eNNOV
Software for Life

# Ennov PV-Analyzer

## Pharmacovigilance Signal Detection Software

Automated signal detection is essential to enure the MAH not only meets their regulatory obligations, but is also able to achieve exceptional levels of product insight.

## The Signal Detection Challenge

Since 2012, there is greater emphasis on the Market Authorization Holder (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. Clinical and spontaneous adverse event data should be incorporated with information from other relevant sources in this approach. This expectation is evident as critical and major findings in inspections related to a lack of sufficient signal detection have been reported.

## PV-Analyzer for Signal Detection

Ennov's PV-Analyzer offers great potential for any company to integrate a feature rich, easy-to-use, statistical analysis platform into its signal detection program.

PV-Analyzer can be populated with case data from in standard E2B format. Furthermore, adverse event data may be imported for use as background data such as FDA's Open FDA initiative, EMA and other internal sources.

The application, which is designed for use out-of-the-box by business users, offers a broad array of statistics as well as powerful data cubing and visualization functionality. By being able to run fast and efficient reviews of adverse event data, the MAH can quickly and routinely examine the dataset for potential signals that may require further evaluation.
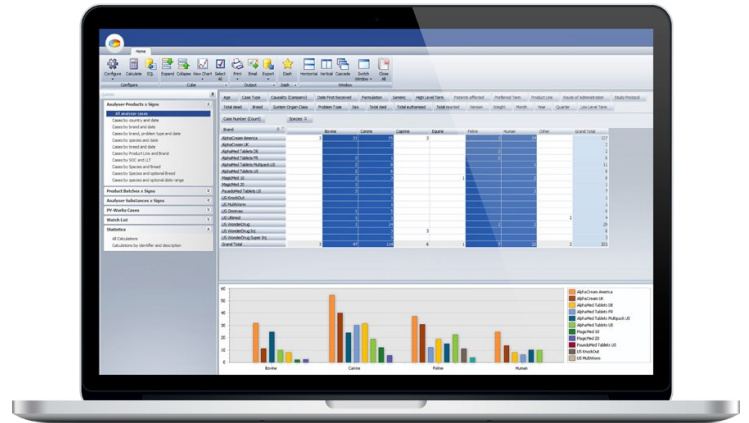
### Core capabilities

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| Three dimensional data cube |
| Frequentist and Bayesian statistics |
| Configurable numerator and denominator data sets |
| Configurable data set stratification |
| Flexible ad-hoc query tool |
| Extensive graphical presentation options |
| Direct export to Microsoft Excel and SAS |

### Key Features

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| User-friendly interface |
| Stratification of analyses by multiple factors |
| Configurable alert thresholds with notifications |
| Comparison of incidence of labelled and unlabeled terms |
| Analysis by product, ingredient and batch number |
| Analysis at different MedDRA / VedDRA levels |
| Analysis of product interactions |
| Analysis by time period |

Cloud-based or On Site

Multi-Platform

ISO 9001:2015 Certified

## Comprehensive Statistics

- Proportional reporting ratio (PRR)
- Reporting odds ratio (ROR)
- Observed to expected ration (OE)
- Chi-squared significance
- Information content (IC)
- Empirical Bayesian geometric mean (EBGM)
- Multi gamma poisson shrinker (MGPS)

# PV-Analyzer – 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**