An artificial intelligence toolkit for pharmacy

An introduction and resource guide for pharmacists

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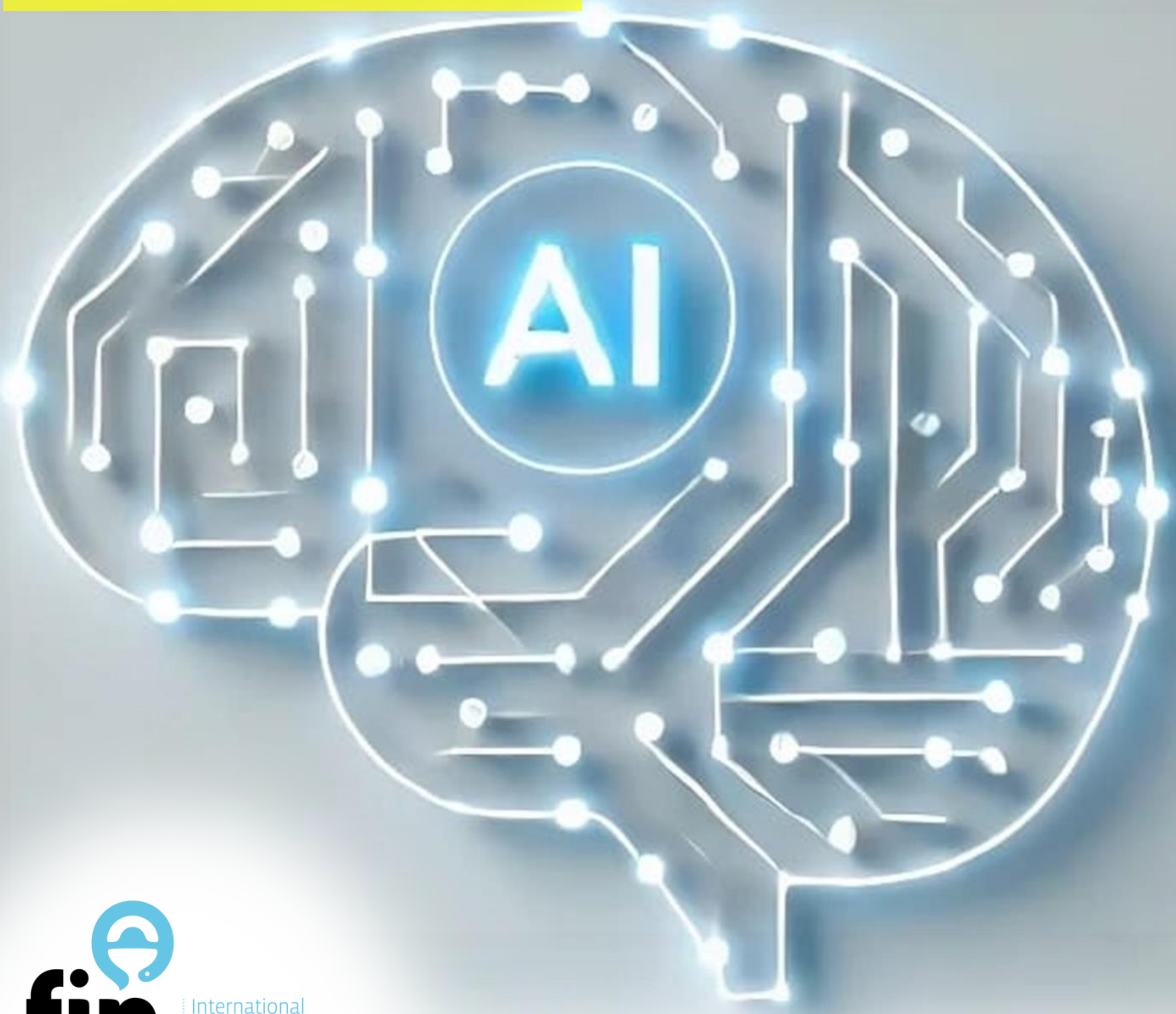

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Contents

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1 Executive summary

The "Artificial intelligence toolkit for pharmacy" is a resource designed to assist pharmacists in integrating AI technologies into their practice. Developed by the International Pharmaceutical Federation (FIP), this toolkit aims to bridge the gap between the rapidly evolving field of AI and the practical needs of pharmacists.

Purpose and importance of AI in pharmacy: AI is revolutionising healthcare by enabling the analysis of vast amounts of medical data, assisting in clinical decision-making, personalising patient treatments, predicting disease outbreaks, and optimising operational workflows. Closely aligned with FIP Development Goal 20 (Digital Health), AI helps build a digitally competent pharmacy workforce, improving clinical care, disease screening, health systems management, and pharmaceutical research. Nonetheless, pharmacists face critical challenges, including data privacy, cybersecurity threats, potential algorithm biases, and ethical concerns.

FIP's commitment and initiatives: FIP is committed to guiding and supporting pharmacists on the effective use of AI technologies. In 2023, FIP established an AI working group to identify the needs of its constituencies around AI and enhance inter-sectoral collaboration. This group aims to bridge knowledge gaps and promote the understanding and use of AI technologies among pharmacists and pharmaceutical scientists.

Toolkit objectives: This toolkit provides a high-level guide for pharmacists, offering an overview of AI implementation considerations, practical applications, and inspiring innovation. It aims to empower pharmacists to deliver safer, more effective, and personalised patient care without undermining their critical thinking or professional judgment.

AI and FIP Development Goals: The toolkit supports the delivery of the FIP's Development Goals, and aligns with the UN Sustainable Development Goals, focussing on education and continuous professional development (CPD), digital literacy, and innovation in pharmacy practice. Specific objectives include developing educational resources for digital competence, integrating AI training into professional education, and providing strategic guidance on digital health workforce policies.

Challenges and considerations: Effective integration of AI in pharmacy requires pharmacists to understand AI's capabilities and limitations, selecting appropriate tools tailored to specific challenges. Key considerations include ensuring data quality, regulatory compliance, ethical frameworks, and infrastructure investment. Additionally, addressing equitable access is vital to prevent exacerbating existing health disparities and inequities.

Conclusion: This toolkit aims to serve as a comprehensive resource, enabling pharmacists to navigate the complexities of AI, capitalise on its potential, and clearly understand its limitations. By fostering innovation, collaboration, and a proactive approach, FIP seeks to enhance AI's role in pharmacy practice, ultimately driving improvements in patient care and global health outcomes.

2 Preface

2.1 Purpose of the toolkit

Artificial intelligence (AI) is a branch of computer science dedicated to creating systems capable of performing tasks that typically require human intelligence, such as learning, reasoning, problem-solving, and pattern recognition. AI applications are increasingly utilized to analyse large volumes of medical data, assist clinical decision-making, personalize treatment plans, predict disease outbreaks, and optimize operational workflows in healthcare settings.

Digital health is a priority for FIP, guiding pharmacists on how best to use digital advancements to support healthcare delivery, pharmacy practice, and pharmaceutical research. AI is an emerging area within digital health that has immense potential to improve efficiency in clinical care, disease screening and surveillance, clinical care, optimising health systems management and facilitating advanced pharmaceutical research and development. Furthermore, AI has the potential to promote equity in healthcare access globally, empowering patients to actively manage their healthcare needs. However, even with the plethora of AI digital enablers entering the pharmacy sector, AI presents its own challenges and poses risks in data privacy concerns, safety risks, encoded biases, and cybersecurity threats.

FIP acknowledges its responsibility to collaborate, guide, and educate pharmacists globally on effectively utilizing AI to achieve optimal health outcomes. FIP is committed to fostering an environment where pharmacists can confidently adopt these technologies. In 2023, with these goals in mind, FIP established an AI working group as a subgroup of the FIP Technology Advisory Group, tasked with mapping AI-related needs of FIP constituencies and providing practical resources and guidance.

This toolkit, developed by the AI Working Group, seeks to bridge the gap between the rapidly evolving field of AI and the practical, everyday needs of pharmacists. It serves as a high-level guide for pharmacists in navigating the complexities of AI applications by providing an overview of considerations for AI implementation. It aims to illustrate practical applications and inspire innovation among FIP constituencies, ensuring they are well-equipped to navigate the evolving AI landscape and leverage the benefits of AI, while understanding its limitations.

Ultimately, this toolkit aims to empower pharmacists and pharmacy teams to confidently integrate AI into their practice in a way that complements their expertise, enabling them to deliver safer, more effective, efficient, and personalized patient care while preserving pharmacists' critical thinking and professional judgment.

2.2 AI & the FIP Development Goals

Launched in September 2020, the FIP Development Goals seek to direct the transformation of the pharmacy profession globally to 2030 (visit https://developmentgoals.fip.org/). Aligning with the UN Sustainable Development Goals (SDGs), a wider global initiative, the FIP Development Goals specifically focus on enhancing pharmacy practice, education, and pharmaceutical sciences. The 'One FIP' Development Goals enable the identification of commonalities and inter-sectoral collaboration within a transformative framework for the pharmacy profession.

The FIP Development Goal on Digital Health (Development Goal 20) is structured around three elements: education and workforce, practice, and science.

Education and workforce: 'Enablers of digital transformation within the pharmacy workforce and effective processes to facilitate the development of a digitally literate pharmacy workforce.'

In the context of AI, this toolkit aims to support the following Development Goal mechanisms:

- Develop courses and training for a digitally literate workforce (FIP Development Goals 1 & 2).
- Embed digital health and literacy competencies within FIP advanced and specialist frameworks (FIP Development Goals 4 & 5).
- Provide multidisciplinary learning tools to enhance digital health literacy (FIP Development Goal 8).
- Promote the use and interpretation of AI in training and education of pharmacists and pharmaceutical scientists. Create opportunities for ongoing education and development to ensure current practice with technology advancements (FIP Development Goal 9).
- Provide guidance on incorporating AI into digital health workforce development policies, including employment (FIP Development Goal 13).

Practice: 'Systems and structures in place to develop and deliver quality digital health and pharmaceutical care services through the digital literacy and utilisation of technology and digital enablers, configuration of responsive digital services to widen access and equity'.

In the context of AI, this toolkit aims to support the following Development Goal mechanisms:

- Provide insight into digital health enablers and AI-driven technologies that support cutting-edge service delivery and clinical decision-making (FIP Development Goal 20).
- Discuss digital literacy and governance concerning ownership, ethics, privacy, operational implications and information quality. Provide guidance for policies to support and enhance health data management and accountability for patient outcomes (FIP Development Goal 20).
- Promote AI-driven digital health initiatives that enhance equitable access to pharmaceutical care (FIP Development Goal 20).

Science: 'Application of digital technology in healthcare delivery and development of innovative medical products.'

In the context of AI, this toolkit aims to support the following Development Goal mechanism:

- Facilitate AI integration as a data science solution, enabling pharmacists to deliver enhanced patient care through innovative healthcare technologies (FIP Development Goal 20).

3 Background

The primary problem that informed the need for this AI toolkit is the integration of AI into daily pharmacy practice in industry, hospital and community settings, aiming to optimise pharmacists' work processes, enhance patient care, stimulate multidisciplinary interaction, and educate pharmacists on the efficient use of AI tools.

The integration of machine learning (ML) and artificial intelligence technologies is reshaping the roles and responsibilities of healthcare professionals, including pharmacists. AI has the potential to augment pharmacists' capabilities across a spectrum of tasks such as medication management (in both a logistical and pharmaceutical context), patient counselling, drug interaction checks, personalised medicine, pharmaceutical research, and much more.

Recent advancements in generative AI have further accelerated AI adoption, prompting the need for thoughtful and responsible deployment. While generative AI holds significant promise for pharmaceutical care; it also presents substantial limitations and challenges that must be addressed, to ensure effective and ethical integration.

A key significant concern is the quality and integrity of data used and produced by AI systems. Since AI outputs are only as reliable as the data they learn from, inaccuracies, biases, or inconsistencies in training datasets can lead to incorrect conclusions or predictions. This is particularly critical in pharmaceutical care where patient safety and efficacy of medications are concerned.

Another critical issue is ‘’AI hallucination’’, where generative AI systems produce incorrect, nonsensical, or fabricated outputs. This poses significant challenges in critical applications such as pharmaceutical care.[1] For instance, AI might produce plausible sounding, yet false medical advice or treatment recommendations, stemming from limitations in training data, pattern recognition errors, or inference mistakes. Addressing these hallucinations involves improving training data quality, implementing verification steps, and ensuring human oversight to maintain accuracy and reliability. As pharmaceutical care providers increasingly integrate AI tools, understanding and mitigating AI hallucinations is crucial to ensure safe and effective patient care.

In addition to technical safeguards and human oversight, regulatory considerations play a central role in the successful integration of AI. Pharmaceutical care is highly regulated, and AI applications must navigate complex regulatory requirements concerning drug development, clinical trials, and patient privacy. Compliance with these regulations on both the local and international level is essential to ensure patient safety and trust in the new technologies being implemented.

Furthermore, the implementation of AI in pharmaceutical care requires substantial investment in terms of infrastructure, training, and management. Health care providers and organisations must be prepared to invest in robust IT systems and staff training to handle these advanced technologies effectively.

Ethical considerations also play a critical role. The use of AI must align with ethical standards concerning patient confidentiality and safety, consent, and the avoidance of bias in treatment recommendations. Ensuring that AI systems are transparent and their workings understandable to regulators and practitioners is crucial for their acceptance and trustworthiness.

Finally, while AI can enhance the personalisation and efficiency of care, there's a risk of deepening existing health disparities if not carefully managed. Ensuring equitable access to the benefits of AI technology in pharmaceutical care is essential to avoid exacerbating health inequalities.

This toolkit will dive further into these topics and provide a list of considerations to keep in mind when exploring ways to leverage AI tools for implementation.

3.1 The fundamentals of AI

AI models are divided into two broad classifications: predictive and generative. Predictive models learn patterns in data and apply those patterns to new data it has never seen before, i.e., to predict potential outcomes. Predictive AI has already found several use cases within pharmacy and in healthcare in general, including tablet recognition, drug design, cancer diagnosis, and population health analysis. Some types of predictive models include:

1. Classification and labelling
2. Risk prediction and forecasting
3. Recommendation

Generative models learn patterns in data to generate new data. The output for generative AI can range from text to spreadsheets to images to video. ChatGPT is a popular example of generative AI. While generative AI has significant potential and is already being leveraged across multiple industries, it also poses significant limitations and risks that must be addressed to ensure it is used in an ethical and responsible manner.

3.1.1 Learning styles for AI

Both predictive and generative models are driven by machine learning. Machine learning models that use neural networks are considered 'deep learning'. By its very nature, deep learning models function as ''black boxes'', which means that the way the model comes to its conclusions is unexplainable by the AI itself or its human user. This can pose conceptual hurdles for regulatory bodies.

The method of learning applied by a particular model or tool will influence its functionality and utility. Not all learning styles are appropriate for a given use. These learning methods are:

1. Supervised
2. Unsupervised
3. Reinforcement

Supervised learning involves training the model on pre-labelled data. Labelled data implies that the machine is provided with a description of the data it is presented with, for example an image of a cat labelled as "CAT". This forms a library of reference material the machine uses when predicting outcomes or generating new data based on unlabelled new data inputs. Supervised learning has been used in healthcare to develop models to predict the presence of a disease, create risk scores or forecast the prognosis of a disease.[2] A predictive AI engine utilising supervised learning has also been applied to drug discovery, resulting in a novel, broad spectrum antibiotic known as Halicin.[3]

A common challenge with supervised learning in healthcare is having enough labelled data. It takes time to create labelled datasets. It tends to be easier to label things like medical images (i.e., x-rays or MRIs). However, it is more difficult when labelling a medical event or outcome, such as an exacerbation of a chronic condition, which requires domain expertise and making judgement calls. Not everyone may interpret the data in the same way, which in turn impacts the ultimate output of the model. Privacy and security are also an issue in creating and sharing labelled datasets.

Unsupervised learning involves training a model on unlabelled data. Deep learning is then used for the machine to identify patterns, relationships or similarities in the data. Often these patterns are unidentifiable by humans reviewing the same data. An example would be conducting a cluster analysis that groups patients into different phenotype groups based on similarities in many variables or data points available for each patient. However, one must be careful if using this learning method to make a predictive model; unsupervised learning models can also be prone to nonsensical or biased outputs as they have not been trained on what an acceptable output would be.

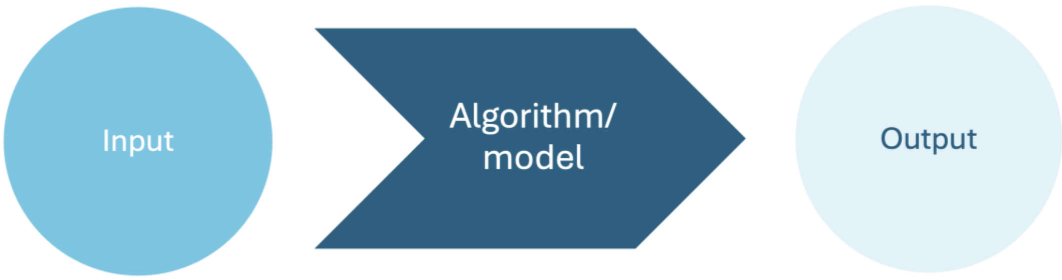
Supervised and unsupervised learning are very powerful in identifying patterns, including text, chemical structures, DNA sequences, images, and video and using them in making predictions. However, it is less powerful in dynamic environments, where the sequence of a series of events or decisions is important to the outcome. For such purposes, reinforcement learning may be more applicable.

Reinforcement learning "rewards" the model for making correct decisions. The model learns to predict the next action or set of actions that increase the likelihood of a delayed reward.[4] The reward process needs to be programmed into the model, so that after every decision the model makes, it receives either a positive reward or a negative reward. This lets the model know if decisions are taken in the right direction. Two significant experiments were conducted using an AI model known as AlphaZero to play the games of Go and chess.[5] Using reinforcement learning, the model learned what series of game moves were most likely to result in the delayed reward of winning the game. The model developed novel strategies that had never occurred to humans in the history of the game of chess. At the time of writing, no human has beaten AlphaZero. The concept of reinforcement learning can be applied to the medical field where multiple decisions are made for a future distant reward, such as survival to hospital discharge or making medication adjustments to achieve a target A1C.

3.1.2 Types of AI tools

AI is a broad technology category; however, all AI tools or applications can be broken down into three major components: the input, the algorithm/model, and the output as outlined in Figure 1.

Figure 1: AI model components



Understanding each of these components is important to understanding how the technology can be leveraged in each situation. Table 1 outlines the different types of AI tools available based on the input data the model uses.

Table 1: Types of AI tools based on input

Model input	AI tool description
Vision	These are models that use images as their input data. This includes diagnostic tools for examining medical images such as chest X-rays or CT scans. An example includes a pill identification model able to identify unlabelled pills and tablets with 85% accuracy.[6]
Text	Models that use text as the input means that they can interact with natural speech or text. This can be in the form of a chatbot (similar to tools like ChatGPT), or it could be a document classification model.
Voice	These types of models take raw voice audio as the input. Examples include dictation programmes, smart speakers or devices, or smart assistants on mobile devices. There are also AI-enabled clinical applications that use voice markers to diagnose or to measure a patient's stress levels.
Tabular	Tabular data includes any type of data that could be organised or stored in a spreadsheet. Models that use this type of data include risk predictor algorithms.
Multi-modal	A multi-modal model indicates that the model can accept more than one type of input. For example, a chatbot may respond to text, but also to an uploaded image.

3.2 Assessing the performance of AI

Assessing the performance of machine learning models is crucial for validating the technical robustness and accuracy of these models but also for ensuring transparency, accountability, and building trust among users.

Performance metrics serve as the foundational tools that guide developers and stakeholders in understanding how well a model performs in various scenarios, identifying strengths and weaknesses, and making informed decisions about model improvements and applications.

The following section summarises common methodologies and tools used to evaluate AI models and ensure interpretability for transparency and understanding.

3.2.1 Why measure performance?

Measuring the performance of AI models is not merely a technical necessity but a foundational practice for establishing transparency, trust, and accountability. Transparency involves providing clear and accessible information about how models function and their performance, ensuring that users can understand and trust the AI's insights to support decision making. Accountability ensures that developers and organisations are responsible for their models' performance, the ethical implications, and the potential impact on patients. Model cards serve as an important tool to help achieve this.

3.2.2 How to be transparent, accountable, and build trust

Model cards serve as comprehensive and structured guides with essential details about a machine learning model.[7] They provide a standardised framework for information about the model’s characteristics, performance, limitations, and intended use cases, and allow a comparative analysis between different models. Google Research developed the Model Card Toolkit (MCT) to increase transparency in machine learning. The MCT helps developers create model cards, which provide essential information about a model's origins, intended use, and ethical considerations. By using the MCT, developers can easily document their models and ensure they are used responsibly.[8] Looking at a model card should help one determine if a model is appropriate for a specific task or use. A typical model card can include various components, as described in Table 2.

Table 2: Components of a model card

Component	Detail
Description	Brief description and unique identification of the model, including time of production and model version, if applicable.
Purpose, users, and context	Clear articulation of the model’s intended purpose, answering questions such as: for what purpose the model was developed; for which purpose the model is not suitable to be used; the potential users that can benefit; the context in which it should or should not be applied; and potential limitations of generalisation for different purposes, users and contexts.
How to use	Understandable guidelines written in simple language to ensure users can effectively deploy the model. If possible, flowcharts and schemes should be provided to ease the user's comprehension.
Performance metrics	Metrics vary according to model type and purpose (e.g., generation, prediction, classification, etc.). It is important that performance metrics are accompanied by an interpretation of what they mean within the context of use. Whenever possible, examples should be provided to facilitate the user’s understanding, particularly related to the uncertainty around the model’s results. When applicable, the model’s performance across different population subgroups should be listed to provide insight into potential biases that may exist.

Training data	Transparency of the training data is essential. This includes the source, quality, any preprocessing steps applied and any specific groups or subgroups that may be over or underrepresented. Understanding the dataset helps users gauge the model's applicability and potential biases.
Ethics	Ethical considerations are paramount in AI. This includes addressing bias, fairness, and privacy. Ensuring that models do not perpetuate biases, and that user data is handled responsibly is critical for maintaining ethical standards.
Uncertainty	Every model has limitations and uncertainties. Documenting these helps manage user expectations and informs them of potential risks and areas where the model might underperform.
Author, code, license, and ownership	Clearly stating the authorship, availability of the code, licensing terms, and ownership rights enhances transparency and encourages community contributions and improvements.
Contacts and resources	Providing contact information and additional resources supports users in understanding and effectively using the model. It also opens channels for feedback and improvement.

To better understand the specific metrics used to evaluate how well a model performs, Table 3 provides an overview of the metrics which might be seen on a model card or provided by the model developers.

Table 3: Model metrics, their use, and examples

Model type	Metrics for measuring performance	Description	Example
PREDICTIVE AI			
Classification	Accuracy Precision Recall F1 Score Sensitivity Specificity ROC-AUC Confusion Matrix *For definitions of these metrics, see next section.*	Evaluates models that label or categorise inputs into classes. Metrics assess the correctness of predictions.	**Example**: A model classifies patient records into categories like prescription refill requests or appointment scheduling enquiries. **Applying performance metrics:** High accuracy and precision indicate correct categorisation, minimising errors. High recall ensures important categories are not missed. A high Area Under the Receiver Operating Characteristic Curve (ROC-AUC) combined with Confusion Matrix (see Table 4) suggests effective distinction between categories.
Regression	Mean Squared Error (MSE) R^2 Mean Absolute Error (MAE) Root Mean Squared Error (RMSE)	Evaluates models predicting continuous values. Metrics measure the deviation between predicted and actual values.	**Example**: A dose prediction model for personalised medicine. **Applying performance metrics:** Low MSE and RMSE indicate close alignment between predicted and actual dosages, reducing underdosing or overdosing risks. A high R^2 suggests the model effectively

			captures the relationship between patient characteristics and required dosage.
Time series	Mean Absolute Percentage Error (MAPE) Root Mean Squared Error (RMSE)	Evaluates accuracy and error in future value predictions based on past data.	**Example**: A forecasting model predicts future medication demand. **Applying performance metrics**: Low MAPE and RMSE indicate accurate forecasts, helping maintain optimal inventory levels.
GENERATIVE AI			
Generation	**Large Language Models (LLM):** Perplexity (PPL) [9] Bilingual Evaluation Understudy (BLEU)[10, 11] General Language Understanding Evaluation (GLUE)[12] Recall-Oriented Understudy for Gisting Evaluation (ROUGE)[13]	Measures similarity between generated and reference content.	**Example:** A model generates medication counselling scripts tailored to patients. **Applying performance metrics:** A high BLEU score indicates that the scripts closely match high-quality references prepared by clinical pharmacists, ensuring patients receive accurate and comprehensible advice.

3.3 Performance metrics for classification models

It is beyond the scope of this toolkit to provide a comprehensive view of all performance metrics, so this section goes into greater detail around some of the most common model performance metrics one might come across. Precision, recall, F1 score, specificity, and sensitivity are frequently used metrics to assess a model's effectiveness for prediction through classification.[14] The ROC-AUC curve and Confusion Matrix are useful tools to understand a model's capacity to distinguish between different classes on prediction. The following content explains the theoretical fundamentals of these metrics.

- **Precision**, also known as positive predictive value, measures the accuracy of positive predictions made by the model. It is particularly useful in scenarios where the cost of false positives is high. Precision answers the question: "Of all the instances predicted as positive, how many are actually positive?"

  The formula for precision is given by:

  $$Precision = \frac{TP}{TP + FP}$$

  TP (True Positives) are the instances correctly predicted as positive.
  FP (False Positives) are the instances incorrectly predicted as positive.

- **Recall**, also known as sensitivity or true positive rate, measures the model's ability to identify all relevant instances. It is crucial in situations where missing a positive instance is costly. Recall answers the question: "Of all the actual positive instances, how many did the model correctly identify?"

  The formula for recall is:

  $$Sensitivity\ (Recall) = \frac{TP}{TP + FN}$$

  TP (True Positives) are the instances correctly predicted as positive.
  FN (False Negatives) are the instances incorrectly predicted as negative.

- **F1 Score** is the mean of precision and recall, providing a balance between the two metrics. It is particularly useful when there is an uneven class distribution (i.e., one of the classes is rare) or when both false positives and false negatives need to be minimised.

  The formula for the F1 score is:

  $$F1\ Score = 2\ x\ \frac{Precision\ x\ Recall}{Precision + Recall}$$

- **Specificity**, also known as true negative rate, measures the model's ability to identify negative instances correctly. It is important in situations where the cost of false negatives is high. Specificity answers the question: "Of all the actual negative instances, how many did the model correctly identify?"

  The formula for specificity is:

  $$Specificty\ = \frac{TN}{TN + FP}$$

- **ROC AUC Curve** is a graphical representation of a classifier's performance. The Receiver Operating Characteristic (ROC) curve plots the true positive rate (sensitivity) against the false positive rate (1-specificity) at various threshold settings. The Area Under the Curve (AUC) provides an aggregate measure of the model's performance across all thresholds. A model with an AUC of 1 is perfect, while an AUC of 0.5 suggests no discriminative ability.

- **Confusion Matrix** is a table used to describe the performance of a classification model on a set of test data for which the true values are known. It allows visualisation of the performance of an algorithm. The matrix is N x N, where N is the number of classes. It provides insights into the types of errors being made by the classifier.

The confusion matrix in Table 4 has the following structure:

Table 4: Confusion matrix

	Predicted positive	**Predicted negative**
Actual positive	True positive (TP)	False negative (FN)
Actual negative	False positive (FP)	True negative (TN)

Assessing the performance of AI models through structured and transparent methods is crucial for fostering trust and accountability. By prioritising transparency, ethical considerations, and involving end users in the assessment process, AI developers can create models that are not only technically sound but also trustworthy and aligned with user needs.

4 Ethical considerations

4.1 Creating AI that is trustworthy

Recent advancements in machine learning (ML) and artificial intelligence (AI) have transformed various industries, including healthcare. While these technologies offer tremendous potential benefits, they also pose ethical dilemmas that must be addressed to ensure responsible and equitable use. The "Ethics guidelines for trustworthy AI" by the High-Level Expert Group on Artificial Intelligence (HLEG on AI), commissioned by the EU in 2019, provides comprehensive guidelines for ensuring ethical and trustworthy development and deployment of AI.[15] According to the Guidelines, trustworthy AI should be:

1. **Lawful** – respecting all applicable laws and regulations;

2. **Ethical** – respecting ethical principles and values; and

3. **Robust** – from a technical perspective whilst also taking into account its social environment.

The guidelines outline seven key requirements that AI systems should meet to be considered trustworthy (see Table 5).

Table 5: Seven key requirements for trustworthy AI

Key Requirement	Details
1. Human agency and oversight	AI systems should support human autonomy and decision-making, with humans ultimately accountable for AI outcomes.
2. Technical robustness and safety	AI systems must be secure, reliable, and resilient throughout their lifecycle to avoid unintended harm
3. Privacy and data governance	AI systems should respect privacy, ensuring protection of personal data and compliance with data protection regulations.
4. Transparency	The processes and decisions made by AI systems should be explainable, understandable, and accessible to users.
5. Diversity, non-discrimination, and fairness	AI systems should be inclusive and fair, avoiding biases and discrimination based on various attributes.
6. Societal and environmental well-being	AI development and deployment should benefit society and the environment, promoting sustainability and societal well-being.
7. Accountability	Stakeholders involved in AI systems (developers, deployers, etc.) should be accountable for their decisions and actions related to AI.

4.2 The ethical considerations of applying AI in healthcare

The ethical implications of using ML and AI in healthcare are complex and multifaceted. While these technologies offer transformative potential—such as improving patient safety—they also introduce ethical challenges such as bias in patient care when influencing clinical decision-making.[16]

One example of a major ethical concern is "inconclusive evidence", which highlights that algorithms are probabilistic and never infallible.[17] For example, a smartwatch might incorrectly diagnose an irregular heartbeat due to inaccuracies in heart rate measurements. Such errors can arise when algorithms are calibrated to general population norms—such as specific skin tones—rather than individual patient characteristics. This demonstrates how biases in AI development can lead to disparities in patient care.

Additionally, responsible AI deployment in healthcare must address patient safety, privacy, transparency, fairness, informed consent, and workforce implications, particularly within pharmacy practice.[18] Ensuring ethical AI integration requires careful consideration of the four foundational principles[19] of medical ethics:

- Autonomy – a patient's right to self-determination;
- Beneficence – the responsibility to 'do good';
- Non-maleficence – the responsibility to 'do no harm'; and
- Justice – to treat all equally and equitably.

By proactively addressing these ethical challenges, we can maximise the benefits of AI in healthcare while upholding ethical standards and ensuring patient welfare.

The challenge of defining ethical AI: Despite widespread acknowledgment that AI should adhere to ethical principles, there is ongoing debate regarding the practical definition of "ethical AI." This includes uncertainties around specific ethical requirements, technical standards, and best practices for implementation. The World Health Organization (WHO) has outlined key ethical principles for AI in healthcare, including: protecting autonomy; promoting human well-being; ensuring transparency, explainability and intelligibility; fostering responsibility and accountability; ensuring inclusiveness and equity; and, promoting responsive development.[20] Similarly, a review of the global landscape of AI ethics guidelines identified five converging ethical principles: transparency, justice and fairness, non-maleficence, responsibility, and privacy.[21] Taking these ethical principles into account, the following section elaborates on key ethical issues that must be considered for the responsible implementation of AI in healthcare.

4.2.1 Ethical Issues

4.2.1.1 Privacy and security

- The use of ML and AI involves handling large volumes of sensitive patient data, raising concerns about privacy breaches and data security.
- Methods for anonymisation and encryption of data must be robust to protect patient confidentiality.
- Researchers and end-users need to consider the confidentiality and privacy risks associated with the data used.
- Privacy and security measures should address both training data fed into the machine and the outputs resulting from the machine learning findings.

4.2.1.2 Transparency

- Machine learning models can be complex and difficult to interpret. Researchers and AI developers must consider the transparency and explainability of their models.[22]
- ML and AI algorithms often operate as "black boxes," making it challenging to understand their decision-making processes.

- Ensuring that machine learning is transparent allows for better reproducibility and understanding of the underlying processes.

- Ensuring transparency in algorithmic outputs and establishing accountability for algorithmic errors or biases are critical ethical considerations.[22]

4.2.1.3 Accountability

- Throughout the machine learning process, accountability is paramount. Models should be used only for their intended purposes, and stakeholders must be aware of their responsibilities.

- Researchers, AI developers, and end-users such as clinicians, should maintain accountability to prevent unintended consequences or misuse of machine learning outcomes.

4.2.1.4 Bias and fairness

- ML models trained on biased datasets can perpetuate or amplify existing biases in healthcare, leading to inequitable treatment.

- Bias can also be introduced through the model architecture itself and decisions made during the training process.[23]

- Ethical ML practices require strategies to identify and mitigate bias in data and algorithms to ensure fairness and equity in healthcare delivery.

4.2.1.5 Informed consent

- Patients may not fully understand the implications of AI-driven diagnostics or treatment recommendations.[24]

- Ensuring informed consent for AI-enabled interventions involves educating patients about AI's role and limitations in healthcare decision-making.

4.2.1.6 Impact on healthcare professionals

- ML and AI technologies may alter the roles and responsibilities of healthcare professionals, potentially leading to workforce displacement or deskilling.

- Ethical guidelines should address the ethical implications of technology-driven changes in professional practices and job roles.

4.2.2 Mitigation strategy for the ethical deployment of AI in healthcare

To effectively address the ethical challenges associated with AI deployment within healthcare, stakeholders from both the healthcare and technology sectors must collaborate to develop comprehensive guidelines and regulations. Table 6 outlines key mitigation strategies and actions for the ethical integration of AI, focusing on enhancing ethical decision-making and actively engaging pharmacists and other stakeholders.

Table 6: Strategies for the ethical deployment of AI

Strategy	Actions
Establish clear ethical guidelines	• Develop and disseminate ethical guidelines governing the development and deployment of AI technologies in healthcare, addressing key issues such as bias, transparency, patient privacy, and environmental considerations.

Integrate ethics training into educational programmes		• Incorporate ethics training into educational curricula for healthcare professionals specialising in digital health, including AI.[24] • Provide ongoing professional development opportunities focused on the ethical use of AI in both clinical practice and science.
Implement robust auditing and validation mechanisms		• Develop mechanisms for regular auditing and validation of AI algorithms to detect and address biases and ensure fairness. • Engage third-party auditors to provide independent assessments of AI systems.
Engage patients and communities		• Actively involve patients and communities in discussions about the role and impact of AI on healthcare decision-making processes. • Ensure transparency with patients about how their data is used and obtain explicit consent.
Deploy an enhanced ethical decision-making framework	Comprehensive stakeholder engagement	• Involve a diverse range of stakeholders, including AI and ML developers, healthcare decision-makers, research ethics committees, regulators, and others committed to promoting equitable and responsible use of clinical ML technologies.
	Integration of ethical norms	• Align the ethical design of AI and ML tools with established norms within the healthcare environment, encompassing principles of biomedical ethics, clinical research ethics, and social justice.
	Holistic ethical guidance across the AI and ML lifecycle	• Emphasise ethical considerations at each stage of AI and ML integration in healthcare, reflecting on the implications of these principles for fostering fairness in ML applications.
Empower pharmacists as end users	Assessing model transparency	• Train pharmacists to interpret AI recommendations and understand the underlying decision-making processes.[25] • Ensure AI systems have comprehensive documentation detailing their design, training data, and decision rationale (see section on Assessing Model Performance).
	Identifying and mitigating bias	• Regularly monitor AI outputs for signs of bias and report any inconsistencies to relevant authorities or developers. • Utilise feedback mechanisms to report biases and collaborate with developers to improve model fairness.
	Ensuring fairness and equity	• Advocate for equitable AI use across all patient demographics, ensuring AI does not disproportionately impact vulnerable populations.[23] • Verify AI recommendations, particularly in complex cases, to ensure they enhance patient care quality.
	Ongoing education and training	• Engage in continuous professional development to stay updated on AI advancements and ethical considerations. • Reflect on the ethical implications of AI in everyday practice and integrate these considerations into patient care. • Create a culture of accountability among end-users, who have a responsibility to prevent unintentional harms caused by the models they use.

	Patient and community engagement	● Communicate openly with patients about the role of AI in their care, explaining the rationale behind AI-driven recommendations. ● Foster community dialogue addressing public concerns and enhancing trust in AI technologies.
	Proactive risk management	● Develop strategies to anticipate and address potential ethical dilemmas, such as AI errors, hallucinations or unintended consequences. ● Collaborate with other healthcare professionals to share best practices and improve AI deployment in pharmacy.

By implementing the mitigation strategies in Table 6, pharmacists can play a crucial role in ensuring the ethical and responsible use of AI in healthcare. Empowered with the right tools and knowledge, pharmacists can help mitigate risks and maximise the benefits of AI for patient care, contributing to a more transparent, fair, and patient-centred approach, fostering trust and accountability in AI applications.

5 ISO regulations and compliance

When integrating AI technology into pharmacy practice, it's essential for pharmacists to navigate several critical areas effectively to ensure compliance on important areas like patient data confidentiality, quality and algorithm reproducibility, and ICT security. AI systems used in pharmacy practice must adhere to specific healthcare and IT-related regulations which vary by country or region.

5.1 General AI regulation

AI regulations vary significantly across different global regions, reflecting each area's unique approach to balancing innovation with oversight. Across the regions, there is a clear trend towards establishing frameworks that ensure AI is used ethically and responsibly without stifling innovation. While Europe emphasises robust regulatory frameworks, the Americas are characterised by a more decentralised and sector-specific approach. Asia-Pacific shows a mixed strategy. Table 7 further describes the regulatory landscape across each region.

Table 7: Regional AI regulation

Region	Regulation landscape
Europe	The European Union (EU) has been proactive with its comprehensive "AI Act," which classifies AI applications based on risk levels and sets stringent requirements for high-risk uses, including biometric surveillance and subliminal manipulation. This legislation emphasises transparency, accountability, and fairness in AI use, aiming to align with European values of human oversight and privacy. The UK's strategy focuses on principles of safety and transparency while emphasising avoidance of overly restrictive regulations to foster AI development and promote innovation.[26]
Americas	In the USA, there is not yet unified AI legislation; instead, the country employs various guidelines and frameworks to manage AI applications, often focusing on sector-specific measures. Canada has introduced the AI and Data Act (AIDA), promoting safety and responsible AI practices, and Brazil is actively developing comprehensive AI legislation to regulate high-risk AI systems and ensure transparency and accountability in AI deployments.
Asia-Pacific	China has taken significant steps in AI regulation with specific laws for algorithmic recommendations and deep synthesis technologies, aiming to ensure content integrity and fairness while maintaining control over AI innovations. Japan relies more on non-binding guidelines and sector-specific rules rather than comprehensive national legislation, promoting a flexible approach to support AI innovation. India and other Asian countries are currently formulating its approach, signaling a shift towards more definitive regulations soon.
Africa	Various countries are at different stages of developing national strategies and policies to manage and harness the benefits of AI technology. Legislation and guidelines are still heavily reliant on the various data protection laws. Nations like South Africa, Mauritius, Egypt, and Kenya are pioneering efforts to draft and implement AI guidelines that address both the opportunities and ethical challenges posed by AI. These initiatives often consider adapting global standards, such as the EU's AI Act, to local contexts, promoting innovation while safeguarding ethical values and societal norms. The African Union is also playing a role, suggesting a move towards a more unified continental strategy. However, challenges such as limited technological infrastructure and the need for local AI expertise remain significant hurdles. These regional differences highlight the importance of international collaboration and dialogue to harmonise AI governance, ensuring that global standards can accommodate local needs while promoting safe and beneficial AI development globally.

5.2 Data protection and privacy in general in healthcare

Protecting the confidentiality, integrity, and availability of patient data is paramount. AI systems process vast amounts of sensitive data, and ensuring this data is protected against unauthorised access, breaches, and leaks is a fundamental ethical and legal requirement. Effective data protection measures help maintain patient trust, a cornerstone of healthcare provision. Failure to protect data can lead to financial losses, erosion of patient trust, and severe regulatory penalties, including criminal prosecution in certain jurisdictions.

In the USA, HIPAA (Health Insurance Portability and Accountability Act) is a primary regulatory framework that pharmacies must comply with to protect patient information.[27] Pharmacies must ensure that all systems handling patient data, including AI technologies, meet HIPAA standards to avoid penalties such as those enforced on entities like CVS Pharmacy and Rite Aid for improper disposal of personal health information (PHI). Pharmacies in the USA must adopt robust encryption for stored data and secure transmission protocols to meet HIPAA requirements.

In Europe, similar protections are provided under the General Data Protection Regulation (GDPR).[28] Under GDPR, pharmacists must ensure the confidentiality of patient data with strict access controls, and monitor for unauthorised access. Pharmacy owners should conduct regular reviews of data retention policies and ensure that staff understand the importance of patient confidentiality.

The African union has adopted the Convention on Cyber Security and Personal Data Protection to facilitate alignment of legislation across member states. This convention is not binding but serves as a guideline. Across the continent, 36 out of 55 countries have enacted data protection laws. South Africa has enacted the Protection of Personal Information Act (POPIA) which applies to any processing of personal information. It imposes criminal consequences for failing to adequately protect personal data. The act stipulates rights and responsibilities of data subjects and users, security measures required and how information can be sent out of the country, which has implications for any offshore data processing. Similarly, Egypt, Kenya, Nigeria, and Zimbabwe have implemented their respective Data Protection Acts (DPA).

5.2.1 Human-centred AI

Pharmacists must maintain a human-centred approach, ensuring that AI supports but does not replace the personal interaction and care that is critical in healthcare. Equity in healthcare access is another vital consideration; pharmacists must be vigilant that AI tools do not inadvertently exacerbate disparities by favouring certain populations over others. Continuous education on AI developments and ethical guidelines is essential, empowering pharmacists to make informed decisions and advocate for the responsible use of technology. By balancing innovation with ethical vigilance, pharmacists can harness AI to enhance patient care while upholding the profession's core values of trust, confidentiality, and equity.

5.2.2 Clinical validation and reproducibility of the algorithms

Regulation around AI applications varies by country. Autonomous AI applications are those that operate without a human to verify or check the output. Some countries require robust clinical validation for autonomous AI, meaning that the AI application must be tested and proven to be safe and effective for its intended use. Regulation for these types of applications are often included within medical device regulations. Applications that are not autonomous may not require such strict regulation.

In Europe, the Medical Device Regulation (MDR) is crucial for pharmacists integrating AI technology into healthcare, as it provides a comprehensive framework ensuring the safety, efficacy, and quality of medical devices, including AI-driven tools.[29] Under MDR, AI technologies classified as medical devices must meet stringent requirements for risk management, clinical evaluation, and post-market surveillance. For pharmacists, adherence to MDR is essential to ensure that AI tools used in patient care are reliable, secure, and comply with European standards. This regulation also emphasises transparency and traceability, ensuring that AI systems are not only effective but also explainable and accountable, ultimately protecting patient safety and enhancing trust in AI-driven healthcare solutions.

In the USA, AI technology in healthcare is primarily regulated by the Food and Drug Administration (FDA) under its Digital Health and Software as a Medical Device (SaMD) frameworks.[29, 30] The FDA evaluates AI-driven tools based on their intended use, potential risk to patients, and whether they meet the criteria for a medical device. For AI technologies classified as medical devices, the FDA requires a rigorous review process, including premarket approval or clearance, to ensure safety, effectiveness, and quality. The agency also emphasises post-market surveillance and the need for continuous learning and adaptation of AI systems, ensuring they maintain performance standards over time. This regulatory approach aims to balance innovation with patient safety, providing a robust framework for the integration of AI into healthcare. However, AI applications that are used only as clinical decision support are often not required to be tested and proven safe and effective before use, because there is a human safety net. These AI applications must still be responsibly deployed in a way that promotes safety and minimises risk, understanding that the burden of responsibility falls on the clinical end-user to ensure efficacy and safety. It is important to be able to distinguish between AI applications that require validation and those that do not.

In Asia, the regulation of AI technology in healthcare varies across different countries, but several leading nations such as Japan, China, and South Korea are developing comprehensive frameworks to govern the use of AI in medical contexts. In Japan, the Pharmaceuticals and Medical Devices Agency (PMDA) oversees AI technologies that qualify as medical devices, focusing on safety, efficacy, and post-market monitoring, similar to the FDA's approach. China has implemented strict regulations through the National Medical Products Administration (NMPA), requiring rigorous testing and approval for AI medical devices, with a strong emphasis on data security and patient privacy. South Korea, under the Ministry of Food and Drug Safety (MFDS), also regulates AI in healthcare, mandating approval processes and ensuring continuous monitoring of AI tools in the market. Overall, while regulatory frameworks in Asia are still evolving, there is a clear trend toward aligning with international standards, ensuring that AI in healthcare is safe, effective, and secure across the region.

5.2.3 Interoperability standards

Ensuring that AI systems in pharmacy practice adhere to interoperability standards like Health Level 7 (HL7) or Fast Health Interoperability Resource (FHIR) is crucial for seamless data exchange across different healthcare systems.[31] This compatibility helps in maintaining a unified and efficient healthcare information environment.

5.2.4 Cybersecurity measures

Pharmacies must implement strong cybersecurity measures to protect against threats. This includes employing encryption, secure access controls, and regular security audits to safeguard patient information. Strategies like two-factor authentication and robust password policies are recommended to enhance security. ISO27001 and ISO27799 to protect health data are essential certifications to consider.

5.2.5 Accessibility and inclusivity

AI tools should be accessible to all users, including those with disabilities, and designed to prevent healthcare disparities. This requires careful design and implementation practices to ensure that AI systems are usable by a diverse patient population and do not inadvertently exclude any groups.

AI can be designed to emphasise inclusivity by ensuring that algorithms are trained on diverse and representative datasets, which helps to mitigate biases and improves the system's performance across different demographic groups. For example, in healthcare, AI can be developed to consider varying genetic backgrounds, socioeconomic factors, and gender differences, ensuring that diagnostic tools and treatment recommendations are effective for all populations. Additionally, AI interfaces can be designed to be accessible to individuals with disabilities, incorporating features like voice recognition for those with limited mobility or visual impairments. Multilingual support and culturally sensitive content are other ways AI can be tailored to serve a broader range of users, ensuring that technology benefits everyone, regardless of their background or abilities.

By addressing these areas, pharmacists can effectively use AI to complement their expertise, enabling safer, more effective, and personalised patient care. Each region may have specific regulatory requirements, and staying informed through continuous education and monitoring of regulatory updates is essential for maintaining compliance and ensuring the effective use of AI in pharmacy practice.

5.2.6 Considerations for the future

As pharmaceutical care providers increasingly implement AI technology, future trends in AI regulation to keep in mind include the potential for stricter data privacy laws, particularly concerning patient data, and the establishment of clearer guidelines on AI accountability and transparency. Regulators may require AI systems in healthcare to undergo rigorous testing and validation processes to ensure safety and efficacy, similar to the approval process for new drugs. Additionally, there could be a push for more robust frameworks that ensure AI-driven decisions remain explainable and interpretable to healthcare providers and patients, to maintain trust and uphold ethical standards in patient care.

6 Common barriers to implementation

While an AI model's accuracy and performance are crucial, its ultimate clinical efficacy is determined by its practical application within the deployment environment. Even the most advanced AI models can fall short of their potential if they are not effectively integrated into practice. The deployment of AI models presents various barriers and challenges that must be addressed to ensure their successful implementation and impact.

6.1 Algorithmic bias

Bias in AI occurs when the algorithms produce systematic and unfair discrimination against certain individuals or groups. This can stem from biased training data, flawed model design, data and concept drift, or improper deployment. In the context of healthcare and pharmaceuticals, the consequences of such biases can be particularly severe, affecting patient outcomes and treatment efficacy.[32, 33] Fortunately, there are strategies that can be deployed to help address bias, as described in Table 8. While these strategies may not eliminate bias, they can help mitigate it.

Table 8: Key strategies to address algorithmic bias

Strategy	Detail
Diverse data collection	Ensuring that training data is representative of diverse populations can help mitigate bias. This involves collecting data from various demographic, geographic, and socio-economic backgrounds.
Algorithmic fairness	Implementing fairness-aware algorithms that actively check for and correct bias during model training can prevent biased outcomes. Given the various models of fairness, each addresses different aspects of bias, such as demographic parity For further learning, the Alan Turing Institute offers a course [34] on assessing and mitigating bias and discrimination in AI, which provides practical techniques and comprehensive insights into algorithmic fairness.
Continuous monitoring	Regular audits of AI systems to detect and address bias are essential. This involves setting up feedback loops where the system's outputs are continually assessed for fairness. There are multiple definitions for fairness. Castelnovo et al.[35] define fairness through the following concepts: ● Individual fairness: Similar individuals should receive similar outcomes. This includes concepts like Fairness Through Awareness (FTA) and Fairness Through Unawareness (FTU), which deal with treating individuals similarly based on their features without considering sensitive attributes like gender. ● Group fairness: This focuses on treating groups equally and includes: ○ Independence (demographic parity): Decisions should be independent of sensitive attributes. ○ Separation (equality of odds): Ensuring equal error rates across groups. ○ Sufficiency (calibration): Ensuring predictions are equally accurate across groups.
Transparency and explainability	Making AI systems transparent and their decision-making processes explainable can help identify and rectify bias. Stakeholders must understand how and why AI systems make certain decisions. Although deep learning algorithms are intrinsically unexplainable, some tools can be used to help predict how the model makes its decisions.
Add your own guardrails	The case of generative AI is a different issue. Data that did not exist is generated in the model’s outputs. Since these models are not trained to be factual, a major concern with these models is hallucinations, where the model provides a response that is false or inaccurate. Furthermore, these models are non-deterministic: when given a single prompt,

	there are many correct (and incorrect) answers. Prompt engineering plays a crucial role in this case.

6.2 Model drift

Model drift, when the performance of an AI model degrades over time due to changes in underlying data patterns, is a critical issue.[36] If not appropriately managed, it can lead to the model slowly becoming more inaccurate over time. Table 9 lists strategies for minimising the impact of model drift.

Table 9: Strategies to manage model drift

Strategy	Detail
Regular retraining	Periodically retraining models with new data ensures they remain accurate and relevant.
Performance monitoring	Setting up continuous monitoring systems to track model performance in real-time allows for early detection of drift. Metrics such as accuracy, precision, recall, and F1-score can be monitored.
Version control	Maintaining version control for models helps track changes and reverts to previous versions if necessary. This also aids in understanding the evolution of the model's performance.
Anomaly detection:	Implementing anomaly detection systems can alert stakeholders to unexpected changes in model behavior, prompting timely interventions.

6.3 Overfitting

Overfitting occurs when a model learns the noise in the training data instead of the signal, leading to poor generalisation on unseen data.[37] This results in models performing very well during the training phase but performing poorly when they are tested on any data outside the training dataset. To prevent overfitting, the strategies in Table 10 can be implemented.

Table 10: Strategies to reduce overfitting

Strategy	Detail
Cross-validation	There are techniques and best practices that can be used called cross-validation, which is a technique to assess a model's accuracy by training and testing it on different subsets of data to ensure it performs well on various data sets. An example of this is k-fold cross-validation.
Regularisation techniques	These are techniques that penalise models for being too complex, promoting simplicity and generalisation. Examples of regularisation methods include L1 (Lasso) and L2 (Ridge).
Pruning and early stopping	Pruning decision trees (a type of machine learning model) and stopping the training process early when performance on validation data starts to degrade are effective methods to combat overfitting.
Ensemble methods:	Ensemble methods involve using multiple techniques at once to improve generalisation and reduce the likelihood of overfitting.

6.3.1 Additional barriers to keep in mind

In addition to technical challenges, such as minimising bias, managing drift, and reducing overfitting, there are significant administrative and human-related barriers to integrating AI into practice. These include navigating complex clinical workflows and adequately training pharmacists on new tools and processes. Successful implementation also depends on engaging end users and fostering their willingness to adopt the new technology. Table 11 outlines important barriers that must be addressed to support successful AI integration.

Table 11: Additional challenges to implementation

Barriers	Detail
Integrating with complex workflows	Integrating AI into complex pharmaceutical and clinical workflows involves several considerations. This is a major challenge to AI adoption and implementation.[38]
Interoperability	Ensuring AI systems can seamlessly integrate with existing IT infrastructure and software systems is crucial. This involves using standard protocols and APIs (application programming interfaces) for communication. Also, having necessary resources (both human and economic) is crucial.
User training and support	Providing comprehensive training and support for end users is essential to facilitate smooth adoption. This includes creating user-friendly interfaces and offering ongoing technical support.
Workflow customisation	AI solutions should be tailored to fit the specific needs and processes of the pharmacy, pharmaceutical company, organisation, or individuals who are using it. Customisation ensures that AI tools complement existing workflows rather than disrupting them.
Scalability	AI systems should be designed to scale with the organisation's growth. This involves planning for increased data volumes, additional functionalities, and expanded user bases.
Collaboration and communication	Promoting collaboration between AI experts, pharmacists, and other stakeholders is vital. Clear communication channels help ensure that AI solutions address real-world challenges effectively. Both technical expertise and industry know-how are needed to integrate both worlds. Adding AI to a company should be supported by a whole culture pushing past barriers and complications.
High initial costs	The development and deployment of AI solutions require substantial investment in infrastructure, skilled personnel, and technology, which can be a deterrent for many organisations.[32, 38]
Change management	Integrating AI into existing workflows requires a cultural shift within organisations. Resistance to change among staff and stakeholders can hinder the adoption process.[32, 38]

6.4 Selecting the right tool by establishing the pros and cons

Selecting the right tool is not always easy and often more than one AI solution could be effective. It may not always be the functional capabilities of the tool that drive the decision, but other factors that come into play, such as the technical environment in which it will be implemented, the cost of creating, building, or maintaining the model, the level of transparency needed, regulations, or data access, among others.

When selecting the right tool, one must take the capabilities and limitations of the tool into account, but also the implementation design. For example, building a generative AI tool to provide health information to patients, carries a higher risk if the tool is patient-facing. However, if the model provides information to a clinician who first reviews it before it is provided to a patient, the risk is much lower. For the second scenario, the options of what tools can be used are much broader because it may not be necessary to have all the guardrails in place right away that would be needed for the first scenario.

Likewise, building a clinical decision support tool for drug dosing in a critical care environment involves different considerations. Creating a model that recommends what dose a patient should receive each day is very different to creating a model that alerts a clinician that the patient's condition is changing (or is predicted to change soon) and prompts the clinician to evaluate what dose adjustment is needed. Both scenarios would require different training data to build the model because the output of each model would be different. For the first scenario, the output of the model is a recommended dose (e.g., 5 mg). For the second scenario, the model output predicts whether or not a dose adjustment will be required, which involves less risk because a clinician is still making the decision, but it is augmented with AI. For the first scenario, a reinforcement learning model may be more appropriate, while a supervised learning model may be more appropriate for the latter.

6.4.1 Weighing the pros and cons between models

When using deep learning AI tools, there are many benefits, but also general limitations to keep in mind, such as data dependency and limited model interpretability (see Table 12). Diving deeper, it is essential to weigh the strengths and weaknesses of different AI models based on their type, learning style, and input data. Figure 2 outlines commonly used AI models, while Table 13 provides a high-level summary of the pros and cons to consider for each model type, depending on how the models are implemented and the ultimate goal of deployment.

Table 12: General pros and cons of deep learning models

Pros	Cons
Adaptability: One can improve the performance of the model, as it is exposed to more data.	Data dependency: Requires large amounts of data to train effectively and accurately.
Versatility: Applicable to a wide range of problems, from image recognition to natural language processing	Opacity: Complex models like deep neural networks can be "black boxes," making it hard to understand how decisions are made

Figure 2: Deep learning models

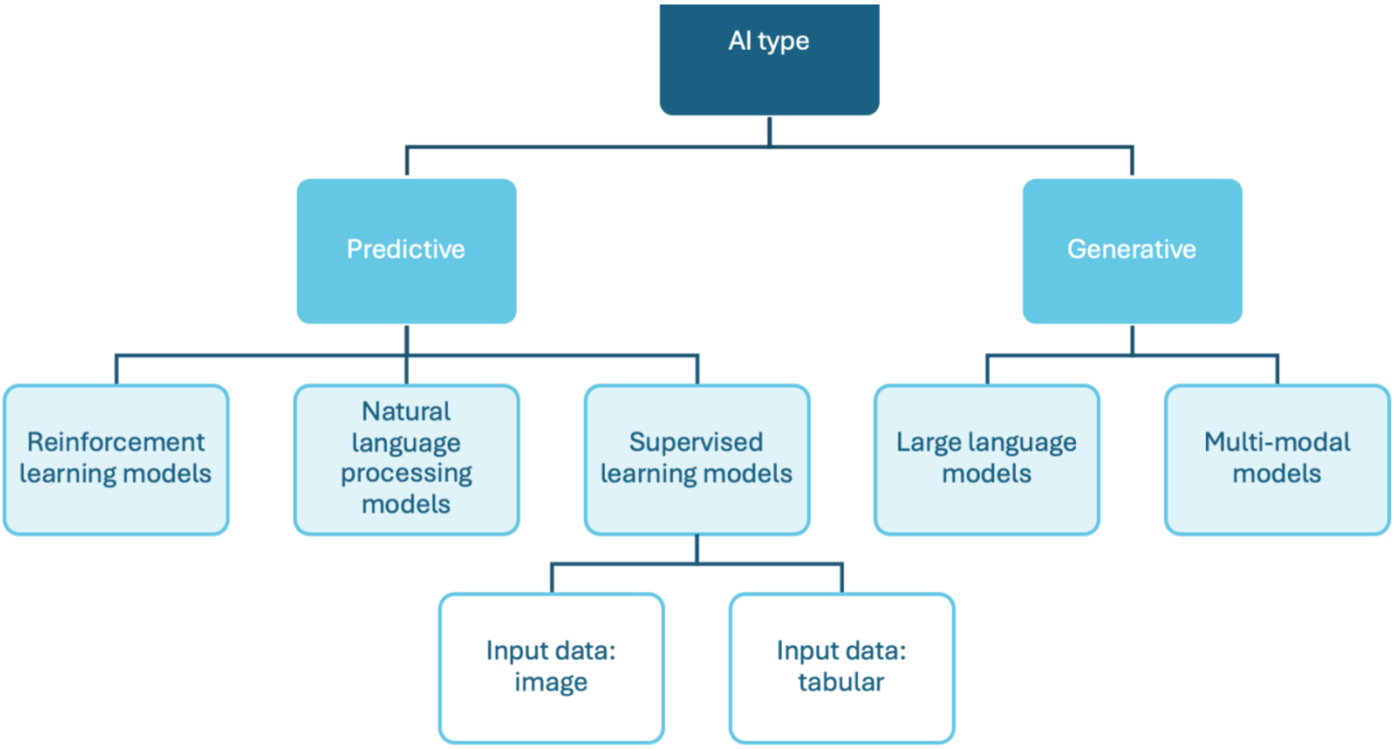


Table 13: High-level summary of pros and cons to consider for different model types

Model	Examples (not all-inclusive)	Pros	Cons	Considerations
Generative natural language processing tools (large language models)	**Chatbot** • A computer programme that processes natural text and simulates a conversation with a human[39] **Content creation** • Generates original text based on a prompt **Document classification** • Labels a document based on the topic or other feature **Summarisation** • Generates a summary of a document or prompt	• Does not require input data to be structured • Versatile • A single model can be used for many different purposes • Many products/resources do not require coding and are easy to use • For general uses, many models are ready to use "out of the box" (e.g. does not require additional training or fine tuning) • Models can be connected to an external data source	• Not trained to be accurate. Prone to hallucinations. • Contextual limitations: Struggle with understanding context, sarcasm, and nuanced language • Bias: Can inadvertently learn and propagate biases present in training data • Can struggle with domain-specific tasks • Model does not include any information (e.g., current events, new drugs, guideline updates) that occurred after its training data knowledge cutoff date	• Usually, it is not practical to develop in-house. Often must use an existing foundation model. • Some models are proprietary while others are open source • Performance varies across different models. Some are more accurate at certain skills than others (medical knowledge, mathematics, reasoning, drug information, etc.). • It is important to review how a model performs against various benchmarks, how it was trained, its training data cutoff, and sources/risk for bias. However, not all models share this data. • Requires using techniques such as Retrieval Augmented Generation (RAG) for the model to provide real-time information or answer questions about a specific document or internal knowledge base.

Model	Examples (not all-inclusive)	Pros	Cons	Considerations
Non-generative natural language processing tools	**Classification:** • Labelling the topic of a document **Data extraction:** • Extracting a diagnosis or medication list from a clinical note **Predictive:** • Using hospital clinical notes to estimate the risk of a patient needing end-of-life care	• Developers have more control over the model output • Can be built with less data • Does not require as much computing power (able to be run easier on individual devices) • Effective for narrow use cases	• It takes longer to build; requires AI expertise • Not generalisable and specific. Models created for one use are not able to be used for other purposes without retraining. • Often requires labeled data for training, which can be resource intensive to build	• Can be built in-house • Using pre-trained weights can help improve accuracy • Depending on the underlying model and use of neural networks or not, these models may be more comprehended than other black box models that use neural networks
Multi-modal generative AI models	**Chatbots:** • A computer programme that simulates a conversation with a human by processing text, images, audio and/or video **AI assistants:** • Multiple models coordinating with each other and/or other tools to complete a task	• Can interact with models through multiple channels • Models can be designed to allow for follow-up questions and back-and-forth dialogue (e.g., after asking a model to look at an image, the user can ask follow-up questions based on the model's description/response)	• The same limitations for generative AI apply to multi-modal models	• Not all models are truly multi-modal. Some appear to be multi-modal by combining several different models (e.g., text-generator, image-generator, transcription model, etc.) together. • Considerations are similar to those for generative natural language processing tools above

Model	Examples (not all-inclusive)	Pros	Cons	Considerations
Supervised learning model - image recognition	**Diagnostic:** ● Diagnosing or characterising disease features from medical imaging [40-42]	● Many AI solutions have demonstrated sufficient accuracy, safety, and reliability as determined by regulatory bodies, such as the Food and Drug Administration (FDA)[43]	● Models are black boxes and are not explainable ● Can often only be used with images of the same size, type and resolution it was trained on ● May be tied to a specific imaging device - if switching devices, would require a new model	● If using a deep learning model for medical imaging from a third-party vendor, check if the model has been approved by the applicable drug or device regulatory body (e.g., FDA, USA; Health Sciences Authority, Singapore; South African Health Products Regulatory Authority (SAHPRA), South Africa; INFARMED, Portugal; Medicines and Healthcare Products Regulatory Agency (MHRA), United Kingdom of Great Britain and Northern Ireland)[44]
Supervised learning model - tabular data	**Risk predictions/forecasting:** ● Creating a risk score for the likelihood of a patient being re-admitted to hospital after discharge[45] ● Predicting drug shortages[46]	● Many existing tools for implementation ● Can achieve high accuracy and performance ● A significant amount of healthcare data already exists in tabular format ● Can be fine-tuned based on local data ● Can be used to map existing data to a new metric or risk score (e.g., mapping pedometer data to a walking stability score)	● Models are black boxes and are not explainable ● May not always perform better than traditional statistical methods (e.g., logistic regression) ● Requires large amounts of data to see performance gains over simpler statistical methods ● Perpetuates pre-existing errors and bias in data ● Not generalisable	● Not ideal for "recommendation" systems - it does not truly predict the best action, but predicts what actions were taken historically (which may not always have been correct) ● It can be difficult and resource intensive to scale. Every new use case typically requires a new model and training data

Model	Examples (not all-inclusive)	Pros	Cons	Considerations
Reinforcement learning model	**Recommendation systems:** ● Optimises a sequence of actions/decisions to achieve a long-term goal	● Can learn without explicit supervision, making them suitable for tasks where annotated data is scarce or unavailable ● Designed to maximise a reward that might be far in the future (e.g., what series of actions should be taken in a game to win) ● Excels in problems that require a sequence of actions to achieve a goal	● These models can often have unintended consequences if the reward function is not well defined ● Black box ● The model may make unpredictable decisions to "explore" other action pathways, which could be unsafe in a healthcare environment ● It is difficult to implement guardrails in the model to prevent it from making unsafe recommendations	● Well-aligned to a healthcare environment where the "reward" may be a long-term outcome, rather than a short-term benefit. For example, multiple treatment decisions are made during a long hospitalisation stay with the goal of increasing the chance of the patient surviving to discharge (long-term goal) ● These models should be integrated with knowledge-based systems to create safety guardrails ● Rigorous validation is needed to ensure the right "reward" was chosen and that the model isn't accidentally optimising for the wrong one

7 Implementation checklist

As a summary to the information in the AI toolkit, the following checklist serves as a list of questions to help guide discussions when pursuing implementation of an AI tool or solution. It is not meant to serve as a comprehensive guide, but rather it should be used as a starting point. Each work environment or setting will have unique requirements that must be taken into consideration.

Checklist	
Defining the use case	
☐	What problem is the AI tool meant to solve?
☐	Can the problem be solved with a non-AI-enabled solution or tool?
☐	Have all the appropriate stakeholders been engaged, including both decision-makers and end users?
☐	How will this tool fit into the existing workflow or how will the workflow be adjusted based on the tool?
Model selection	
☐	Will the AI model be developed in-house or will a third-party vendor be used?
☐	If building the model in-house, does sufficient training data exist?
☐	If using a third-party foundation model, will it require fine-tuning (additional training) with local or domain-specific data?
☐	If using a third-party AI-powered product or software, does it need to be evaluated and approved as safe and effective by a regulatory body (e.g., FDA cleared software as a medical device)? If so, has it been?
☐	If using an existing model, how well does the model perform (see Table 3)? How does it compare with other models or existing benchmarks?
Compliance	
☐	Will the model have access to or utilise protected health information?
☐	Will using the model require data to be shared outside of the organisation? For example, does the model require using an Application Programming Interface (API) or is the data shared with a cloud server external to the organisation? If so, what limitations does this pose on what data can be included in the input of the model?
☐	What compliance regulations must be followed (see section on Compliance and ISO regulation)?
☐	Can the model be deployed locally?
Vendor selection	
☐	If using a third-party vendor, do they provide a model card (as described in Table 2) or details about their training data and model performance (see metrics in Table 3)?
☐	How often does the vendor audit model performance or retrain their model?
☐	Does the vendor provide updated performance metrics after any model updates are deployed?
Safety	
☐	Have the potential failure modes of the model been outlined? What will the mitigation strategies be?
☐	How will the model be audited on a continual basis?
☐	How often does the model need to be re-validated based on potential drift?
☐	Based on the model's training data, is the model less accurate for specific subpopulations? How will this be mitigated?

8 Training and development of competence in AI

8.1 What do pharmacists need to know about AI?

For pharmacists and pharmacy teams in both hospital and community settings, the following competencies are essential to harness the full potential of these technologies:

- **Understanding of generative AI capabilities and limitations:** Pharmacists must comprehend what generative AI tools can and cannot do, including their scope, reliability, and the contexts in which they operate optimally. This knowledge ensures appropriate reliance on AI for decision-making, avoiding over trust that could lead to errors.

- **Data literacy:** The ability to interpret and evaluate data output from AI tools is crucial. Pharmacists need to understand how to read, analyse, and make informed decisions based on the data generated by AI, which is essential for accurate patient care and medication management.

- **Ethical and legal considerations of AI use:** Understanding the ethical implications and legal boundaries of using AI in pharmacy practice is paramount. This includes patient privacy concerns, data security, and the ethical use of AI in decision-making processes to ensure patient safety and compliance with regulations.

- **Critical thinking and decision-making:** While AI can provide recommendations, the ultimate decision-making responsibility lies with the pharmacist. The ability to critically assess AI-generated advice, considering the unique contexts and needs of each patient, is essential for effective pharmacy practice.

- **Communication skills:** Pharmacists must effectively communicate AI-generated information to patients and healthcare teams. This includes translating complex AI data into understandable advice and ensuring that AI-supported decisions are transparent and justifiable.

- **Continuous learning and adaptability:** The field of AI is rapidly evolving; therefore, pharmacists need to commit to ongoing education and adaptation to new technologies. This continuous learning ensures that pharmacy practice remains at the cutting edge, using the most current AI tools to improve patient care.

- **Collaborative skills for interdisciplinary teams:** Working with interdisciplinary teams, including IT professionals, data scientists, and other healthcare providers, is crucial for implementing and optimising AI tools in pharmacy practice. Effective collaboration ensures that AI implementations are well-coordinated and meet the diverse needs of healthcare delivery.

- **Patient-centred care:** Pharmacists must ensure that AI tools are used in a way that prioritises patient needs and outcomes. This involves using AI to personalise medication management and support, enhancing the quality of care delivered to patients.

- **Innovation and creativity:** Finally, as in all ecosystems that work with AI, pharmacists should cultivate an innovative mindset, seeking creative ways to apply AI in pharmacy practice. This includes developing new workflows, patient care strategies, and management practices enhanced by AI, driving forward the pharmacy field.

Each of these competencies is critical for pharmacists and pharmacy teams to effectively integrate generative AI tools into their practice. Together, they enable the delivery of high-quality, efficient, and personalised patient care, ensuring that pharmacy professionals remain at the forefront of healthcare innovation.

8.2 Knowledge and skills for AI

Integrating generative AI tools into pharmacy practice represents a transformative shift towards more efficient and effective healthcare delivery. In pharmacy practice, AI systems are increasingly used to optimise medication management, enhance prescription accuracy, and streamline inventory control. For instance, AI-powered prescription verification systems can automatically detect potential errors in medication orders, reducing the burden of manual verification tasks for pharmacists. While this improves efficiency and patient safety, it also affects the traditional role of pharmacists in overseeing medication dispensing processes and providing clinical care. Pharmacists need to adapt to working alongside AI systems, requiring new skills in managing and interpreting AI-generated data.

Pharmacists eager to learn more about AI and its applications in healthcare and pharmacy practice have a variety of learning environments at their disposal. Online courses and webinars offered by institutions such as Coursera, edX, Udemy, and universities provide foundational knowledge on AI, its principles, and healthcare applications and are easily accessible.

In Asia, Coursera China offers tailored courses in partnership with top Chinese universities, focusing on AI in healthcare with content available in Mandarin. NUS-ISS (National University of Singapore, Institute of Systems Science) provides specialised programmes on AI in healthcare, catering to professionals in Singapore and surrounding regions. K-MOOC (Korean Massive Open Online Course), supported by the Ministry of Education in South Korea, offers AI-related courses with a focus on applications in healthcare and pharmacy, available in Korean. Additionally, NTU's Nanyang Technological University in Singapore offers executive education and online learning modules on AI applications in healthcare, targeting healthcare professionals across Asia. These platforms provide pharmacists with region-specific insights and skills to effectively integrate AI into their practice.

Professional organisations, like the American Society of Health-System Pharmacists (ASHP) and the International Pharmaceutical Federation (FIP), offer specialised training sessions, workshops, and conferences focused on AI in pharmacy practice. Academic journals and publications often feature articles on AI research and case studies, keeping pharmacists updated on the latest advancements and practical applications.

Collaboration with multidisciplinary teams, including data scientists and healthcare professionals through seminars and hands-on projects, can provide practical insights and real-world experience. Additionally, participation in AI-focused forums and discussion groups, both online and within professional networks, fosters an environment of continuous learning and knowledge sharing.

These diverse educational resources can help equip pharmacists with the skills and understanding needed to effectively integrate AI into their practice, to enhance patient care and optimise healthcare delivery.

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Annex - Glossary of terms used in this toolkit

Term	Definition
Algorithm	A sequential procedure or set of rules, designed to solve a particular problem or perform a specific task. It is a clear, finite sequence of instructions that takes an input, processes it, and produces an output.
Application Program Interface (API)	A set of guidelines and protocols that enable different software applications to communicate with one another. It outlines the methods and data formats that applications use to request and exchange information, allowing for smooth interaction. APIs are frequently used to integrate systems, services, or applications, helping with tasks such as data retrieval, invoking services, and sharing functionalities.
Artificial Intelligence (AI)	A branch of computer science dedicated to creating systems capable of performing tasks that typically require human intelligence, such as learning, reasoning, problem-solving, and pattern recognition.
Artificial general intelligence (AGI)	A type of AI that has the human-like ability to understand, learn, and apply knowledge across a broad range of tasks, similar to human cognitive abilities. AGI can adapt to new challenges, reason through problems, and transfer knowledge from one domain to another.
Artificial pharmacology intelligence (API)	The use of advanced artificial intelligence techniques to analyse and interpret data related to pharmacology. It aims to enhance the understanding of drug interactions, drug discovery, and the effects of substances on biological systems.
Big data	A vast collection of data that are too big for traditional data management systems to process. AI uses big data to enhance model efficiencies in learning and analysis.
Data science	An interdisciplinary field focused on extracting insights and knowledge from data through a variety of techniques, such as statistical analysis, data mining, machine learning, and data visualisation.
Deep learning	Involves the use of large, multi-layer artificial neural networks that process data using continuous (real number) representations. It offers improved generalisation from small datasets and scales more efficiently with large datasets and computing resources.
Deployment	The process of integrating an AI model into a production environment to make predictions and analyses based on data.
Generative AI (pharmacy)	Generative AI in pharmacy refers to the application of advanced AI techniques that can create new data, solutions, or insights based on existing information. These technologies leverage machine learning models, particularly generative models, to enhance various aspects of pharmaceutical practice and research.
Large language model (LLM)	LLMs are a specific type of generative AI model focused on producing human-like text. While generative AI refers to a broad range of AI techniques and models designed to create new content—whether text, images, audio, or video—LLMs specialise in text generation.
Machine learning (ML)	A branch of AI that focuses on how computer agents can enhance their perception, knowledge, reasoning, or actions through experience or data. Machine learning integrates concepts from fields such as computer science, statistics, psychology, neuroscience, economics, and control theory.
Natural language generation (NLG)	A branch of artificial intelligence dedicated to developing systems that automatically create human-like text from structured data. NLG allows computers to generate written content, including reports, summaries, or responses, in natural language. This process transforms data, facts, or insights into coherent and meaningful sentences or paragraphs, improving how humans understand and interact with information. NLG is widely applied in areas such as chatbots, automated reporting, content creation, and personalised communication.

Natural language processing (NLP)	A field of artificial intelligence focused on enabling computers to understand, interpret, and generate human language. It involves the development of algorithms and models that allow machines to process and analyse text or speech data in a way that is meaningful and useful.
Neural network	Computer models inspired by the human brain's structure. These interconnected artificial neurons, organised in layers, learn from data to make predictions in machine learning, underpinning deep learning.
Prompt	The input that a user puts into to an AI model to receive a specific response.
Retrieval augmented generation (RAG)	An advanced technique in natural language processing that combines information retrieval with text generation.
Robotic process automation (RPA)	A rival technology that uses software robots to automate repetitive tasks based on fixed rules and inputs, often performing tasks more efficiently than humans.

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