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ENNOV PHARMACOVIGILANCE SUITE

Ennov PV-Works
Human Pharmacovigilance Software

A flexible software system designed to support 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 PV Data Management

The Ennov PV-Works database has been designed around the ICH E2B guideline such that every E2B data field maps to a specific database field. Coding to MedDRA is simple. In addition to paper reporting outputs such as CIOMS and MedWatch 3500s, an electronic reporting function is included. Aggregate listing outputs like PSUR, DSUR, and PBRER are simple to generate using built-in tools. In addition to simple yet comprehensive data entry and reporting functions, the fully integrated workflow functionality will ensure SOP compliance and that critical reporting deadlines are met. Regulatory compliance is afforded with the adherence to key requirements such as FDA 21 CFR Part 11 and the provision of a full audit trail.

> 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
- Automatically generated reports to communicate signal status
- Integrated spell checker
- Integrated query tool
- Automated letter generation
- Case data export

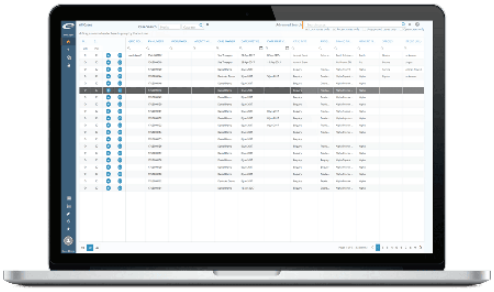
> KEY FEATURES

- Manages spontaneous and clinical trial adverse events, technical inquiries and product complaints
- Compatibility with third-party query and reporting tool
- Easy to configure workflows
- Streamlined case review and data approval concept
- Supports pharmaceutical, biological, medical device, and cosmetic vigilance

Cloud Based or On Premises | **Multi-Platform** | **ISO 9001:2015 Certified**

Advanced Capabilities Ensure Compliance

PV-Works is a process driven system. A purpose-built workflow engine is integrated with comprehensive safety functionality to provide management control of pharmacovigilance processes. The software also includes a wide range of powerful querying functionality, allowing business teams to monitor case handling, track compliance, and execute in-depth trend analysis. PV-Works submits electronic adverse event (AE) reports in full compliance with the ICH E2B standards. Furthermore, electronic medical device AE reports may be submitted to FDA CDRH in eMDR format. The systems is easily integrated with standard AS2 gateway software to manage electronic submissions.



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	PROVIDING YOU FREEDOM OF CHOICE
20 years and 300+ Life Science customers, with many more in other industries.	**Available as cloud-based or on-premises deployment:** You can switch between deployment options at any time.
Modern architecture and user interface: 100% web-based. Highly scalable. User-centric design.	**We make you autonomous:** System configuration and management require no IT skills.
Our commitment to your success: Very high customer satisfaction. 98.5% of projects delivered on time and within budget.	**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

Our comprehensive QMS improves operational efficiency and ensures regulatory compliance

CLINICAL

Our total solution for capturing and managing Clinical Trial information streamlines clinical operations

REGULATORY

Our world-class Regulatory content and information management software accelerates HA approvals

PHARMACOVIGILANCE

Our end-to-end solution for collecting, reporting and analyzing human and vet PV data minimizes risk

COMMERCIAL

Our complete management of professional events ensures DMOS, EFPIA, HCP and COI compliance