White Paper

Generative AI: The Future of Pharmacovigilance

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Introduction

In today's complex, rapidly evolving pharmacovigilance landscape where the amount of data continues to grow exponentially, generative artificial intelligence (AI) presents an opportunity to improve efficiency of manual tasks and glean valuable insights from the overwhelming amounts of data. However, generative AI is far from perfect, and it would be a mistake to blindly rely on it. There needs to be humans in the loop to maintain control and provide oversight.

Context

In an event held in Boston, the panelists responded to a series of questions about the current pharmacovigilance landscape, challenges and opportunities related to implementing generative AI into pharmacovigilance workflows, and strategies that life sciences companies can use to facilitate a smooth integration of generative AI in these workflows.

Key takeaways

Changes in the pharmacovigilance landscape are affecting life sciences company priorities. Uwe Trinks, global practice lead in pharmacovigilance technologies at IQVIA, sees the following factors impacting the ever-changing pharmacovigilance landscape and companies' priorities.

- **Increasing regulatory requirements.** Compliance has always been a priority, but it has become even more difficult and complex with advancements in novel modalities and technologies.
- **A shortage of qualified people.** This shortage of qualified people has been a key factor behind increased investments in automation over the past two decades. "We have automated anything we could, with traditional SQL code," says Dr. Trinks.
- **The emergence of AI.** Just as it seemed there was nothing more that could be done with traditional code, along came AI and now generative AI. Trinks sees AI as presenting a huge opportunity and encouraged life sciences companies to embrace it, because the industry will have far more data and will need AI to derive insights from this data.

"Now, we have this tremendous opportunity with artificial intelligence."

— Uwe Trinks, IQVIA

Life sciences companies are considering generative AI

Based on the complexities of today's pharmacovigilance landscape, life sciences companies have increased their use of digital tools and are now considering generative AI. The industry has experienced a great deal of change, which has been supported through the use of digital tools. Now, life sciences companies are rapidly learning about and exploring generative AI. Alison Sloane, general manager of IQVIA Vigilance Detect, sees both positives and negatives.

- **Positives include** creating code, data generation and summarization, boosting and accelerating current AI application, and enabling patient-centric tools improving patient support programs.
- **Negatives involve** bias, lack of reliability and lack of confidence in the data and the outputs.

"You can bring generative AI into the fold, but to quote Sam Altman, the CEO of OpenAI, 'It is a mistake to be relying on it.'"

— Alison Sloane, IQVIA Vigilance Detect

Sloane advised life sciences companies to:

- Get the right tools.
- Use and apply those tools correctly.
- Focus on managing the risks.

The challenges

While there are benefits to implementing generative AI as part of pharmacovigilance workflows, there are also multiple challenges.

Many pharmacovigilance activities are performed manually, including case management, signal management, and aggregating reports. These manual activities require entire teams and organizations. Nneka Okere, senior director of pharmacovigilance at Nurix Therapeutics, noted that with the growth in technology, some actions have been automated. However, with an increase in the volume of adverse events, she sees some organizations struggling. Okere is hopeful AI can help address some of these inefficiencies.

Some of the challenges Okere believes organizations need to consider prior to implementing generative AI include:

- **Strategy.** Do not implement generative AI for the sake of it; have a clear purpose and strategy for doing do.
- **Data privacy.** Life sciences companies need to be cautious not to expose patient data when training and using generative AI models.
- **Data quality.** There is a great deal of discussion about "garbage in, garbage out." The effectiveness and efficiency of an AI model depends on the quality of the data used to train it.
- **Integration.** Implementing any new system causes disruption to an organization's workflow. Organizations need to have resources to handle this integration and disruption.
- **Costs.** The cost of implementing generative AI within pharmacovigilance is substantial.

Figure 1: Challenges to consider prior to implementing generative AI

Other challenges mentioned by panelists included training the models, avoiding bias, general reluctance to embrace something new, and challenges associated with refining and controlling these models. Maintaining control over these models requires having a "human in the loop."

Responsible AI implementation

Responsible AI implementation is important for sponsors and end users. Hua Carroll, senior director at Biogen, advocated that sponsors engage in and support responsible AI development and implementation. The more sophisticated and advanced the AI tools are, the more that humans need to be involved and provide oversight.

Carroll stressed the importance of sponsors keeping a balance, a balance between efficiency and control. She said the type of human oversight that will be required depends on the scope of the AI model and risk analysis and can be implemented at different points of the AI development and implementation cycle. A certain level of comfort in the AI tool by the end user is needed to fully realize the advantages AI can provide. The type and scope of oversight needs to be fit for purpose and balanced.

Carroll also emphasized it is the end user's responsibility to have a solid and critical review and understanding of any AI tool before implementing it. Some important areas for end users to keep in mind include:

- What training dataset is used? If and how does this training dataset differ from the end user's own data?
- What are the limitations?
- What does the retraining plan look like?

In addition, Carroll cautioned, both sponsors and end users need to beware of bias. Knowing that bias may exist will enable taking a proactive approach in identifying and mitigating potential bias, whether it's inherent in the AI tool or from the data.

"The more sophisticated and advanced AI tools are, the more that we as humans need to know how to oversee the development, testing, and implementation…and then we'll help evaluate the impact and implications of AI models."

— Hua Carroll, Biogen

There are multiple strategies that life sciences companies need to undertake to facilitate a smooth integration of generative AI into their pharmacovigilance workflows.

Mark Novas, vice president of medical safety and risk management at Moderna, explained his company has made significant investments in a large language model that has access to the totality of the data at Moderna. The organization has found this model to be extremely helpful in providing insights.

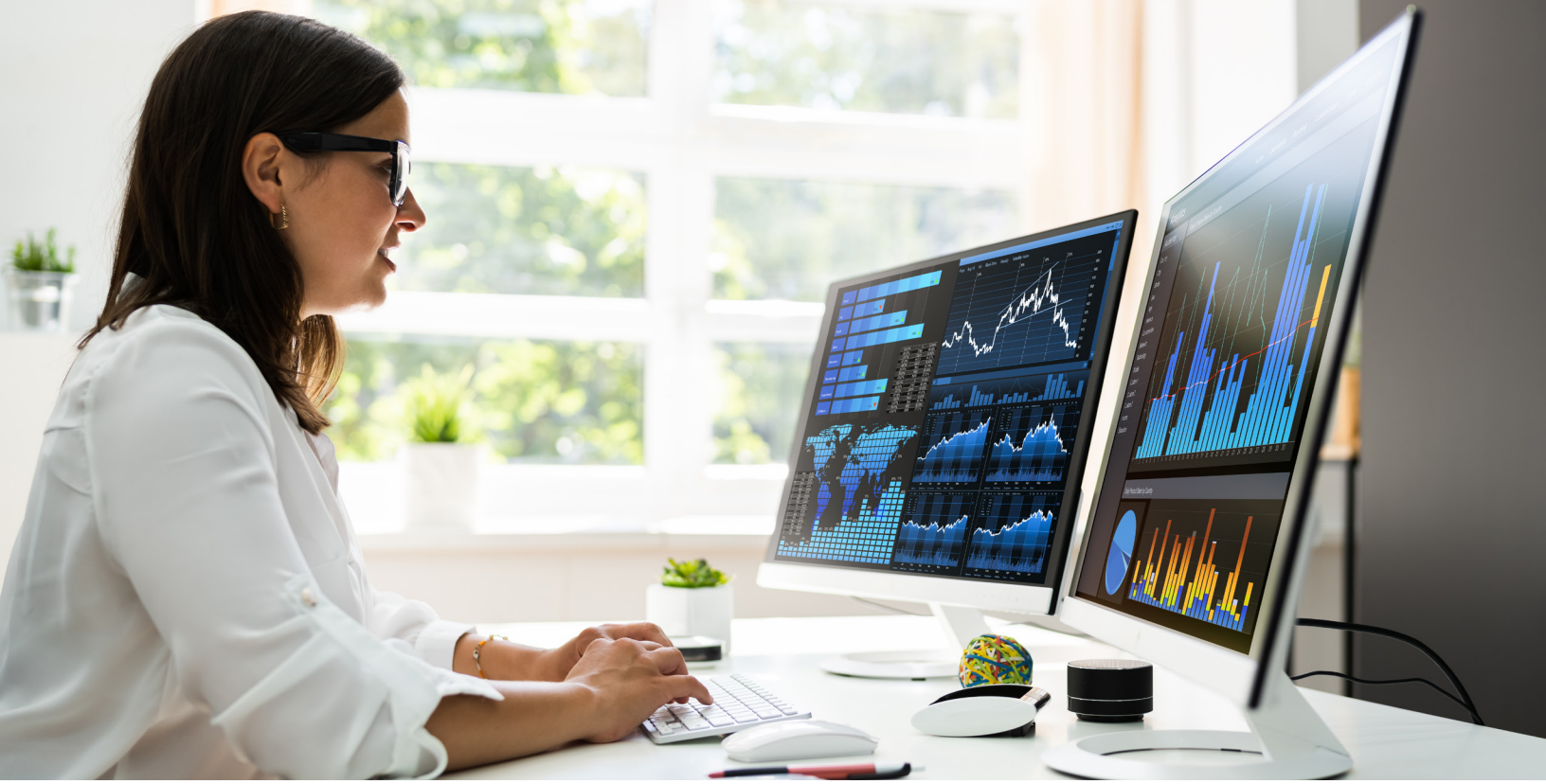
In contrast to others who compared generative AI to a misbehaving child that needs to be closely watched, Novas likened ChatGPT to a smart, but sometimes misguided, graduate student. He said that the graduate student can produce helpful work, but you need to pay close attention to this work and you definitely can't turn in this work as your own, because you could get in trouble.

"The change management piece cannot be emphasized enough."

— Mark Novas, Moderna

Mark Novas offered thoughts on 10 considerations for organizations related to implementing generative AI:

1. **Have a very specific use case** for generative AI that solves a specific, practical problem. This use case creates focus and provides a business case for the investment of time and money.
2. **Data quality and standardization is critical**. It is important to collect data in a way that can be analyzable by a computer.
3. **Integrate data scientists** into the problems you are trying to solve.
4. **Consider regulatory compliance.** Regulators are struggling with how to keep up and with how to regulate AI. Meanwhile, those who manage compliance within life sciences companies are reluctant to embrace change. Regulation is an area where industry needs to come together and push to help standardize around future regulations.
5. **Ensure continuous validation** to confirm the outputs being provided are the outcomes that are desired.
6. **Train humans on prompt engineering**. Moderna invests to have senior leaders attend courses to become good at writing prompts.
7. **Keep a human in the loop.**
8. **Scalability.**
9. **Interoperability.**
10. **Engage in change management.** As with other major change efforts, get senior-level buy-in, move slowly to generate incremental wins that show value, and celebrate wins along the way.



In reflecting on the **10 considerations for implementing generative AI** shared by Novas, Uwe Trinks advised organizations not to expect or require perfection when implementing generative AI. He said, "Perfect is the enemy of good, and what we need is good enough."

The panelists see many innovative applications emerging for generative AI in pharmacovigilance. Among the applications mentioned was the use of generative AI by pharmacovigilance teams in compiling the data and creating a first draft of the requisite filing documents. While humans on the team would still need to review and edit this draft, generative AI could save considerable time and could help jumpstart the document preparation for the filing process. Similarly, generative AI could help in creating investigator's brochures (IBs) and protocols, as well as any other type of regulatory document required for a pharmacovigilance workflow.

AI is also seen as having great value in improving clinical efficiency and outcomes. AI can provide early signal detection, as there are already AI tools that can review X-rays faster and more effectively than humans. Trinks sees AI providing value in any situation where a large amount of data needs to be quickly reviewed to inform insights. He believes AI will take on the grunt work currently operated by humans, therefore allowing humans to spend their time on more valuable aspects of managing the drug lifecycle.

"I think that organizations should look at the costs from a long-term investment perspective."

— Nneka Okere, Nurix Therapeutics

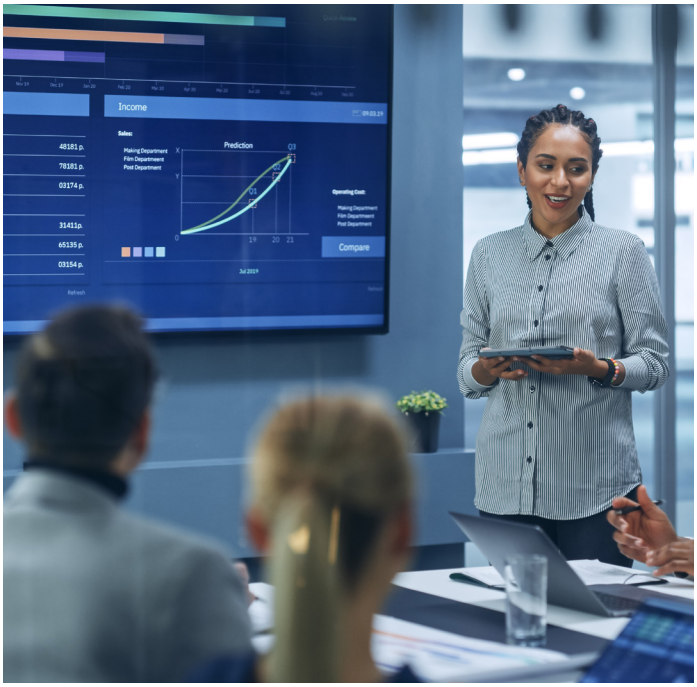
Key takeaways

- Changes in the pharmacovigilance landscape are affecting life sciences company priorities.
- Based on the complexities of today's pharmacovigilance landscape, life sciences companies have increased their use of digital tools and are now considering generative AI.
- While there are benefits to implementing generative AI as part of pharmacovigilance workflows, there are also multiple challenges.
- Responsible AI implementation is important for sponsors and end users.
- There are multiple strategies that life sciences companies need to undertake to facilitate a smooth integration of generative AI into their pharmacovigilance workflows.
- The panelists see many innovative applications emerging for generative AI in pharmacovigilance.

Conclusion

While there has been tremendous hype surrounding AI and generative AI, there are real-world opportunities to use generative AI to improve the field of pharmacovigilance, and these opportunities will continue to grow. Generative AI has the potential to save time in creating IBs, protocols, and regulatory filings, while improving and expediting signal management.

However, adoption and implementation of generative AI presents challenges and risks that must be managed. To provide value, generative AI needs to be used on specific use cases to solve specific problems. It requires human oversight with a "human in the loop," as well as continuous validation. And issues such as data privacy, data quality, integration, and cost all must be considered.



While the challenges and risks are significant, there is optimism these challenges can be addressed and the risks can be managed. It is unrealistic to expect generative AI to be perfect, but even if imperfect, it can still represent a significant improvement from the current state and will only provide greater value over time.

"You need to have a human in the loop who constantly looks at the AI model and corrects it."

— Uwe Trinks, IQVIA

About the authors

ALISON SLOANE
General Manager,
IQVIA Vigilance Detect

As general manager of IQVIA's Vigilance Detect, Alison Sloane's focus is on driving the vision to provide customers with a tech-enabled optimized approach to adverse event and safety risk detection in structured and unstructured data. Sloane has 25 years of Pharmacovigilance experience across clinical trials, post marketing, endpoint management, regulatory reporting, and line management.

Sloane's PV leadership roles included European leadership of a pharmacovigilance unit, global leadership of clinical endpoint management and adjudication, and global leadership of regulatory reporting. Responsibilities involved growing the teams, building out and optimizing processes, introducing automation and AI, and directing the operational, contractual, financial, and customer-facing aspects of the Pharmacovigilance organization.

Sloane graduated from Trinity College, Dublin, Ireland, with an Honors degree in natural science and an MSc and a diploma in statistics. Since 2016, Sloane's roles have been focused on PV automation and innovation, leveraging her 20+ years of safety experience.

UWE TRINKS
Global Practice Lead,
Pharmacovigilance Technologies,
IQVIA

Uwe Trinks, practice leader, PV technologies, IQVIA, has over 35 years of life sciences experience. Prior to joining Foresight Group in 2009 and its acquisition by IQVIA in 2017, Trinks served as the CIO of Sentrx, where he led hosting and managed services for over 25 Argus safety database instances for 10 years. Previously, he served as the executive director and head of research information management for Novartis Pharmaceuticals. He started his career as an oncology researcher at Ciba-Geigy in Basel, Switzerland. Trinks earned an M.S. in organic chemistry and natural products chemistry, from the Federal Institute of Technology (ETH) in Zurich, Switzerland and a Ph.D. in organic chemistry also from the Federal Institute of Technology (ETH). He has also completed postdoctoral research in biochemistry at Stanford University in Palo Alto, California.

HUA CARROLL
MD, Senior Director, Biogen

Hua Carroll obtained her M.D. degree from Beijing Medical University, and practiced as an OB/GYN. She has 20+ years' experience in the pharmaceutical industry, and holds a unique skill set that straddles pharmacovigilance (PV), safety operations, and medical safety. Her expertise includes ICSR case processing and medical assessment, safety signal detection, and benefit/risk management in both clinical and post-marketing settings. Carroll is passionate about artificial intelligence in PV to improve data quality and consistency, and thereby, ultimately improve patient safety. Carroll is a recognized PV leader in industry and is invited to participate in industry forums to share her expert opinion. She is also a member of the CIOMS Working Group XIV Artificial Intelligence in Pharmacovigilance.

NNEKA OKERE
Senior Director, Pharmacovigilance, Nurix Therapeutics

Nneka Okere is the director of pharmacovigilance (PV) at Nurix Therapeutics. She is a registered nurse with master's degrees in nursing and healthcare administration and has over 10 years of PV experience in different therapeutic areas including oncology, cell therapy, and rare disease. Okere has experience developing PV systems and processes, leading PV teams responsible for all PV activities for multi-phase studies, vendor selection and oversight, and global case management. She enjoys volunteering her time to mentor internal and external colleagues and currently serves as the co-chair of the communications committee for Women in Bio (WIB), Philadelphia Chapter, and an advisory member for California State University Women in Leadership program.

To learn more, contact **SafetyPV@iqvia.com** today.

MARK NOVAS
MD, VP, Medical Safety & Risk Management, Moderna

Mark Novas is a seasoned biopharmaceutical medical executive with 17+ years of broad global experience in pharmacovigilance/drug development, medical safety and risk management, and medical affairs. He is currently VP, clinical safety & risk management, at Moderna. He is also the co-founder of the techbio startup CartaBio and sits on the board of directors at Cerboriva Biotechnology. He's worked across many therapeutic areas (cardiovascular, respiratory, immunology/inflammation, neurology, oncology, and rare diseases) on multiple innovative medicine.

After completing his residency at Mayo Clinic, Novas initially practiced medicine as a flight surgeon in the USAF supporting the flying mission and the Euro-Nato Joint Jet Pilot Training program. He subsequently grew his industry career and expertise in roles of increasing responsibility at Amgen, Biogen, Alexion, and Agios. Through his different tenures, Novas has led global teams with broad accountability, has authored numerous medical publications and has received multiple awards and honors throughout his career.

Novas received his MD at the University of Texas and his MBA at MIT Sloan School of Management.

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