

Davis Polk

The AI revolution in drug development – Key legal considerations

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Overview

01

How AI is being used
in drug development

02

Legal risks

03

Risk mitigation
strategies

What is AI?

A quick primer on terminology

The FDA defines Artificial Intelligence (AI) as:

A branch of computer science, statistics, and engineering that uses algorithms or models to perform tasks and exhibit behaviors such as learning, making decisions, and making predictions.

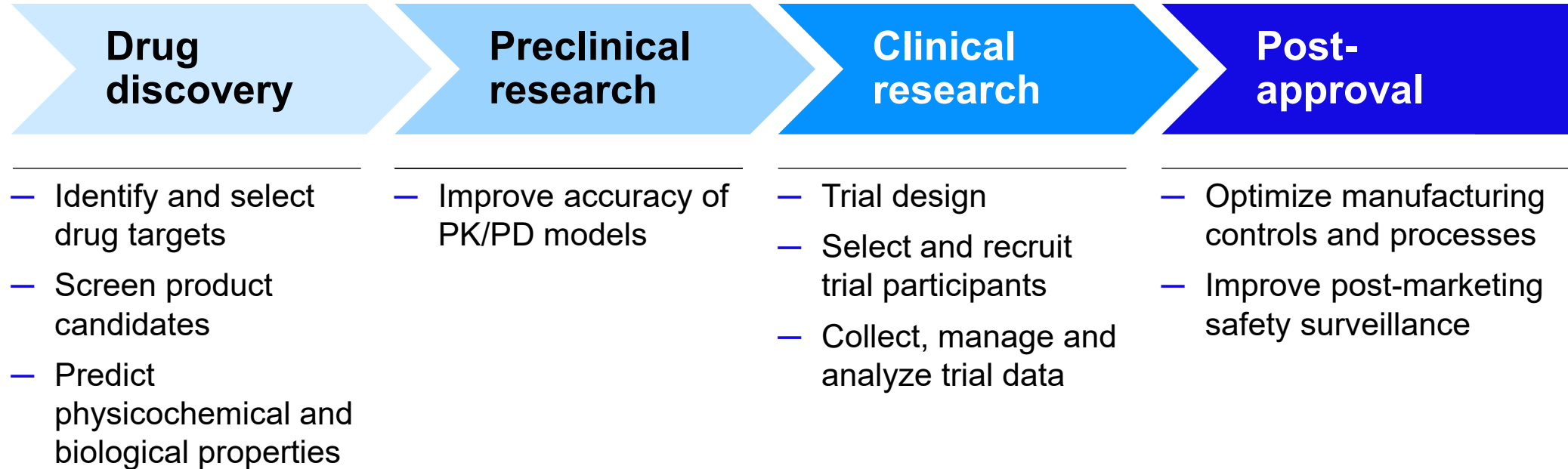
AI encompasses a range of technologies including:

- Machine Learning
- Deep Learning
- Neural Networks

AI is **trained** on broad or curated data sets, or iterative trials, that result in **emergent rules and behaviors** that drive the system's functionality rather than relying on hard-coded logic or rulesets.

How is AI being used in drug development?

Example use cases across the drug development lifecycle



Legal issues arising from AI input

Third-party rights in training/input data

Intellectual property rights

- AI systems may be trained on unlicensed data
 - *Getty Images v. Stability AI*
 - *Doe v. GitHub*
 - *UMG v. Anthropic*
 - *NYT v. OpenAI*
 - Impact of *Warhol v. Goldsmith*
- Availability of fair use defense uncertain and context-specific

Data privacy rights

- Training data may include genomic data or other sensitive medical information
- Increased compliance burden for AI system operators

Legal issues arising from AI input (cont.)

Other issues

Use restrictions

- Publishers may also impose additional restrictions on how data can be used with AI systems
 - Negotiated limitations
 - Terms of use
- If training data is licensed, what is the scope of the license? R&D only?

Confidentiality issues

- Prompts or other input may include trade secrets or other proprietary information
 - e.g., biological targets
- Can an AI service provider access this information? If so, what restrictions apply?

Accuracy & reliability

- Training data may be flawed, inaccurate or biased
- This may impact the quality and value of the output of AI systems for drug development

Legal issues arising from AI output

Is AI-generated output protectable?

Current state of U.S. law:

- Under U.S. patent law, an AI system cannot be an “inventor” of the output that it generates.
 - *Similar principles apply under U.S. copyright law.*
- Only a human being can be an “inventor” and therefore create a patentable invention.
- As a result, certain AI-generated output may have no inventor under U.S. law, meaning the work would not be protectable.
- However, the use of an AI system as part of conceiving an invention does not disqualify the invention from being patentable.

Legal issues arising from AI output (cont.)

Is AI-generated output protectable? (cont.)

There is no clear bright-line rule in U.S. law regarding the degree of human inventorship required in producing AI-generated output for a human user to be the inventor of such output.

- The greater the degree of human involvement in producing AI-generated output, the more likely it is that such output may be deemed “invented” by a human and protectable under patent law.
- The USPTO suggests each claim of a patent requires an inventor, joint inventor, or co-inventor who is a natural person that **significantly contributes** to the claim’s conception.
- **What can be a sufficiently significant contribution when working with AI?** Unclear, however, the following examples may be more likely to support a claim of inventorship:
 - Designing, building or training an AI system in view of a specific problem to elicit a particular solution
 - Constructing prompts in view of a specific problem to elicit a particular solution
 - Modifying AI output to create the claimed invention
- Merely supervising or overseeing an AI system, or reducing an AI-generated invention to practice, is unlikely to be sufficient.

Legal issues arising from AI output (cont.)

Other issues

Allocating rights in output

- What rights do the AI service provider and service recipient have in AI-generated output?
 - *This is an important issue even where AI output is not legally protectable*
- Rights in AI-generated output will be determined by the applicable contractual arrangements
- Many AI service providers seek to reserve certain rights, including:
 - to further train their AI system
 - to develop or improve their services
 - to produce output for others

Ensuring accuracy

- Lack of explainability may make it difficult to identify and address errors

Third-party infringement risk

- The output of an AI system may include material that infringes third-party intellectual property rights
- AI service providers have deployed different strategies to address this:
 - technical measures
 - indemnification obligations

Regulatory risks

European Union

- Artificial Intelligence Act expected to be enacted in early 2024
- Risk-based framework with additional compliance obligations for “high risk” AI systems
- May become a *de facto* global standard given first mover status and broad territorial scope (similar to the impact of the GDPR)

United States

- Prospects of comprehensive federal AI regulation are uncertain
- Increased scope for executive and agency action, including by FDA
 - *Oct. 2023 – Executive Order on the Safe, Secure, and Trustworthy Development and Use of Artificial Intelligence*
- As with data privacy, states may look to fill the legislative void, resulting in patchwork regulation of AI

“AI/ML will undoubtedly play a critical role in drug development, and FDA plans to develop and adopt a flexible risk-based regulatory framework that promotes innovation and protects patient safety.”

— FDA, May 2023

Risk mitigation strategies

Implement guardrails and controls:

- Establish a cross-organizational AI governance team comprised of leaders from key areas (including scientific and legal)
- Develop internal policies, procedures and controls to implement and enforce AI risk mitigation rules and strategies, including:
 - establishing permitted uses
 - limiting the information shared with AI systems
 - requiring identification of AI-generated output
- Appropriate AI governance protocols should also be included in collaboration and partnership agreements

Ask questions and conduct due diligence:

- How was the AI system developed and trained?
- What licenses or controls does the AI service provider have in place in relation to third-party rights?
- How robust are the cybersecurity and open source software practices of the AI service provider and its key vendors?
- Is the service recipient able to conduct diligence on material updates or changes to the AI system?

Risk mitigation strategies (cont.)

Clearly specify contractual rights:

- What rights does the AI service provider have in:
 - training or input data provided by the service recipient?
 - output created at the direction of the service recipient?
- What are the parties' respective liabilities for third-party infringement claims?
- Indemnification and other contractual protections should not be as a substitute for diligence

Securing value in output:

- Maximize the prospects of patentability through governance and record-keeping
- Consider alternatives to patent protection:
 - Trade secrets
 - Regulatory exclusivity
- Implement appropriate validation mechanisms to identify potential red-flags as early as possible in the development lifecycle

Questions for leadership

Six key questions boards and senior leaders should be asking about their company's use of AI:

- 1. Do we have an AI governance team?**
 - What is its makeup and mandate, and how often does it meet?
- 2. What frameworks and principles are guiding our responsible use of AI?**
 - Are we implementing AI systems in a manner consistent with our development, ESG, DEI and other critical goals and corporate initiatives?
 - What are best practices in our industry and what are our competitors doing?
- 3. What policies, procedures and controls do we have in place with respect to the use of AI?**
 - How are we determining when those guardrails must be updated to manage new or evolving risks?
- 4. How are we training our personnel?**
 - What steps are we taking to ensure appropriate use of AI in compliance with our principles, policies, procedures and controls?
- 5. How are our key suppliers and service providers using AI?**
 - Do we need to update our onboarding, vendor audit or other processes, and applicable contracting terms or licenses (with both vendors and customers), to account for use of AI systems?
- 6. Are we getting an appropriate return on our investment in AI?**
 - How are we tracking and measuring our use of AI and related costs and benefits?

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