be used in various fields such as finance, healthcare, and transportation to make better decisions and improve outcomes. Another important benefit of AI and ML is their ability to work 24/7 without getting tired or making

errors due to fatigue or human error. This has enabled businesses to automate routine tasks and reduce the workload on human employees, allowing them to focus on more complex tasks that require human intelligence. However, there are also concerns around the ethical implications of AI and ML, particularly around issues of bias and transparency. As AI systems are only as good as the data they are trained on, there is a risk that they may reflect the biases and prejudices present in the data. This can lead to unfair or discriminatory outcomes, particularly in fields such as hiring and criminal justice. To address these concerns, researchers are developing new techniques for ensuring fairness and transparency in AI systems, such as explainable AI and algorithmic auditing. These techniques aim to make AI systems more transparent and accountable, enabling humans to understand how they work and make more informed decisions. In conclusion, AI and ML are two exciting fields that are changing the way we live and work. They offer numerous benefits, such as improved efficiency, accuracy, and decision-making, but also pose significant ethical challenges. As the field continues to evolve, it is important to address these concerns and ensure that AI and ML are developed in a responsible and ethical manner [1–6].

Artificial intelligence (AI) and machine learning (ML) have the potential to revolutionize the healthcare industry by improving patient care, safety, and drug safety. The ability of AI and ML to analyze vast amounts of data and identify patterns can help healthcare professionals make more accurate diagnoses, improve treatment outcomes, and reduce medical errors [1–6].

One of the main areas where AI and ML can improve patient care is in medical imaging. AI algorithms can analyze medical images such as X-rays, CT scans, and MRIs to detect abnormalities and identify patterns that may not be visible to the human eye. This can help radiologists make more accurate diagnoses and improve treatment outcomes for patients. Another area where AI and ML can improve patient care is in predictive analytics. By analyzing patient data such as medical history, genetic information, and lifestyle factors, AI systems can predict the likelihood of developing certain diseases and provide personalized treatment recommendations. This can help healthcare professionals intervene earlier, prevent disease progression, and improve patient outcomes. AI and ML can also play a significant role in patient safety by identifying and preventing medication errors. Medication errors are a leading cause of preventable harm in healthcare, and AI and ML algorithms can help reduce the risk of medication errors by analyzing patient data, detecting potential drug interactions, and providing real-time alerts to healthcare professionals. Drug safety is another area where AI and ML can have a significant impact. AI systems can analyze large datasets to identify potential safety issues with drugs, such as adverse drug reactions, and help pharmaceutical companies develop safer drugs. By predicting potential safety issues with drugs before they reach the market, AI and ML can help reduce the risk of harm to patients and improve the safety of drugs. However, there are also challenges to implementing AI and ML in healthcare. One of the main challenges is ensuring the accuracy and reliability of AI algorithms. As AI systems are only as good as the data they are trained on, there is a risk of bias and errors if the data is not representative or contains errors. It is essential to

validate the accuracy and reliability of AI algorithms before they are used in patient care. Another challenge is the ethical implications of using AI and ML in healthcare. There are concerns about the potential for AI algorithms to reinforce existing biases in healthcare, such as racial or gender biases. It is important to ensure that AI algorithms are designed to be fair and unbiased, and that they do not perpetuate discrimination or inequality. Finally, there are concerns around data privacy and security. As healthcare data is highly sensitive and confidential, it is essential to ensure that AI and ML systems are designed to protect patient privacy and maintain the security of patient data. In conclusion, AI and ML have the potential to transform patient care, safety, and drug safety in healthcare. By analyzing large amounts of data and identifying patterns, AI algorithms can help healthcare professionals make more accurate diagnoses, improve treatment outcomes, and reduce medical errors. However, there are challenges to implementing AI and ML in healthcare, such as ensuring the accuracy and reliability of AI algorithms, addressing ethical concerns, and ensuring data privacy and security. It is essential to address these challenges to ensure that AI and ML are used responsibly and ethically in healthcare [1–6].

7.2 History

The history of artificial intelligence (AI) and machine learning (ML) dates back to the mid-twentieth century, with the development of early computer technology and the birth of the field of AI research [1–6]:

In the 1950s, computer scientists began exploring the concept of AI and the possibility of developing machines that could think and learn like humans. This led to the development of early AI programs, such as the logic theorist and the general problem solver, which were designed to solve complex problems using logical reasoning and rule-based systems.

In the 1960s and 1970s, AI research continued to advance, with the development of new programming languages and algorithms for reasoning and knowledge representation. This led to the development of expert systems, which were designed to simulate the knowledge and expertise of human experts in various fields.

In the 1980s and 1990s, the focus of AI research shifted toward machine learning, which involves the use of algorithms and statistical models to enable machines to learn from data and make predictions. This led to the development of neural networks, which are systems of interconnected nodes that can learn and adapt based on data inputs.

The rise of the internet and the availability of vast amounts of data in the 2000s and 2010s led to a new era of AI and ML research, with the development of deep learning algorithms and the emergence of big data analytics. Deep learning involves the use of deep neural networks to learn and make predictions from large datasets, while big data analytics involves the use of AI and ML algorithms to analyze and make sense of vast amounts of data.

Today, AI and ML are being used in a wide range of applications, from self-driving cars and virtual assistants to healthcare and finance. The development of advanced AI and ML technologies, such as natural language processing, computer vision, and robotics, is continuing to push the boundaries of what is possible with machine intelligence.

However, as AI and ML become more advanced, there are also concerns about their impact on society and the economy. There are concerns about the potential for job displacement and the ethical implications of using AI and ML in decision-making processes. As a result, there is a growing emphasis on developing AI and ML systems that are transparent, accountable, and ethical, and that are designed to work collaboratively with humans to address complex problems and challenges.

The use of artificial intelligence (AI) and machine learning (ML) in drug safety is a relatively new application of these technologies. However, the development of AI and ML has already had a significant impact on drug safety research and regulation.

In the early days of drug safety research, pharmacovigilance relied primarily on spontaneous reporting systems, where healthcare professionals and patients could report adverse drug reactions to regulatory authorities. However, this approach had limitations, such as under-reporting and the inability to detect rare or delayed adverse events.

In the late 1990s and early 2000s, the use of electronic health records (EHRs) and other sources of real-world data (RWD) began to gain traction in drug safety research. These data sources provided researchers with access to vast amounts of data on drug use and adverse events, which could be analyzed to identify potential safety issues.

The development of AI and ML in the 2000s and 2010s has further revolutionized drug safety research by enabling researchers to analyze and make sense of vast amounts of data more efficiently and effectively. AI and ML algorithms can analyze large datasets and identify patterns and associations that may not be apparent through traditional analysis methods.

One application of AI and ML in drug safety is the detection of adverse drug reactions (ADRs). By analyzing EHRs and other sources of RWD, AI and ML algorithms can identify potential ADRs and predict which patients may be at higher risk for developing ADRs. This can help healthcare professionals and regulatory authorities identify and address potential safety issues earlier.

Another application of AI and ML in drug safety is the prediction of drug–drug interactions (DDIs). By analyzing data on drug use and patient characteristics, AI and ML algorithms can predict which drug combinations may lead to harmful DDIs. This can help healthcare professionals and regulatory authorities make more informed decisions about drug prescribing and regulation.

AI and ML are also being used to identify and prioritize potential safety issues with drugs during the drug development process. By analyzing preclinical and clinical trial data, AI and ML algorithms can identify potential safety issues and predict which patients may be at higher risk for developing adverse events.

In conclusion, while the use of AI and ML in drug safety is a relatively new field, it has already had a significant impact on drug safety research and regulation. By enabling researchers to analyze and make sense of vast amounts of data more efficiently and effectively, AI and ML algorithms can help healthcare professionals and regulatory authorities identify and address potential safety issues earlier. As the development of AI and ML continues, it is likely that these technologies will continue to play an increasingly important role in drug safety research and regulation [1–6].

7.3 Rationality of Artificial Intelligence and Machine Learning for Drug Safety

The use of artificial intelligence (AI) and machine learning (ML) in drug safety is based on the rationality that these technologies can help identify potential safety issues earlier and make more informed decisions about drug development, prescribing, and regulation [1–6]. One key advantage of AI and ML in drug safety is their ability to analyze vast amounts of data from multiple sources, including electronic health records (EHRs), clinical trials, and other real-world data (RWD). By analyzing this data, AI and ML algorithms can identify patterns and associations that may not be apparent through traditional analysis methods and can identify potential safety issues earlier. For example, AI and ML algorithms can be used to identify potential adverse drug reactions (ADRs) by analyzing data on drug use and patient characteristics. This can help healthcare professionals and regulatory authorities identify and address potential safety issues earlier, potentially reducing the risk of harm to patients. Another advantage of AI and ML in drug safety is their ability to predict drug–drug interactions (DDIs). By analyzing data on drug use and patient characteristics, AI and ML algorithms can predict which drug combinations may lead to harmful DDIs. This can help healthcare professionals and regulatory authorities make more informed decisions about drug prescribing and regulation, potentially reducing the risk of harm to patients. Furthermore, AI and ML can help optimize drug development by identifying potential safety issues earlier in the development process. By analyzing preclinical and clinical trial data, AI and ML algorithms can identify potential safety issues and predict which patients may be at higher risk for developing adverse events. This can help drug developers make more informed decisions about which drugs to pursue, potentially reducing the risk of harm to patients and saving time and resources in the drug development process. However, it is important to note that AI and ML algorithms are only as good as the data they are trained on. If the data is biased or incomplete, the algorithms may produce inaccurate or unreliable results. Therefore, it is important to ensure that the data used to train AI and ML algorithms is representative and of high quality. In conclusion, the rationality of using AI and ML in drug safety is based on their ability to analyze vast amounts of data and identify potential safety issues earlier. By

helping healthcare professionals and regulatory authorities make more informed decisions about drug development, prescribing, and regulation, AI and ML can potentially reduce the risk of harm to patients and improve overall drug safety. However, it is important to ensure that the data used to train AI and ML algorithms is representative and of high quality to ensure accurate and reliable results [1–6].

7.4 Importance of Artificial Intelligence and Machine Learning for Drug Safety

The importance of artificial intelligence (AI) and machine learning (ML) in drug safety cannot be overstated. These technologies have the potential to revolutionize the way drug safety is monitored, evaluated, and regulated, leading to improved patient safety and more effective healthcare [1–6]. One of the key benefits of AI and ML in drug safety is their ability to analyze vast amounts of data quickly and accurately. By analyzing electronic health records (EHRs), clinical trials, and other sources of real-world data (RWD), AI and ML algorithms can identify potential safety issues earlier and predict which patients may be at higher risk for developing adverse events. This can lead to earlier detection of safety issues and improved patient outcomes. Another benefit of AI and ML in drug safety is their ability to predict drug–drug interactions (DDIs) and identify potential adverse drug reactions (ADRs). By analyzing data on drug use and patient characteristics, AI and ML algorithms can identify which patients may be at higher risk of experiencing harmful drug interactions or developing adverse reactions. This can help healthcare professionals and regulatory authorities make more informed decisions about drug prescribing and regulation, potentially reducing the risk of harm to patients.

Furthermore, AI and ML can help optimize drug development by identifying potential safety issues earlier in the development process. By analyzing preclinical and clinical trial data, AI and ML algorithms can identify potential safety issues and predict which patients may be at higher risk for developing adverse events. This can help drug developers make more informed decisions about which drugs to pursue, potentially reducing the risk of harm to patients and saving time and resources in the drug development process. In addition, AI and ML can help improve pharmacovigilance and post-marketing surveillance. By analyzing data from multiple sources, including social media and patient forums, AI and ML algorithms can help identify potential safety issues that may not be reported through traditional spontaneous reporting systems. This can lead to more comprehensive monitoring of drug safety, and earlier identification of safety issues. Overall, the importance of AI and ML in drug safety lies in their ability to help healthcare professionals and regulatory authorities make more informed decisions about drug development, prescribing, and regulation. By identifying potential safety issues earlier, predicting drug interactions and adverse reactions, and improving pharmacovigilance and post-marketing

surveillance, AI and ML have the potential to improve patient safety and outcomes, and reduce the risk of harm from drugs [1–6].

7.5 Applications of Artificial Intelligence and Machine Learning in Drug Safety

1. Signal detection: AI and ML can be used to detect signals of adverse drug reactions (ADRs) in large datasets. These algorithms can identify potential safety issues that might have been missed by traditional methods.
2. Pharmacovigilance: AI and ML can be used to monitor adverse events associated with drugs in real time. This can help identify safety issues early and enable quicker responses.
3. Drug–drug interactions: AI and ML can be used to predict potential drug–drug interactions (DDIs) based on patient-specific data. This can help healthcare providers avoid prescribing drugs that might interact negatively with other medications.
4. Predictive modeling: AI and ML can be used to build predictive models that can identify patients who are at higher risk of experiencing adverse drug reactions. This can help healthcare providers make more informed decisions about prescribing medications.
5. Clinical trial design: AI and ML can be used to design more efficient clinical trials that can identify safety issues earlier and reduce the number of patients needed to participate.
6. Adverse event classification: AI and ML can be used to classify adverse events into specific categories based on patient data, drug characteristics, and other factors. This can help healthcare providers and regulators better understand the nature of adverse events and how to prevent them.
7. Drug discovery: AI and ML can be used to accelerate the drug discovery process by predicting the efficacy and safety of new drug candidates. This can help identify potential drug candidates with higher success rates and lower risk of adverse events.
8. Drug repurposing: AI and ML can be used to identify new uses for existing drugs by analyzing large datasets of patient and drug information. This can help identify potential applications for existing drugs that may have been overlooked.
9. Real-world evidence analysis: AI and ML can be used to analyze real-world evidence (e.g., electronic health records, claims data) to identify safety signals and monitor drug performance in a more comprehensive and efficient way.
10. Patient monitoring: AI and ML can be used to monitor patients for adverse events in real time and provide personalized recommendations for treatment adjustments or interventions.
11. Drug efficacy prediction: AI and ML can be used to predict the efficacy of a drug based on patient data, drug characteristics, and other factors. This can help

healthcare providers make more informed decisions about which drugs to prescribe for a specific patient.

12. Precision medicine: AI and ML can be used to analyze patient data and identify subgroups of patients who are likely to respond positively or negatively to a specific drug. This can help tailor treatments to individual patients and improve patient outcomes.
13. Adverse event reporting: AI and ML can be used to automate the reporting of adverse events to regulatory agencies. This can help streamline the reporting process and improve the accuracy of data reported.
14. Drug label management: AI and ML can be used to manage drug labels by identifying and analyzing adverse event reports, updating labels with new safety information, and providing recommendations for label changes.
15. Drug recall management: AI and ML can be used to manage drug recalls by identifying affected products, contacting patients and healthcare providers, and tracking the recall process.
16. Drug utilization review: AI and ML can be used to review drug utilization patterns and identify potential issues, such as overuse or underuse of certain medications. This can help improve the appropriate use of drugs and prevent adverse events.
17. Drug labeling analysis: AI and ML can be used to analyze drug labeling information to identify potential safety issues and improve the clarity of labeling information.
18. Drug shortage management: AI and ML can be used to manage drug shortages by analyzing supply chain data and identifying potential issues that may lead to shortages.
19. Patient adherence monitoring: AI and ML can be used to monitor patient adherence to medication regimens and provide personalized recommendations for improving adherence.
20. Drug cost optimization: AI and ML can be used to optimize drug costs by analyzing patient data and identifying the most cost-effective treatment options that also maintain safety.

7.6 Advantages of Artificial Intelligence and Machine Learning for Drug Safety

There are several advantages of using AI and machine learning for drug safety:

1. Improved accuracy: AI and machine learning algorithms can analyze large datasets with high accuracy, which can lead to more precise and reliable detection of adverse events and safety issues.
2. Faster processing time: AI and machine learning algorithms can process large amounts of data much faster than humans, which can lead to faster detection of safety issues and earlier intervention to prevent adverse events.

3. **Personalized treatment:** AI and machine learning algorithms can analyze patient-specific data to identify patients who may be at higher risk of adverse events or who may benefit from a particular drug. This can help healthcare providers tailor treatments to individual patients for better outcomes.
4. **More efficient drug development:** AI and machine learning algorithms can help identify potential safety issues earlier in the drug development process, which can help reduce the time and costs associated with developing new drugs.
5. **Better regulatory oversight:** AI and machine learning algorithms can help regulatory agencies monitor drug safety more effectively by analyzing large datasets and identifying safety signals more efficiently.
6. **Enhanced patient safety:** Overall, the use of AI and machine learning in drug safety can help improve patient safety by enabling earlier detection of safety issues, more accurate and precise identification of adverse events, and more personalized treatment.

In summary, the advantages of AI and machine learning for drug safety include improved accuracy, faster processing time, personalized treatment, more efficient drug development, better regulatory oversight, and enhanced patient safety.

7.7 Disadvantages of Artificial Intelligence and Machine Learning for Drug Safety

While there are many potential advantages of using AI and machine learning for drug safety, there are also some potential disadvantages and challenges, including:

1. **Bias:** AI and machine learning algorithms can be biased based on the data they are trained on, which can lead to inaccurate or unfair predictions. For example, if a dataset used to train an algorithm is not representative of the population as a whole, the algorithm may produce biased results.
2. **Lack of transparency:** Some AI and machine learning algorithms can be complex and difficult to interpret, which can make it challenging to understand how they arrive at their conclusions or identify errors or biases.
3. **Data quality:** The accuracy and reliability of AI and machine learning algorithms depend on the quality of the data used to train them. Poor quality data can lead to inaccurate predictions and unreliable results.
4. **Data privacy and security:** AI and machine learning algorithms often require large amounts of sensitive patient data to be effective, which raises concerns about privacy and security. This is particularly important in healthcare, where patient data must be kept confidential and secure.
5. **Regulatory challenges:** The use of AI and machine learning in healthcare is subject to regulatory oversight, and there may be challenges in obtaining regulatory approval for new AI-based tools and technologies.

6. **Implementation and adoption:** The adoption and integration of new AI-based tools and technologies into existing healthcare systems and workflows can be challenging and may require significant investment and resources.

Overall, the use of AI and machine learning in drug safety has the potential to revolutionize healthcare, but it is important to be aware of these potential disadvantages and challenges to ensure that these technologies are used effectively and ethically.

7.8 Tips for the Best Practice of Artificial Intelligence and Machine Learning for Drug Safety

Here are some tips for best practices when using AI and machine learning for drug safety:

1. **Ensure data quality:** The accuracy and reliability of AI and machine learning algorithms depend on the quality of the data used to train them. It is important to use high-quality, representative data to ensure the accuracy and fairness of predictions.
2. **Address bias:** Addressing bias in AI and machine learning algorithms is critical to ensuring fair and accurate predictions. This can be done by using diverse datasets, testing algorithms for bias, and implementing algorithms that can be easily audited and explained.
3. **Ensure transparency:** Ensuring the transparency of AI and machine learning algorithms is critical to building trust and ensuring that predictions can be verified and audited. This can be done by using explainable AI algorithms and making the decision-making process clear and interpretable.
4. **Maintain data privacy and security:** It is important to maintain data privacy and security when using AI and machine learning in healthcare. This can be done by implementing strict data access controls, using data encryption, and ensuring that all data handling practices are compliant with relevant regulations.
5. **Engage with regulators:** It is important to engage with regulatory bodies when developing and implementing AI and machine learning-based tools for drug safety. This can help ensure that these tools are compliant with relevant regulations and guidelines.
6. **Involve healthcare providers:** Involving healthcare providers in the development and implementation of AI and machine learning-based tools can help ensure that these tools are effective and relevant to clinical practice.
7. **Evaluate effectiveness:** It is important to continuously evaluate the effectiveness of AI and machine learning-based tools for drug safety. This can be done through rigorous testing and evaluation, as well as ongoing monitoring of real-world use.

8. Collaborate with experts: Working with experts in drug safety, data science, and healthcare can help ensure that AI and machine learning-based tools are designed and implemented effectively.
9. Use a multidisciplinary team: Developing and implementing AI and machine learning-based tools requires expertise from multiple disciplines, including data science, medicine, and regulatory affairs. Using a multidisciplinary team can help ensure that all aspects of the project are considered and addressed.
10. Use appropriate evaluation metrics: Selecting appropriate evaluation metrics is critical to ensuring that AI and machine learning-based tools are effective and accurate. It is important to select metrics that are relevant to the specific problem being addressed and to continuously evaluate and improve the metrics as needed.
11. Use explainable AI: Using explainable AI algorithms can help ensure that predictions are interpretable and can be verified and audited. This can help build trust in the predictions and ensure that they are used effectively.
12. Consider ethical implications: It is important to consider the ethical implications of using AI and machine learning for drug safety. This includes ensuring that patient privacy and security are maintained, addressing potential biases, and ensuring that the predictions are used ethically and responsibly.
13. Foster a culture of continuous improvement: Continuous improvement is critical to ensuring that AI and machine learning-based tools are effective and accurate. This includes ongoing evaluation and monitoring, as well as a willingness to adapt and improve the tools as new data and information becomes available.
14. Use reliable data sources: When using data to train AI and machine learning algorithms, it is important to use reliable and diverse data sources. This can help reduce the risk of bias and ensure that the algorithms are accurate and effective.
15. Consider the limitations of AI and machine learning: While AI and machine learning can be powerful tools for drug safety, they also have limitations. It is important to understand these limitations and use them appropriately.
16. Use validated algorithms: Validated algorithms have been tested and shown to be effective for their intended use. Using validated algorithms can help ensure that the predictions are accurate and reliable.
17. Ensure scalability: When developing AI and machine learning-based tools for drug safety, it is important to ensure that they can be scaled up for use in real-world settings. This includes considering factors such as data storage, computing power, and user interface design.
18. Evaluate the impact on healthcare delivery: The use of AI and machine learning for drug safety can have a significant impact on healthcare delivery. It is important to consider the impact on healthcare providers, patients, and healthcare systems when developing and implementing these tools.
19. Address ethical concerns: The use of AI and machine learning in healthcare raises ethical concerns, such as concerns around bias and privacy. It is important to address these concerns and ensure that the tools are used ethically and responsibly.

20. Foster collaboration and knowledge sharing: Collaboration and knowledge sharing are critical to advancing the field of AI and machine learning in drug safety. It is important to foster a culture of collaboration and sharing best practices, tools, and data.

By following the best practices, it is possible to develop and implement AI and machine learning-based tools for drug safety that are accurate, fair, and effective, while also maintaining patient privacy and security and complying with relevant regulations and guidelines.

7.9 Conclusion

This chapter has discussed the use of AI and machine learning in drug safety. The use of AI and machine learning in drug safety holds great promise for improving patient safety, reducing adverse drug events, and advancing the field of pharmacovigilance. However, there are also potential limitations and ethical concerns that must be carefully considered and addressed. By following the best practices such as using reliable data sources, using validated algorithms, ensuring scalability, and addressing ethical concerns, it is possible to develop and implement AI and machine learning-based tools for drug safety that are effective, accurate, and ethical. With continued collaboration, knowledge sharing, and a commitment to ongoing improvement, AI and machine learning can play an important role in advancing drug safety and improving patient outcomes.

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