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AI in Post-Approval Drug Safety: Effective Management of Real-World Patient Data

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Drug safety challenges don't stop once a therapy completes clinical trials and reaches the market. Surprises in emerging safety profiles can derail promising programs even after a drug is approved. Today, artificial intelligence (AI)-powered models are helping pharmacovigilance (PV) teams detect these risks faster through the streamlining of post-approval safety data management.

Much of the early adoption of AI in PV has focused on using large language models (LLMs), hybrid data extraction pipelines, and human-in-the-loop oversight in the processing of post-market safety data. These solutions are often deployed at scale through functional service provider (FSP) partnerships between pharmacovigilance service providers and drug developers.

Through a combination of expertise in both PV and AI/automation, FSP partners bridge domain knowledge and advanced technology to bring about optimal solutions. FSP partners provide specialized systems and expertise to manage safety data pipelines in an accurate and compliant manner, supporting biopharma and biotech companies who wish to avoid the overhead of building internal infrastructure.

What's changed: From manual safety workflows to AI-enabled processing

Historically, safety teams have had to work with scattered, inconsistent, and often unstructured data (adverse event forms, literature articles, web screenshots), consuming significant time and resources that could be better applied to critical safety assessments and decision-making.

Today, AI ingests safety-relevant content across formats (structured database outputs, semi-structured forms, and unstructured text), then extracts and normalizes key fields for downstream integration into the safety database. A hybrid approach that validates high-volume structured sources while using LLM-supported extraction for the long tail of unstructured inputs offers an ideal blend of approaches.

Two catalysts have lowered barriers to AI adoption over the last five years. First, the unprecedented case volumes seen during the COVID-19 vaccine rollout highlighted the limits of manual review and forced affected organizations to deploy AI tools to process these reports efficiently and accurately. Second, growing access to LLMs has made automated extraction of insight from unstructured content dramatically more feasible. FSP partners can help drug developers with lower case volumes, where internal AI implementation otherwise would be cost-prohibitive. They can also quickly deploy AI solutions across programs, increasing confidence and ensuring more consistency.

Practical steps for AI-enabled post-approval safety

Successfully implementing AI for post-market safety requires workflows that are actionable, auditable, and scalable. Engaging an experienced FSP partner can help accelerate adoption by providing specialized expertise, standardized processes, and oversight, ensuring these steps are implemented efficiently and effectively:

- **Start with high-impact data sources**
  Validate intake technology to ensure it captures the most common document formats first, then expand to LLM-assisted extraction for less common formats. This strikes the right balance between accuracy and flexibility at the earliest stages.
- **Design for explainability and oversight**
  AI outputs should remain human-readable and auditable. While AI can extract and normalize key safety information, trained PV professionals review the outputs and approve final entries into the safety database. This hybrid, human-in-the-loop workflow ensures all safety decisions are defensible, compliant, and traceable, supporting governance and regulatory requirements.
- **Model ROI with the real workflow in mind**
  AI requires setup and integration; detailed cost–benefit modeling should account for case sources, volumes, and complexity.
- **Plan for scale – and variability**
  Flexible configurations can adapt as programs evolve and document formats shift. This includes incorporating continuous validation of AI extraction outputs and periodic review of unstructured data sources to maintain accuracy over time.

Human-in-the-Loop Oversight: Ensuring Safe, Compliant AI Deployment

While the practical steps above establish the workflow, it is critical to maintain human oversight throughout the process to ensure data integrity, regulatory compliance, and clinical relevance.

FSP partners play a key role by combining domain knowledge with automation capabilities, providing both technical oversight and operational consistency. By pairing AI efficiency with PV

expert review, organizations can scale safely, maintain compliance, and maximize efficiencies for post-market safety monitoring.

Looking ahead: From downstream lessons to upstream advantage

AI-driven post-market safety is now operational in real-world PV systems. As workflows mature, AI continues to support earlier detection of potential safety risks while maintaining human oversight. Lessons learned in these downstream processes can inform future enhancements, such as smarter risk prioritization and semi-automated regulatory reporting. By pairing advanced technology with experienced personnel, companies can detect risks faster, protect patients, and ensure compliance, all while reducing operational burdens. Engaging experienced FSP partners helps companies overcome implementation challenges, scale AI tools efficiently, and maximize their value.