ENNOV PHARMACOVIGILANCE SUITE

Ennov PV-Works Vet

Veterinary Pharmacovigilance Software

A flexible software system designed to support animal health/veterinary pharmacovigilance business processes and technical services case handling practices, while meeting your company safety and world-wide regulatory reporting requirements.

The Pharmacovigilance Challenge

Developing or implementing a system to collect, manage, report and evaluate patient safety data can be time consuming and expensive. Companies of all sizes require a system that is compliant with global regulations, easy to access and use, fast to implement, and simple to maintain.

An ideal system should be flexible, should integrate with other databases, and should be designed to manage not only adverse events from clinical trials and those occurring spontaneously in the field but can also manage medical inquiries and product quality complaints for all medical products, including traditional pharmaceuticals, biomedical products and medical devices.

Comprehensive Vet PV Data Management

Ennov PV-Works Vet is a flexible software system designed to support animal health/veterinary pharmacovigilance. In addition toits simple yet comprehensive data entry and reporting functions, its fully integrated workflow functionality ensures SOP compliance and that critical reporting deadlines are met.

PV-Works Vet is a process driven system. A purpose-built workflow engine is integrated with comprehensive safety functionality to provide management control of pharmacovigilance processes. PV-Works Vet also includes a wide range of powerful querying functionality, allowing business teams to monitor case handling, track compliance, and execute in-depth trend analysis.

Core capabilities

- ICH E2B compliant safety data collection and reporting
- Coding of cases against current MedDRA dictionary
- Extensive data validation, cross-field checks and use of pick lists
- Duplicate check functionality
- Integrated spell checker
- Integrated query tool
- Automated letter generation
- Case data export

Key Features

- Manages spontaneous and clinical trial adverse events, technical inquiries and product complaints
- Compatibility with with third-party query and reporting tool
- Easy to configure workflows that mirror existing business processes
- Streamlined case review and data approval concept
- Supports pharmaceutical, biological, medical device, and cosmetic vigilance
- Available as cloud-based or on-premises deployment
- FDA 21 CFR Part 11 compliance

Cloud-based or On Site

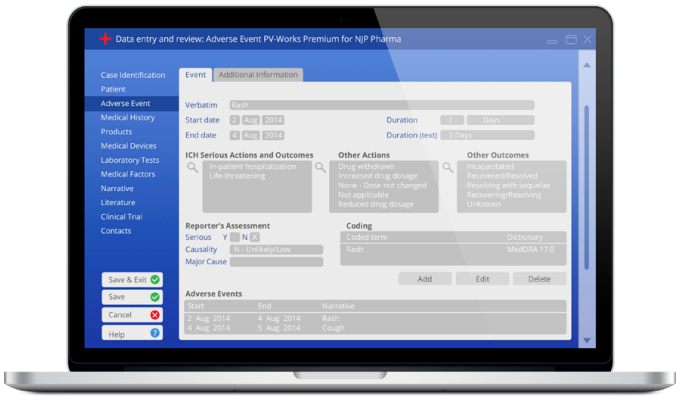
Multi-Platform

ISO 9001:2015 Certified

Over 200 Life Sciences Companies Around the World Use Ennov Software

Advanced Capabilities Ensure Compliance

PV-Works Vet submits electronic reports of animal health data to the EMA and all EU Competent Authorities using the EUVeterinary XML format. The HL7 compliant XML schema that is required by FDA CVM and is defined by VICH is also supported. PV-Works Vet is easily integrated with standard AS2 gateway software to manage electronic submissions. Acknowledgement messages and batch submissions are comprehensively handled. The import of compliant XML formats is also fully supported, allowing receipt of cases submitted to industry directly from European Competent Authorities.



PV-Works Human – Part of the Ennov Pharmacovigilance Suite

PV-Works Human | PV-Works Vet | PV-Analyzer | PV-Signal Manager | PV-Entry | PV-Express

Why Choose Ennov?

Hundreds of companies trust Ennov

- **Over 15 years of experience providing PV solutions**
  200+ life sciences customers, many more in other industries.
- **Modern architecture and user interface**
  100% web-based, Highly scalable. User-centric design.
- **Our commitment to your success**
  Very high customer satisfaction. 98.5% of projects delivered on time and within budget.

Providing you freedom of choice

- **Available as cloud-based or on-premises deployment**
  You can switch between deployment options at any time.
- **We make you autonomous**
  System configuration and management require no IT skills.
- **Improved security and optimized performance**
  Data is hosted locally for total flexibility. Single tenancy minimizes business interruptions

Learn more about our unified content and information management platform to support the entire Life Sciences product development continuum at **www.ennov.com**

Quality | Clinical | Regulatory | Pharmacovigilance | Commercial