The Next Frontier in Patient Safety

The Emerging Role of AI, Machine Learning, and LLMs in Pharmacovigilance

Shivdeep Singh
THE PEN & PROTOCOL

Insights from *Cobert's Manual of Drug Safety and Pharmacovigilance, 4th Edition (2025)*

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The Emergency Room of the Company

Exploding Data Volume: Millions of adverse event reports annually create a "large sea of available information."

Regulatory Complexity: Increasing "divergences in the US and EU" and "enormous fragmentation and duplication of efforts" create a challenging global landscape.

High Stakes: The constant pressure to protect public health and the ethical obligation to "do safety" right.

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Finding the Signal in the Noise

In the US, in 2022... 2.3 million [reports were] sent to the manufacturers who then forwarded these cases to the FDA.

With this volume, how do we find the 'proverbial needle in the haystack' faster and more reliably than through traditional 'global introspection'?

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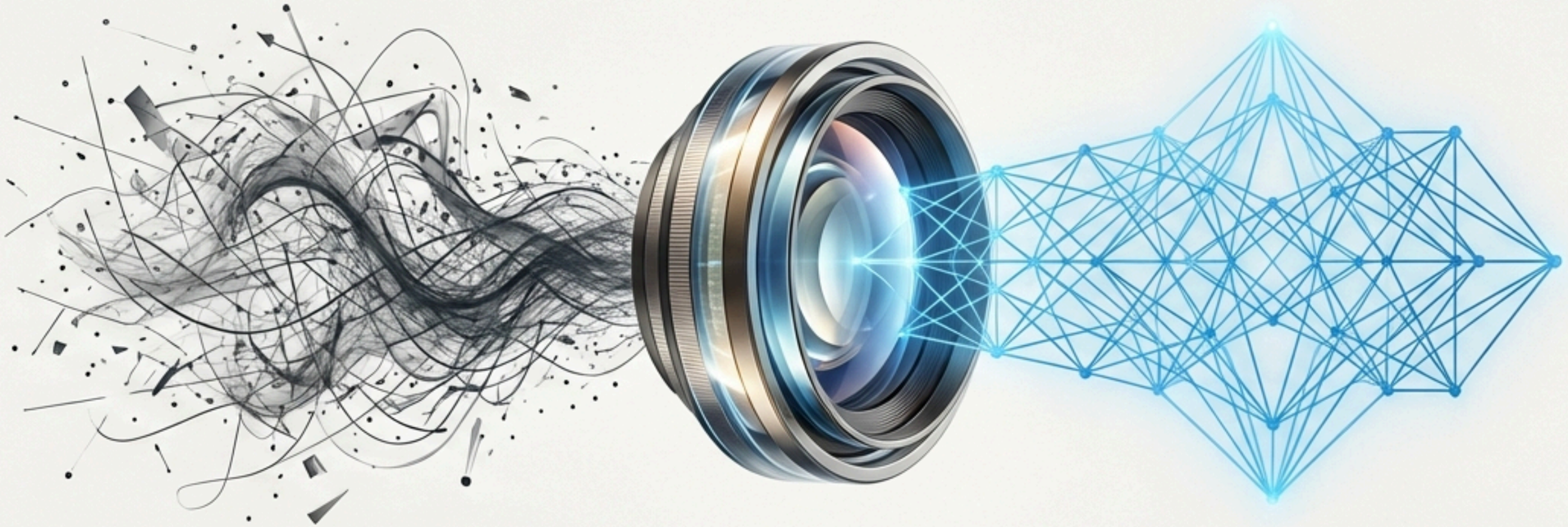
A Necessary Evolution



Artificial Intelligence is moving from the fringe to the forefront, offering practical solutions for core PV tasks.

“Artificial intelligence is an obvious domain which will bring solutions for some PV tasks... PV will look enormously different in 5 or 10 years.” — Cobert’s Manual

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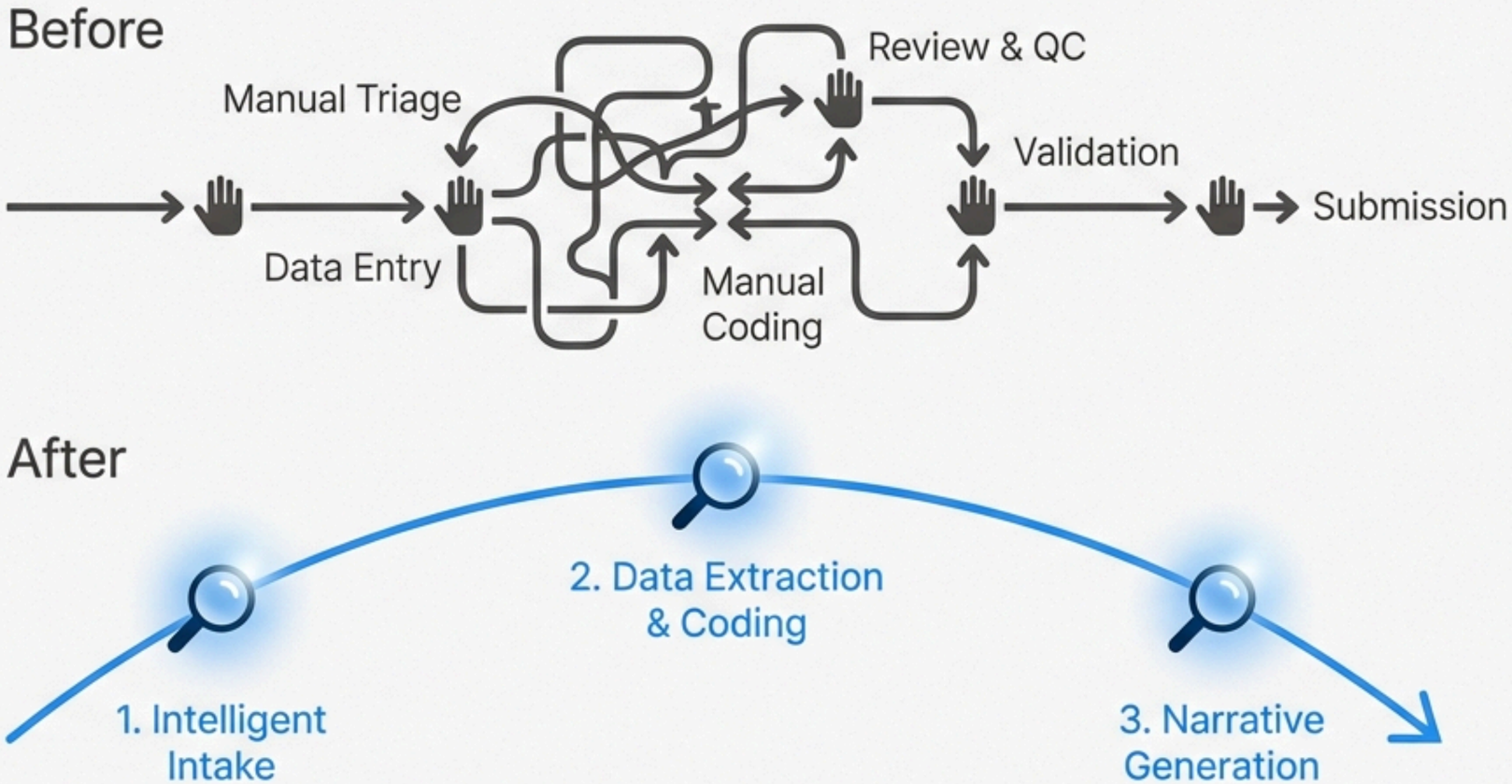
From Manual Effort to Automated Insight in Case Processing



The Benefit:
Drastically improved efficiency, higher data quality, and faster time-to-submission, freeing human experts for higher-value analysis.

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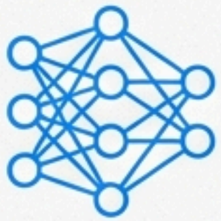
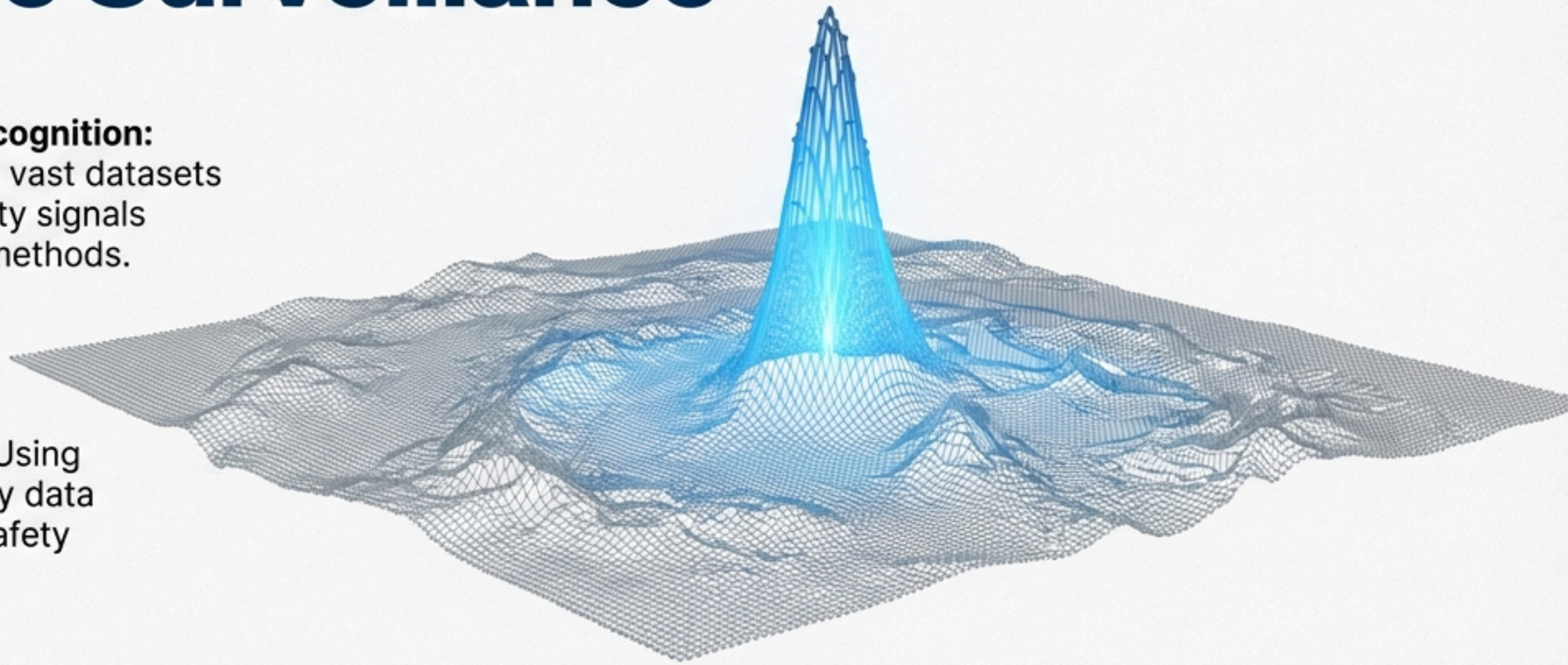
Supercharging Signal Detection for Proactive Surveillance



Advanced Pattern Recognition: ML algorithms analyze vast datasets to uncover subtle safety signals missed by traditional methods.

Predictive Modeling: Using pharmacoepidemiology data to forecast potential safety issues.

Automated Systematic Reviews: A research technique that collects, assesses, and summarizes empirical evidence.



The Benefit: A fundamental shift from a reactive to a proactive safety posture, enabling earlier detection and intervention.

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The Future PV Professional: Your New Co-Pilot

AI augments, not replaces, human expertise. The focus of the professional shifts from repetitive tasks to analysis, strategy, and decision-making.

Future-Ready Skills:

- Critical evaluation of AI outputs
- Data science and analytics literacy
- Strategic benefit-risk assessment
- Regulatory and ethical oversight

“Jobs will change, disappear and new ones will open up. Needed skill sets will change.” — Cobert’s Manual

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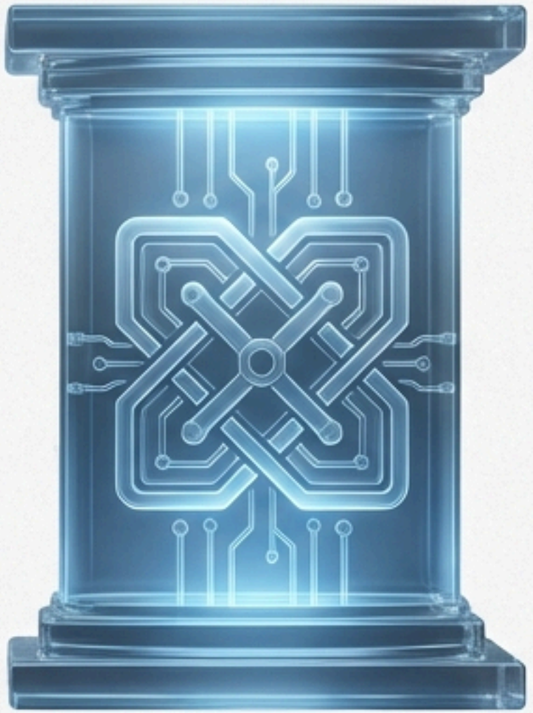
A Call for Responsible Innovation

Regulatory Acceptance

Regulatory Acceptance: Aligning AI validation with health authority expectations.

Model Transparency

Model Transparency: Avoiding “black box” issues and understanding the “why” behind an AI’s conclusion.



Data Privacy & Security

Data Privacy & Security: Ensuring compliance with global regulations like GDPR and HIPAA.

Ethical Oversight

Ethical Oversight: Guarding against algorithmic bias and manipulation by “malevolent individuals.”

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Enhancing Patient Safety at Scale

From Reactive
→ **Proactive**

From Manual
→ **Intelligent**

From Overloaded
→ **Empowered**

By embracing AI as a strategic partner, Pharmacovigilance can fulfill its core mission more effectively than ever before—protecting public health and ensuring the safe and effective use of medicines for all.

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“Hopefully, readers, especially those not in the field, will understand that drug safety, like all other areas of medicine, is as much an art as it is a science.”

— *Cobert’s Manual of Drug Safety and Pharmacovigilance*

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