

Enterprise PV Modernization and Multi-Platform Upgrade for a Global Innovator Pharmaceutical Company

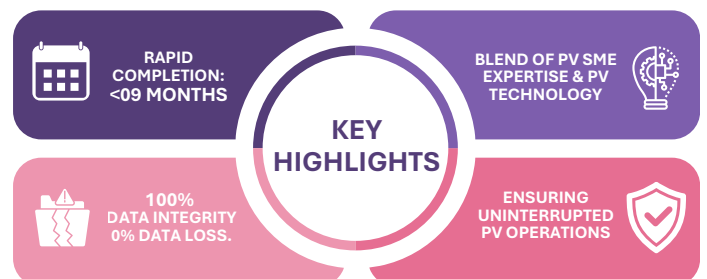
Fidelity Health Services

INTRODUCTION

A **global life sciences organisation** initiated a major modernisation of its Pharmacovigilance ecosystem with the aim of creating a more unified, compliant, and future ready safety environment. The programme required a **full upgrade from LSSMV to LSMV** along with the enablement of **LSRA, LSAS, LifeSphere Literature Intelligence, and EVTriage**.




The client needed a partner who could bring structured thinking, dependable execution, and a clear understanding of Pharmacovigilance realities while ensuring that daily safety operations continued without disruption.

FHS deployed a specialized team of **eight full-time PV technology and operations SMEs** who executed all workstreams simultaneously across **less than nine months**. Throughout the transformation, FHS maintained **100% operational continuity for more than 30 country affiliates/partners**, enabling the client to **modernize its PV landscape without compromising compliance or patient safety**. This collaboration reflects why FHS exists. The organisation focuses on meaningful PV work that demands precision, trust, and a commitment to strengthening safety systems without drawing attention away from what matters the most, patient safety.



"FHS supported this transformation by aligning its expertise to the client's pace and priorities."

TRANSFORMATION SUMMARY

 Transformation Challenge	 FHS Strategic Actions	 Business Impact
Migrating 20+ Years of Legacy Safety Data (LSSMV → LSMV) <u>500,000+ ICSRs migrated</u>	3-Tier mapping, workflow aligned rules, and multi cycle testing with 150+ validations.	Zero data loss, validated migration, audit ready LSMV.
Upgrading 4 major PV systems in parallel	Synchronized configurations, 20+ Cognos reports, automated scheduling and QBEs, and standardized rules and workflows.	Unified PV ecosystem, backward compatible reporting, faster global reporting.
Regulatory diversity across 100+ countries	Regulatory rules matrix, global validation libraries, multi regional UAT, and US aligned delivery.	Region compliant outputs, zero submission delays, standardized operations.
Aggressive <9-Months Timeline	High speed sprints, daily governance and risk control, and rapid defect triage.	On time delivery, no missed milestones, controlled execution.
Maintaining BAU During Transformation	Shadow mode ICSR processing, DEC and complaint handling, and 2,000+ case verifications.	Faster onboarding, training ready documentation, improved audit readiness.
Updating DEC/WI/SOPs	Full rewrite of DEC, WIs, and SOPs, supported by training materials and adoption guides.	Zero downtime, continuous safety operations, no backlog.
Automation and tool enhancements	ANG templates, auto follow up workflows, and SSO with dashboards.	Faster decisions, strong alignment, high stakeholder confidence.
Multi-Geo Coordination	Center led governance, real time visibility, and a shared priority model.	Reduced effort, faster processing, better visibility.

“Transforming Global PV Operations: From Legacy Migration to Automated, Inspection-Ready, Multi-System Excellence.”



FHS CONTRIBUTIONS - HOW WE DELIVERED EXCELLENCE

SAFETY DATABASE UPGRADE AND MIGRATION



FHS executed full mapping, configuration, validation, and migration of 20+ years of safety data, including touchless submissions, rule configuration, ISP workflows, duplicate case setup, auto-narratives, sender comment templates, auto-follow-up workflows, gateway connectivity, and new regulatory gateway setups. All validation documents, including Configuration specification, Validation plan, Migration Plan, UAT Protocol, UAT Report, & RIT, were delivered.



ADVANCED LSRA MODERNISATION (COGNOS-BASED)

FHS built 20+ Cognos custom reports, corrected gaps in standard LSRA outputs, recreated legacy QBEs, automated LSRA scheduling, and self-enabled on Cognos to eliminate vendor dependency.



LSAS, LSLI & EVTRIAGE ENABLEMENT

Full configuration, testing, and alignment with LSMV data, rules, and workflows for LSAS, LSLI, and EVTriage.



PV OPERATIONS CONTINUITY

Shadow processing, live case verification, complaint handling, and submission rule validation ensured uninterrupted operations.



TRAINING & HYPERCARE

Workshops, end-user training, operational support, and stabilization assistance were provided.

KEY OUTCOMES THAT REDEFINED THE CLIENT’S PV OPERATIONS



A fully modernised PV ecosystem delivered without a single hour of downtime.



Faster reporting and greater visibility through LSRA and Cognos.



Seamless migration of more than five hundred thousand ICSRs across thirty markets.



Reduced manual effort through automation and workflow intelligence.



Zero data loss in a twenty-year legacy migration.



Cost efficiency through internal reporting capability.



A unified, regulatory-ready environment validated end-to-end.



A future-ready PV foundation that supports scale, speed, and compliance confidence.



CLIENT TESTIMONIALS



“FHS delivered expertise & agility, making our global PV upgrade seamless & compliant.”

“Fidelity Health Services (FHS) played an instrumental role in our recent global PV transformation, including the upgrade from LSSMV to LSMV and the implementation of LSRA, LSAS, and LitPro. Their subject matter expertise allowed them to quickly understand our systems and integrate seamlessly with our teams. Despite the complexity of migrating two decades of legacy data and executing multiple workstreams in parallel, FHS demonstrated exceptional flexibility, agility, and commitment.

They supported U.S. time zones, collaborated across 30+ global affiliates, and maintained clear communication while ensuring uninterrupted business operations. We greatly appreciate their professionalism, technical depth, and solution-oriented approach. Thanks to FHS, we achieved a smooth, compliant, and timely transition to our modernized PV ecosystem. We highly recommend their services and look forward to continuing our long-term partnership.”

**DIRECTOR, PV DATABASE, GLOBAL PHARMACOVIGILANCE & RISK MANAGEMENT
- US BASED INNOVATOR PHARMACEUTICAL MNC**



CONTACT US

Our team will respond within minutes and map your transformation journey.

Your next PV ecosystem begins with one conversation. Please reach out to us to know more about us..



USA - OHIO

Fidelity Pharmacovigilance Inc.
7975 Plantation Dr, Mason, OH 45040, USA.



CANADA - TORONTO

Fidelity Pharmacovigilance Corp.
9 Mansfield St, Brampton, Ontario, L6S 2X8, CA



UK - LONDON

Fidelity Pharmacovigilance (UK) Limited
Kemp House, 160 City Road, London, EC1V 2NX, UK



INDIA - AHMEDABAD

Fidelity Health Services Pvt. Ltd.
527, Iconic Shymal, Shymal Crossroads, 132 Feet
Ring Road, Satellite, Ahmedabad-380015, India



INDIA - PUNE

Fidelity Health Services Pvt. Ltd.
E-302, Marvel Diva, Magarpatta Road, Hadapsar,
Pune - 411013, Maharashtra, India



Nisarg Bhavsar (nisarg@fidelityhs.com)
Tarun Jain (tarun@fidelityhs.com)



+1 (888) 881-3820

