RegDocs365
Life Sciences IT Solutions

A Scalable, Affordable PV Platform with Real Solutions for SMEs

Introducing the Pharmacovigilance (PV) Module for RegDocs365™

Pharmacovigilance (PV) is critical to the safety of medicines, ensuring that adverse effects are detected, assessed, and managed to protect public health. However, most PV solutions on the market are designed for large pharmaceutical companies — meaning they are often complex, costly, and inaccessible for smaller businesses.

Developed in collaboration with Regxia, RegDocs365's PV module offers an affordable and scalable solution tailored specifically for small to mid-sized companies, making it easier than ever to meet post-authorization safety commitments.

Why Choose the PV Module for RegDocs365?

Small companies often struggle with manual processes or patchwork solutions for managing PV, but with this module, those challenges are a thing of the past.

COMPLETE END-TO-END WORKFLOW	From case intake to signal detection, this module covers the entire pharmacovigilance process, supporting your team from the moment a new event is reported through adjudication and regulatory submission.
FULLY COMPLIANT	Our solution meets the stringent requirements of global regulatory authorities, ensuring that your PV processes are always in line with industry standards.
AFFORDABLE AND SCALABLE	Unlike the big players, which can be prohibitively expensive for smaller companies, our PV module is cost-effective and designed to grow with your business.
INTUITIVE AND EASY TO USE	This module has a user-friendly interface that allows for seamless case processing, from reporting adverse events to generating line listings suitable for periodic safety reports.

Key Features Include

STREAMLINED CASE INTAKE

Receive and categorize adverse event reports from various sources, including healthcare professionals, patients, and regulatory authorities. Easily track the report's status and ensure timely processing.

COMPREHENSIVE CASE MANAGEMENT

Process cases easily, send them for adjudication, assess for regulatory reportability, and generate reports in compliance with requirements.

SIGNAL DETECTION & MANAGEMENT

Detect and analyze safety signals with confidence, helping you proactively manage risks and ensure your products' safety.

The Fit-for-Purpose Solution

This PV Module is a perfect example of a fit-for-purpose solution. While large companies have expansive needs, smaller companies require streamlined, efficient, and cost-effective solutions. Regxia, a consulting group specializing in regulatory affairs and pharmacovigilance, saw firsthand the gap in the market for smaller businesses and partnered with Court Square Group to create a PV solution that meets this need.

The Pharmacovigilance Module for RegDocs365 empowers smaller companies with the tools they need to stay compliant and competitive in an ever-evolving regulatory landscape. Say goodbye to manual processes and cobbled-together solutions — this module offers a complete, streamlined system that fits your budget and your business needs.

Ready to simplify your pharmacovigilance operations?

Meet Court Square Group

As a leading managed services technology company dedicated to empowering those who change lives in the pharmaceutical and life sciences space, Court Square partners with the market's most innovative technology companies to provide platforms and point solutions that accelerate decision-making, reduce operational costs, and improve company-wide productivity. Our partnership with Regxia provides our clients and partners with private, secure, and regulatory-compliant technology so they can move to market quickly.