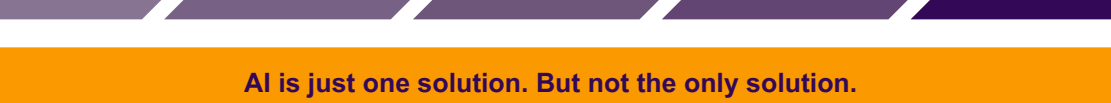


AI-ENABLED PHARMACOVIGILANCE: Practical Strategies for Smarter Safety Operations

AI is Everywhere. That Doesn't Mean it Belongs Everywhere.

Pharmacovigilance (PV) involves a lot of manual work. Information is often fragmented, and experienced people spend too much time gathering and moving it instead of applying their expertise to improve patient safety. AI could change that, but only if it genuinely improves the process.

Start With the Problem, Not the Technology



AI is just one solution. But not the only solution.



Process Redesign



Deterministic Automation



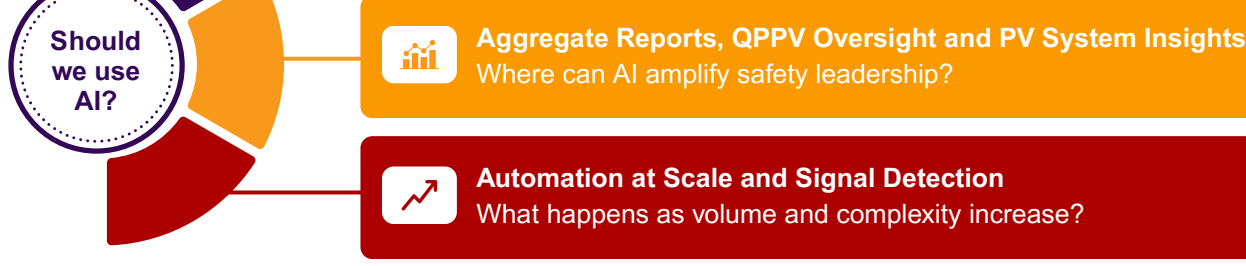
AI / Machine Learning (ML)



Human Expertise

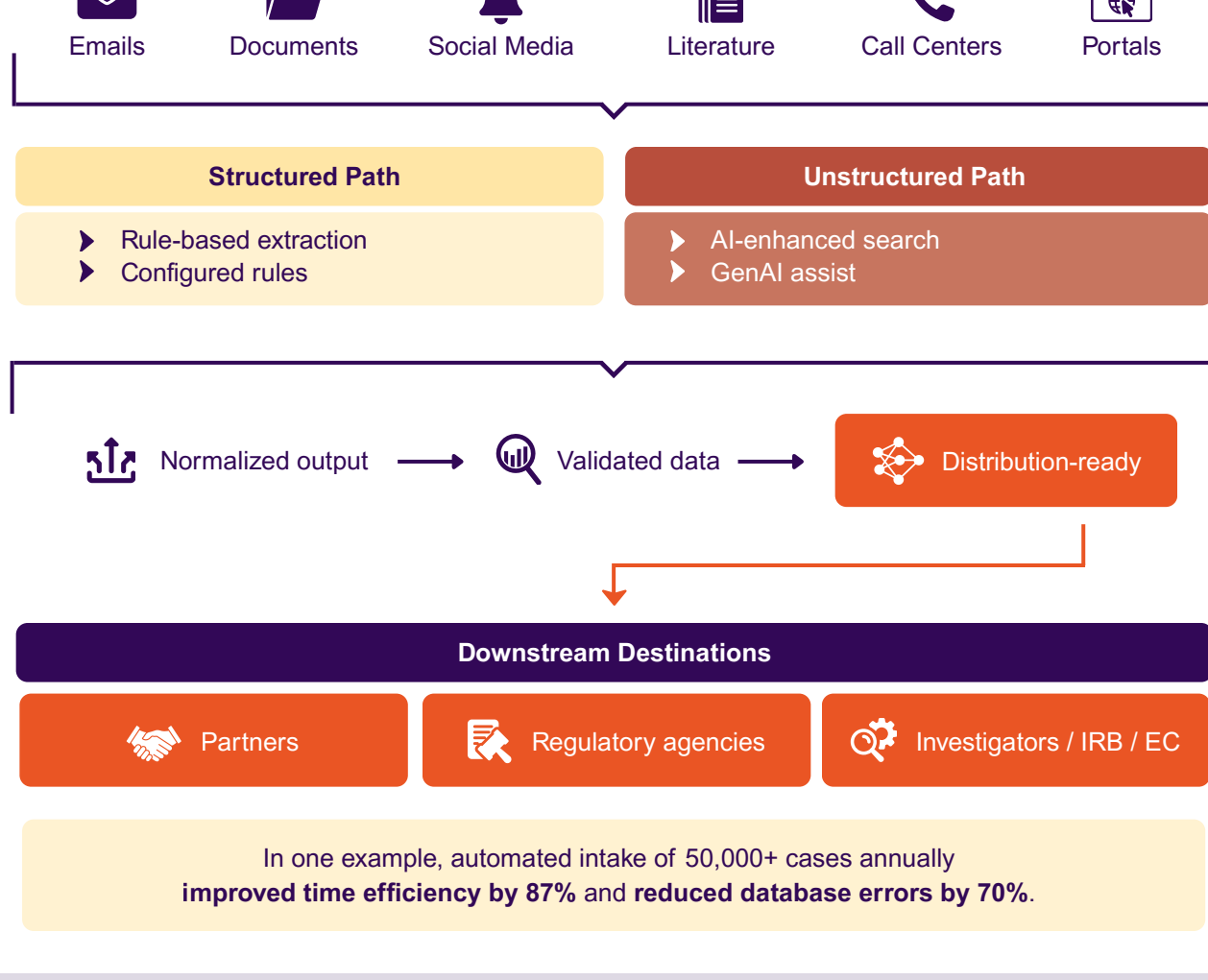
Putting AI to the Test

The right technology, level of human involvement and measure of success vary by problem. That human involvement includes critical oversight roles, such as the Qualified Person responsible for Pharmacovigilance (QPPV).



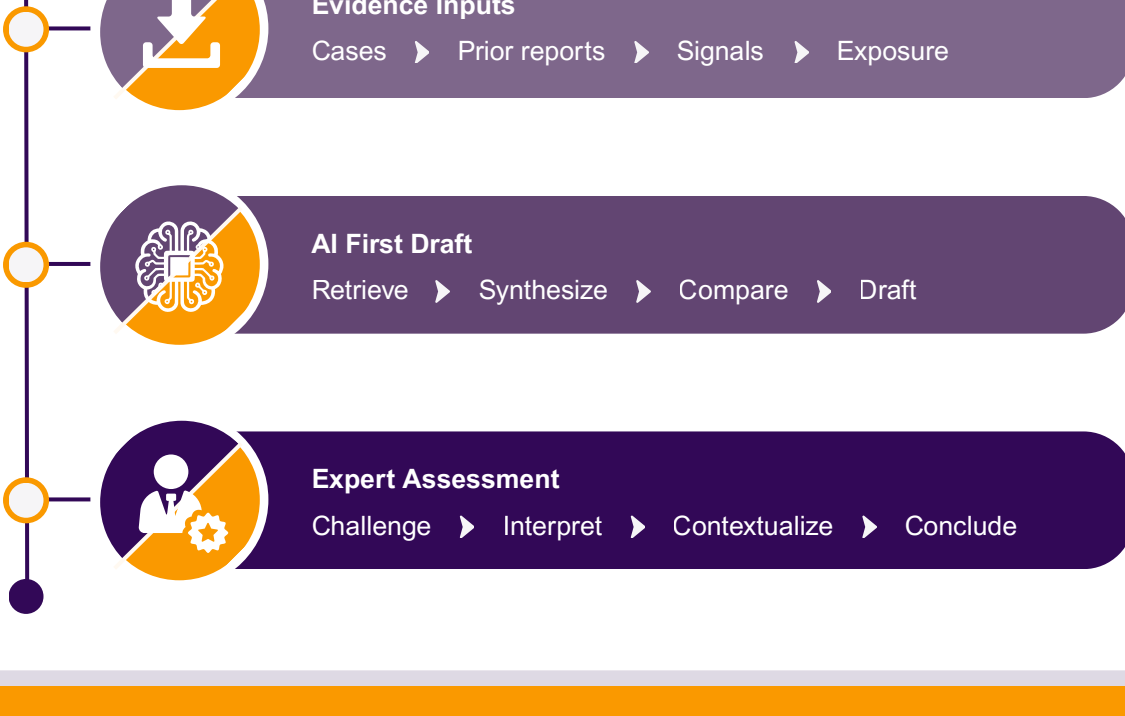
Case Intake & Operations

More safety information, formats and handoffs are increasing the manual burden of case intake. Rules and AI can help classify incoming information and prepare standardized data for downstream use.



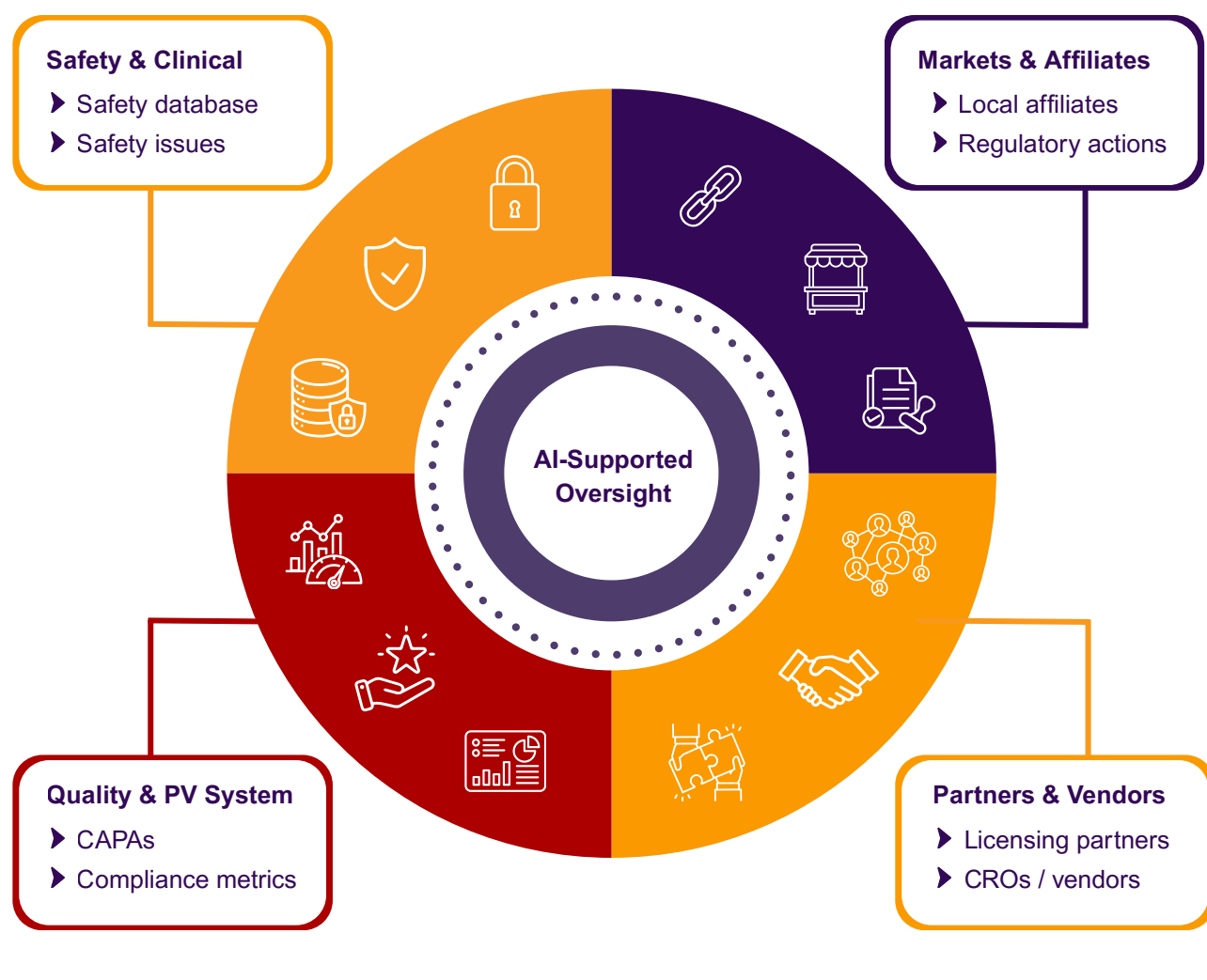
Aggregate Reports: Let AI Eliminate the Blank Page

AI can create the first draft, while safety experts review, challenge and interpret the evidence to reach the scientific conclusion.



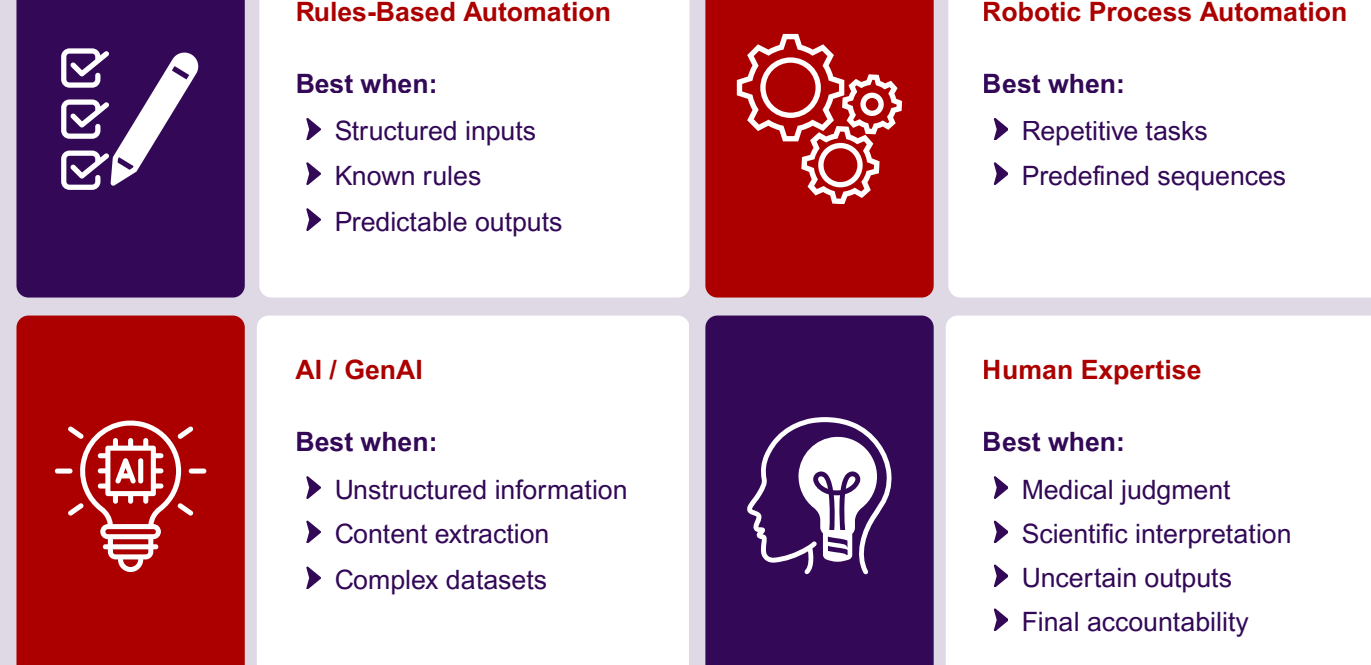
The QPPV Problem: Too Much Information, in Too Many Places

Relevant PV information can sit across databases, affiliates, partners, vendors and quality systems. AI can help connect it so QPPVs can find what needs attention faster.



AI Isn't Always the Smartest Automation

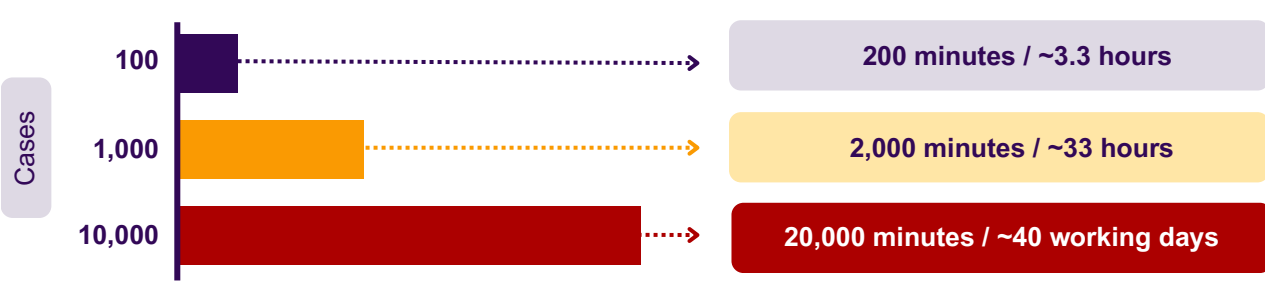
Choose the simplest, most reliable approach for the task, whether that is rules, RPA, AI or human expertise.



What Changes at Scale

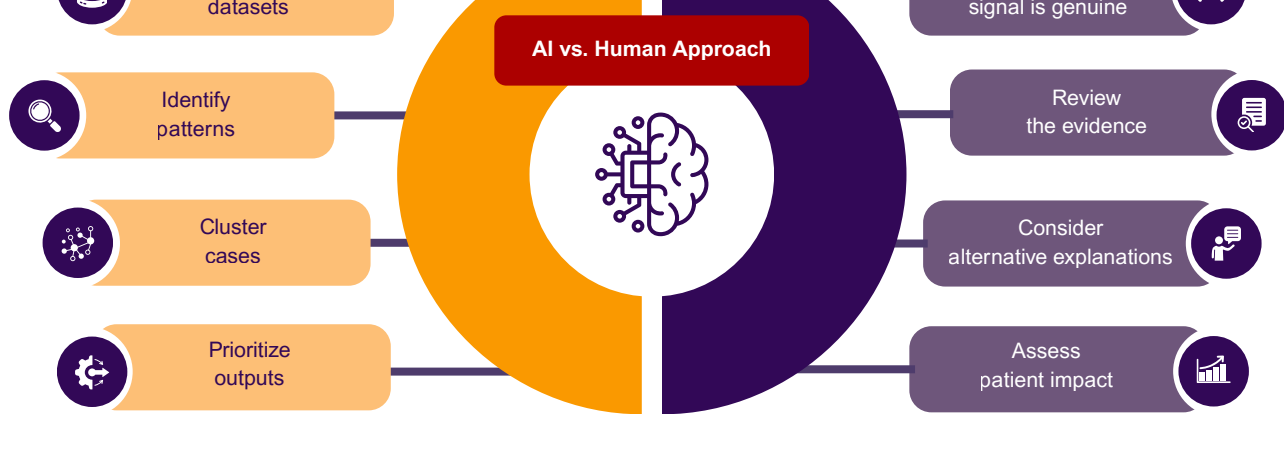
A workflow may be manageable at 100 cases and harder to sustain at 1,000 or 10,000.

What happens when a workflow adds just 2 extra minutes per case?



Signal Detection: Finding the Needle

Detection can be AI-assisted. Evaluation, scientific judgment and regulatory accountability remain human responsibilities.



AI can surface possible signals. Safety experts assess what they mean.

What Does Successful AI Adoption Look Like?

Measure What Changes in the Process

AI should improve the overall process in a way teams can see and measure. Teams can ask:

- ✓ Was the original problem clearly defined?
- ✓ Did the selected technology fit the task?
- ✓ Were clear controls and human responsibilities established?
- ✓ Did quality, speed, capacity or visibility improve?
- ✓ Was work reduced, or did it move elsewhere?

AI can shoulder repetitive, high-volume work. Scientific and medical judgment stays with the people responsible for patient safety.