Artificial Intelligence in the Generic & Biosimilar Medicines Industry

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disclaimer

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What is AI and how does it work?

AI is the practice (through science and engineering) of making machines perform tasks that typically require human intelligence.

AI works by learning patterns from massive amounts of data using algorithms that mimic how humans process information.

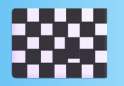
What can AI do and why use it?

learn from data

like how Netflix recommends shows

understand language

like chatbots or voice assistants



recognize patterns

e.g., as in fraud detection or medical diagnoses

make decisions

e.g., self-driving cars, smart thermostats

create content

text, images, music, video

✨ **use AI to help us solve problems and do things better** ✨

speed, consistency, accuracy (fewer errors), compliance

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types of AI

1

Narrow AI

focused on one task

(*e.g.*, facial recognition)

General AI

hypothetical future AI that can understand, learn, and apply knowledge across any domain, like a human

(*e.g.*, conducting scientific research)

Machine Learning

a subset of AI where systems learn from data

Deep Learning

a more advanced form of machine learning using neural networks

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What is an algorithm?

al·go·rithm (n): a step-by-step set of instructions used to solve a problem or perform a task

example: sock-sorting algorithm

goal: organize socks into matching pairs

steps:

(1) lay all socks flat on a surface

(2) pick one sock

(3) search for a sock with the same color and pattern

(4a) if found, place them together as a pair

(4b) if not, set the sock aside

(5) repeat until all socks are paired or sorted

Where are we today?

content generation, formatting & publishing

deficiency analysis & submission improvement

labeling

translations

quality checks

document summaries

intelligence analysis

other operational efficiencies

pharmacovigilance use case: finding signals

How long would it take a human who reads at average speed to review 1,000 pages of scientific literature?

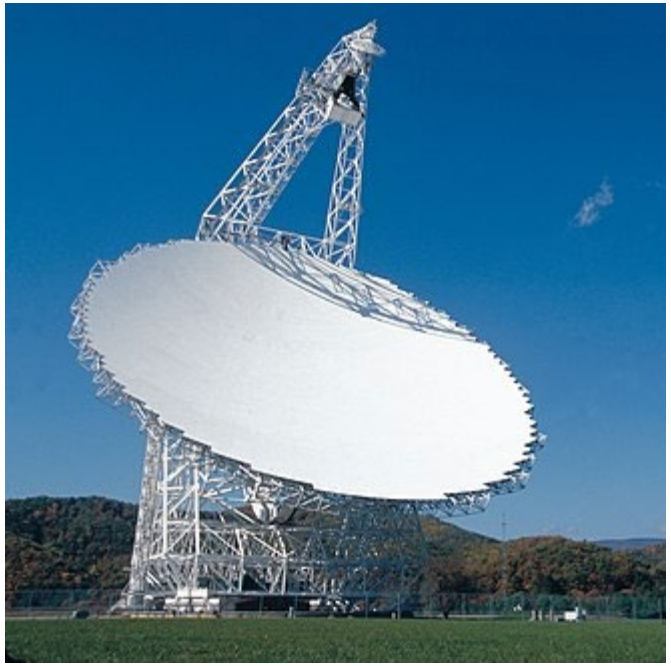
Advanced scientific/technical material is read at ~6 pages/hour[1]

1,000 pages @ 6 pages/hour = 167 hours
At 8 hours/day (no breaks) = 21 days

How long would it take AI? Minutes to summarize, a couple hours for more critical review

1. Reading Speed Statistics – WordsRated

pharmacovigilance prompt



pharmacovigilance prompt for AI (simplified):

(1) find and read all articles that reference adverse events involving patients who took drug X
(2) provide details on what happened to each patient who used drug X who experienced an adverse event
(3) indicate if patients were using any other drugs or had other comorbidities
(4) indicate disposition of patient

future state: how is the drug connected to the adverse event, if at all?
(currently evaluated using human intelligence)

Where can we go tomorrow?

CAR AND DRIVER

Hertz Is Using AI to Scan Your Rental Car for Damage

The technology uses cameras and machine learning algorithms to comb over the vehicle's body, glass, tires, and undercarriage for damage and maintenance issues. The scanners replace the need for manual inspections

https://www.caranddriver.com/news/a65176049/hertz-ai-scan-rental-car-damage/

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FDA exploring AI tools for sameness evaluations

https://sam.gov/workspace/contract/opp/a86bf7ee18214db2afec6966682a4814/view

August 2025 | $250,000 FDA → DigiM Solution LLC

To explore advanced imaging technologies and AI assisted image analysis to facilitate product development and ANDA assessment of complex generics.

Goals of the project include:

- development of an AI-assisted image analysis tool
- development of a database “containing data on microstructure of various complex formulations with the potential to serve as virtual references for supporting generic development and approval
- to use the models to predict generic drug performance

if you give a mouse a cookie

FDA should apply an enhanced benefit-risk framework to evaluations aided by AI. Any tools used should only be looking for and FDA potentially acting on *clinically meaningful* differences.

Enhanced benefit-risk means taking into account whether information is truly needed to support approval, and with consideration for patient access to medicines.

benefit-risk-based approach

Good news!

FDA *is* thinking about a benefit-risk-based approach for AI


Considerations for the Use of Artificial Intelligence to Support Regulatory Decision-Making for Drug and Biological Products

Guidance for Industry and Other Interested Parties

DRAFT GUIDANCE

This guidance document is being distributed for comment purposes only.

U.S. Department of Health and Human Services
Food and Drug Administration
Center for Drug Evaluation and Research (CDER)
Center for Biologics Evaluation and Research (CBER)
Office of Combination Products (OCP)
Office of Inspections and Investigations (OII)

Selections from FDA draft guidance *Considerations for the Use of Artificial Intelligence To Support Regulatory Decision-Making for Drug and Biological Products*

- Evaluating the credibility of an AI model for a particular **context of use**
- Assessing the AI model's **risk**
- Explicitly does not address the use of AI models (1) in drug discovery or (2) when used for operational efficiencies that **do not impact patient safety, drug quality**, or the reliability of results from a nonclinical or clinical study

other potential R&D applications

connect CMC, biologic structure, and clinical effect for biosimilars

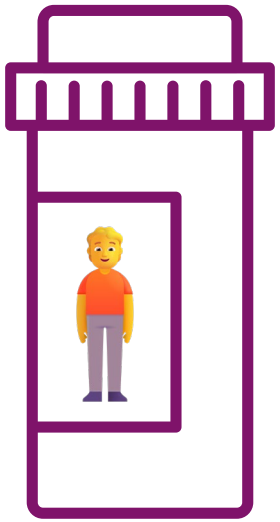
determining whether and how small differences in molecules have a clinical impact

virtual interviewers to minimize bias from humans

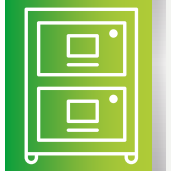
clinical site selection

personalized labels

potential future use



challenges



data in proprietary databases that companies may not want to share; privacy implications

oversimplification of complex scientific and technical matters

data integrity & hallucination

conclusion

benefits & risks

still early

more & better data

regulate only where value added

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