

Ennov PV-Signal Manager

Safety Signal Management Software

A fully searchable repository of all signal management activity, allowing users to review previous data and conclusions and evaluate the evolution of a given signal over time.

The Signal Management Challenge

The requirement to demonstrate a robust approach to signal detection and management is not new. More and more, global Health Authorities place greater expectations on the MAH to establish and maintain a comprehensive signal strategy, over and above the underlying obligation for regular single case and aggregate reporting. The MAH is expected to support a risk-based approach, using globally available data, across the entire product lifecycle.

Once signals are identified via statistical data evaluation, individual case review, medical literature, social media noise, etc. they must be collected, documented, and evaluated to determine their risk level and follow-up steps.

Workflow Driven Efficiency

In Pharmacovigilance, a signal is essentially a hypothesis of a risk with data and arguments that support it. With PV Signal Manager, you can easily translate your hypothesis into a risk level by quickly and effectively evaluating the data you have and incorporating the data you may need from other sources.

Using established business process management technology, Ennov's PV Signal Manager uses configurable forms and workflow to capture key data about your signal and guide it through prioritization, evaluation, classification and review. Follow-up actions are automated and aligned with your company's risk management program.

Core capabilities

Configurable data collection forms and process
Signal evaluation, analysis, and categorization of potential risk level
Dashboard for management overview
Built in alerts to ensure timely management of signals
Automatically generated reports to communicate signal status

Key Features

Elegant, easy-to-use interface
Streamlines signal capture and work-up
Modern and intuitive layout
Automatic "push" of statistically derived signal data for evaluation and follow-up
100% web-based
21 CFR Part 11 compliant



Cloud-based or On Site



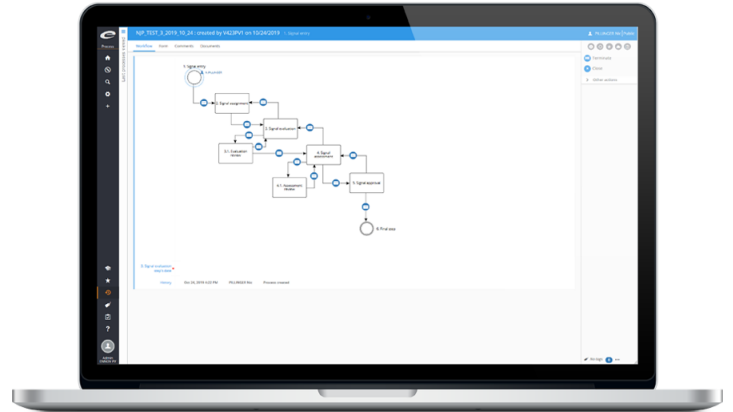
Multi-Platform



ISO 9001:2015 Certified

A Total Integrated Solution for PV Signals

Ennov PV Signal Manager is a fully searchable repository of all signal management activity, allowing users to review previous data, conclusions, and evaluate the evolution of a given signal over time. It facilitates timely and appropriate internal and external communication regarding the signal and can be integrated with Ennov PV-Analyzer – another innovative Ennov product used for the qualitative and quantitative review of adverse event data. Signals derived from the robust set of built-in statistical analyses included with PV-Analyzer are populated via our REST API and used to record signal information and its defined risk level.



PV-Signal Manager – 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