



Driving Pharmacovigilance Excellence:

Fidelity's Dynamic Support for Global Pharmaceutical Companies in CIS Markets.

Fidelity Health Services: Your Comprehensive Pharmacovigilance Partner

AT A GLANCE

Efficient Pharmacovigilance (PV) systems and regulatory compliance are crucial in the pharmaceutical and healthcare sector. This case study highlights Fidelity Health Services (FHS) collaboration with pharmaceutical companies in the Commonwealth of Independent states (CIS) to implement robust PV systems and maintain regulatory compliance. It signifies the role of FHS, a PV services provider, in setting up and enhancing a reamlined PV system for various pharmaceutical companies operating in Azerbaijan, Armenia, Belarus, Georgia, Kazakhstan, Kyrgyzstan, Moldova, Mongolia, Tajikistan, Turkmenistan, Ukraine, and Uzbekistan.

CHALLENGES FACED BY CLIENTS

Amendments to pharmacovigilance regulations in CIS nations since 2020 have created compliance challenges for pharmaceutical companies, leading to financial losses from delayed dossier processing and regulatory query responses. A tailored and adaptable pharmacovigilance strategy is crucial in the dynamic regulatory environment of CIS-countries to mitigate financial risks.

SOLUTIONS

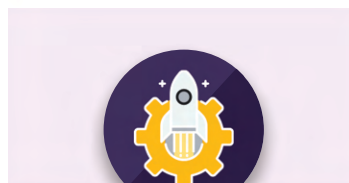
FHS offers a comprehensive suite of solutions designed to navigate the intricate regulatory landscape of PV in CIS countries.

- PV SUPPORT @ PRODUCT REGISTRATION
- PV SUPPORT @ PRODUCT APPROVAL
- ROUTINE PV ACTIVITIES FOR PATIENT SAFETY 1

HIGHLIGHTS

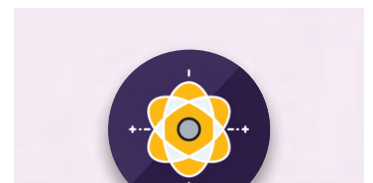
FHS delivered a comprehensive services of the country specific PV needs in the CIS regions, covering:

- Local personnel responsible for PV
- Risk Management Plans
- Periodic Safety Update Reports
- PV System Master File



100+

Product Approvals



100%

Submission Compliance



DURING PRODUCT REGISTRATION

Throughout the registration process, FHS supported clients by fulfilling local dossier requirements. This encompassed activities such as

- ✓ Risk management plans,
- ✓ PV documentation like PSMF & SDEA,
- ✓ Appointing local PV responsible person,
- ✓ Submitting safety update reports,
- ✓ Addressing queries from health authority/ies.

POST APPROVAL & ROUTINE PV

Post product approval, FHS assists its clients

- ✓ Set up & configuration in Safety Database
- ✓ Medical Information System,
- ✓ Literature Search strategies & management,
- ✓ Basic PV training,
- ✓ Managing routine PV activities (ICSRs, PSURs)

Ensuring overall patient safety & regulatory compliance.

OUTCOME & CONCLUSION



DURING PRODUCT REGISTRATION

Garnered high class satisfaction with topnotch quality & 100% submission compliance rate.



EFFICIENT WORK DELIVERABLES

Delivered 50 RMPs, 40 PSURs and 12 PSMFs cumulatively for our clients.



CLIENT CONTENTMENT

Demonstrating efficient PV system set-up yielded in quicker TAT for product approvals.

FHS SERVICE OFFERINGS



DRUG SAFETY SERVICES



MEDICAL INFORMATION SYSTEM



FUNCTIONAL RESOURCE MANAGEMENT



PHARMACOVIGILANCE CONSULTANCY

CLIENT'S TESTIMONIALS

“ Highly experienced, enthusiastic, trustworthy and professional case processing and aggregate report writing teams, which you can rely on, in managing challenging situations effortlessly. We are absolutely satisfied with the pharmacovigilance services offered by them. ”

★★★★★

HEAD - DRUG SAFETY & MEDICAL AFFAIRS

Indian based global pharmaceutical company having presence in Russia , CIS, EU and other ROW markets.

“ Fidelity Health Services goes above and beyond to ensure the well-being of its clients. The professionalism and compassion demonstrated by their staff have truly set them apart in the pharmacovigilance service industry. The attention to detail, prompt response to inquiries, and comprehensive PV solutions provided by Fidelity Health Services have exceeded our expectations. I wholeheartedly recommend their services to anyone seeking top-notch PV with a personal touch. ”

★★★★★

KEY CONTACT PERSON

Indian based global pharma company having presence across CIS region.