Designing PV Systems for Humans and Agentic AI

Responsible system design for agentic AI in regulated Pharmacovigilance

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The Reality of Pharmacovigilance in 2026

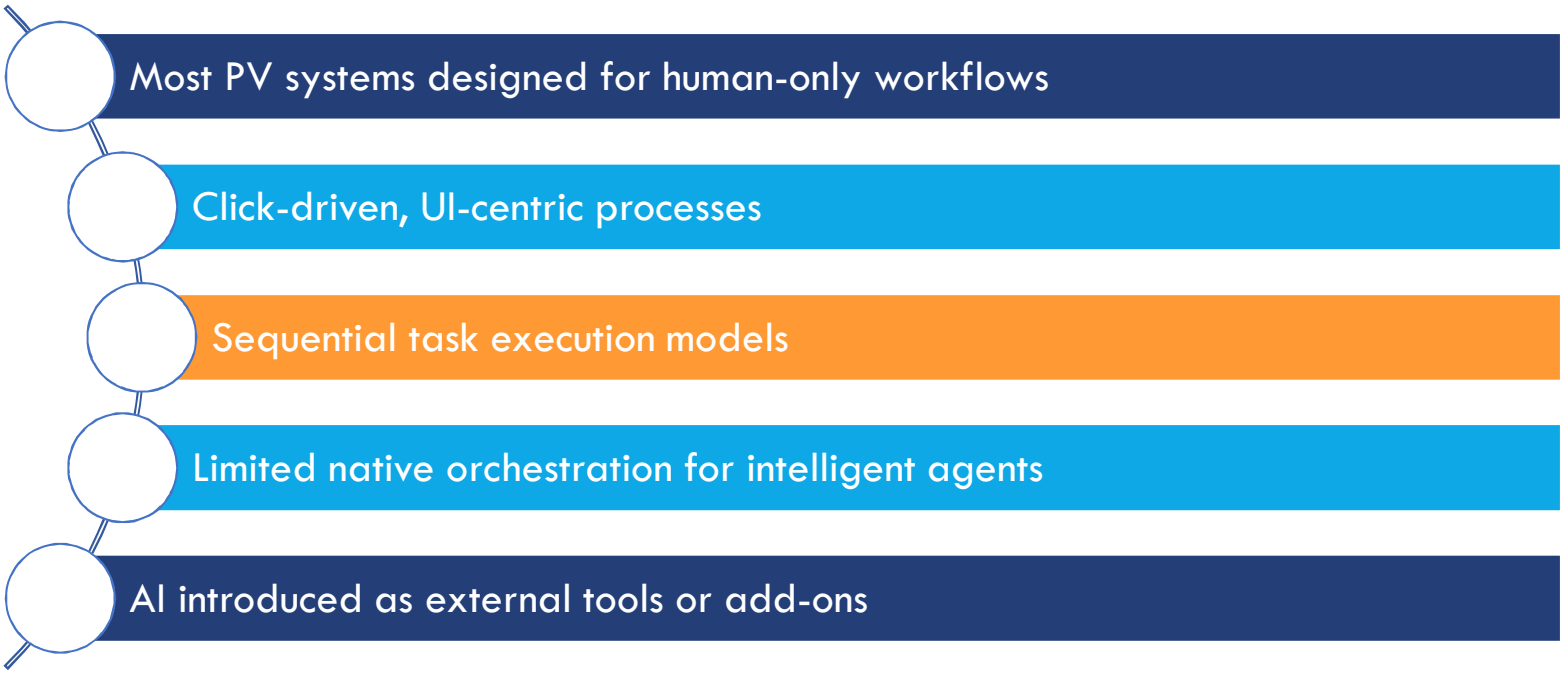
AI adoption is being pushed faster than PV system evolution

- Rising regulatory scrutiny
- Rapid adoption of AI and automation tools
- Legacy PV systems largely unchanged in architecture
- Automating / applying AI to existing processes
- Growing gap between technological capability and system design

The Core Problem: An Architectural Mismatch

AI is not being integrated into purpose-built systems —

AI is retrofitted into systems designed solely for human interaction

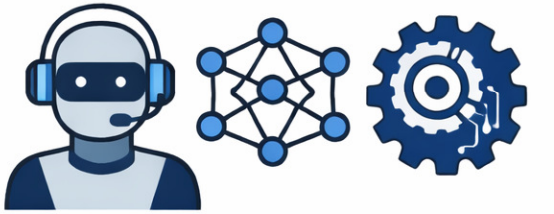


Design Principle: Systems for Humans AND Agentic AI

AI should be treated as a system actor, not an external tool

Future PV systems will have dual primary actors

Human Experts
(Medical, Safety, QA)



Agentic AI Components

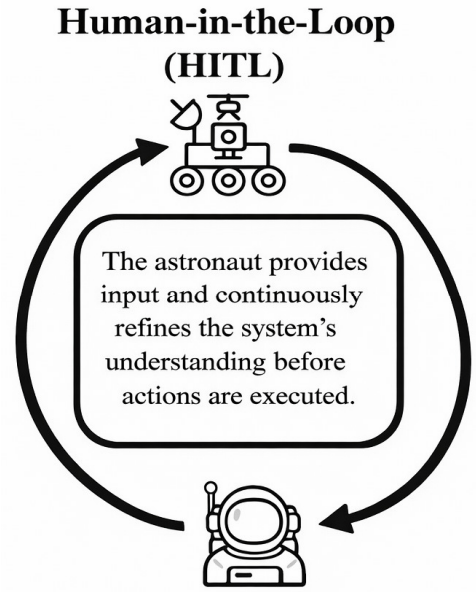
- Structured data access and orchestration required
- Interpretable outputs for both humans and regulators
- Native integration instead of bolt-on automation layers

Understanding HITL vs HOTL

The objective is not to replace humans, but to reposition them

Human-in-the-Loop (HITL): The Expert

- Executes and validates operational steps
- High manual interaction
- Suitable for high-risk and novel processes



Human-on-the-Loop (HOTL): The Supervisor

- Humans supervise and govern AI-driven workflows
- Exception-based intervention
- Focus on high-value oversight and decision-making

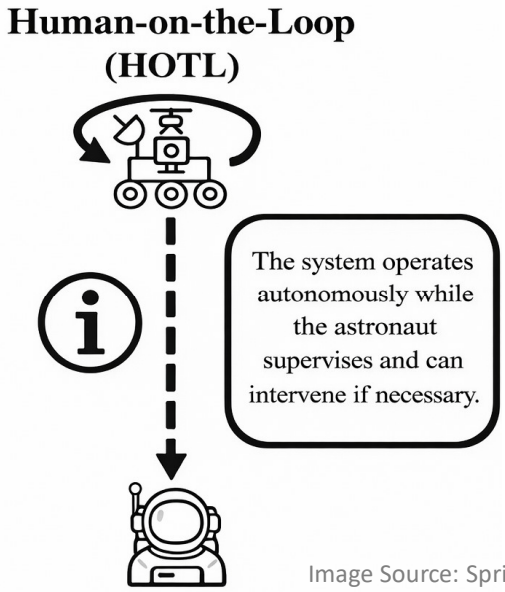
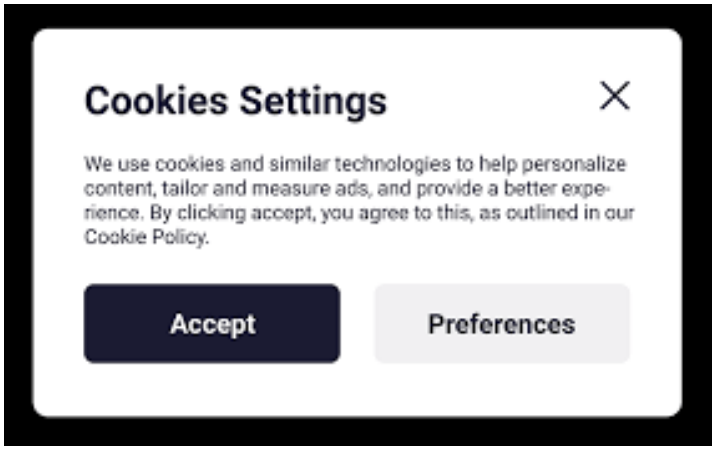


Image Source: Springer

When HITL fails: The Risk of the “Complicit Human”

Poor HITL design creates passive confirmation rather than true oversight



- Meaningful review interfaces instead of checkbox validation
- Explainable AI outputs with rationale visibility
- Risk-based review triggers with differentiation between routine and critical cases
- Clear confidence scores and uncertainty indicators

Building Trust: A Risk-Based Path from HITL to HOTL

Trust in AI systems must be earned through transparency, performance and auditability

Phase 1 — Full HITL - High-risk tasks - Full human validation

Phase 2 — Conditional HITL - Confidence thresholds - Targeted human review

Phase 3 — HOTL - Exception-based supervision - Continuous Surveillance - Interception

Always Risk-based
What is the consequence if…?

Established trust does not end monitoring – models can deteriorate and more adapted ones released

Alignment with CIOMS Principles: Fairness and Equity

Fairness and equity are system design responsibilities, not just model features

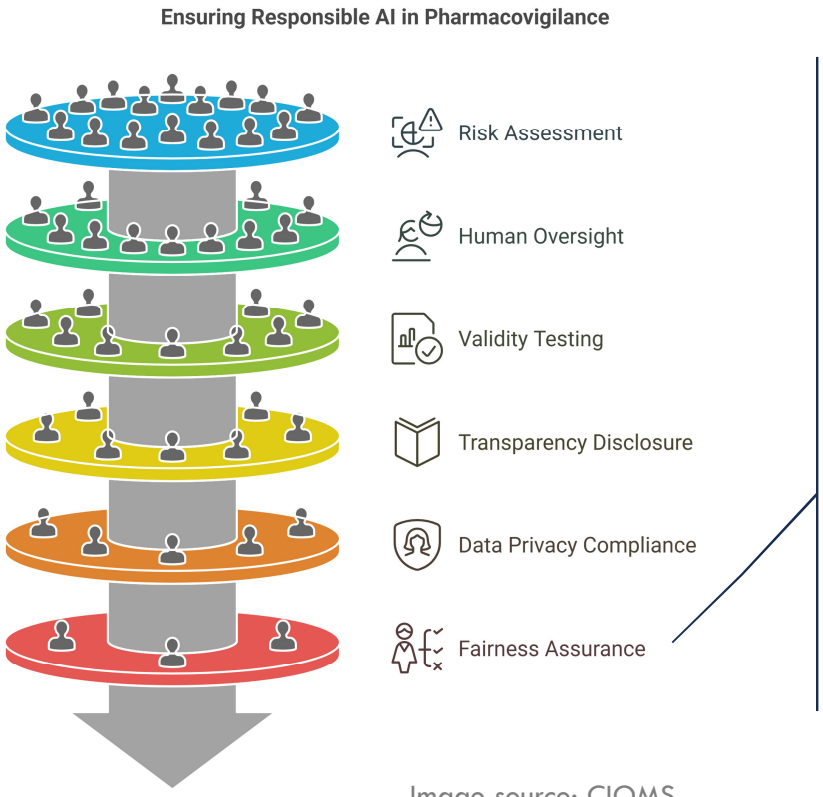


Image source: CIOMS

- Potential Risks in PV AI Systems: - Language bias in case intake - Regional reporting disparities - Training data imbalance - Underrepresentation of specific populations
- Design Safeguards: - Diverse and representative datasets - Bias monitoring and fairness audits - Human review for sensitive classifications - Transparent documentation of model limitations

Continuous Model Evaluation & Future-Proof PV Architecture

AI models evolve rapidly — PV systems must continuously evaluate, replace and govern them

WHY THIS MATTERS

- Rapid evolution of AI models
- Regulatory expectations for validated performance
- Need for ongoing benchmarking and monitoring

CONTINUOUS MODEL EVALUATION

- Performance tracking over time
- Benchmarking against emerging models
- Audit logs for model decisions
- Controlled model replacement processes

FUTURE-PROOF PV ARCHITECTURE

- Model-agnostic architecture
- Modular system design
- Interoperable AI components
- Native auditability & traceability
- Governance-by-design approach

Future-ready PV platforms must be flexible, explainable, auditable — and able to safely integrate better models as they emerge.

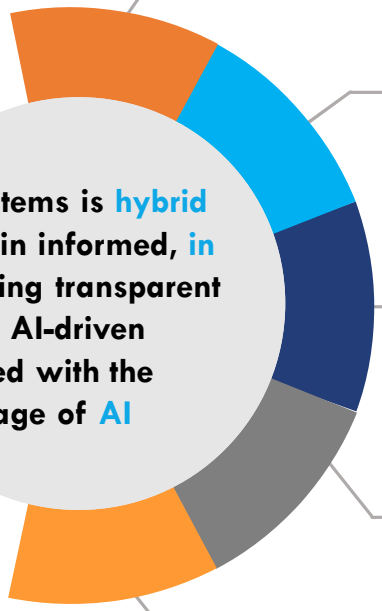
Strategic Implications for PV Organisations

Transformation is a System Design, not only a Technology Adoption Challenge

- Shift from manual processing to intelligent supervision
- Redefinition of safety professional roles
- Increased importance of governance frameworks
- Vendor and system selection based on architecture, not just AI features

The Future is Human-on-the-Loop

Take-Away Messages



The future of PV systems is hybrid where humans remain informed, in control, and supervising transparent and trustworthy AI-driven workflows, paired with the responsible usage of AI

1. AI will not fix poorly designed processes / systems
2. Just because you *can* use AI does not mean you *should*
3. Human expertise remains central in regulated PV
4. Trustworthy AI requires transparency, fairness, and continuous evaluation
5. Risk-based transition from HITL to HOTL is essential

Thank You!

Let’s Redefine the Future of Drug Safety - Together.

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