ennov
Software for Life

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ENNOV PHARMACOVIGILANCE SUITE

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

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
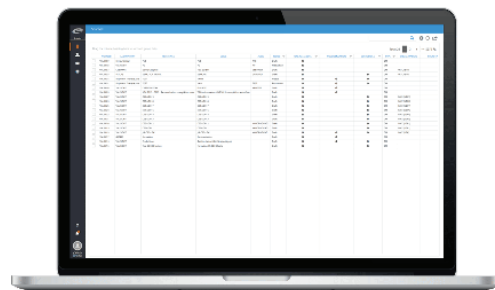
Direct export to Microsoft Excel and SAS

⟩ KEY FEATURES

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 Premises   **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	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.
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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