



Empirica™ Trace

Building a Successful Pharmacovigilance and Risk Management Strategy

Core Capabilities:

- Collect, manage and automate safety data for drugs, biologics, devices and vaccine products throughout product life cycle
- Web-based, thin client design reduces IT installation, validation and support costs
- Automated features designed to boost productivity and accuracy of safety departments
- Report distribution for timely compliance with regulatory deadlines
- Empirica Gateway submits E2B adverse event reports electronically

New Features Include:

- Fully integrated, real-time safety management reporting and analysis
- Case list reports with support for Structured MedDRA Queries (SMQs)
- Enhanced E2C compliance including pregnancy reporting (prospective and retrospective exposure) and PSUR
- Addendum reporting for ad hoc date ranges
- Support for “Insignificant Changes” to case data during follow-up reporting
- Support for triage entry, placing data in a staging area, including flexible duplicate checking logic
- Quick entry data option for rapid case data entry
- Duplicate case search capabilities
- Support for MedDRA recoding, including impact analysis, coded event terms and synonyms
- Lookup and duplicate features to assist during data entry

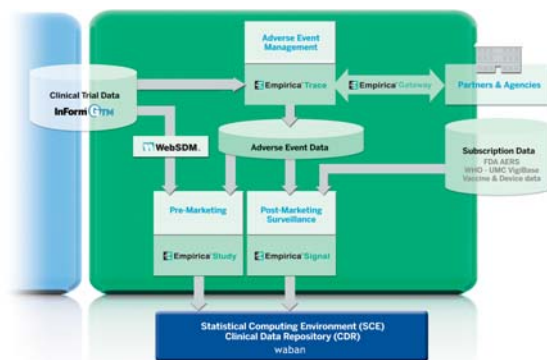
The Product Safety Imperative

The pharmaceutical industry has been under fire for a series of high-profile product safety problems, which have called attention to general industry pharmacovigilance practices. For regulators and manufacturers, the consequences of failing to ensure the safety of products have never been greater.

To meet the demands of implementing a successful pharmacovigilance strategy that minimizes risk, companies need accurate safety data in real time, and the ability to immediately analyze, draw conclusions, submit regulatory reports and base decisions on accurate and timely information.

Phase Forward’s Empirica suite of innovative pharmacovigilance and risk management solutions delivers Adverse Event Reporting, Data Mining, Signal Detection and Signal Management capabilities that help companies identify potential safety problems and manage risk effectively across the full product life cycle.

Empirica Suite: Comprehensive Pharmacovigilance and Risk Management



EmpiricaTrace: Comprehensive Adverse Event Management

The ability to manage the risk of safety problems begins with accurate, timely and complete data about adverse events. Phase Forward’s Empirica Trace product helps many types of organizations—small, medium and large biopharmas, medical device manufacturers and contract research organizations (CROs)—collect, code, analyze and report adverse events, as well as meet regulatory reporting deadlines and global requirements. This Web-based product provides a single, powerful and modern solution for adverse event management that helps to speed information delivery, prevent delays and provide visibility into work-in-process and due dates.

Timely, Accurate and Flexible Regulatory Compliance

Report distribution functionality based on flexible pre-defined rules provides automated delivery of reports to recipients based on case characteristics, product identity and recipient requirements much more efficiently than manual reporting. The Empirica Trace product supports general case list reports, blinded reports and periodic reporting requirements for line listings of events and detailed analysis of the impact of new findings on the safety profile of the product in an automated and coordinated manner, so deadlines are promptly met with complete, accurate information.

What Sets Empirica Trace Apart?

Modern Architecture

Built to protect your investment long-term

- Web-based, easy and fast to deploy
- Simple system administration and support

Complete

Single system covers end-to-end process requirements

- Simplified licensing and implementation
- Installed with minimal configuration

Powerful

Enhanced automation and configurable workflow

- Triage and quick entry
- Drives productivity in safety management activities

Compliant

Regulatory reporting requirements can be easily met

- Comprehensive data collection, management, reporting and submission
- Designed for use in a 21 CFR 11-compliant environment

Empirica Trace Dictionary Support includes:

MedDRA
WHO-DD
Others as required

Standard Empirica Trace Regulatory Reports include:

PSUR
CIOMS-I
CIOMS-II
ICH E2C-compliant PSUR
FDA-approved 3500A MedWatch for drugs, biologics, vaccines and medical devices
Periodic FDA reports (IND, NDA)
European Commission Medical Device Incident Reports
Investigational Product Annual Report
Ethics Committee Report
VAERS

Specialized Services (Available Separately):

Implementation services to configure Empirica Trace to meet company-specific needs
Data migration
Validation
Systems integration

Proactive Pharmacovigilance: A Life-cycle Approach

While data capture and regulatory compliance are fundamental requirements, companies are also increasingly focused on identifying ways to extract the maximum value from their safety data with highly proactive strategic pharmacovigilance programs. The Empirica Trace product provides the fundamental building block for efficiently capturing and managing spontaneous report data across the full product life cycle, from clinical development through post-marketing. Combined with advanced techniques such as data mining, data visualization and signal detection and management products, the Empirica Trace software can deliver a powerful and complete platform for companies to realize the benefits of proactive pharmacovigilance and risk management.

Powerful Reporting Toolset

The Empirica Trace safety database is complemented by a configurable query engine, a full range of status and productivity reports and an integrated, visual reporting environment. Additional Empirica suite tools may also be licensed to support signal detection and analysis, signal management and clinical trials signal detection.

Report Distribution: Getting the Right Report to the Right Recipient On Time

		REPORT RECIPIENTS (Regulators, Affiliates or Licensed Partners)			
		US FDA CDER	US FDA CDRH	US FDA CBER	DE BfArM
PRODUCTS	Drugs	Amoxicillin	Serious & Unexpected		Foreign & Serious & Unexpected
	Biologics	HRIG 2	Serious & Spontaneous		Serious Domestic & US Unexpected
	Vaccines	Hepatitis-B		All Serious	
	Medical Devices	Drug-Eluting Stent		All Cases	Domestic & All Serious

- User friendly
- Configurable
- Pre-defined rules

The Empirica Suite

Phase Forward's complete solution for pharmacovigilance and risk management uses Empirica Trace as its foundation. The system's companion electronic submission option, the Empirica Gateway product, offers full support for E2B submission of case reports to regulators and receipt of data via E2B standard files. The Empirica Signal product performs data mining using publicly available data for marketed products. The Signal Management module facilitates the ongoing monitoring and tracking of safety signals, such as those identified in Empirica Signal. The Empirica Study product supports signal detection from clinical trials data as it accumulates during development.

The Phase Forward Advantage

The development of the Empirica suite and delivery of Empirica-related services are managed by Phase Forward's Lincoln Safety Group, one of the most experienced and respected teams in the industry. Only Phase Forward can offer such a highly skilled and experienced team with a proven track record of working with safety experts in the government and commercial sectors.

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