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IN THIS ISSUE

How Close Are We to 100% AI-Driven Workflows?

by Dr. Balaji Ommurugan

Pharmacovigilance (PV) is undergoing a massive transformation, with AI, automation, and advanced analytics reshaping workflows. While a fully touchless PV system—where AI manages safety monitoring without human intervention—is the ultimate goal, we are still in a hybrid phase where AI enhances human efficiency but does not fully replace expert oversight.

The pharmaceutical industry, regulators, and AI developers are working towards 100% automation, but critical challenges remain. So, how far are we from fully AI-driven pharmacovigilance workflows?

Let's explore the current state of automation, remaining challenges, and the road ahead.

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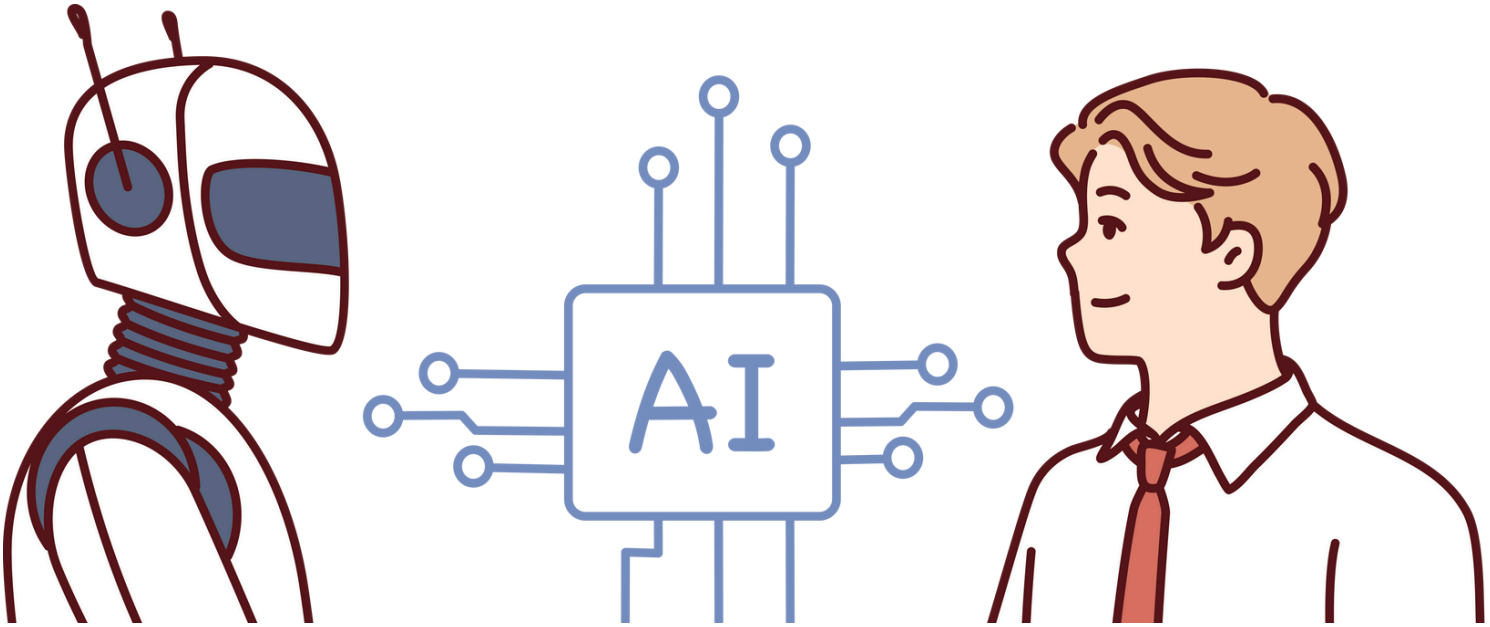


How AI is Changing Case Management

by Dr. Balaji Ommurugan

The Individual Case Safety Report (ICSR) is a cornerstone of pharmacovigilance, ensuring the timely reporting of adverse drug reactions (ADRs) to regulators. Traditionally, ICSR processing has been manual and labor-intensive, requiring extensive human effort for data extraction, validation, and causality assessment. With Artificial Intelligence (AI), Natural Language Processing (NLP), and Machine Learning (ML), ICSR management is evolving into a highly automated process, reducing processing time, minimizing errors, and improving efficiency. However, full automation remains a challenge, as human expertise is still needed for complex cases.

The Traditional ICSR Workflow: A Labor-Intensive Process

Before automation, ICSR processing involved multiple manual steps, including:

Case Intake & Data Extraction:

- Collecting ADR reports from electronic health records (EHRs), emails, PDFs, call centers, and social media
- Extracting patient, drug, event, and reporter details

Case Validation & Data Structuring:

- Checking for completeness and consistency
- Converting unstructured case data into structured E2B(R3)-compliant formats

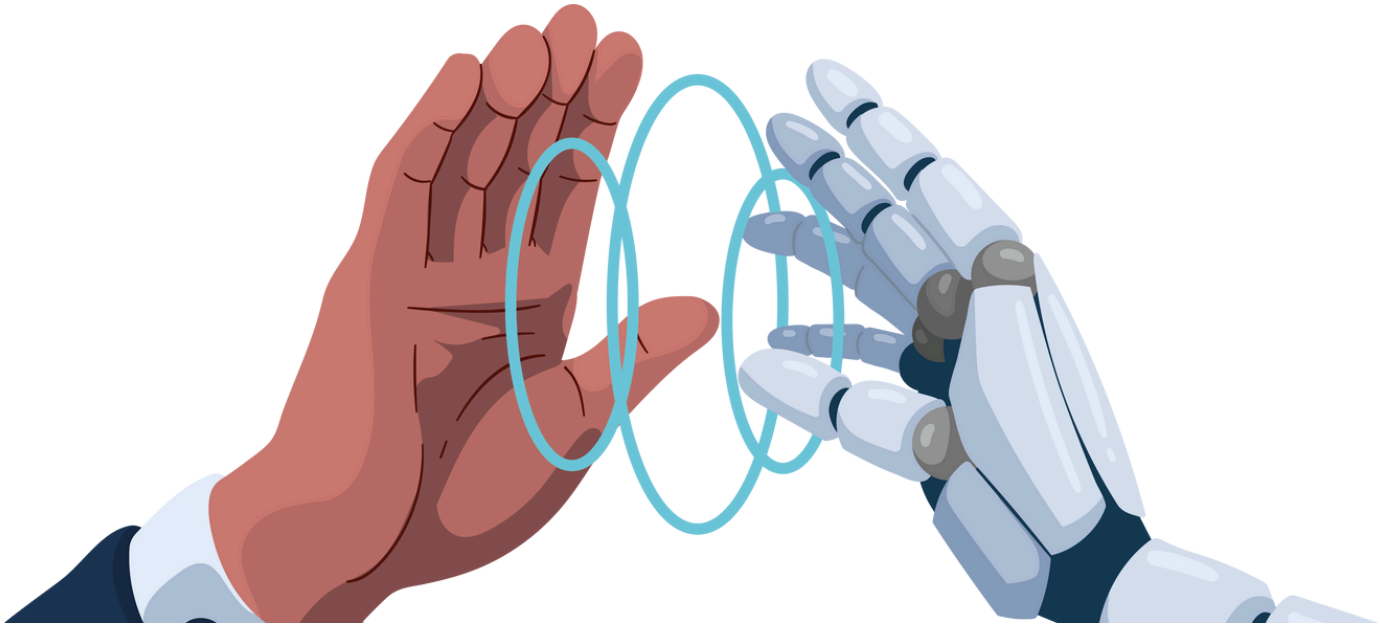
Causality Assessment & Medical Review:

- Assessing drug-event relationships using WHO-UMC or Naranjo scale
- Reviewing the case for seriousness, expectedness, and regulatory compliance

Case Submission & Reporting:

- Formatting and submitting reports to regulatory agencies (FDA, EMA, MHRA, PMDA, TGA, etc.)
- Ensuring timely expedited reporting (15-day/7-day rules)

Problem: Manual processing is time-consuming, error-prone, and expensive, often leading to delays in safety signal identification.



AI-Driven ICSR Processing: How Far Have We Come?

AI is now automating each stage of ICSR processing, reducing workload by 80% in some areas. Here's how:

AI in Case Intake & Data Extraction

Current Automation Level: ~85%,AI-driven tools extract ADR details from unstructured data sources, including:

- EHRs & medical records (via AI-based text recognition)
- Emails, PDFs, and faxed documents (via Optical Character Recognition - OCR)
- Call center recordings (via Speech-to-Text AI)
- Social media & patient forums (via NLP sentiment analysis)
- AI eliminates duplicate case entries using entity recognition models

NLP classifies and maps extracted data to structured E2B(R3) fields, ***What's Next?,*** Future AI models will improve multilingual ADR extraction from global sources, enabling real-time case intake & automatic data structuring.

AI in Causality Assessment & Medical Review

- Current Automation Level: ~65%
- AI evaluates causality using machine learning models trained on historical ADR cases
- NLP extracts clinical context from case reports & medical literature
- AI generates preliminary case assessments, reducing workload for medical reviewers

***Challenges Remaining*:**

- AI cannot replace clinical judgment for complex cases (e.g., rare ADRs)
- Regulatory agencies still require human validation for causality decisions

What's Next?

- AI will integrate real-world evidence (RWE) & patient health data for better causality predictions
- Explainable AI models will increase regulatory acceptance

AI in Case Submission & Regulatory Reporting

Current Automation Level: ~90%.

- AI ensures E2B(R3) & ICH compliance for automated submissions
- AI formats cases and submits them directly to FDA, EMA, MHRA, PMDA, TGA
- AI-driven alerts ensure timely reporting (e.g., 7-day expedited cases)

Challenges Remaining:

- AI cannot self-audit or explain compliance deviations
- Regulators require human oversight before final case submission

What's Next?

- AI-powered self-auditing tools for regulatory deviation detection
- More automated regulatory reporting frameworks for seamless compliance

The Future of AI in ICSR Processing: Towards Full Automation

- Current AI-powered automation in ICSR processing: ~80%
- Remaining challenges: AI explainability, regulatory trust, and complex case interpretation
- The Future: AI + Human Hybrid Model → Gradual Shift Towards Full Automation.

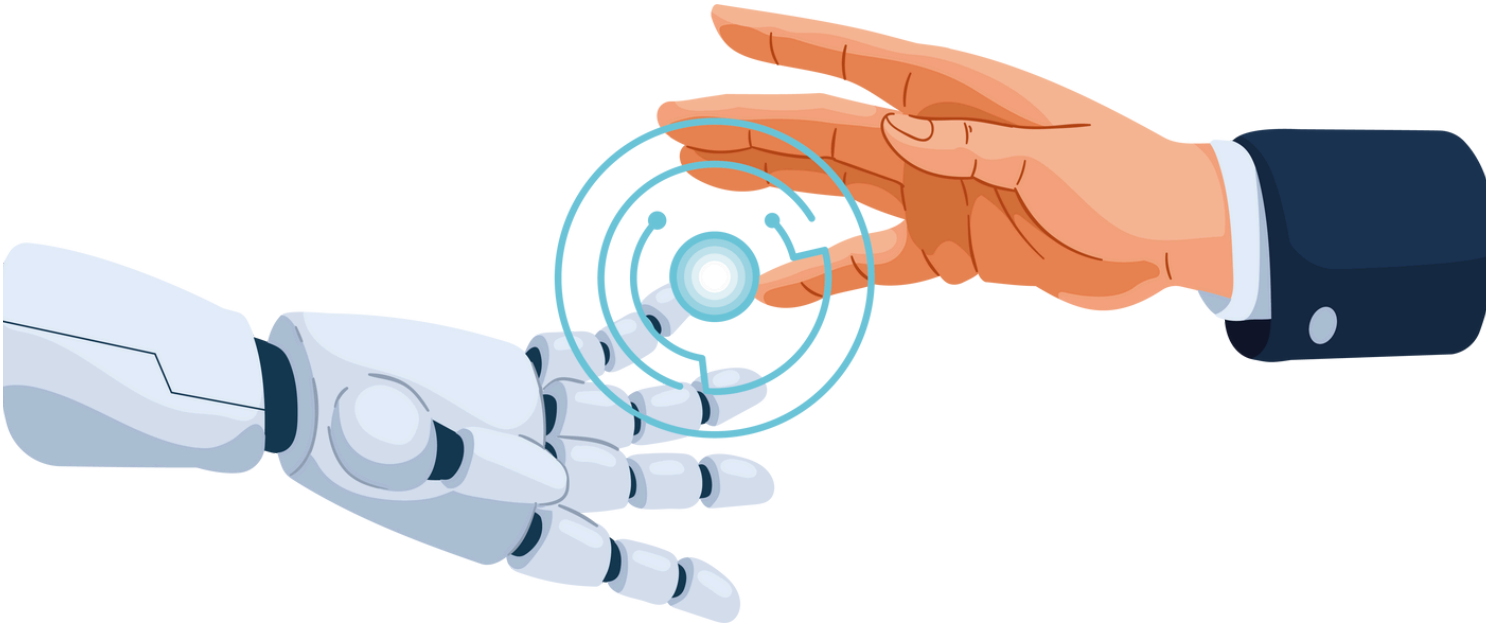
What Will AI-Driven ICSR Processing Look Like in 5 Years?

- 100% automated case intake (AI-driven real-time ADR extraction)
- Self-learning AI for causality assessment (AI models trained on large clinical datasets)
- Fully automated reporting systems (Regulatory-approved AI for submissions)

However, regulatory agencies still require human oversight, so hybrid AI-human workflows will continue in the near future.

Final Thought:

AI is not replacing PV professionals but making their work more efficient, accurate, and scalable. The goal is not to eliminate human oversight, but to enable smarter, faster, and more reliable drug safety monitoring.



Literature Screening: 90% Automation & What's Next?

by Dr. Balaji Ommurugan

Pharmacovigilance (PV) relies heavily on scientific literature as a critical source for identifying adverse drug reactions (ADRs), emerging safety signals, and regulatory intelligence. Regulatory agencies like the European Medicines Agency (EMA) and U.S. Food and Drug Administration (FDA) mandate pharmaceutical companies to conduct continuous, systematic literature monitoring to detect potential safety concerns.

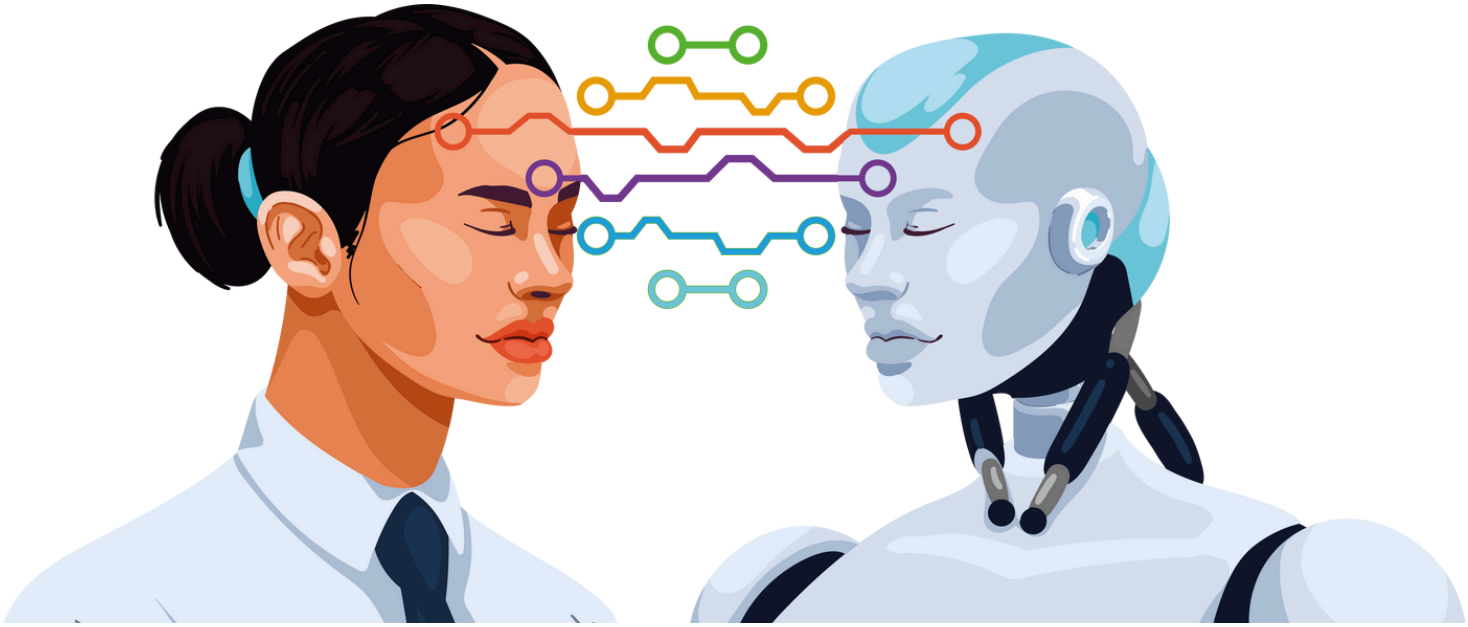
Traditionally, literature screening was a manual, time-consuming process, requiring PV teams to sift through thousands of articles across multiple databases (e.g., PubMed, Embase, Scopus, Google Scholar) to identify relevant safety information. Today, Artificial Intelligence (AI), Natural Language Processing (NLP), and Machine Learning (ML) have automated nearly 90% of the literature screening process, significantly reducing workload and improving efficiency.

But how does AI automate literature screening, and what challenges remain? Let's break it down.

Traditional Literature Screening: A Manual & Time-Intensive Process

Before automation, PV professionals had to

- Manually search multiple scientific databases for drug safety-related articles
- Filter articles based on drug names, adverse events, and pharmacovigilance relevance
- Manually review abstracts and full-text papers to assess safety signals
- Extract key data (e.g., drug-event relationships, patient demographics, outcomes)
- Check for duplicates and categorize reports based on regulatory requirements
- Document findings and report



AI-Powered Literature Screening: How Automation Works

AI now automates 90% of literature screening, using NLP, ML, and deep learning to process large volumes of literature in real-time.

AI-Powered Literature Search & Filtering

Current Automation Level: 95%

AI continuously monitors multiple literature sources, including:

- Scientific journals (PubMed, Embase, Scopus, Web of Science)
- Regulatory agency reports (EMA, FDA, WHO newsletters, MHRA Yellow Card reports)
- Preprints and open-access papers
- Social media & patient forums (for real-world evidence monitoring)

AI automatically filters articles based on:

- Drug name (Generic & Brand)
- Adverse event keywords (MedDRA-coded terms)
- Indications & safety outcome

NLP-based AI ensures real-time surveillance, reducing manual searching efforts

Challenges Remaining:

AI still struggles with ambiguous terminology and variations in drug names across regions.

What's Next?

Advanced context-aware AI will improve keyword recognition for drug synonyms and cross-language searches.

AI in Abstract & Full-Text Review

Current Automation Level: 85%

NLP models scan article abstracts & full-text papers to:

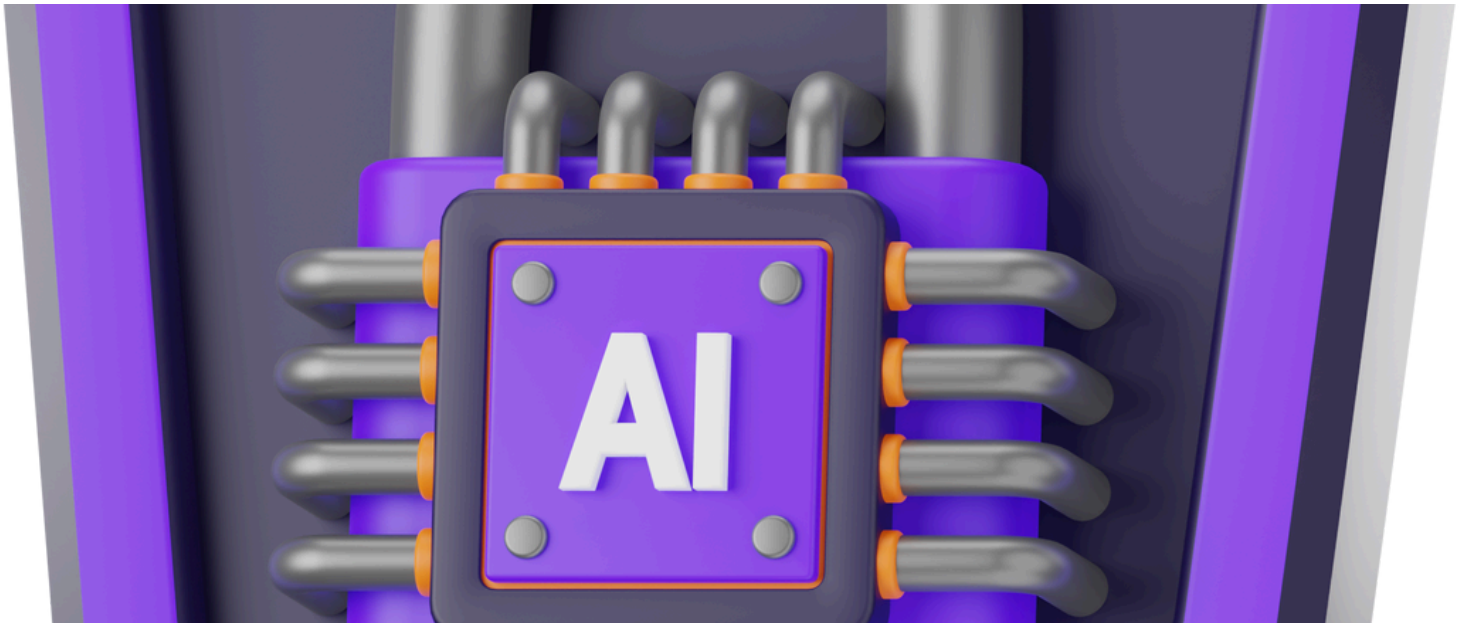
- Identify drug-event relationships
- Classify case reports based on causality, severity, and seriousness
- Detect off-label drug usage & emerging risks
- AI-based summarization helps PV professionals quickly assess articles
- Deep learning models score articles based on relevance & priority

Challenges Remaining:

- AI sometimes misclassifies articles (e.g., distinguishing between clinical studies vs. case reports)
- Multilingual articles (e.g., Japanese, Chinese, Russian) require specialized NLP models

What's Next?

- Multilingual NLP models will improve cross-border literature screening
- AI will be trained to better distinguish between research studies & case reports



AI in Adverse Event Extraction & Data Structuring

Current Automation Level: 80%

AI extracts key safety data from articles, including:

- Drug name, dose, and administration details
- Adverse event type, severity, and outcome
- Patient demographics (age, gender, medical history)
- Causality assessment (e.g., WHO-UMC scale, Naranjo algorithm)
- AI automatically maps extracted data to E2B(R3) formats for regulatory compliance

Challenges Remaining:

AI still struggles with rare or unexpected ADRs that lack structured reporting and
Some complex medical phrases require human interpretation

What's Next?

Knowledge Graphs & AI-driven context analysis will improve extraction of complex drug-event relationships

AI in Duplicate Detection & Signal Prioritisation

Current Automation Level: 90%

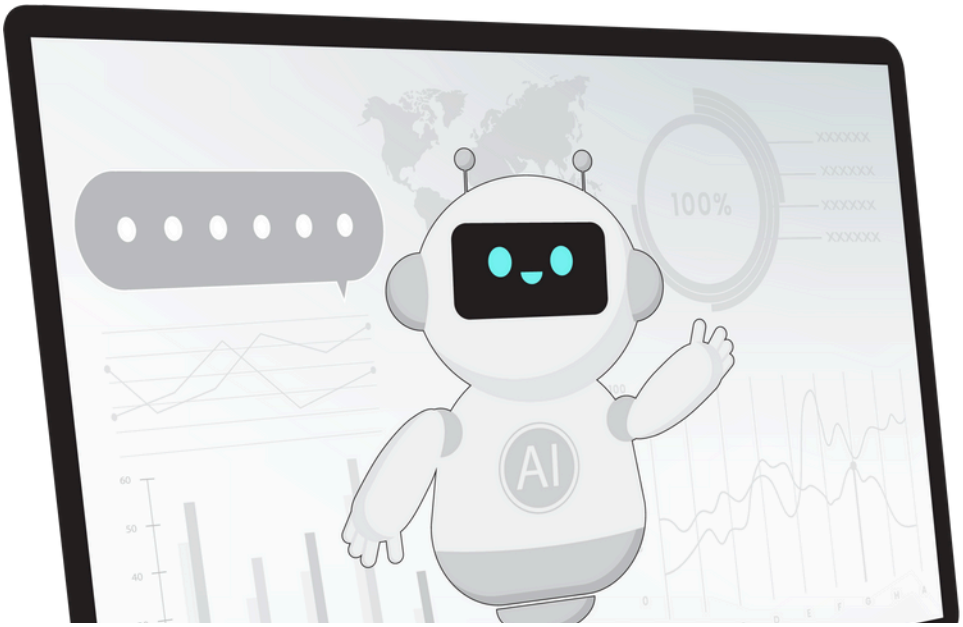
- AI detects duplicate case reports across multiple literature sources
- NLP & ML models prioritize high-risk signals for immediate review
- AI generates preliminary signal detection reports for PV teams

Challenges Remaining:

AI cannot yet independently validate a new safety signal without human oversight

What's Next?

AI-driven causal inference models will enhance signal validation & risk scoring



AI in Literature-Based Signal Detection &

Current Automation Level: 85%

AI automatically flags potential safety signals and integrates them into:

- Signal detection workflows
- Periodic Safety Update Reports (PSURs) & Periodic Benefit-Risk Evaluation Reports (PBRERs)
- Regulatory submissions (EMA, FDA, MHRA, PMDA)
- AI generates draft safety reports for final human validation

Challenges Remaining:

AI-generated reports still require human review before submission

What's Next?

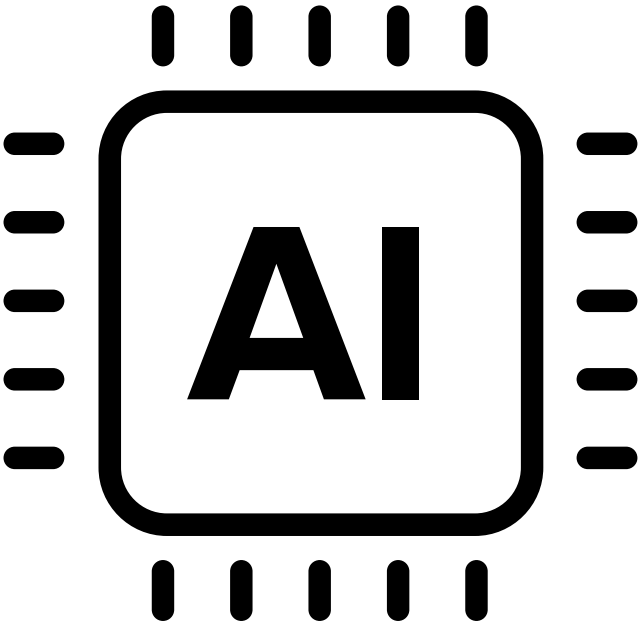
Regulatory-approved AI models will reduce the need for manual validation

What's Next for AI in Literature Screening?

- AI will integrate real-world data (EHRs, patient forums) for better risk assessment
- Deep learning will refine signal detection by linking literature data with global ADR databases
- Regulatory agencies will eventually approve AI-driven literature monitoring for automated compliance

Final Thought:

- AI is not replacing PV professionals but making literature screening faster, smarter, and more reliable.
- The goal is to eliminate human inefficiencies, not human expertise.



AI in Signal Detection: Strengths & Gaps in Current Models

by Dr. Balaji Ommurugan

Signal detection is a critical component of pharmacovigilance (PV), ensuring early identification of potential adverse drug reactions (ADRs). Traditional signal detection relies on disproportionality analysis (DPA), Bayesian methods, and manual case reviews, which are often slow, labor-intensive, and prone to human error. With the rise of Artificial Intelligence (AI), Machine Learning (ML), and Natural Language Processing (NLP), AI-powered signal detection tools can now process vast amounts of spontaneous adverse event reports, literature data, and real-world evidence (RWE) to identify, assess, and prioritize safety signals faster than ever before. However, current AI models still face key limitations that prevent full automation and regulatory trust. This article explores the strengths and gaps in today's AI-driven signal detection models and what's next for the future of AI in PV.

Strengths: How AI Enhances Signal Detection

AI Handles Large Data Volumes with Speed & Precision

AI processes millions of safety reports in seconds, unlike manual review, which can take weeks. AI integrates multiple data sources for signal detection, including:

- Spontaneous reporting databases (FAERS, EudraVigilance, VigiBase)
- Electronic Health Records (EHRs) & claims data
- Social media & patient forums (for early detection of consumer-reported ADRs)
- Scientific literature & clinical trial reports

Example:
AI models can scan FAERS (FDA Adverse Event Reporting System) and detect a pattern of liver toxicity linked to a new drug within minutes, whereas traditional methods might take months.
Remaining Challenge: AI still struggles with data quality issues, such as incomplete, duplicate, or misreported adverse events.

AI Enhances Disproportionality & Statistical Analysis

AI-driven disproportionality analysis (DPA) goes beyond traditional methods like:

- Proportional Reporting Ratio (PRR)
- Reporting Odds Ratio (ROR)
- Empirical Bayesian Geometric Mean (EBGM)
- Information Component (IC - Bayesian approach)
- AI-powered deep learning models improve on these methods by adjusting for confounders, reducing false positives, and identifying complex drug-event relationships.

***Example*:**

AI models can adjust for co-medications and underlying diseases, helping to avoid false associations.

***Remaining Challenge*:** AI models still require human oversight to validate whether a statistical signal is clinically relevant.

AI Improves Qualitative Signal Detection

AI-powered Natural Language Processing (NLP) extracts safety insights from:

- Case narratives in safety reports
- Scientific literature
- Regulatory agency reports & social media

***Example*:**

NLP scans medical case reports and detects that multiple patients experienced acute kidney injury after taking a specific antibiotic, even though traditional statistical methods didn't flag the issue.

AI can perform causal inference analysis by connecting:

- Drug exposure
- Patient history
- Reported adverse events

***Example*:**

An AI model identifies that a new oncology drug causes heart arrhythmias only in patients with a history of hypertension, highlighting a specific risk factor.

***Remaining Challenge*:**

AI still struggles with ambiguous, unstructured, and multilingual data that require manual review.

AI Reduces False Positives & Prioritizes True Safety Signals

AI can rank safety signals based on:

- Clinical relevance (serious vs. non-serious ADRs)
- Frequency & recurrence
- Biological plausibility (mechanistic link to the drug)
- Regulatory importance

Example:

AI prioritizes drug-induced liver injury (DILI) signals over non-serious skin rashes, ensuring urgent cases get immediate attention.

Remaining Challenge:

AI cannot yet replace expert judgment in deciding whether a signal is truly actionable.

Gaps: Challenges in Current AI Signal Detection Models

AI Struggles with Data Quality & Standardization

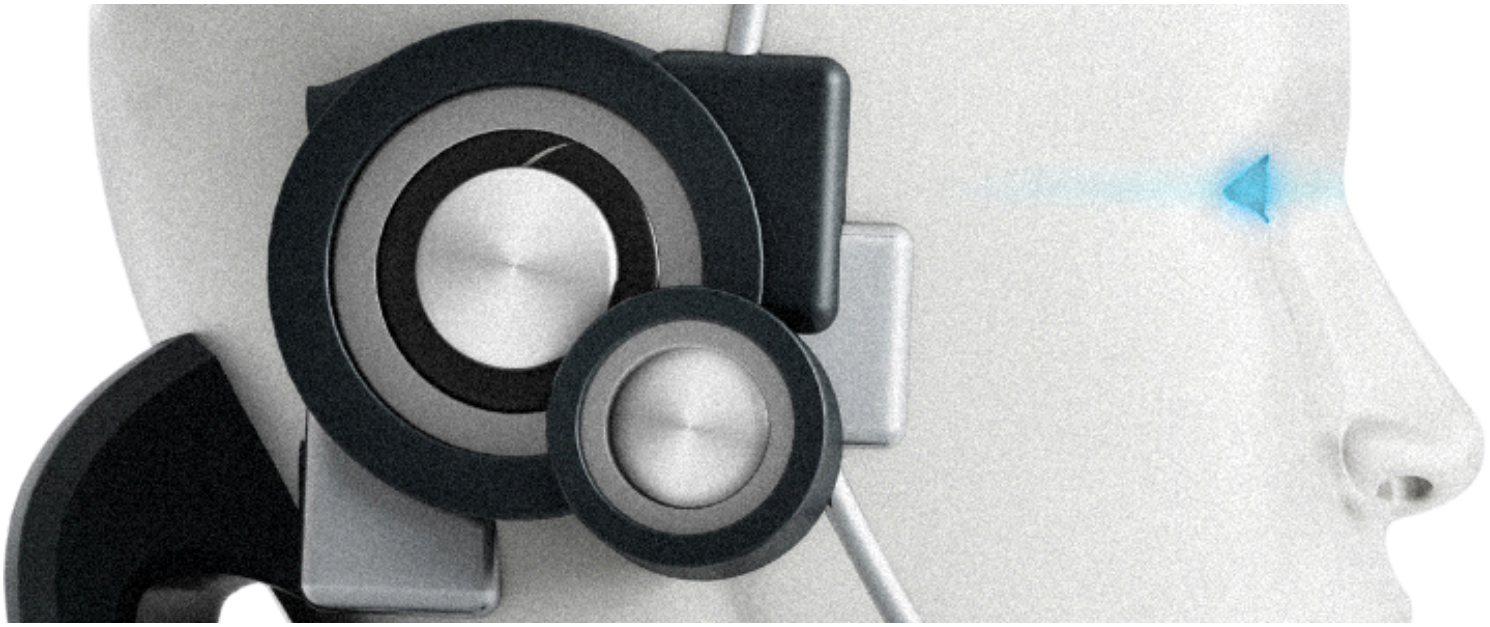
- Many adverse event reports are incomplete, duplicated, or misclassified, making it difficult for AI to extract accurate insights.
- Variability in terminology, drug names, and coding systems (MedDRA, WHO-DD) creates inconsistencies.

Example:

The same adverse event might be reported as “hepatic failure,” “liver toxicity,” or “elevated liver enzymes”, confusing AI models.

Solution:

AI models need better data cleaning, deduplication, and standardization algorithms to improve accuracy.



AI Lacks True Causal Inference Capabilities

AI identifies correlations but struggles to prove causation.

AI cannot distinguish between:

- A true ADR
- An event caused by underlying disease
- A reaction due to drug interactions

Example:

AI detects a signal linking antidepressants to increased suicidal ideation, but is the drug causing it, or is depression itself the risk factor?

Solution:

AI needs to incorporate causal inference models to separate true safety signals from background noise.

AI Struggles with Rare or New Adverse Events

- AI requires large datasets to detect patterns, meaning rare ADRs are often missed.
- Emerging safety risks (e.g., COVID-19 vaccine myocarditis cases) are harder for AI to predict.

Example:

AI struggled to detect early cases of myocarditis linked to mRNA COVID-19 vaccines because the data was limited and evolving.

Solution:

AI should integrate real-world data (EHRs, insurance claims, patient registries)to improve detection of rare safety signals.

Regulatory Agencies Do Not Fully Trust AI-Generated Signals

- EMA, FDA, and MHRA require human validation of AI-generated signals.
- AI lacks transparency, making it hard for regulators to understand how decisions were made.

Example:

A black-box AI model flags drug-induced seizures, but regulators need explainable AI to confirm why the signal is real.

Solution:

AI models need explainability, auditability, and regulatory validation before full adoption.

What's Next for AI in Signal Detection?

Future Enhancements for AI Models

- AI-powered knowledge graphs to map drug-disease-event relationships
- Multi-source integration combining FAERS, EHRs, literature, and social media
- Explainable AI (XAI) for transparent decision-making
- Automated signal validation workflows to reduce human intervention

The Path to Fully Automated Signal Detection

- AI currently automates 80% of the signal detection process
- The next step is regulatory-approved AI models with human oversight gradually reducing over time

Final Thought:

AI is revolutionizing signal detection, but it is not replacing human experts yet. The future lies in AI-human collaboration, ensuring faster, more accurate, and regulatory-compliant pharmacovigilance.

Regulatory Compliance & Reporting: How Close Are We to Full Automation?

by Dr. Balaji Ommurugan

Pharmacovigilance (PV) and drug safety regulations have become increasingly complex, requiring pharmaceutical companies, contract research organizations (CROs), and healthcare providers to ensure compliance with ICH, FDA, EMA, MHRA, and other global regulatory agencies. Traditionally, regulatory compliance and reporting have been manual, labor-intensive, and prone to human error. Companies must collect, process, validate, and submit reports for Individual Case Safety Reports (ICSRs), Periodic Safety Update Reports (PSURs), Risk Management Plans (RMPs), and Signal Detection Reports—a process that demands high accuracy, timeliness, and strict adherence to guidelines. With Artificial Intelligence (AI), Machine Learning (ML), and automation technologiesevolving, the question arises: How close are we to fully automating regulatory compliance and reporting? In this article, we explore the current state of automation, its benefits, challenges, and the future of AI-driven pharmacovigilance compliance and reporting.

Current State of Automation in Regulatory Compliance & Reporting

Automated Adverse Event Reporting (ICSR Processing)

Regulatory agencies require companies to submit Individual Case Safety Reports (ICSRs) for adverse drug reactions (ADRs). Traditionally, this process involved:

- Manual data entry and case assessment
- Medical review by human experts
- Formatting according to E2B(R3) standards
- Submission to regulatory agencies

Current AI-powered automation allows:

- Natural Language Processing (NLP) to extract key information from medical records, literature, and patient reports.
- Robotic Process Automation (RPA) to standardize ICSRs in E2B(R3) format for regulatory submission.
- Automated medical review using AI-driven causality assessment models.

Example:

AI-based ICSR tools can now process, validate, and submit case reports to regulatory agencies with 80% automation, reducing the burden on pharmacovigilance teams.

Remaining Challenge:

Full automation is not yet possible, as expert human oversightis still needed for complex cases.

Periodic Reporting: PSURs, PBRERs, and RMPs

Pharmaceutical companies must submit Periodic Safety Update Reports (PSURs) and Risk Management Plans (RMPs), which involve:

- Compiling safety data from clinical trials, post-marketing surveillance, and real-world evidence (RWE)
- Identifying new risks and benefit-risk updates
- Creating narrative summaries and justifications for safety concerns

Current AI automation in periodic reporting includes:

- AI-driven data aggregation from multiple sources (EHRs, safety databases, literature, FAERS, VigiBase, EudraVigilance).
- Automated benefit-risk analysis using ML algorithms to detect safety trends.
- NLP-based summarization of safety concerns for regulatory reporting.

Example:

AI-powered tools can now generate draft PSURs and RMPs with 60-70% automation, significantly reducing the manual workload.

Remaining Challenge:

Regulatory agencies still require expert interpretation, as AI cannot fully replace human decision-making in safety assessments.

Signal Detection & Automated Regulatory Submissions

Signal detection involves:

- Monitoring adverse event databases
- Identifying emerging safety signals
- Conducting quantitative and qualitative signal assessments
- Submitting risk assessment reports to regulators

Current AI-powered automation in signal detection:

- Automated disproportionality analysis (DPA) using PRR, ROR, EBGM, IC.
- Qualitative AI models to assess causality and prioritize signals.
- Real-time API-based reporting to regulatory databases.

Example:

AI-driven signal detection systems can now flag safety concerns faster than human analysts, allowing for early regulatory intervention.

Remaining Challenge: Full automation is difficult due to data variability, causality complexities, and the need for regulatory trust in AI-generated signals.

Benefits of AI-Driven Automation in Regulatory Compliance & Reporting

Faster Report Generation & Submission

- AI reduces PSUR, RMP, and ICSR processing times by over 70%.
- Automated tools can generate reports in real-time, ensuring regulatory compliance deadlines are met.

Improved Data Accuracy & Compliance

- AI-powered data validation tools reduce errors in E2B(R3) formatting.
- NLP-based data extraction improves case completeness and prevents duplicate reporting.

Cost Savings & Workforce Optimization

- Automating repetitive tasks allows PV professionals to focus on risk assessment and decision-making.
- Reduces the need for large case processing teams, leading to significant cost savings.

Better Risk Management & Proactive Compliance

- AI-driven signal detection enables proactive safety monitoring, reducing regulatory penalties.
- Real-time adverse event tracking allows for early intervention before safety crises occur.

Challenges Preventing Full Automation

Lack of Regulatory Trust in AI

- Regulatory agencies require human oversight to validate AI-generated reports.
- AI-driven decision-making is still a black box, making it difficult to audit.

Variability in Data Quality

- Incomplete, inconsistent, and duplicated adverse event reports can mislead AI models.
- Differences in regulatory requirements across regions make automation challenging.

Limited AI Causal Inference Capabilities

- AI struggles to differentiate correlation from causation, leading to false positive signals.
- Expert interpretation is still needed for final risk assessments.

Future of Full Automation in Regulatory Compliance & Reporting

AI-Powered Regulatory Compliance Assistants

AI-driven virtual compliance agents will assist companies in interpreting regulations and generating compliance reports automatically.

End-to-End Cloud-Based Automation

Integrated AI systems will connect EHRs, safety databases, literature sources, and regulatory portals for seamless real-time compliance reporting.

Blockchain for Compliance & Auditability

Blockchain will provide secure, tamper-proof regulatory records, increasing trust in AI-driven compliance systems.

Explainable AI for Regulatory Approval (XAI)

Future AI models will be fully transparent, allowing regulators to audit AI-driven decisions.

Conclusion: Are We Ready for Full Automation?

- Current AI-driven automation covers 70-80% of regulatory compliance tasks but still requires human oversight for final validation and risk assessment.
- The next step is to develop fully explainable AI models that regulators can trust for automated decision-making.
- Within the next 5-10 years, AI-driven compliance reporting will be 90-95% automated, with real-time submissions and proactive risk management.

However, full automation will require overcoming regulatory skepticism, improving AI explainability, and standardizing global compliance frameworks.

The Future of AI-Driven PV: Emerging Technologies & Path to Full Automation

by Dr. Balaji Ommurugan

AI-Enhanced Causal Inference for Safety Assessments

One of the biggest challenges in pharmacovigilance (PV) is differentiating correlation from causation. Future AI models will integrate causal inference techniques, such as:

- Knowledge Graphs & Ontologies: AI will connect drug-adverse event relationships using structured biomedical knowledge.
- Bayesian Networks & Probabilistic Graphical Models: These methods will help AI determine the likelihood that a drug truly caused an adverse event.
- AI-Driven Real-World Evidence (RWE): Future AI systems will analyze vast amounts of real-world data (EHRs, claims data, patient registries) to strengthen causal assessments.

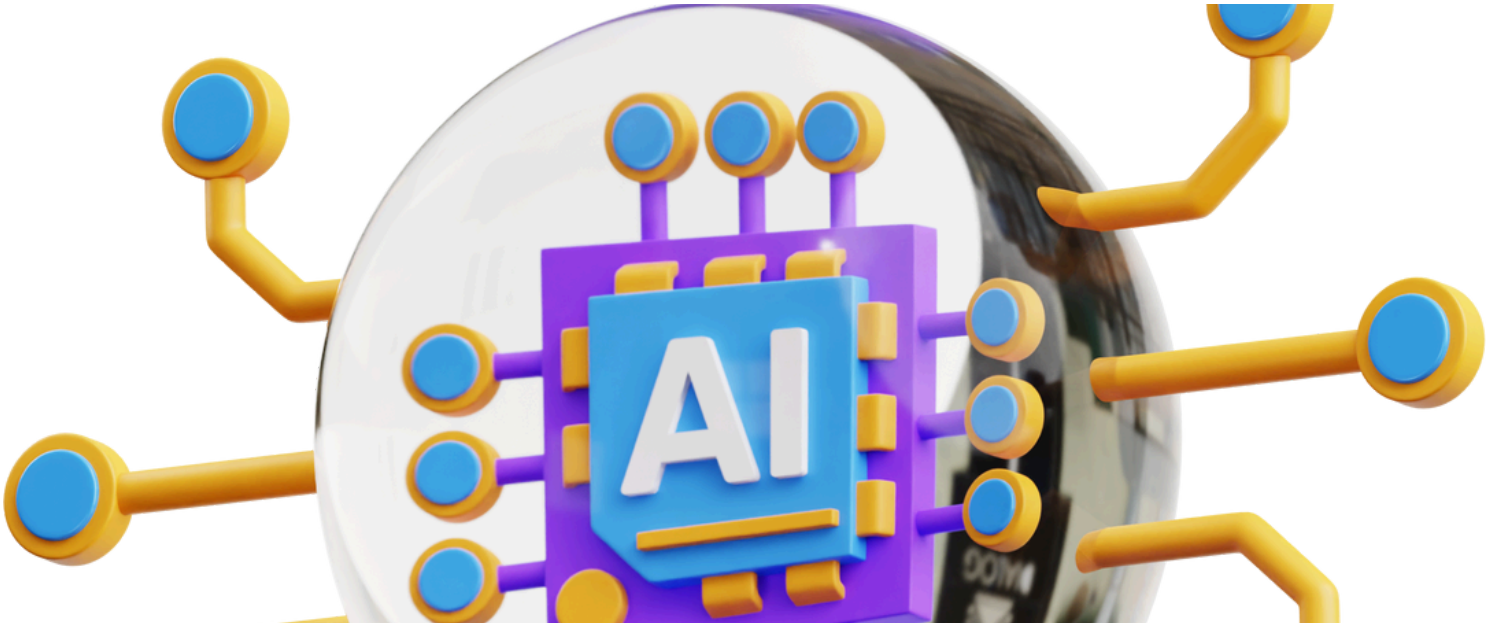
Impact:
AI will provide scientifically justified causal links, reducing reliance on manual expert review.

Explainable AI (XAI) for Regulatory Acceptance

AI-driven pharmacovigilance must be explainable, auditable, and compliant with global regulatory frameworks. Emerging solutions include:

- Interpretable Machine Learning (IML): AI will generate human-readable justifications for adverse event assessments.
- Regulatory AI Sandboxes: Controlled environments where regulators test AI-driven PV systems before approving them for real-world use.
- AI-Augmented Regulatory Submissions: AI will draft PV reports with embedded audit trails for transparency.

Impact:
Trustworthy AI will accelerate regulatory adoption and facilitate automated compliance validation.



Blockchain & Federated Learning for Secure, Decentralized PV Data

As data privacy laws (GDPR, HIPAA, PIPL) tighten, AI-based PV systems will shift toward secure, decentralized architectures:

- Blockchain for Immutable PV Records: Ensuring tamper-proof audit trails for adverse event reporting and safety signals.
- Federated Learning: AI models will learn from distributed pharmacovigilance data without centralizing patient information, maintaining data privacy.
- Self-Sovereign Identity (SSI) for Adverse Event Reporting: Patients will have control over their health data while still contributing to global safety monitoring.

Impact:
AI-driven PV will be privacy-compliant, secure, and globally integrated, enabling real-time adverse event monitoring.

AI-Driven Global Data Standardization & Harmonization

Currently, PV data is fragmented across multiple regulatory bodies and reporting systems. Future AI innovations will focus on:

- Automated Data Mapping & Standardization: AI will harmonize data across FAERS, VigiBase, EMA EudraVigilance, MHRA Yellow Card, and national databases.
- Ontology-Based NLP for Multi-Language Case Processing: AI-driven translation and standardization will improve case identification across global markets.
- Unified AI-Powered PV Platforms: AI will integrate regulatory datasets, clinical trial data, and real-world evidence (RWE) into a single pharmacovigilance intelligence system.

Impact:
AI will enable real-time, standardized, cross-border pharmacovigilance, eliminating data silos.

Autonomous AI Agents for End-to-End PV Automation

By 2035, we may see the rise of autonomous AI agents capable of handling full-cycle pharmacovigilance operations, including:

- Self-Learning PV Systems: AI will continuously update itself based on new regulations and safety signals.
- AI-Powered Regulatory Negotiation Assistants: AI will interact directly with health authorities for safety submissions and clarifications.
- Real-Time AI Surveillance of Drug Safety: AI will autonomously flag potential risks before they escalate into safety concerns.

Impact:
AI-driven PV will shift from reactive (detecting safety issues after they occur) to proactive & predictive pharmacovigilance.

The Future: AI-Augmented, Not AI-Replaced PV

While full automation is on the horizon, the most realistic future is an AI-augmented pharmacovigilance system where:

- AI handles 95% of routine PV tasks
- Humans supervise AI-driven decisions for compliance & ethics
- AI becomes a trusted partner rather than a replacement

The Next Decade:
AI will make PV smarter, faster, and safer—but human oversight will always remain for regulatory and ethical validation.

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