AI & Drug Discovery Symposium: Revolutionizing the Future of Medicine

Jumpstart your week with a deep dive into the future of medicine as part of Goodwin's exclusive programming during the BIO International Convention in Boston. Join us for a dynamic symposium where industry leaders and AI pioneers come together to unveil how artificial intelligence is revolutionizing drug discovery. Don't miss this chance to explore groundbreaking technologies and connect with the minds shaping tomorrow's healthcare.

RSVP **here** to attend and see below for more details!

Date & Time: Monday June 16 from 1:00 PM – 4:30 PM ET

Location: Goodwin's Boston Office, 100 Northern Avenue. Boston, MA 02210

1:00 – 1:30 PM | Registration & Lunch

1:30 – 2:00 PM | Panel: AI Governance and AI Security

- Kaitlin Betancourt, Partner, Goodwin
- Jud Welle, Partner, Goodwin
- Tom Doughty, Chief Information Security Officer, Generate:Biomedicines

2:05 – 2:40 PM | Panel: Diligence Considerations with Tech Acquirers and IP Risks from AI in Drug Discovery and Development

- Marty Gomez, Partner, Goodwin
- Sarah Solomon, Partner, Goodwin
- Robert Carroll, Partner, Goodwin
- Hilary Eaton, CBO, Profluent
- Jen Asher, PhD, Founder and CEO, 1910 Genetics

2:40 – 3:00 PM | Networking/Coffee Break

3:00 – 3:30 PM | Fireside Chat: Advancing a New Era of Programmable Biology Through AI

- Joe Theis, Partner, Goodwin
- Mike Nally, CEO, Generate:Biomedicines

3:35 – 3:45 PM | FDA Insights on AI in Drug Development

- Qi Liu, Co-Chair of CDER AI Council; Lead of CDER AI Review Rapid Response Team, U.S.

Food and Drug Administration (*virtual*)

3:50 – 4:30 PM | Panel: Smarter Drug Development – The Role of AI in Regulatory Strategy

- Julie Tibbets, Partner, Goodwin
- Alexander Morgan, MD, PhD, Partner, Khosla Ventures
- Tracey Sikora, Vice President of Research & Clinical Programs of the National Organization for Rare Disorders (NORD); Co-Founder of Every Cure

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FDA Publishes Its First Draft Guidance On Use of Artificial Intelligence in the Development of Drugs and Biological Products

On January 7, 2025, the FDA issued a draft guidance called **Considerations for the Use of Artificial Intelligence to Support Regulatory Decision-Making for Drug and Biological Products**. The document clarifies how sponsors, manufacturers, and other industry developers should approach artificial intelligence (AI) to support safe, effective development and marketing of AI-based tools.

The guidance discusses the use of AI models in the nonclinical, clinical, post-marketing, and manufacturing phases of the drug product life cycle, where the specific use of the AI model is to produce information or data to support regulatory decision-making as it relates to safety, efficacy, or the quality of the product. It does not cover AI use in drug discovery or operational efficiencies that do not affect patient safety, drug quality, or study reliability.

Read the full alert **here**.

USPTO’s New Guidance on AI-Assisted Inventions: The Impact on the Use of AI in the Life Sciences

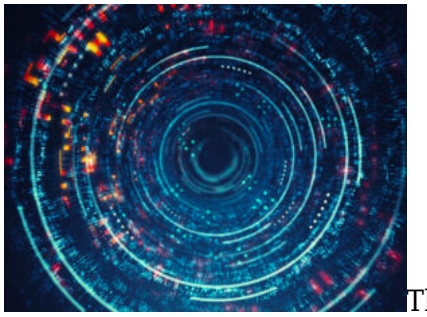
 On February 12, 2024, the US Patent Office and Trademark Office (USPTO) released the Inventorship Guidance for AI-assisted Inventions (**the Guidance**). We previously discussed the Guidance **here**.

Following up on the Guidance, the USPTO released two examples illustrating what the USPTO considers proper inventorship analyses for AI-assisted inventions. Each example sets forth different fact patterns and walks through an analysis of whether one or more human individuals qualify as inventors. Acknowledging that life sciences companies are increasingly employing AI systems to help identify molecular targets and/or design therapeutic molecules, one of the two examples focuses on the use of AI to develop therapeutic molecules: Developing a Therapeutic Compound for Treating Cancer (**Example 2**).

Life sciences companies using AI-assisted systems should carefully consider whether their current R&D efforts allow for natural persons to provide a significant contribution such that the resulting efforts may properly identify a human inventor.

Read the full alert **here**.

FDA Issues Artificial Intelligence/Machine Learning (AI/ML)-Enabled Device Software Functions Draft Guidance

 The U.S. Food and Drug Administration recently issued its **draft guidance** entitled "Marketing Submission Recommendations for a Predetermined Change Control Plan for Artificial Intelligence/Machine Learning (AI/ML)-Enabled Device Software Functions." The draft guidance follows the passage of the Food and Drug Omnibus Reform Act of 2022 (FDORA), which explicitly authorized the Agency to approve or clear Predetermined Change Control Plans (PCCPs).

We summarize some of the key takeaways from FDA's draft guidance. Read the client alert **here**.

US Artificial Intelligence Regulations: Watch List for 2023

 Companies are developing, deploying, and interacting with artificial intelligence (AI) technologies more than ever. At Goodwin, we are keeping a close eye on any regulations that may affect companies operating in this cutting-edge space.

For companies operating in Europe, the landscape is governed by a number of in force and pending EU legislative acts, most notably the EU AI Act, which is expected to be passed later this year; it was covered in our prior client alert here: **EU Technology Regulation: Watch List for 2023 and Beyond**. The United Kingdom has recently indicated that it may take a different approach, as discussed in our client alert on the proposed framework for AI regulation in the United Kingdom here: **Overview of the UK Government's AI White Paper**.

For companies operating in the United States, the landscape of AI regulation remains less clear. To

date, there has been no serious consideration of a US analog to the EU AI Act or any sweeping federal legislation to govern the use of AI, nor is there any substantial state legislation in force (although there are state privacy laws that may extend to AI systems that process certain types of personal data).

Read the client alert **here**.